

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, and 423

[CMS-4157-FC]

RIN 0938-AQ86

Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes

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

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period revises the Medicare Advantage (MA) program (Part C) regulations and prescription drug benefit program (Part D) regulations to implement new statutory requirements; strengthen beneficiary protections; exclude plan participants that perform poorly; improve program efficiencies; and clarify program requirements. It also responds to public comments regarding the long-term care facility conditions of participation pertaining to pharmacy services.

DATES: *Effective dates:* These regulations are effective on June 1, 2012 unless otherwise specified in section I.B. of this final rule with comment period (see Table 1). Amendments to the definitions of “other health or prescription drug coverage” at § 423.2305 and “supplemental benefits” at § 423.100 are effective January 1, 2013.

Comment date: We will only consider public comments on the issues specified in section II.B.5 of this final rule with comment period, Independence of LTC Consultant Pharmacists, if we receive them at one of the addresses specified in the **ADDRESSES** section of this final rule with comment period, on June 11, 2012.

Applicability dates: In section I.B. of the preamble of this final rule with comment period, we provide a table (Table 1) which lists revisions that have an applicability date other than the effective date of this final rule with comment period.

ADDRESSES: In commenting, please refer to file code CMS-4157-FC. Because of staff and resource limitations, we cannot accept comments by facsimile (Fax) transmission.

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

1. *Electronically.* You may submit electronic comments on this regulation

to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address *Only:* Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4157-FC, P.O. Box 8013, Baltimore, MD 21244-8013.

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

3. *By express or overnight mail.* You may send written comments to the following address *only:* Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4157-FC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments *only* to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

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

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-1066 in advance to schedule your arrival with one of our staff members.

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

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

FOR FURTHER INFORMATION CONTACT: Christian Bauer, (410) 786-6043, and Kathryn Jansak, (410) 786-9364, General information.

Christopher McClintick, (410) 786-4682, Part C issues.

Deborah Larwood, (410) 786-9500, Part D issues.

Kristy Nishimoto, (206) 615-2367, Part C and D enrollment and appeals issues.

Deondra Moseley, (410) 786-4577, Part C payment issues.

Irina Chaudhuri, (410) 786-8628, Part D payment issues.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

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

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Acronyms

- AO Accrediting Organization
- ADS Automatic Dispensing System
- AEP Annual Enrollment Period
- AHFS American Hospital Formulary Service
- AHFS-DI American Hospital Formulary Service-Drug Information
- AHRQ Agency for Health Care Research and Quality
- ALJ Administrative Law Judge
- ANOC Annual Notice of Change
- 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
- CMR Comprehensive Medication 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
- 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
- DRA Deficit Reduction Act of 2005 (Pub. L. 109-171)
- DUM Drug Utilization Management
- EGWP Employer Group/Union-Sponsored Waiver Plan
- EOB Explanation of Benefits
- EOC Evidence of Coverage
- ESRD End-Stage Renal Disease
- FACA Federal Advisory Committee Act
- FDA Food and Drug Administration
- 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
- ICD-9-CM Internal Classification of Disease, 9th, Clinical Modification Guidelines
- ICEP Initial Coverage Enrollment Period
- ICL Initial Coverage Limit
- ICR Information Collection Requirement
- ID Identification
- IPPS [Acute Care Hospital] Inpatient Prospective Payment System
- IRE Independent Review Entity
- IVC Initial Validation Contractor
- 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 Insurance Commissioners
 NCPDP National Council for Prescription Drug Programs
 NCQA National Committee for Quality Assurance
 NDA New Drug Application
 NDC National Drug Code
 NGC National Guideline Clearinghouse
 NIH National Institutes of Health
 NOMNC Notice of Medicare Non-Coverage
 NPI National Provider Identifier
 OIG Office of Inspector General
 OMB Office of Management and Budget
 OPM Office of Personnel Management
 OTC Over the Counter
 Part C—Medicare Advantage
 Part D—Medicare Prescription Drug Benefit Program
 PBM Pharmacy Benefit Manager
 PDE Prescription Drug Event
 PDP Prescription Drug Plan
 PFFS Private Fee For Service Plan
 POA Present on Admission (Indicator)
 POS Point-of-Sale
 PPO Preferred Provider Organization
 PPS Prospective Payment System
 P&T Pharmacy & Therapeutics
 QIO Quality Improvement Organization
 QRS Quality Review Study
 PACE Programs of All Inclusive Care for the Elderly
 RADV Risk Adjustment Data Validation
 RAPS Risk Adjustment Payment System
 RHIA Registered Health Information Administrator
 RHIT Registered Health Information Technician
 RPPO Regional Preferred Provider Organization
 SEP Special Enrollment Periods
 SHIP State Health Insurance Assistance Programs
 SNF Skilled Nursing Facility
 SNP Special Needs Plan
 SPAP State Pharmaceutical Assistance Programs
 SSA Social Security Administration
 SSI Supplemental Security Income
 TPA Third Party Administrator
 TrOOP True Out-of-Pocket
 U&C Usual and Customary
 UPIN Uniform Provider Identification Number
 USP U.S. Pharmacopoeia

SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Executive Summary

1. Purpose

a. Need for Regulatory Action

We are publishing this final rule with comment period for the Medicare Advantage (Part C) and prescription drug (Part D) programs to make changes as required by statute, including the Affordable Care Act, as well as improve

the program through modifications that reflect experience we have obtained in administering the Part C and Part D programs and/or address requests for clarification received from stakeholders such as health plans and Part D sponsors. The five different sections of the preamble cover the specific means by which we believe the final rule will: (1) Implement statutory provisions; (2) strengthen beneficiary protections; (3) exclude plan participants that perform poorly; (4) improve program efficiencies; and (5) clarify program requirements.

b. Legal Authority

Our authority for this final regulation stems from the Social Security Act (the Act). As is discussed in more detail in section I.C. of this final rule with comment period, the Balanced Budget Act of 1997 (BBA) and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) created, respectively, the Medicare Advantage (MA) program (Part C) and the Medicare Prescription Drug Benefit Program (Part D). Congress continues to amend the Act and change both Parts C and D, and this final regulation includes modifications required by, for instance, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) and the Affordable Care Act.

2. Summary of the Major Provisions

a. Coverage Gap Discount Program (§ 423.100, § 423.505(b), § 423.1002, and Subpart W (§ 423.2300 Through 423.2410))

The Affordable Care Act made several amendments to Part D of Title XVIII of the Act, including adding sections 1860D–43 and 1860D–14A of the Act, and amending section 1860D–2(b) of the Act. Beginning on January 1, 2011, these amendments started phasing out the Part D coverage gap, or “donut hole” for Medicare beneficiaries who do not already receive low-income subsidies from CMS by establishing the Medicare Coverage Gap Discount Program (Discount Program). We implemented the Discount Program through program instructions due to the January 1, 2011 implementation deadline. Although not required, we are codifying most of the existing Discount Program requirements (that is, those that we have previously implemented through the relevant Agreements and guidance) through full notice and comment rulemaking to provide additional transparency and a formal framework for operating the Discount Program and enforcing its requirements.

b. Pharmacy Benefit Manager’s Transparency Requirements (§ 423.501 and § 423.514)

Section 1150A of the Act, as amended by section 6005 of the Affordable Care Act, requires Part D sponsors and entities that provide pharmacy benefits management services to report various data elements. The statute further specifies that this information is confidential and generally shall not be disclosed by the government or by a plan receiving the information, with certain exceptions that allow the government to disclose the information in a non-identifiable form. There are penalties for those that fail to meet the requirements of this provision. We are codifying the reporting requirements, confidentiality protections, and penalty provision in this final rule with comment period.

c. Who May File Part D Appeals With the Independent Review Entity (§ 423.600 and § 423.602)

This change to our regulations allows prescribers to request a reconsideration on an enrollee’s behalf without obtaining an appointed representative form. We believe this change will make the Part D appeals process more accessible to beneficiaries. The legal authority for this policy is section 1860D–4(g) of the Act.

d. Plan Performance Ratings as a Measure of Administrative and Management Arrangements and as a Basis for Termination or Non-Renewal of a Medicare Contract (§§ 422.510, 423.505, and 423.509)

Each year, we issue performance quality ratings, using a 5-star system where 5 stars indicates the highest quality, of Part C and D plan sponsors. The plan ratings are based on a series of measures that correspond to operational requirements of the Part C and D programs. We have established that 3 stars reflects an average level of performance and is the lowest acceptable rating for plan sponsors. Sponsors that fail for three consecutive years to achieve at least a 3-star rating have demonstrated that they have substantially failed to meet the requirements of the Part C and D programs and failed to take timely and effective corrective action. Therefore, we are adopting the authority to terminate the contracts of Part C and D sponsors that fail to achieve at least a 3-star plan rating for 3 consecutive years. The data used to calculate the plan ratings is plan performance data that serves as evidence that the sponsor has reached the substantial failure standard

that CMS must use, pursuant to section 1857(c)(2) of the Act, to make a contract termination decision.

e. New Benefit Flexibility for Fully-Integrated Dual Eligible Special Needs Plans (FIDE SNPs) (§ 422.102)

This provision specifies that, subject to CMS approval, and as specified annually by CMS, certain dual eligible SNPs (D-SNPs) that meet integration and performance standards may offer additional supplemental benefits beyond those CMS currently allows other MA plans to offer, where CMS finds that the offering of such benefits could better integrate care for the dual eligible population. Such benefits may include nonskilled nursing services, personal care services, and other long-term care services and supports designed to keep dual eligible beneficiaries out of institutions. We would require D-SNPs that offer these additional supplemental benefits to do so at no additional cost to the beneficiary. We believe that providing certain D-SNPs that meet integration and performance standards the flexibility to offer additional supplemental benefits could better integrate care for the dual eligible population, help prevent health status

decline, and reduce the quantity and cost of future health care needs.

f. Clarifying Coverage of Durable Medical Equipment (§§ 422.100 and 422.111)

This provision permits a Medicare Advantage plan to limit durable medical equipment (DME) to specific “preferred” brands and manufacturers as long as the plan complies with several requirements intended to ensure that the enrollee continues to have access to all categories of DME specified in the Social Security Act. Beneficiary protections include access to all preferred brands, a transition period permitting enrollees to retain DME when changing plans, exceptions to plan limitations based on medical necessity, the ability to appeal a plan’s denial of DME based on brand/manufacturer, and plan disclosure of DME limitations to enrollees.

g. Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse, and Waste Control Program (§§ 423.104 and 423.153)

The daily cost-sharing rate requirement provides a financial incentive to Medicare Part D

beneficiaries to ask their prescribers whether less than a month’s supply of a drug would be appropriate because, if so, the Part D sponsor will apply lower, pro-rated cost sharing when the prescription is dispensed, which also reduces costs and waste. Sponsors will not be required to provide daily cost-sharing rates upon request until January 1, 2014.

h. Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (§ 423.120)

Part D sponsors must include an active and valid prescriber National Provider Identifier (NPI) on prescription drug event records (PDEs) that they submit to CMS, which will assist the Federal government in fighting possible fraudulent activity in the Part D program, because prescribers will be consistently and uniformly identified. This policy will not interfere with beneficiary access to needed medications because Part D sponsors must validate the NPI at point of sale, and if this is not possible, permit the prescription to be dispensed and obtain the valid NPI afterwards.

3. Summary of Costs and Benefits

Preamble section	Provision description	Total 6 year costs	Total 6 year benefits
II.A.1	Coverage Gap Discount Program (§§ 423.100, 423.505(b), 423.1002, and Subpart W (§§ 423.2300–423.2410)).	\$1.3 billion: Cost to Federal government \$76 M: Cost to Part D sponsors. \$29.8 billion: Cost to manufacturers.	\$29.7 billion in manufacturer discounts for Part D enrollees. Provides additional health benefits through increased adherence to medication regimens; and allows beneficiaries to reach the catastrophic coverage phase more quickly.
II.A.3	Pharmacy Benefit Manager’s Transparency Requirements (§§ 423.501 and 423.514).	N/A (Nearly all data elements are already collected for other purposes).	Promotes PBM transparency to Part D sponsors and Medicare.
II.B.4	Who May File Part D Appeals with the Independent Review Entity (§ 423.600).	\$5.84 million: Cost to Federal government. \$450,000: Cost to Part D sponsors.	Improves beneficiary access to the Part D appeals process.
II.C.2	Plan Performance Ratings as a Measure of Administrative and Management Arrangements and as a Basis for Termination or Non-Renewal of a Medicare Contract (§§ 422.510, 423.505, and 423.509).	N/A	<i>For beneficiaries:</i> Provides assurance that they are making a plan election from among only those sponsors that demonstrate a commitment to providing high quality service. <i>For CMS:</i> Emphasizes further CMS’ commitment to driving improvement in the health care and prescription drug benefit markets.
II.D.2	New Benefit Flexibility for Certain Dual Eligible Special Needs Plans (D-SNPs) (§ 422.102).	\$0.36 million to MA organizations	<i>For beneficiaries:</i> The flexibility for certain D-SNPs to offer additional supplemental benefits is in keeping with our objective of keeping Medicare-Medicaid (“dual eligible”) beneficiaries who are at risk of institutionalization in the community. <i>For CMS:</i> \$135.1 million in savings that accrue to the Federal Medicaid program and the Medicare program. <i>For States:</i> \$2.62 million in savings to the State Medicaid program.

Preamble section	Provision description	Total 6 year costs	Total 6 year benefits
II.D.4	Clarifying Coverage of Durable Medical Equipment (§§ 422.100 and 422.111).	N/A	N/A.
II.D.6	Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse, and Waste Control Program (§§ 423.100, 423.104 and 423.153).	\$0.5 million: cost to Part D sponsors	Over \$1.8 billion in estimated savings to the Part D program. Savings to beneficiaries who take advantage of option in consultation with their prescribers through lower cost-sharing for prescriptions. Reduction of medication waste.
II.E.11	Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (§ 423.120).	\$30.7 million: cost to Part D sponsors	Improved capability to fight fraud in the Medicare Part D program.

B. Effective and Applicability Dates

We note that these regulations will be effective 60 days after the publication of this final rule with comment period, except for two regulations whose effective dates are mandated by statute and one regulation whose effective date we are choosing to delay. Section 175(b) of MIPPA provides that barbiturates for specified health conditions and benzodiazepines be considered as Part D drugs for prescriptions dispensed on or after January 1, 2013. Similarly, section 10328 of the Affordable Care Act requires that, for plan years beginning on or after 2 years after the date of its

enactment, Part D sponsors offer to targeted beneficiaries annual comprehensive medication reviews (CMRs). The Affordable Care Act was enacted on March 23, 2010; accordingly, the revision regarding CMRs in LTC settings will become effective January 1, 2013. Additionally, we have delayed the effective date of the change to the policy on who may file Part D appeals with the Independent Review Entity to clarify that physicians and other prescribers may not request reconsiderations on behalf of beneficiaries until the beginning of the 2013 plan year (unless they are the beneficiary's authorized representative).

Unless specified in this final rule with comment period, the effective date and the applicability date are the same. There are some instances in which they may vary. For instance, because the health and drug plans under the Part C and D programs operate under contracts with CMS that are applicable on a calendar year basis, some provisions will not be applicable prior to contract year January 1, 2013. In Table 1 we provide a list of revisions whose applicable dates vary from the effective date of 60 days after publication of this final rule with comment period.

TABLE 2—FINALIZED REVISIONS WITH EFFECTIVE AND/OR APPLICABLE DATES OTHER THAN 60 DAYS AFTER PUBLICATION

Preamble section	Section title	Effective date applicability date
II.A.1	Coverage Gap Discount Program	The definition of “other health or prescription drug coverage” under § 423.2305 and change to the existing definition of “supplemental benefits” under § 423.100 are: effective 60 days after date of publication applicable 01/01/13 Note: All remaining regulations related to the Coverage Gap Discount Program remain: Effective 60 days after date of publication applicable 60 days after date of publication
II.A.2	Inclusion of Benzodiazepines and Barbiturates as Part D Covered Drugs.	effective 01/01/13 applicable 01/01/13
II.B.1	Good Cause and Reinstatement into a Cost Plan	effective 60 days after date of publication applicable 01/01/13
II.B.2	Requiring MA plans to disclose Member ID cards	effective 60 days after date of publication applicable 01/01/13
II.B.4	Clarifying Who May File Part D Appeals with the Independent Review Entity.	effective and applicable 01/01/13
II.C.1	CMS Termination of Health Care Prepayment Plans	effective 60 days after date of publication applicable 01/01/13
II.D.1	Cost Contract Plan Public Notification Requirements in Cases of Non-Renewal.	effective 60 days after date of publication applicable 01/01/13
II.D.2	Flexibilities for Certain Fully-Integrated Dual Eligible Special Needs Plans.	effective 60 days after date of publication applicable 01/01/13
II.D.4	Clarifying Coverage of Durable Medical Equipment	effective 60 days after date of publication applicable 01/01/13
II.D.5	Broker and Agent Requirements	effective 60 days after date of publication applicable 01/01/13
II.E.6	Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse, and Waste Control Program.	effective 60 days after date of publication applicable 01/01/14
II.E.2	Extending MA and Part D Program Disclosure Requirements to Section 1876 Cost Contract Plans.	effective 60 days after date of publication applicable 01/01/13

TABLE 2—FINALIZED REVISIONS WITH EFFECTIVE AND/OR APPLICABLE DATES OTHER THAN 60 DAYS AFTER PUBLICATION—Continued

Preamble section	Section title	Effective date applicability date
II.E.3	Clarification of, and Extension of Regional Preferred Provider Organization Plan Single Deductible Requirements to, Local Preferred Provider Plans.	effective 60 days after date of publication applicable 01/01/13
II.E.4	Technical Change to Private Fee-For-Service Plan Explanation of Benefits Requirements.	effective 60 days after date of publication applicable sometime after 2013 application cycle (when EOB model for all MA plans are finalized)
II.E.5	Application Requirements for Special Needs Plans	effective 60 days after date of publication applicable 01/01/13
II.E.6	Timeline for Resubmitting Previously Denied MA Applications	effective 60 days after date of publication applicable 01/01/13
II.E.7	Clarification of Contract Requirements for First Tier and Downstream Entities.	effective 60 days after date of publication applicable 01/01/13
II.E.9	Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings.	effective 01/01/13 applicable 01/01/13
II.E.11	Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers.	effective 60 days after date of publication applicable 01/01/13

C. Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) created a new “Part C” in the Medicare statute (sections 1851 through 1859 of the 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 1860D–42 of the Act) entitled the Medicare Prescription Drug Benefit Program, and made significant changes to the existing Part C 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 January 28, 2005 **Federal Register** (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 September 2008 and January 2009, we issued Part C and D regulations (73 FR 54226 and 74 FR 1494, respectively) to implement provisions in the Medicare Improvement for Patients and Providers Act (MIPPA) (Pub. L. 110–275). We promulgated a separate interim final rule in January 2009 to address MIPPA provisions related to Part D plan formularies (74 FR 2881). In April 2010, we issued Part C and D regulations (75

FR 19678) 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 then-recent legislative changes.

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 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 provisions enacted in 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 the October 11, 2011 **Federal Register** (76 FR 63018), we published a proposed rule with proposed revisions to the Medicare Advantage (MA) program (Part C) and prescription drug benefit program (Part D). The goals of this proposed rule were to: Implement provisions from the Affordable Care Act (ACA) and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA); strengthen beneficiary protections; exclude plan participants that perform poorly; improve program efficiencies; and clarify program requirements for contract year 2013. The proposed rule also included consideration of changes to the long term care facility (LTC) conditions of participation relating to pharmacy services.

II. Provisions of the Proposed Rule and Analysis and Response to Public Comments

We received approximately 516 items of timely correspondence containing comments on the proposed rule published in the October 11, 2011 **Federal Register** (76 FR 63018). Commenters included health and drug plan organizations, insurance industry trade groups, provider associations, pharmacists (including consultant pharmacists) and pharmacy associations, representatives of hospital and long term care institutions, pharmacy benefit managers, drug manufacturers, mental health and disease specific advocacy groups, beneficiary advocacy groups, private citizens, ombudsmen, and others.

In this final rule with comment period, we address all comments and concerns regarding the policies included in the proposed rule. We also reference, in the comment and response sections of this final rule with comment period, some comments that were outside the scope of the revisions we proposed in October 2011. We present a summary of public comments, as well as our responses to them in the applicable subject-matter sections of this final rule with comment period.

In the sections that follow, we discuss finalized revisions to the regulations in 42 CFR parts 417, 422, and 423 which govern the MA and prescription drug benefit programs. We also considered—but for the present decided against—making changes to the regulations setting forth the Medicare conditions of participation for long-term care facilities, which are currently codified at 42 CFR part 483. The preamble for the final rule will follow the structure of the October 2011 proposed rule and cover issues by topic area. Accordingly, our proposals address the following five specific goals:

- Implementing provisions of MIPPA and the Affordable Care Act.
- Strengthening beneficiary protections.
- Excluding poor performers.
- Improving program efficiencies.
- Clarifying program requirements.

Several of the proposed revisions and clarifications affect both the MA and prescription drug programs, while a few affect cost contracts under section 1876 of the Act. Within each of the five major sections of the preamble to this final rule with comment period, we discuss provisions in order of appearance in the associated regulations; a chart at the beginning of each of the five sections provides subsection numbers and titles and the associated regulatory citations.

Although we are not finalizing all the revisions proposed, discussion (including comments and responses) of non-finalized proposals will still appear in the same order as was the case in the October 2011 proposed rule.

A. Implementing Statutory Provisions

We are finalizing all three provisions in this section, two of which implement sections of the Affordable Care Act and one which implements a MIPPA mandate. In this final rule with comment period, we consolidate and codify previous guidance regarding the Coverage Gap Discount Program mandated by the Affordable Care Act. We believe this consolidation will provide stakeholders a central, clear source of direction. We are also finalizing regulations under a MIPPA provision which will provide treatment for beneficiaries who require benzodiazepines and, as specified, barbiturates. Lastly, we are finalizing regulations implementing section 6005 of the Affordable Care Act, which contains several reporting requirements for Part D sponsors and entities that provide pharmacy benefits management services to Part D sponsors. The changes based on provisions in the Affordable Care Act and MIPPA are detailed in Table 2.

TABLE 2—PROVISIONS TO IMPLEMENT STATUTORY PROVISIONS

Preamble section	Provision	Part 423	
		Subpart	Section(s)
II.A.1	Coverage Gap Discount Program	Subpart C	423.100
		Subpart K	423.505
		Subpart T	423.1000
		Subpart T	423.1002
		Subpart W (new)	423.2300–423.2345
II.A.2	Inclusion of Benzodiazepines and Barbiturates as Part D Covered Drugs	Subpart C	423.100
II.A.3	Pharmacy Benefit Manager's Transparency Requirements	Subpart K	423.501
			423.514

1. Coverage Gap Discount Program (§§ 423.100, 423.505(b), 423.1000, 423.1002, and 423.2300 Through 423.2345 (Subpart W))

Section 3301 of the Affordable Care Act made several amendments to Part D of Title XVIII of the Act, including adding sections 1860D–43 and 1860D–14A of the Act, and amending section 1860D–2(b) of the Act. Beginning on January 1, 2011, these amendments started phasing out the Part D coverage gap, or “donut hole” for Medicare beneficiaries who do not already receive low-income subsidies from CMS by establishing the Medicare Coverage Gap Discount Program (Discount Program)

and gradually increasing coverage in the coverage gap for both generic drugs (beginning in 2011) and brand name drugs and biological products (beginning in 2013). By 2020, beneficiary cost-sharing for applicable beneficiaries for all covered brand-name and generic drugs and biological products after the deductible will equal 25 percent until they reach catastrophic coverage.

The Discount Program makes manufacturer discounts available at the point-of-sale to applicable Medicare beneficiaries receiving applicable drugs while in the coverage gap. In general, the discount on each applicable drug is

50 percent of an amount equal to the negotiated price of the drug (less any dispensing fee). In general, manufacturers must agree to provide these discounts by signing an agreement with CMS in order for their applicable drugs to continue to be covered under Medicare Part D. We note that we have authority under section 1860D–43(c) of the Act to make an exception that allows coverage without an agreement, but based on the current level of participation by manufacturers and the breadth of applicable drugs covered by Discount Program Agreements, we do not anticipate needing to exercise such authority.

While manufacturer discounts under the Discount Program must be made available at point-of-sale, the Affordable Care Act does not specify how this should be done. At the same time, it prohibits us from receiving or distributing any funds of the manufacturer under the program. In order to provide point-of-sale discounts, we determined that an entity must have the information necessary to determine at that point in time that the drug is discountable, the beneficiary is eligible for the discount, the claim is wholly or partly in the coverage gap, and the amount of the discount, taking into consideration negotiated plan prices and that plan supplemental benefits must pay before the discount amount can be determined. We determined that the only entities that have the information necessary to provide point-of-sale discounts under the Discount Program are Part D sponsors. Only the Part D sponsor knows which Part D drugs are on its formulary and which enrollees have obtained an exception to receive a non-formulary Part D drug. The Part D sponsor has the low-income subsidy (LIS) information for beneficiaries that is necessary to exclude such claims from the Discount Program. The Part D sponsor tracks gross drug spend and TrOOP costs, which are necessary for determining when the beneficiary enters and exits the coverage gap. In addition, only the Part D sponsor knows which portion of the claim is in the coverage gap. For these reasons, we have determined that the Part D sponsor can accurately provide the discount at point-of-sale.

Section 1860D–14A(d)(5) of the Act authorizes us to implement the Discount Program through program instruction. We used this authority to issue program guidance to Part D sponsors on May 21, 2010, with an abbreviated notice and comment period, instructing them to provide applicable discounts on applicable drugs to applicable beneficiaries at point-of-sale beginning on January 1, 2011. The guidance also specified that Part D sponsors would report discount amounts to us, that we would invoice manufacturers on a quarterly basis for these discounts, and that the manufacturers would repay each Part D sponsor directly for the invoiced discount provided on the manufacturers' behalf. We determined that this model was necessary because Part D sponsors needed to provide the discounts at point-of-sale (as explained previously) and we needed to coordinate the discount payments between manufacturers and Part D sponsors to ensure discounts were

appropriately provided by the Part D sponsors and reimbursed by the manufacturers without directly receiving or distributing manufacturer funds (which we are prohibited from doing by section 1860D–14A(d)(2)(A) of the Act).

We implemented the Discount Program through program instruction due to the January 1, 2011 implementation deadline. Although not required, we are codifying most of existing Discount Program requirements (that is, those that we have previously implemented through the relevant Agreements and guidance) through full notice and comment rulemaking to provide additional transparency and a formal framework for operating the Discount Program and enforcing its requirements.

a. Scope (§ 423.2300)

Subpart W of part 423 implements provisions included in sections 1860D–14A and 1860D–43 of the Act. This subpart sets forth requirements as follows:

- Condition of coverage of drugs under Part D.
- The Medicare Coverage Gap Discount Program Agreement.
- Coverage gap discount payment processes for Part D sponsors.
- Provision of applicable discounts on applicable drugs for applicable beneficiaries.
- Manufacturer audit and dispute resolution processes.
- Resolution of beneficiary disputes involving coverage gap discounts.
- Compliance monitoring and civil money penalties.
- The termination of the Discount Program Agreement.

In this section, we summarize the provisions of subpart W and respond to public comments.

b. Definitions (§ 423.2305)

Proposed § 423.2305 included definitions for terms that are frequently used in this subpart. Those terms we believe need additional clarification are described separately in this section of the final rule with comment period.

(1) Applicable Beneficiary

Applicable beneficiary is defined in § 423.100. We clarify that enrollees in employer-sponsored group prescription drug plans (as defined in § 423.454) may qualify as applicable beneficiaries.

(2) Applicable Drug

Applicable drug is defined in § 423.100. We clarify that applicable drugs include all covered Part D drugs marketed under a new drug application

(NDA) or biologics license application (BLA) (other than a product licensed under section 351(k) of the Public Health Service Act). This means that such drugs and biological products would be subject to an applicable discount in the coverage gap even if a Part D sponsor otherwise treats the product as a generic under its benefit. Conversely, covered Part D drugs that are marketed under trade names and generally thought of as brand-name drugs or biological products, but are not approved under an NDA or licensed under a BLA (other than a product licensed under section 351(k) of the Public Health Service Act), are not applicable drugs that would be subject to an applicable discount in the coverage gap. Finally, drugs excluded from Part D under section 1860D–2(e)(2)(A) of the Act are not covered Part D drugs and therefore, such drugs would not be applicable drugs subject to an applicable discount even if covered by the Part D sponsor under an enhanced benefit. Part D sponsors would need to make these determinations on a National Drug Code (NDC) by NDC basis.

The second part of the definition provides that an applicable drug is either available on-formulary if a Part D sponsor uses a formulary, or available under the benefits provided by a Part D sponsor that does not use a formulary, or available to a particular beneficiary through an exception or appeal for that particular beneficiary. Applicable drugs covered under transition requirements and emergency fill policies are considered covered through an exception and, therefore, would be subject to applicable discounts.

In addition, we interpret the definition of an applicable drug for purposes of the Discount Program to exclude Part D compounds. While Part D sponsors may cover compounds with at least one Part D drug ingredient, and that ingredient would be an applicable drug if dispensed on its own, in light of the operational difficulty in accurately determining which portion(s) of a Part D compound represents the Part D drug, we believe that the applicable drug determination must be made with respect to the compound as a whole. Given that a compound as a whole is not approved under an NDA or BLA, a compound does not meet the definition of an applicable drug.

(3) Incurred Costs

Section 3301 of the Affordable Care Act amends section 1860D–2(b)(4) of the Act by adding subparagraph (E) when applying subparagraph (A) to include the negotiated price (as defined in

paragraph (6) of section 1860D–14A(g) of the Act) of an applicable drug of a manufacturer that is furnished to an applicable beneficiary under Medicare Coverage Gap Discount Program regardless of whether part of such costs were paid by a manufacturer under such program, except that incurred costs shall not include the portion of the negotiated price that represents the reduction in coinsurance resulting from the application of paragraph (2)(D) (that is, gap coverage). Therefore, we proposed to revise the definition of incurred costs in § 423.100 by adding the following language to paragraph (2)(ii) of such definition—“or by a manufacturer as payment for an applicable discount (as defined § 423.2305) under the Medicare Coverage Gap Discount Program (as defined in § 423.2305)”. This would mean that all applicable discounts paid by manufacturers would be treated as incurred costs for purposes of calculating the beneficiary’s TrOOP.

(4) Manufacturer

Section 1860D–14A(g)(5) of the Act defines manufacturer under the Discount Program as any entity which is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law. We proposed to adopt this statutory language in § 423.2305 and also add the following clarifying language “but includes entities otherwise engaged in repackaging or changing the container, wrapper, or labeling of any applicable drug product in furtherance of the distribution of the applicable drug from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer for use.” We proposed adding this language to the definition to track the defined term in the Discount Program Agreement, and because we believe this is the only practical way to define manufacturer under the Discount Program so that we can accurately assign responsibility for the discounts. While applicable drugs may actually be made by a limited number of companies, many more companies commonly label, relabel or repackage drug products and market them with unique labeler codes. It would be very difficult, if not impossible, to track all labeled, relabeled or repackaged products back

to the original maker of the drug if we limited the definition of manufacturer to the original maker. Therefore, for purposes of the Discount Program, we interpret the definition of “manufacturer” in § 423.2305 to mean any company associated with a unique labeler code included in the NDCs of the applicable drugs dispensed by pharmacies.

Applicable drugs are generally marketed with labels that include the product’s NDC number. In any NDC, the labeler code segment uniquely corresponds to a single company. While the same applicable drug may be marketed by multiple companies, only one company is linked to a unique labeler code. All manufacturers of applicable drugs, meaning all companies that label applicable drugs with unique labeler codes, would be required to sign an agreement for any applicable drugs with such labeler codes to be covered under Medicare Part D as of January 1, 2011. Only one manufacturer would be identified with each labeler code and, therefore, only one manufacturer would be responsible for paying applicable discounts associated with that labeler code at any given time.

(5) Medicare Part D Discount Information

In accordance with section 1860D–14A(d)(3)(C) of the Act, we require the TPA to provide adequate and timely information to manufacturers, consistent with the Discount Program Agreement with the manufacturers, as necessary for the manufacturer to fulfill its obligations under the Discount Program. Accordingly, we require the TPA to invoice each manufacturer each quarter on behalf of Part D sponsors for the applicable discounts advanced by the Part D sponsors to applicable beneficiaries and reported to CMS on the prescription drug event (PDE) records. The TPA also provides information to the manufacturer along with each quarterly invoice that is derived from applicable data elements available on PDE records as determined by CMS. We proposed to define this information in § 423.2305 as Medicare Part D Discount Information.

Generally, the Medicare Part D Discount Information would include certain claim-level detail derived from the PDE record. Information such as applicable drug NDC, dispensing pharmacy, quantity dispensed, date of service, days supply, prescription and fill number, and reported gap discount would be provided. We would provide this information so that a manufacturer could evaluate the accuracy of claimed

discounts and resolve disputes concerning the manufacturer’s payment obligations under the Discount Program.

Under the current Medicare Coverage Gap Discount Program Agreement with manufacturers, “Medicare Part D Discount Information” refers to the information derived from applicable data elements available on PDEs and set forth in Exhibit A of the Agreement that will be sent from the TPA to the manufacturer along with each quarterly invoice. However, we proposed to apply CMS’s cell-size suppression policy to the information we would release to manufacturers when 10 or fewer beneficiaries with the same applicable drug (identified as having the same first 2 segments of NDC) have claims at the same pharmacy (“low-volume claims”). Specifically, we proposed to withhold the pharmacy identifier information for these claims as an additional safeguard for preventing manufacturers from receiving information that could potentially be used to identify beneficiaries.

(6) Negotiated Price

We proposed to define negotiated price for purposes of the Discount Program consistent with section 1860D–14A(g)(6) of the Act, which defines “negotiated price” in terms of its meaning in § 423.100 as of the date of enactment of the section (that is, as of March 23, 2010), except that such definition does not include dispensing fees. Part D vaccine administration fees would be excluded from the definition of negotiated price for purposes of the Discount Program because we believe that, for purposes of the Discount Program, they are analogous to dispensing fees, which are explicitly excluded from the definition of negotiated price for purposes of determining the applicable discount. Unlike sales tax, dispensing fees and vaccine administration fees pay for services apart from the applicable drug itself. This is made clear by the fact that a vaccine administration fee may be billed separately from the dispensing of the vaccine. Sales tax remains included in the definition of negotiated price under the Discount Program. Thus, we proposed to define “negotiated price” for purposes of the Discount Program and this subpart as: the price for a covered Part D drug 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) is reduced by those discounts, direct or indirect subsidies,

rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point-of-sale; and (3) excludes any dispensing fee or vaccine administration fee for the applicable drug.

Further, although the statutory definition speaks only to the negotiated price with respect to a network pharmacy, given that there is no limitation on an applicable beneficiary's entitlement to applicable discounts on applicable drugs obtained out-of-network, we do not believe Congress intended to exclude these discounts from the Discount Program. Therefore, we proposed to specify in § 423.2305 that the negotiated price also means, for purposes of out-of-network claims, the plan allowance as determined under § 423.124, less any dispensing fee and vaccine administration fee.

(7) Other Health or Prescription Drug Coverage

Section 1860D–14A(c)(1)(A)(v) of the Act requires that the applicable discount get applied before any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries. Section 423.2305 of the proposed rule would define the term “other health or prescription drug coverage” as any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries. This would include any programs that provide coverage or financial assistance outside of Part D. Thus, the applicable discount would apply before any “other health or prescription drug coverage” such as state pharmaceutical assistance programs (SPAPs), Aids Drug Assistance Programs (ADAPs), Indian Health Service, or supplemental coverage required by the Commonwealth of Puerto Rico.

In addition, we proposed to include in the definition of “other health or prescription drug coverage” any coverage offered through employer group health or waiver plans (EGWPs) other than basic prescription drug coverage as defined in § 423.100. We also proposed to make a conforming change to the definition of supplemental benefits in § 423.100 to exclude benefits offered by EGWPs. With respect to EGWPs, this would mean that a manufacturer discount always would be applied before any additional coverage

beyond Part D, whether offered by the EGWP itself or by another party. We believe a clear standard in this regard is necessary to ensure we can properly administer the Discount Program for EGWP enrollees in light of our existing policies and procedures with respect to EGWPs.

Comment: A commenter recommended that we allow the determination of “applicable drug” status to be based upon plan formulary categorization as “brand name” or “generic” as opposed to being based upon the FDA approved marketing category.

Response: We disagree with this commenter. Section 1860D–14A(g)(2) of the Act clearly defines an applicable drug based upon its FDA marketing category as approved under a new drug application or licensed under a biologics license application. The definition proposed in § 423.2305 is consistent with the statute, and we do not have the authority to define it differently based upon formulary categorization.

Comment: A commenter supported our exclusion of Part D compounds from the definition of an applicable drug. However, another commenter stated that our exclusion of compounds from the definition of applicable drug was inconsistent with including compounds in the definition of a Part D drug.

Response: We disagree with the commenter that stated our exclusion of compounds from the definition of “applicable drug” was inconsistent with including compounds in the definition of a Part D drug. Whereas Part D sponsors can accurately determine that a compound has at least one Part D ingredient and the costs associated with such ingredient(s), we believe there are additional complexities associated with trying to accurately determine and validate discounts on an ingredient-level basis that require us to consider the compound as a whole for purposes of the Discount Program. Moreover, because a compound as a whole is not approved by the FDA under a new drug application or licensed under a biologics license application, a compound does not meet the definition of an applicable drug.

Comment: A few commenters supported our proposal to withhold specific data elements from the Medicare Part D Discount Information for low-volume claims. However, several commenters opposed our proposal. These commenters emphasized that the Medicare Part D Discount Information does not include any identifying beneficiary information and that under the Discount Program

Agreement, manufacturers cannot: (1) link Medicare Part D Discount Information to any other data; or (2) use Medicare Part D Discount Information for purposes unrelated to the Coverage Gap Discount Program, such as to identify beneficiaries. They believe that all of the Medicare Part D Discount information is necessary to accurately validate claims and to determine that a drug was appropriately covered under Medicare Part D as opposed to Medicare Part B.

Response: We appreciate all of the comments and have decided not to finalize the proposal to withhold additional data elements for low-volume claims. This proposal was intended to codify a prior CMS policy to withhold certain data elements on low-volume claims that has since changed and is no longer applicable.

Comment: A number of commenters requested that CMS change the definition of negotiated price under the Coverage Gap Discount Program to include dispensing and vaccine administration fees so that it is consistent with the other phases of the benefit. Further, they recommended that if the definition is not changed, we require point-of-sale notice that the dispensing fee or vaccine administration fee is not discounted and also include similar language on the explanation of benefits.

Response: Section 1860D–14A(g)(6) of the Affordable Care Act defines “negotiated price” for purposes of the Coverage Gap Discount Program and gap coverage in terms of its meaning in § 423.100 as of the date of enactment of the section (that is, as of March 23, 2010), except that such definition does not include dispensing fees. Since the statute clearly excludes dispensing fee from the definition, we do not have the authority to include it in the definition. As for vaccine administration fees, we continue to believe that, for purposes of the Discount Program, they are analogous to dispensing fees and, therefore, do not fall within the definition of “negotiated price.”

We also believe it is neither necessary nor practical to require beneficiary notification on every discounted claim that the beneficiary is responsible for paying the entire dispensing fee or vaccine administration fee. Electronic pharmacy transactions processed under the Health Insurance Portability and Accountability (HIPAA) approved National Council for Prescription Drug Programs electronic standard do not provide pharmacies with sufficient information at point-of-sale to know whether the beneficiary is paying the dispensing fee on a claim. Nevertheless,

we understand there is a need for more clarification with respect to beneficiary liability for dispensing and vaccine administration fees for applicable drugs in the coverage gap and thus have provided guidance in the 2013 Advance Notice clarifying how manufacturer, beneficiary, and Part D sponsor liabilities, including dispensing fee liabilities, for coverage gap claims must be determined beginning in 2013.

Comment: Several commenters supported our proposal to define all supplemental benefits offered by employer group waiver plans (EGWPs) as other health or prescription drug coverage that are not Part D benefits. However, a few commenters opposed the proposal and contend that CMS does not have the authority to adopt this proposal and that it would be imprudent to adopt the proposal even if CMS had the authority to do so. They state that CMS cannot use its waiver authority under section 1860D–22(b) of the Act because it is not a waiver of a requirement that hinders the design of, the offering of, or the enrollment in employer sponsored coverage.

Response: We disagree with the commenters who believe that we do not have the authority to exclude any coverage offered through EGWPs, other than basic prescription drug coverage as defined in § 423.100, from the definition of Part D supplemental benefits and, therefore, treat them as other health or prescription drug coverage. Under current waivers authorized by section 1860D–22(b) of the Act, EGWP sponsors submit only one formulary and a standard-defined benefit package for review by CMS. We waived the requirement for EGWPs to submit final benefit packages and formularies because we believe upholding the requirement would hinder the design, offering, or enrollment in employer-sponsored coverage given the additional complexity and level of effort that would be required of EGWPs to submit all applicable information on all such benefit packages. Consequently, we have never reviewed any supplemental benefits offered through EGWPs as Part D benefits nor have we provided guidance that such benefits are Medicare or non-Medicare benefits. In the absence of such guidance, we are aware that some EGWPs previously may have considered these supplemental benefits to be Medicare benefits while others may have considered them to be non-Medicare benefits.

As discussed in the proposed rule, the Discount Program now makes it crucial to be able to distinguish Part D benefits (which apply before the applicable discount) from non-Medicare benefits

(which apply after the applicable discount). In order to make this distinction consistently and accurately, we believe it is necessary to define all such supplemental benefits as other health or prescription drug coverage because requiring submission of benefit packages would hinder the design of, the offering of, or the enrollment in employer-sponsored coverage for the same reasons that we currently waive the requirement for EGWPs to submit final benefit packages and formularies as well as a high probability that many of these supplemental benefits are also governed by other non-Medicare rules (for example ERISA) and collective bargaining agreements that could make it difficult to comply with Part D rules. Moreover, while the submission requirement itself would be a hindrance, the effort required to restructure benefits to provide all additional gap coverage as other coverage in order to maximize discounts, which we could not prevent, would add costs and complexity to the provision of EGWP coverage and, therefore, additionally hinder the design and offering of employer sponsored coverage. Accordingly, we believe it is necessary to use the waiver authority under section 1860D–22(b) of the Act to explicitly exclude any supplemental benefits offered through EGWPs (which we do not review and have never reviewed) from Part D supplemental benefits and define them as other health or prescription drug coverage.

Comment: Several commenters requested that we clarify the effective date for defining any coverage offered through EGWPs, other than basic prescription drug coverage as defined in § 423.100, as other health or prescription drug coverage is January 1, 2013.

Response: We clarify that, beginning on January 1, 2013, EGWP supplemental benefits over basic Part D coverage must be treated as other health or prescription drug coverage. We are designating January 1, 2013 as the applicable date of this requirement in order to avoid midyear disruptions of operations for any EGWPs that currently treat supplemental benefits as Medicare benefits and therefore, calculate the discount after applying such benefits. This will provide them time to align their systems to meet the January 1, 2013 requirements.

Comment: A commenter requested that CMS clarify that coverage offered through EGWPs, other than basic prescription drug coverage as defined in § 423.100, will be defined as other health or prescription drug coverage only for purposes of the Coverage Gap

Discount Program but not for other purposes such as appeals and grievances.

Response: Beginning January 1, 2013, any coverage offered through EGWPs, other than basic prescription drug coverage as defined in § 423.100, will be defined as other health or prescription drug coverage and not considered Medicare benefits. This definition applies to all of Medicare Part D and is not limited to the Discount Program. While the Discount Program triggered our decision to explicitly exclude supplemental coverage offered through EGWPs from Part D supplemental benefits, we believe it is necessary to apply the exclusion more broadly for the same reasons it is necessary under the Discount Program. Specifically, because we do not receive and review these benefits we cannot appropriately oversee their provision and requiring submission of these benefits needs to be waived because we believe it would hinder the design of, offering, or enrollment in employer sponsored coverage. Therefore, other Medicare Part D requirements, such as those related to appeals and grievances, will not apply to these non-Medicare benefits.

After consideration of the public comments received, we are finalizing these definitions with one modification. We are not finalizing our proposal to withhold some of the Medicare Part D Discount Information from manufacturers on low-volume claims. All definitions will be effective and applicable 60 days after publication of the rule, except for the definition of “other health or prescription drug coverage” found in § 423.2305 and the conforming change to the definition of supplemental benefits in § 423.100 to exclude benefits offered by EGWPs, which definition and change to an existing definition will on January 1, 2013.

c. Condition for Coverage of Drugs Under Part D (§ 423.2310)

Section 1860D–43(a) of the Act specifies that in order for coverage under Part D to be available for the covered Part D drugs (as defined in section 1860D–2(e) of the Act)) of a manufacturer, that manufacturer must agree to participate in the Discount Program, enter into a Discount Program Agreement, and enter into an agreement with the TPA. Although the statute contemplates that all manufacturers of covered Part D drugs must sign Discount Program Agreements in order for coverage under Part D to be available for such drugs, when read in context with the other provisions governing the Discount Program, we believe the

plainest reading of section 1860D–43(a) of the Act is both inappropriate and infeasible. Thus, in implementing the Discount Program last year, we specified in program guidance that the exclusion from Part D coverage applies only to the applicable drugs of a manufacturer that fails to sign the Agreement and participate in the Discount Program. We currently apply the exclusion from Part D coverage only to a manufacturer's applicable drugs. Other Part D drugs, such as generic drugs (as defined in § 423.4) of a manufacturer continue to be covered under Medicare Part D irrespective of the manufacturer's participation in the Discount Program. We proposed to codify this policy in regulations.

Section 1860D–43(c)(1) of the Act authorizes us to allow coverage for drugs that are not covered by Discount Program Agreements if we have made a determination that the availability of the drug is essential to the health of beneficiaries under this part, and we proposed to codify this requirement in § 423.2310(b) of our proposed rule. However, we believe it is highly unlikely that we will need to exercise this authority given the strong participation by manufacturers in the Discount Program since 2011 and the likely availability of therapeutic alternatives for any Part D drugs.

Comment: Many commenters supported our proposal to exclude only applicable drugs that are not covered by a signed manufacturer agreement from Medicare Part D and continue to allow coverage of other Part D drugs, such as generic drugs, irrespective of a manufacturer's participation in the Coverage Gap Discount Program. However, a commenter recommended that we delay codifying this proposal until the Discount Program is fully implemented and until evidence exists that manufacturers plan to continue participating in the Discount Program.

Response: We agree with commenters that supported our proposal and do not believe it is necessary to delay codifying it until there has been more experience with the Discount Program. We believe it is important to codify this provision now to provide certainty about our policy.

After consideration of the public comments received, we are finalizing the policies in this section without modification except for the technical correction to § 423.2315(b)(7) that clarifies manufacturers must provide timely information about discontinued drugs to enable the publication of accurate information regarding what drugs, identified by NDC, are in current distribution.

d. Medicare Coverage Gap Discount Program Agreement (§ 423.2315)

Section 1860D–14A of the Act requires us to enter into agreements with manufacturers that participate in the Discount Program and to establish a model agreement in accordance with terms specified under section 1860D–14A(b) of the Act that provides for the performance of duties required under section 1860D–14A(c)(1) of the Act. In consultation with manufacturers, we established the model agreement on August 1, 2010 and proposed to codify in § 423.2315 provisions that we believe must be included in the model agreement in order to meet the statutory requirements in these sections.

(1) Obligations of the Manufacturer

Section 1860D–14(A)(b)(1) of the Act specifies that the Discount Program Agreement between CMS and the manufacturers shall require manufacturers to provide applicable beneficiaries access to applicable discounts for applicable drugs of the manufacturer at the point-of-sale. In light of how the Discount Program has been structured (see the discussion in section II.A.1. of the October 11, 2011 proposed rule) (76 FR 63018) we proposed to implement this requirement as set forth in the current Discount Program Agreement. That is, we proposed in § 423.2315(b)(2) to require manufacturers to reimburse all applicable discounts provided by Part D sponsors on behalf of the manufacturer for all applicable drugs having NDCs with the manufacturer's FDA-assigned labeler code(s) that were invoiced to the manufacturer within a maximum of 3 years of the date of dispensing based upon information reported to CMS by Part D sponsors and used by the TPA to calculate the invoice.

In order for CMS and Part D sponsors to determine which applicable drugs are covered by Discount Program Agreements, the manufacturers must provide CMS in advance with the FDA-assigned labeler code(s) for all applicable drug NDCs covered by their Discount Program Agreement. Under the current Discount Program Agreement, manufacturers must provide all of their labeler codes to CMS and must promptly update CMS with any additional labeler codes for applicable drugs no later than 3 business days after learning of a new code assigned by the FDA. We included this requirement in the Discount Program Agreement because, for the reasons previously described, it is the most efficient and accurate way to track which manufacturer is responsible for paying

the applicable discount for an applicable drug and to assist Part D sponsors in determining which drugs are applicable drugs. We maintain an up-to-date listing of the labeler codes covered under the Discount Program Agreements on the CMS Web site so that Part D sponsors can determine which labeler codes are covered by a Discount Program Agreement. To ensure that we have up-to-date information for this purpose, § 423.2315(b)(4) would require manufacturers to provide CMS with all labeler codes for all the manufacturer's applicable drugs and promptly update CMS with additional labeler codes for applicable drugs no later than 3 business days after learning of a new code assigned by the FDA.

To permit CMS and Part D sponsors to accurately identify applicable drugs, we proposed to codify the requirement set forth in the Discount Program Agreement that manufacturers electronically list and maintain an up-to-date electronic listing of all NDCs of the manufacturer, including the timely removal of discontinued NDCs, in the FDA NDC Directory. We believe this requirement will help ensure that all currently marketed applicable drugs are subject to the applicable discount and that only currently marketed applicable drugs are subject to the discount. Because manufacturers know the regulatory and marketing status of their products, they are in the best position to make this information available to Part D sponsors and CMS. We believe maintaining an up-to-date FDA electronic listing provides the most efficient, timely, and authoritative mechanism to accomplish this purpose while placing little additional burden on manufacturers that already must use the FDA electronic registration and listing system to comply with other FDA requirements. In this final rule with comment period, we are making a technical correction to this requirement by specifying that manufacturers provide timely information about discontinued drugs to enable the publication of accurate information regarding what drugs, identified by NDC, are in current distribution. This language replaces the requirement that manufacturers timely remove discontinued NDCs in the FDA NDC Directory because we realized that it is the FDA that makes the determination to remove NDCs based upon information provided by the manufacturer.

We also proposed to require manufacturers to maintain up-to-date NDC listings with the electronic database vendors for which they provide their NDCs for pharmacy claims

processing. Part D sponsors and the rest of the pharmacy industry rely upon these databases for adjudication of pharmacy claims at the point-of-sale, including discounting applicable drugs, and, therefore it is imperative that the information in these databases is accurate and up-to-date. Our proposal would require manufacturers to ensure that electronic database vendors are prospectively notified of expiration dates for NDCs of products that are no longer available on the market. We believe this requirement will benefit manufacturers because it will ensure that applicable discounts cease being applied as of the last lot expiration date of an applicable drug that is no longer on the market.

In implementing the Discount Program Agreement, we required manufacturers to pay each Part D sponsor in the manner specified by us within 38 calendar days of receipt of an invoice and Medicare Part D Discount Information for the quarterly applicable discounts included on the invoice. As previously described, we implemented the Discount Program such that Part D sponsors pay applicable discounts on behalf of manufacturers in order to comply with the statutory mandate that discounts be provided at the point-of-sale, and therefore we require manufacturers to reimburse Part D sponsors promptly because it is the manufacturers that are financially responsible for payment of applicable discounts. Given this structure, we proposed to codify this requirement at § 423.2315(b)(3). We further proposed in § 423.2315(b)(10) to require that manufacturers pay the quarterly invoices to accounts established by Part D sponsors via electronic funds transfer, unless otherwise specified by CMS, and within 5 business days of the transfer provide the TPA with electronic documentation of payment in a manner specified by CMS. We believe these requirements are appropriate because they provide sufficient time for manufacturers to process the information in order to make the payments and are generally consistent with manufacturer obligations under the Medicaid Drug Rebate Program. Moreover, § 423.2315(b)(2) would prohibit manufacturers from withholding discount payments for their applicable drugs pending dispute resolution and, therefore, the 38-day requirement applies even if the manufacturer decides to dispute discount payments. As noted in our May 21, 2010 guidance, we believe this requirement is necessary to ensure that the manufacturer discounts are paid to

Part D sponsors in a timely manner and are not delayed due to disputed amounts. We address our proposals with respect to manufacturers' disputes later in this section of the final rule with comment period.

Section 1860D–14A(b)(2) of the Act requires each manufacturer with an executed Discount Program Agreement in effect to collect and have available appropriate data, as determined by CMS, to ensure that it can demonstrate to CMS compliance with the requirements under the Discount Program. In § 423.2315(b)(5), we would codify this requirement by specifying that such information would include data related to manufacturer labeler codes, FDA drug approvals, FDA NDC Directory listings, NDC last lot expiration dates, utilization and pricing information relied on by the manufacturer to dispute quarterly invoices and any other data we determine are necessary to carry out the Discount Program. In addition, manufacturers must collect, have available and maintain such information for a period of not less than 10 years from the date of payment of the invoice. The minimum 10-year retention requirement aligns with the standard Part D record retention requirement for Part D sponsors, thereby ensuring that applicable information would be maintained by manufacturers for the same time period.

Section 423.2315(b)(6) would require manufacturers to comply with the audit and the dispute resolution requirements proposed in § 423.2330, which are discussed in section II.A.1.g. of this final rule with comment period.

Section 1860D–43(a)(3) of the Act requires manufacturers to enter into and have in effect, under terms and conditions specified by CMS, a contract with a third party that CMS contracted with under subsection (d)(3) of section 1860D–14A of the Act. We proposed to codify this requirement in § 423.2315(b)(9) by requiring the manufacturer to enter into and have in effect, under terms and conditions specified by CMS, an agreement with the TPA that has a contract under section 1860D–14A(d)(3) of the Act.

Finally, proposed § 423.2315(b)(11) would restrict the use of information disclosed to the manufacturer on the invoice, as part of the Medicare Part D Discount Information, or upon audit or dispute such that the manufacturer could use such information only for purposes of paying the discount under the Discount Program. This means that manufacturers would be allowed to use the information only as necessary to evaluate the accuracy of invoiced

discounts and resolve disputes concerning the manufacturer's payment obligations under the Discount Program. We believe this is an important limitation because we are making claim-level detail available to manufacturers that is not otherwise available to the public and therefore, should not be used for reasons beyond which it is being made available. As specified in the Data Use Provisions in Exhibit C of the Discount Program Agreement, the manufacturer would be prohibited from using the information to perform any functions not governed by the Discount Program Agreement, including, but not limited to, determination of non-Coverage Gap Discount payments to Part D sponsors and their subcontractors, payments to other providers of health and drug benefits under any Federal health care program or for marketing activities. Nevertheless, we recognize that manufacturers need to account for the discounts for financial statement forecasting and accounting purposes and therefore, these restrictions would not apply to the use of aggregated, summary-level data (that is, not prescription or claim-level data) for such purposes.

(2) Timing and Length of Agreement

Section 1860D–14A(b)(1)(C) of the Act states that in order for an agreement with a manufacturer to be in effect under this section with respect to the period beginning on January 1, 2011, and ending on December 31, 2011, the manufacturer shall enter into such agreement not later than 30 days after the date of establishment of a model agreement. It also states that for 2012 and subsequent years the manufacturer shall enter into such agreement (or such agreement shall be renewed) not later than January 30 of the preceding year. We proposed to codify these requirements in § 423.2315(c)(1) and (c)(2).

Section 1860D–14A(b)(4)(A) of the Act also states that an agreement shall be effective for an initial period of not less than 18 months and shall automatically be renewed for a period of not less than 1 year unless terminated under section 1860D–14A(b)(4)(B) of the Act. To ensure that the end of the initial term of each Discount Program Agreement corresponds to the end of a calendar year, § 423.2315(c)(3) would specify that all Discount Program Agreements have an initial period of 24 months, with automatic renewal for a period of 1 year each January 1 thereafter, unless the agreement is terminated in accordance with § 423.2345.

Comment: A commenter requested that CMS clearly state that the Discount Program Agreement cannot be modified through rulemaking. The commenter argued that the Discount Program Agreement predates the regulations and already states, “the Manufacturer’s full compliance with the responsibilities listed * * * in Section II shall constitute satisfaction of the Manufacturer’s responsibilities under the Discount Program.” They point out that the proposed rule generally tracks the manufacturers obligations set forth in the Discount Program Agreement but are not identical in a number of ways. The commenter recommended that CMS reaffirm that manufacturers’ obligations are limited to those listed in Section II of the Discount Program Agreement.

Response: We disagree with the commenter that we cannot modify the Discount Program Agreement through rulemaking. The Affordable Care Act required us to establish a model Discount Program Agreement, in consultation with manufacturers, and allow for comment on such model agreement. Section IX (g) of the model agreement specifies that CMS retains the authority to amend the model agreement after consulting with manufacturers and allowing for comment on such amendments. While formal rulemaking is not the only mechanism for consulting with manufacturers, we believe the notice and comment rulemaking process clearly meets the requirement for consultation with manufacturers and allowing for comment.

In some instances we proposed new requirements. For example, we proposed to amend the Discount Program Agreement by adding a requirement that manufacturers maintain up-to-date NDC listings with the electronic database vendors for which manufacturers provide NDCs for pharmacy claims processing. In other instances, the proposed language was intended to mirror the current model Discount Program Agreement requirement even if the language is not identical. We will review the language in the model Discount Program Agreement and make conforming changes if we believe it is necessary to remove any ambiguity between the regulation and the model agreement. This is consistent with our approach to amending Medicare Part C/D agreements with Part D sponsors whereby we generally codify requirements and amend the agreements during the next contracting cycle, which in this case will be for calendar year 2014. Nevertheless, these codified requirements become effective 60 days

after the date of publication of this final rule with comment period in the **Federal Register**. Finally, we stated in the proposed rule that we were not codifying all of the provisions in the model Discount Program Agreement; we therefore do not intend to make further changes to any such provisions without first consulting with the manufacturers.

Comment: A few commenters supported our proposal to codify the requirement that manufacturers electronically list and maintain up-to-date electronic listings of all national drug codes (NDCs) of the manufacturer, including the timely removal of discontinued NDCs, in the FDA NDC Directory. These commenters also supported our proposal to require manufacturers to maintain up-to-date NDC listings with the electronic database vendors for which they provide their NDCs for pharmacy claims processing. However, these commenters do not believe our proposal goes far enough because it does not specify that the manufacturer must ensure their listings are accurate and therefore recommend that we impose monetary penalties and sanctions on manufacturers for inaccurate or out-of-date information.

Response: We believe that manufacturers are already required to provide the FDA with accurate information. We continue to work with the FDA on improving the availability of Part D drug information and could potentially implement additional prescription drug event (PDE) measures in the future to ensure that we only accept PDEs with NDCs that represent currently marketed drug products. We do not believe we have the authority under the Discount Program to impose monetary penalties on manufacturers for inaccurate or out-of-date information listed with the FDA, but we will consider other compliance actions against manufacturers that fail to fulfill their obligations under the Discount Program Agreement.

Comment: A commenter requested that we clarify what information proposed in § 423.2315(b)(5) would be required of manufacturers to maintain regarding FDA approval and NDC Directory listing information for 10 years. Specifically, this commenter noted that these two categories are specified in preamble but are not specified in the regulatory text or Discount Program Agreement. Moreover, the commenter requests that we further specify precisely what data CMS believes should be collected, kept available, and maintained by providing illustrative examples.

Response: We specified the FDA approval and NDC Directory listing information in the preamble to help clarify what data related to manufacturer labeler codes needs to be collected, kept available, and maintained. However, for further clarity we will specify these categories in the regulatory text. We also clarify that pertinent NDC expiration dates refers to last lot expiration dates and have made this change to the regulation text. We do not have other examples that further specify the data manufacturers must collect, keep available, and maintain except to specify that such data should include any information that would be useful to either dispute or support a manufacturer’s obligation to pay discounts for its applicable drug products under the Discount Program.

Comment: Many commenters raised concerns with the requirement that a manufacturer must sign a Discount Program Agreement by January 30th of the preceding year because it could result in new drugs being unavailable under Medicare Part D for almost 2 years if this deadline is missed. They point out that some manufacturers may not have been aware of the deadline because they previously did not manufacture any applicable drugs. These commenters recommend that we consider additional measures, such as allowing manufacturers to enter into provisional agreements to join the Discount Program pending FDA approval of a new drug so there would not be a waiting period before the drug could be covered. In addition, these commenters urge CMS to establish a process for using its authority under section 1860D–43(c) of the Act to allow coverage for Part D drugs not covered under agreements if we determine that a drug is “essential to the health of beneficiaries.”

Response: We appreciate the concerns raised by commenters that new drugs manufactured by companies without existing Discount Program Agreements could be excluded from Medicare Part D until the next opportunity to enter into the Discount Program. However, the deadline of January 30th of the preceding year is a statutory deadline. But we already allow, and encourage, manufacturers without drug products currently on the market to sign Discount Program Agreements in advance so that there would be no waiting period if they do begin marketing an applicable drug; a number of companies have done so. We are also aware that some manufacturers have been successful in working out licensing arrangements with other manufacturers that have existing Discount Program Agreements

to temporarily include drug products under such existing agreements and avoid any delay in access under Part D. Based on the current level of participation by manufacturers and the breadth of applicable drugs covered by Discount Program Agreements, we do not believe it is necessary at this time to establish a detailed process for using our authority under section 1860D–43(c) of the Act to allow coverage for applicable drugs not covered by Discount Program Agreements.

After consideration of the public comments received, we are finalizing the proposals in this section with two modifications. We added FDA drug approval data and FDA NDC Directory listing data to the required information in § 423.2315(b)(5) and clarified in § 423.2315(b)(5) that pertinent NDC expiration dates refers to NDC last lot expiration dates.

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

We are finalizing our October 11, 2011 proposed rule to provide monthly interim coverage gap payments to Part D sponsors in § 423.2320(a). The interim payments ensure that Part D sponsors will have the funds available to advance the manufacturer discounts to applicable beneficiaries at the point of sale. We also proposed, and are now finalizing, a process to reconcile the estimated interim coverage gap discount payments with actual Discount Program costs in § 423.2320(b). Coverage Gap Discount Reconciliation will occur after Part D payment reconciliation.

Comment: A number of commenters raised the issue of dispensing fees and vaccine administration fees for applicable drugs in the coverage gap. One requested that CMS clarify plan sponsor responsibility in the gap for applicable drugs. Others noted that the definition of negotiated price is not the same in the coverage gap as it is in the other phases because it excludes the dispensing fee. Commenters noted that if beneficiaries must pay dispensing fees and vaccine administration fees for brand drugs in the gap, this would increase their out-of-pocket costs.

Response: We issued proposed guidance on Part D plan sponsor liability for dispensing and vaccine administration fees in the Advance Notice of Methodological Changes for Calendar Year (CY) 2013 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2013 Call Letter, which was published on February 17, 2012. Based on comments received in response to the Advance Notice, we will finalize a policy in the Final Rate Announcement.

f. Provision of Applicable Discounts (§ 423.2325)

(1) Obligations of Part D Sponsors; Provision of Point-of-Sale Discounts

Section 1860D–14A(c)(1)(A)(ii) of the Act requires the manufacturer discounts to be provided to beneficiaries at the point-of-sale. As discussed previously in this subpart, manufacturer discounts can be provided at point-of-sale only if the entity adjudicating the electronic pharmacy claim has the information necessary to determine at that point in time: (1) The drug is an applicable drug; (2) the beneficiary is an applicable beneficiary; (3) the claim is wholly or partly in the coverage gap; and (4) the amount of the discount, taking into consideration Part D supplemental benefits that pay first. Working with industry experts on electronic transactions, we have determined that the only entity capable of providing the discount at point-of-sale is the Part D sponsor because no other entity would have all four pieces of information at that time. Therefore, § 423.2325(a) would require Part D sponsors to provide applicable beneficiaries with applicable discounts on applicable drugs at point-of-sale on behalf of the manufacturer. Part D sponsors would be required by § 423.2325(b)(1) to determine that: (1) an enrollee is an applicable beneficiary (as defined in § 423.100); (2) a Part D drug is an applicable drug (as defined in § 423.100); and (3) the amount of the applicable discount (as defined in § 423.2305) in order to provide a discount at point-of-sale.

Part D sponsors would use the date of dispensing for purposes of providing an applicable discount at point-of-sale and determining the amount of such discount. However, if later information changes the beneficiary's eligibility for the applicable discount back to the date of dispensing (for example, retroactive low-income subsidy status changes, or retroactive changes resulting from automated TrOOP balance transfers between Part D sponsors via Financial Information Reporting (FIR) transactions), or changes the amount of the applicable discount or the applicable beneficiary's cost sharing, we proposed to require, in § 423.2325(b)(2), that Part D sponsors make retroactive adjustments to the applicable discount as necessary to reflect such changes. For example, if a claim for an applicable drug was originally adjudicated in the initial coverage phase but later moved into the coverage gap as a result of receipt of an automated TrOOP balance transfer amount from a previous Part D sponsor, the applicable discount and the

corrected beneficiary cost-sharing would be reported on the adjusted PDE. Conversely, if an original claim was adjudicated in the coverage gap with an applicable discount but is later reprocessed in the catastrophic phase as a result of the receipt of an automated TrOOP balance transfer amount, the applicable discount reported on the adjusted PDE is the mechanism for refunding the manufacturer.

If an applicable beneficiary has a claim for an applicable drug that straddles the coverage gap and another phase of the Part D benefit, section 1860D14A-(g)(4)(C) of the Act requires that Part D sponsors only provide the discount on the portion of the negotiated price of the applicable drug that falls at or above the initial coverage limit (ICL) and below the annual out-of-pocket threshold. Because our proposed definition of negotiated price for purposes of the Discount Program would exclude both the dispensing fee and vaccine administration fee, proposed § 423.2325(b)(3) would have required the dispensing fee and vaccine administration fee be included in the portion of the negotiated price that falls below the ICL or above the annual out-of-pocket threshold, to the extent possible (that is, as much of the dispensing fee that can be included in the portion below the ICL or above the annual out-of-pocket threshold). However, as discussed later, we are not finalizing this proposal at § 423.2325(b)(3).

Section 423.2325(b)(4) would require Part D sponsors to first determine whether any affected beneficiaries need to be notified by the Part D sponsor that an applicable drug is eligible for Part D coverage whenever CMS specifies a retroactive effective date for a labeler code and then notify such beneficiaries. This situation could occur if participating manufacturers fail to timely notify CMS when a new labeler code becomes available or otherwise fail to provide us with all of their labeler codes as required.

In § 423.2325(c) we proposed to require that Part D sponsors must provide an applicable discount for applicable drugs submitted by applicable beneficiaries via paper claims, including out-of-network and in-network paper claims, if such claims are payable under the Part D plan. We do not believe the point-of-sale requirement was intended to exclude discount payments for claims that were not adjudicated by the Part D sponsor at point-of-sale: even though the statute requires provision of the discount at the point-of-sale, it does not state that applicable beneficiaries are not entitled

to the discount if it was not provided at the point-of-sale. Instead, we believe this requirement was meant to ensure the discount would be available at the point-of-sale when and if a claim is electronically adjudicated. Therefore, beneficiaries would still receive the discount in the limited circumstances when they submit claims for reimbursement that were not adjudicated at the point-of-sale, such as when they needed to obtain a prescription from an out-of-network pharmacy or on an emergency basis.

(2) Collection of Data

Section 1860D–14A(c)(1)(C) of the Act states that we may collect appropriate data from Part D sponsors in a timeframe that allows for applicable discounts to be provided for applicable drugs. Section 423.2325(d) of the proposed rule would require Part D sponsors to provide CMS with appropriate data on the applicable discount provided by the Part D sponsors in a manner specified by CMS. In implementing the Discount Program we determined that using the existing PDE reporting process to collect the necessary data would be most efficient and least burdensome for Part D sponsors. Thus, we would require Part D sponsors to report the applicable discount that was provided at the point-of-sale as part of the PDE record in addition to the other claim-level detail that is reported on the PDE. We would also require Part D sponsors to report confirmation of payment from manufacturers during the quarterly invoice process.

(3) Other Health or Prescription Drug Coverage

Section 1860D–14A(c)(1)(A)(v) of the Act requires that applicable discounts for applicable drugs get applied before any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries as the Secretary may specify. We proposed to codify the requirement in § 423.2325(f) by specifying that an applicable discount must be applied to beneficiary cost-sharing when Part D is the primary payer before any other health or prescription drug coverage is applied. Since the Part D sponsor would provide the discount at the same time as it makes primary payment on the claim, this coordination generally would take place in real time as the claim is adjudicated by the pharmacy in accordance with existing Part D coordination of benefit requirements.

We specify that this requirement would not apply to Medicare secondary payer claims because the beneficiary would not have a Medicare Part D coverage gap on the initial claim to the primary payer. However, this requirement would apply to coordination of benefit claims in which the Part D sponsor coordinates benefits post point-of-sale with another payer who paid primary in error and reimburses that payer and/or the beneficiary for amounts that the plan would have paid as the primary payer.

(4) Supplemental Benefits

Section 1860D–14A(c)(2) of the Act provides that if an applicable beneficiary has supplemental benefits under his or her Part D plan, the applicable discounts shall not be provided until after such supplemental benefits have been applied. Supplemental benefits offered under a Part D plan would have the meaning set forth in § 423.100 (see discussion of supplemental benefits under the proposed definition “other health or prescription drug coverage”). Section 423.2325(e)(1) would codify this requirement by specifying that an applicable discount is applied to beneficiary cost-sharing after supplemental benefits have been applied to the claim for an applicable drug, and paragraph (e)(2) would establish that no applicable discount is available if supplemental benefits eliminate the coverage gap so that a beneficiary has zero cost-sharing on a claim.

If a Part D sponsor offers an individual market plan with supplemental benefits on applicable drugs covered between the plan’s initial coverage limit and the Medicare Part D catastrophic threshold using either coinsurance or fixed copay, the value of the supplemental benefits would need to be calculated first on any claim for an applicable drug as the difference between the proposed supplemental cost-sharing and the coinsurance under the basic benefit. For example, if the supplemental benefit for an applicable drug had a 60 percent coinsurance, the value of the supplemental benefits that would need to be applied first (plan liability) would be 40 percent (100 percent coinsurance under basic minus 60 percent coinsurance) of the negotiated price of the drug. The applicable discount would then be calculated as 50 percent of the negotiated price (as defined in § 423.2305) less the supplemental benefit. Beneficiary cost-sharing would then be the remainder of the negotiated price after the plan liability and applicable discount had been applied.

Thus, in the case of either a coinsurance or copay design for supplemental benefits, the amount the beneficiary pays at point-of-sale would generally be approximately 50 percent of his or her expected cost-sharing under the plan’s benefit package. This amount will change over time as the coinsurance level in the basic benefit for a beneficiary is reduced until it reaches 25 percent in 2020. Proposed § 423.2325(e)(3) would have required that the dispensing fee and the vaccine administration fee be included in the Part D sponsor liability portion of a claim with supplemental benefits. For the same reasons that we proposed to require the dispensing fee and the vaccine administration fee to be applied to the portion of a claim for an applicable drug that falls below the initial coverage limit or above the annual out-of-pocket threshold, to the extent possible, on straddle claims, we believed that including the dispensing fee and the vaccine administration fee in the plan liability supports the statutory goal of alleviating the burden of the coverage gap on applicable beneficiaries.

(5) Pharmacy Prompt Payment

Section 1860D–14A(c)(1)(A)(iv) of the Act requires procedures to ensure that, not later than the applicable number of calendar days after the dispensing of an applicable drug by a pharmacy or mail order service, the pharmacy or mail order service is reimbursed for an amount equal to the difference between: (1) the negotiated price of the applicable drug; and (2) the discounted price of the applicable drug. This amount would be equal to the amount of the applicable discount. The applicable number of calendar days with respect to claims for reimbursement submitted electronically is 14 days, and otherwise, is 30 days. We proposed to implement this requirement in § 423.2325(g) by specifying that Part D sponsors reimburse a pharmacy or mail order service the amount of the applicable discount no later than the applicable number of calendar days after the date of dispensing an applicable drug. This requirement would apply to all network pharmacies, including but not limited to long term care pharmacies and home infusion pharmacies.

Finally, we proposed to add a new paragraph (24) to § 423.505(b) so that the requirements we are proposing in § 423.2325 are included in all Part D sponsor contracts with us.

Comment: A commenter requested that CMS clearly indicate how Part D sponsors implement the plan responsibility for reduced cost-sharing

in the coverage gap beginning in 2013 when the phase-down of coverage gap brand drug cost-sharing will begin to take effect.

Response: We agree that additional clarification is necessary to explain how plans need to determine both plan and beneficiary liabilities for brand-name drug coverage when the additional brand-name coverage in the coverage gap begins to phase in starting in 2013, but this is beyond the scope of this regulation. We addressed the issue in the 2013 Advance Notice by clarifying how manufacturer, beneficiary, and Part D sponsor liabilities, including dispensing fee liabilities, for coverage gap claims must be determined beginning in 2013. In light of that guidance, we will not be finalizing the requirements in proposed § 423.2325(b)(3) and (e)(5) with respect to dispensing and vaccine administration fees, and have redesignated proposed § 423.2325(b)(4) as § 423.2325(b)(3) in the final rule.

Comment: A few commenters opposed the requirement under proposed § 423.2325(b)(4) (redesignated as § 423.2325(b)(3)) that would require Part D sponsors to notify affected beneficiaries whenever CMS specifies a retroactive effective date for a labeler code. They contend that such notice will be less likely to be beneficial to the beneficiary as the Discount Program matures. They also believe it often will be difficult for the Part D sponsor to accurately identify if an alternative product had been prescribed and covered after the initial denial and thus Part D sponsors will cause more enrollee confusion by “over notifying” enrollees.

Response: We disagree with the commenters. We do not believe manufacturers should be excused from their obligation to pay a discount because they failed to timely report a labeler code for an applicable drug to CMS. Moreover, and more importantly, we do not believe the administrative burden on Part D sponsors, which we do not anticipate will be significant, justifies denying a beneficiary access to a discount for which they are entitled. As discussed in the proposed rule, Part D sponsors can minimize any beneficiary confusion by notifying only those beneficiaries that it determines likely still need the drug or who paid for the drug out-of-pocket.

Comment: A commenter recommended that we require that the discount payment be calculated before any Part D supplemental benefits are applied by a Part D plan.

Response: The requirement proposed under § 423.2325(e) is consistent with

the statutory requirement under section 1860D–14A(c)(2) of the Act. We do not have the authority to change the statutory requirement to require the discount payment to be calculated before Part D supplemental benefits are applied by a Part D plan.

Comment: Several commenters supported our proposal to implement the pharmacy reimbursement requirements of section 1860D–14A(c)(1)(A)(iv) of the Act by specifying that Part D sponsors reimburse a pharmacy or mail order service the amount of the applicable discount no later than the applicable number of calendar days after the date of dispensing an applicable drug. The applicable number of calendar days with respect to claims for reimbursement submitted electronically is 14 days, and otherwise, is 30 days. We proposed that this requirement would apply to all network pharmacies including but not limited to long-term care and home infusion pharmacies. Other commenters recommended that we reconsider applying this requirement to long-term care and home infusion pharmacies because current billing practices in these pharmacy settings, such as once a month billing practices, could result in Part D sponsors being out of compliance with the requirements.

Response: We acknowledge that current billing practices in long-term care and home infusion pharmacies could prevent Part D sponsors from complying with this provision if they are not billed by the pharmacy on the date of service. Therefore, we clarify in § 423.2325(g) that for long-term care and home infusion pharmacies, the date of dispensing can be interpreted as the date the pharmacy submits the discounted claim for reimbursement and not the actual date the pharmacy dispensed the medication. After consideration of the public comments received, we are with the exception of the provisions at § 423.2325(b)(3) and (e)(3) finalizing the policies in this section with modification to § 423.2325(g). We note that we are not finalizing the proposed provisions for § 423.2325(b)(3) and (e)(3) and have redesignated proposed § 423.2325(b)(4) as § 423.2325(b)(3) in the final rule.

g. Manufacturer Discount Payment Audit and Dispute Resolution (§ 423.2330)

(1) Third Party Administrator Audits

Section 1860D–14A (d)(3)(D) of the Act permits manufacturers to conduct periodic audits, directly or through contracts, of the data and information

used by the TPA to determine discounts for applicable drugs of the manufacturer under the Discount Program. Section 423.2330(a) would codify the provisions of the Discount Program Agreement governing these audits by specifying the requirements for requesting an audit and the rights of manufacturers associated with conducting audits.

We proposed in § 423.2330(a)(1) that the term periodic be defined as no more often than annually. We believe that this standard would ensure that all manufacturers have an opportunity to conduct meaningful audits within available TPA resources. The proposed definition of periodic represents a balance between frequent audits that may provide the greatest level of detail and very infrequent audits that may be less costly to implement, but may not provide needed information in a timely manner.

Section 1860D–14A(d)(3)(D) of the Act requires that our contract with the TPA permit audits by manufacturers of the data and information used by the TPA to determine discounts for manufacturer’s applicable drugs. Because the statute thus permits the manufacturer to audit data used by the TPA, and importantly, does not grant manufacturers a right to audit CMS or the Part D sponsors, we proposed to specify in regulations that the audit right is limited to information held by the TPA and used to calculate discounts. This means that the manufacturer would not have the ability to audit CMS records or the records of Part D sponsors. We believe the data provided from the TPA provides manufacturers with appropriate and sufficient information to conduct an audit because it provides the claim-level information specified in the Discount Program Agreement that is used to calculate the discounts. We believe that defining the data available for audit also requires balancing considerations between efficiently administering the Discount Program and providing manufacturers with an appropriate level of information to validate invoices. Section 423.2330(a)(3) would establish, consistent with the Discount Program Agreement, that manufacturers may audit a statistically significant sample of the database used by the TPA to calculate gap discounts. We believe that a statistically significant sample provides a balance between allowing an audit to include: (1) All of the data, which would provide complete information, but would be unwieldy in terms of resources; and (2) a very small sample that would have insufficient information but be inexpensive to implement. Moreover, the use of a

statistically valid sample meets generally accepted auditing standards, would provide sufficient data to manufacturers to reach statistically valid conclusions that could be used to dispute discount payments, and is an efficient use of audit resources.

Proposed § 423.2330(a)(3) also supports our obligation to protect the privacy of beneficiary medical information. This section proposed that, with the exception of work papers, audit data may not leave the room where the audit is conducted, which would further protect beneficiary privacy. Another measure to protect the confidentiality of beneficiary medical information is contained in proposed § 423.2330(a)(4), which would specify that the auditor may only release an opinion of the results of the audit and may not release any other information obtained from the audit, including its work papers, to its client, employer, or any other party. We believe these limitations on the distribution of data support beneficiary privacy, while addressing manufacturer need for access to data that are relevant to the calculation of the gap discounts. These regulations all would codify provisions in the current Discount Program Agreement.

(2) Manufacturer Audits

Section 1860D–14A(e)(1) of the Act specifies that each manufacturer with a Discount Program Agreement in effect shall be subject to periodic audit by CMS and we proposed to codify this requirement in § 423.2330(b). Similar to the limitation in § 423.2330(a)(1), we proposed to define the term periodic in § 423.2330(b)(1) as no more often than annually. In § 423.2330(b)(3) we proposed that we would have the right to audit appropriate data of the manufacturer, including data related to a manufacturer's FDA-assigned labeler codes, expiration date of NDCs, utilization, and pricing information relied on by the manufacturer to dispute quarterly invoices, as well as any other data CMS determines are necessary to carry out the Discount Program.

(3) Dispute Resolution

Section 1860D–14A(c)(1)(A)(vii) of the Act requires the Secretary to establish “a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, applicable beneficiaries, and the third party with a contract * * *.”

Therefore, we proposed in § 423.2330(c) a multistage dispute resolution process consisting of: (1) An initial dispute stage; (2) an appeals stage for manufacturers that do not accept the findings of the dispute process; and (3)

a final administrator review when either a manufacturer or CMS disagrees with the outcome of the initial appeals process.

Section 423.2330(c) would include a timetable for the three-stage approach to manage the process most efficiently and to support equal treatment of each appeal. The timetable ensures that manufacturers' disputes are resolved as quickly as possible, while allowing both parties to perform the necessary calculations and investigations to evaluate the gap discount invoice. The proposed timeframes were established by estimating the time required to analyze the data presented, by the volume of claims, and by considering the characteristics of the Discount Program compared to the other similar programs previously noted.

Specifically, we proposed in § 423.2330(c)(1) that manufacturers may dispute quarterly gap discount amounts by providing notice of the dispute to the TPA within 60 days of the receipt of information that is the subject of the dispute. The information is limited to data received from the TPA, or as a result of a manufacturer's audit.

Proposed § 423.2330(c)(2) also states that the notice of dispute be accompanied by supporting evidence that is material, specific, and related to the dispute. We proposed this requirement because the manufacturer bears the burden of proof that the PDE data is incorrect. We also proposed in § 423.2330(c)(3) to codify the Discount Program Agreement provision that manufacturers may not withhold any invoiced amounts pending dispute resolution except for invoiced amounts for applicable drugs without labeler codes provided by the manufacturer to us. The proposition to generally bar the withholding of disputed invoice amounts is justified because gap discounts are owed by manufacturers but are paid by Part D sponsors to beneficiaries at the point-of-sale; we believe that the prohibition of withholding disputed invoices will minimize the risk to Part D sponsors for these discount-related incurred liabilities without significantly increasing the financial risk to a manufacturer because of the extensive quality assurance CMS performs on PDEs submitted by Part D sponsors. The PDE data used to calculate quarterly invoices are of high quality. The PDE data are derived from claims for each prescription submitted to Part D sponsors for payment. Part D sponsors validate each claim to comply with the False Claims Act and as part of their process to reimburse pharmacies for the cost of the drug. In addition, we

implement multiple edits to validate the PDE data submitted by Part D sponsors. Those edits include identification and adjustment of outlier and other inappropriate entries for variables such as discount amount, beneficiary eligibility for the gap discount, incorrect NDCs, etc. Therefore, the burden of proof is on manufacturers to demonstrate that the data used to calculate the quarterly invoice are incorrect.

Section 423.2330(c)(4) would allow manufacturers to request an additional adjudication by the Independent Review Entity (IRE), under contract with CMS, within 30 days of the receipt of an unfavorable determination from the TPA, or if no decision was received from the TPA, within 90 days of the receipt of the dispute submission. This section also proposed that the IRE be required to make a determination within ninety calendar days of receipt of the manufacturer request for an appeal.

Section 423.2330(c)(6) establishes a final administrative step to support an equitable dispute resolution process. We proposed that both manufacturers and CMS would have the right to request a final review of the dispute by the Administrator. Since we administer the Discount Program and manufacturers have financial liability for the discounts, both parties have an interest in ensuring an equitable resolution to the dispute. We proposed that this request be made within 30 days after the manufacturer receives a decision from the IRE to facilitate a timely outcome. Finally, we proposed that the decision of the Administrator would be final and binding.

We proposed to codify the policies as described and welcomed comments on the dispute and appeals process.

Comment: A few commenters recommended that we include affected Part D sponsors in the disputes and appeals process, and that Part D sponsors be given appeal rights if disputes or appeals are upheld.

Response: We do not believe it is necessary, nor would it be helpful, to insert Part D sponsors in every step of every manufacturer dispute and appeal. This process is specifically designed to address manufacturer disputes or appeals and manufacturers have the burden to demonstrate that an applicable discount advanced by the Part D sponsor likely is in error according to standards established in CMS guidance. If the manufacturer satisfies the threshold, the Part D sponsor will be given the opportunity to confirm the accuracy of the discount and if confirmed, the dispute or appeal will be denied. If the manufacturer

dispute or appeal does not meet the standard for demonstrating likely error in the first place, the dispute or appeal will be denied without needing Part D sponsor confirmation. In situations that involve the determination of applicable drug status for an NDC based upon its FDA approval status, CMS will make those determinations based upon the information that was available from the FDA on the date of dispensing. While Part D sponsors will not have the opportunity to appeal determinations that uphold manufacturer disputes or appeals under this process, Part D sponsors have appeal rights under the Part D payment reconciliation process to redress payment disputes, including those related to the Discount Program.

After consideration of the public comments received, we are finalizing the policies in this section without modification.

h. Beneficiary Dispute Resolution (§ 423.2335)

Section 1860D–14A(c)(1)(A)(vii) of the Act requires CMS to provide a reasonable dispute mechanism to resolve disagreements between manufacturers, applicable beneficiaries, and the TPA. While § 423.2330(c) would address the disputes that could arise between the manufacturer and CMS or the TPA, § 423.2335 would provide the beneficiary dispute resolution requirements. Specifically, § 423.2335 would provide that beneficiaries shall have access to the Part D coverage determination and appeals process as described in § 423.558 through § 423.638 for disputes involving the availability and amount of applicable discounts under the Discount Program.

Comment: Some commenters supported CMS' proposal in § 423.2335 to provide beneficiaries with access to the existing Part D coverage determination and appeals process as described in §§ 423.558 and 423.638 for disputes involving the availability and amount of applicable discounts under the Discount Program. However, a commenter raised concerns that the existing process is not well understood by beneficiaries and therefore we should require Part D plans to provide explicit, plain language information on how to file a dispute.

Response: We agree with commenters that supported our proposal. The existing Part D coverage determination and appeals process provides the best and most efficient mechanism for resolving beneficiary disputes involving the availability and amount of applicable discounts. We do not believe it would be beneficial to anyone, most importantly beneficiaries, to establish

an entirely separate and duplicative process. Moreover, we do not believe a new plain language requirement is necessary because Part D plans are already required to use a consumer tested model Evidence of Coverage (EOC) that is intended to explain the existing Part D coverage determination and appeals process in language that is appropriate for beneficiaries.

After consideration of the public comments received, we are finalizing the policies in this section without modification.

i. Compliance Monitoring and Civil Money Penalties (§ 423.2340)

Section 1860D–14A(e)(2) of the Act requires us to impose a civil money penalty (CMP) on a manufacturer that fails to provide applicable beneficiaries applicable discounts for applicable drugs of the manufacturer in accordance with the Discount Program Agreement. The statute sets forth the formula for determining the CMP amount, which will equal the sum of the amount that the manufacturer would have paid with respect to such discounts under the agreement (which will then be used to pay the discounts which the manufacturer had failed to provide) plus 25 percent of such amount. Section 423.2340 would implement these requirements and establish the procedures for imposing and collecting the CMPs in accordance with subpart T of this part. Accordingly, we proposed to revise the definition of “affected party” in subpart T (as defined in § 423.1002) by adding the term “manufacturer” (as defined in § 423.2305) to the definition and clarifying that we interpret the use of “Part D sponsor” throughout subpart T to be synonymous with “affected party”. In accordance with the Discount Program Agreement and proposed § 423.2315(b)(3), manufacturers must pay each Part D sponsor within 38 calendar days of receipt from the TPA of the electronic invoice and Medicare Part D Discount Information for the applicable discounts included on the invoice except as specified in § 423.2330(c)(3). Therefore, we consider a manufacturer to have failed to provide applicable beneficiaries applicable discounts for applicable drugs of the manufacturer in accordance with the Discount Program Agreement if it fails to comply with this requirement unless such failure is due to technical or other reasons beyond the control of the manufacturer, such as a natural disaster. Consequently, we would impose a civil money penalty whenever a manufacturer fails to make full payment on its invoice within 38 calendar days

of receipt of the invoice and Medicare Part D Discount Information for the applicable discount included on the invoice unless such failure is due to technical or other reasons beyond the control of the manufacturer. We plan to add this provision to the Discount Program Agreement.

Section 423.2340(c) codifies the methodology for determining the amount of the CMP as equal to the amount of applicable discount the manufacturer would have paid under the Discount Program Agreement, which will then be used to pay the applicable discount that the manufacturer had failed to provide, plus 25 percent of such amount. This amount may be reduced by any amount that the manufacturer has paid after the 38th calendar day but before the date the CMP is collected. We interpret this to mean that the CMP would be calculated based upon the outstanding invoiced amount that was not paid within 38 calendar days of receipt as required under the Discount Program Agreement and proposed § 423.2315(b)(3) irrespective of any partial or late payments. In other words, a manufacturer's failure to pay the entire invoice amount would trigger the CMP and late payments would not relieve the manufacturer of its obligation to pay an additional 25 percent of the unpaid amount from the invoice. In order to ensure consistency and transparency with the imposition of these civil money penalties, unless the exception applies (that is, the payment is late due to technical or other reasons beyond the control of the manufacturer), we would impose the additional 25 percent on all invoiced amounts not paid within 38 calendar days of receipt, even, for example, if the payment is only 1 day late.

Section 423.2340(d) specifies that if CMS makes a determination to impose a CMP, we would send a written notice of our decision to impose a CMP that includes a description of the basis for the determination, the basis for the penalty, the amount of the penalty, the date the penalty is due, the manufacturer's right to a hearing (as specified under § 423.1006) and information about where to file the request for hearing. To ensure a consistent approach to CMPs, we proposed extending existing appeal procedures for CMPs in subpart T of this part to manufacturers appealing a CMP imposed under the Discount Program. We have utilized this appeals process for more than 20 years for various types of adverse agency determinations affecting an array of medical providers, MA organizations, and Part D sponsors.

We therefore proposed to use this well established process and infrastructure for CMP appeals from manufacturers that have contracted with the Discount Program and are delinquent in paying the discounts as required. To that end, we proposed to revise the definition of “affected party” in § 423.1002 to include manufacturers participating in the Discount Program. Section 423.2340(e) would provide that we would initiate collection of the CMP following expiration of the timeframe for requesting an ALJ hearing, which is 60 calendar days from the CMP determination, as specified in § 423.1020 if the manufacturer did not request a hearing; and CMS would initiate collection of the CMP once the administrative decision is final if a manufacturer requests a hearing and our decision to impose the CMP is upheld.

Section 1860D–14A(e)(2)(B) of the Act states that the provisions of section 1128A of the Act (except subsections (a) and (b)) apply to CMPs under this subpart to the same extent that they apply to a CMP or procedure under section 1128A(a) of the Act. We proposed to codify this requirement in § 423.2340(f). We welcomed comments on this proposal. We did not receive any comments and we are finalizing these provisions as proposed.

j. Termination of Agreement (§ 423.2345)

Section 1860D–14A(b)(4)(B)(i) of the Act provides that we may terminate a Discount Program Agreement for a knowing and willful violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 30 days after the date of notice to the manufacturer of such termination and CMS shall provide, upon request, a hearing concerning such termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if CMS determines appropriate. Section 423.2345 would codify these requirements consistent with the termination provisions in the Discount Program Agreement. For instance, § 423.2345(a)(1) would clarify that “good cause shown” must relate to the manufacturer’s participation in the Discount Program. Our proposed regulation would further specify that we must provide the manufacturer with an opportunity to cure any ground for termination within 30 calendar days of receipt of the written termination notice. In addition, we proposed, consistent with the statutory requirement as reflected in the Discount Program Agreement, that the

manufacturer may request a hearing with a hearing officer concerning such termination if requested in writing within 15 calendar days of receiving notice of the termination, and such hearing must take place prior to the effective date of termination with sufficient time for such effective date to be repealed if we determine appropriate.

In order to address potential timing issues with appeals during the termination process, we proposed to clarify in § 423.2345(a)(2) that termination must not be effective earlier than 30 days after the date of notice to the manufacturer of such termination and must not be effective prior to resolution of timely appeal requests received in accordance with paragraphs (a)(4) and (5) of this section. Proposed paragraphs (a)(4) and (5) state, in part, that CMS will provide a manufacturer with a hearing before the hearing officer about such termination if requested in writing within 15 calendar days of receiving notice of the termination. Further, CMS or a manufacturer that has received an unfavorable determination from the hearing officer may request review by the CMS Administrator within 30 calendar days of receipt of the notification of such determination. Therefore, a termination would not be effective until either the timeframes to pursue a hearing with the hearing officer or CMS Administrator have passed or a final decision has been issued by the hearing officer or CMS Administrator and there is no remaining opportunity to request further review.

We also proposed in § 423.2345(a)(5)(i) to specify that CMS or a manufacturer that has received an unfavorable determination from the hearing officer may request review by the CMS Administrator within 30 calendar days of receipt of the notification of such determination. The Discount Program Agreement currently provides only that a manufacturer may request review of an unfavorable decision by the CMS Administrator. However, we believe that a fair appeals process must ensure that both parties have an opportunity for further review of a decision made by hearing officer. The decision of the CMS Administrator would be final and binding on either party. We requested comments on these termination requirements.

Section 1860D–14A(b)(4)(B)(ii) of the Act provides that a manufacturer may terminate the Discount Program Agreement for any reason. Such termination shall be effective as of the day after the end of the calendar year if the termination occurs before January 30 of a calendar year or as of the day after the end of the succeeding calendar year

if the termination occurs on or after January 30 of a calendar year. We proposed to codify these requirements in § 423.2345(b).

Section 1860D–14A(b)(4)(B)(iii) of the Act states that any termination shall not affect discounts for applicable drugs of the manufacturer that are due under the Discount Program Agreement before the effective date of the termination and we proposed to codify this requirement in § 423.2345(c). However, upon the effective date of the Discount Program Agreement termination, the manufacturer’s drugs would no longer be covered under Medicare Part D. In addition, § 423.2345(d) would specify that we would cease releasing data to the manufacturer except as necessary to ensure the manufacturer reimburses applicable discounts for time periods in which the Discount Program Agreement was in effect and would notify the manufacturer to destroy data files provided by us under the Discount Program Agreement.

Finally, § 423.2345(e) would restrict reinstatement of manufacturers that previously terminated their Discount Program Agreements or had them terminated by CMS to those manufacturers that pay any and all outstanding applicable discounts incurred during any previous periods under Discount Program Agreements.

We did not receive any comments and we are finalizing these provisions as proposed.

2. Inclusion of Benzodiazepines and Barbiturates as Part D Covered Drugs (§ 423.100)

Section 175 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended section 1860D–2(e)(2)(A) of the Act to include barbiturates “used in the treatment of epilepsy, cancer, or a chronic mental health disorder” and benzodiazepines. MIPPA further specified that these amendments apply to prescriptions dispensed on or after January 1, 2013. Accordingly, we proposed to revise the definition of a Part D drug at § 423.100 to include barbiturates used for the three specified medical indications and benzodiazepines that are dispensed on or after January 1, 2013. Like any other prescription drugs under the Part D benefit program, barbiturates as specified and benzodiazepines must meet all other conditions for Part D drugs found in § 423.100.

As in the proposed rule, we once again remind sponsors that it is their responsibility to use the tools (that is, system edits, quality assurance checks) at their disposal to ensure barbiturates

are covered for the conditions specified in the statute. Also, given the vulnerability of both barbiturates and benzodiazepines to misuse and abuse, it is recommended that Part D sponsors use their drug utilization review tools to identify and prevent waste and clinical abuses/misuses.

Comment: A number of commenters endorsed the statutory inclusion of barbiturates as specified and benzodiazepines as covered Part D drugs. Some of these commenters anticipated that the change would result in better treatment of health conditions such as mental health conditions, with a commenter predicting lowered health care spending would stem from better quality of life and health care outcomes. Several supporters opined that the existing tools in the Part D program were sufficient to, for instance, address misuse and protect beneficiaries from harm.

Response: We appreciate the commenter support of the statutory inclusion of these medications.

Comment: Several commenters suggested that CMS restrict access to the drugs by, for instance, removing the medical indications requirements from the regulation, limiting benzodiazepines coverage to short-acting agents, or allowing barbiturates only for seizure disorders.

Response: We lack the authority to restrict drugs through any of the modifications suggested by these commenters because of the clear statutory mandate found in section 175 of MIPPA, which amends section 1860D–2(e)(2)(A) of the Act to include as Part D drugs both barbiturates used in the “treatment of epilepsy, cancer, or a chronic mental condition” and benzodiazepines. Accordingly, our proposed revisions must include as Part D drugs barbiturates for the three medical indications, as well as benzodiazepines.

That we track the statutory language does not, however, mean that there are no restrictions on the availability of barbiturates as specified and benzodiazepines—statutory and regulatory requirements apply to restrict availability. As is the case for all Part D drugs, a barbiturate as specified or a benzodiazepine may only be a Part D drug if it falls within the definition of Part D drug at § 423.100, which would mean that it must—

- Be used for a medically accepted indication;
- Be dispensed only upon a prescription;
- Meet requirements described in section 1927(k)(2)(A)(i) through (iii) of the Act; and

- Not be otherwise excluded from Part D coverage on the basis that payment for such drug, as so prescribed and dispensed or administered to an individual, is available for that individual under Part A or Part B (even though a deductible may apply, or even though the individual is eligible for coverage under Part A or Part B but has declined to enroll in Part A or Part B).

Additionally, for any barbiturates as specified or benzodiazepines that meet the definition of an applicable drug under section 1860D–14A(g)(2) of the Act, in order for coverage to be available under Part D, the manufacturers of the brand drug must participate in the Medicare Coverage Gap Discount Program.

Comment: A number of commenters, many of which endorsed the inclusion, voiced concerns with utilization control issues—with the vast majority of these commenters questioning whether the available Part D utilization tools would be effective enough in restricting access to barbiturates for the specified indications and benzodiazepines as to prevent misuse. In contrast, a few commenters voiced concern that CMS is “encouraging” plans to apply utilization management tools to therapies for chronic conditions, such as mental illnesses. Stating that utilization management tools had impeded beneficiary access to medications in the past, these commenters requested that CMS remove the language about these tools from the preamble.

Response: We do not agree with the commenters who suggested we remove language from the preamble of the proposed rule that discusses the availability of drug management tools. We see no justification to treat barbiturates and benzodiazepines any differently from how we treat all other Part D drugs.

Comment: Many commenters requested more direction and instructions regarding the use of drug utilization tools. A commenter requested that CMS implement restrictions such as a specific quantity limit per year, while the two commenters requested that CMS provide instructions that would, for instance, prevent step therapy and fail first policies for individuals already on these medications. Several commenters indicated that they wanted to use prior authorization (PA) to ensure that barbiturates would be prescribed only when used in the treatment of epilepsy, cancer, or chronic mental health disorders. A few others indicated that when used for certain indications (for instance, barbiturates for uses listed in the statute and benzodiazepines for

epilepsy), barbiturates and benzodiazepines might be part of a protected class—with a commenter stating that in such instances the drugs must be made available to members and another asserting that the drugs must be denied protected class status.

Response: These comments are beyond the scope of the proposed rule. We did not propose to implement any special rules with regard to these drugs; rather, we proposed merely to codify the statutory requirement set forth in section 175 of MIPPA. To the extent we believe additional guidance about these products is necessary or appropriate, we will provide such guidance in the future.

Comment: A commenter requested guidance on the issues as soon as possible, but no later than January 2012, to provide plans enough time for appropriate utilization management as part of the 2013 formulary submissions.

Response: Although this comment is beyond the scope of the proposed rule, we would like to note that we believe our current formulary guidance provides Part D sponsors with the information they need to make such determinations.

Comment: A commenter suggested that the inclusion would impact the accuracy of the current risk adjustment formula because the new drugs would be available only to members with the three specified medical conditions. The commenter accordingly requested that, after January 1, 2013, the risk adjustment factors associated with these specified conditions be increased to reflect the increased costs expected from covering these drugs.

Response: In the calibration of the original Part D risk adjustment model and in subsequent versions, we reasoned that benzodiazepines and barbiturates were substitutable drugs and included the costs of these drugs as a proxy for their substitutes. Given that we never removed either barbiturates or benzodiazepines from our Part D model calibration, the mandated inclusion will not impact the accuracy of the current risk adjustment model. In a discussion in our 2006 Advanced Notice on removing non-covered Part D drugs from the calibration of the risk adjustment, we stated, “Other non-covered drugs, benzodiazepines and barbiturates, were intentionally left in the file because their costs proxy for the costs of substitutes. This was deemed preferable to removing the claims and costs altogether.” See Advance Notice of Methodological Changes for Calendar Year (CY) 2006 Medicare Advantage (MA) Payment Rates, Attachment II, Risk Adjustment Model, page 45.

Comment: A commenter questioned whether CMS had conducted an analysis to determine if all manufacturers of barbiturates and benzodiazepines were currently participating, or would be offered the opportunity to participate in the Coverage Gap Discount Program, because they may have not sought participation when the drugs were excluded.

Response: Given that the Coverage Gap Discount Program only applies to brand drugs and that most barbiturates and benzodiazepines are available as generics, we believe that Part D coverage will be available for most—if not all—types of barbiturates that treat the specified indications and benzodiazepines. Indeed, at this time, we are not aware of any barbiturates as specified or benzodiazepines that will not be covered on the basis that a manufacturer is not participating in the program.

Comment: Several commenters expressed concerns that, because the High Risk Medication (HRM) Part D Plan Rating measure incorporates the Beers list, which identifies benzodiazepines and barbiturates as potentially harmful for the elderly, plan ratings will suffer resulting in lower bonus payments. While a commenter requested that CMS deny Part D coverage of drugs on the Beers list, others requested changes to the rating system itself such as excluding the medications from the HRM measure calculation to give the industry time to understand the impact on the safety of beneficiaries or adjusting the 4-star threshold.

Response: As we noted in our discussion of the Part D High-Risk Medication (HRM) measure in our draft 2013 Call Letter published on February 17, 2012 (page 63), we will continue to explore changes to this measure. Modifications may result from specification changes made by the Pharmacy Quality Alliance (PQA) or National Committee for Quality Assurance (NCQA) as they consider modifying the specifications and medication list based on the American Geriatrics Society's (AGS) update to the Beers List. We will consider applying these updates to future Plan Ratings and changes to the measure medication list will not be retroactively applied for the 2013 Plan Ratings. Rather, we will apply changes to the medication list when evaluating sponsors' CY 2012 or CY 2013 PDE data for the 2014 or 2015 Plan Ratings, respectively. At that time, we will also evaluate the inclusion or exclusion of benzodiazepines and

specified barbiturates in the measure calculation.

After considering the public comments received, we are finalizing the proposed language in § 423.100, with a grammatical clarifying modification. Pursuant to section 175(b) of MIPPA, this revision will be effective January 1, 2013.

3. Pharmacy Benefit Manager's Transparency Requirements (§§ 423.501 and 423.514)

We proposed implementing the provisions of section 1150A of the Act, as amended by section 6005 of the Affordable Care Act, with respect to Part D sponsors and the entities that manage prescription drug coverage under a contract with a Part D sponsor. We now codify the various reporting requirements from the proposed rule to promote transparency of financial transactions involving Part D sponsors and pharmacy benefits managers (PBMs) or other entities that provide pharmacy benefit management services at § 423.514, with a minor, technical correction to the language of § 423.514(e) regarding confidentiality of pharmacy benefits manager data. In addition, we are finalizing with modification the proposed definition of "bona fide service fees" in our regulations at § 423.501.

Comment: A commenter recommended that CMS define "pharmacy benefits manager" to encompass any entity or division of an entity, including a Part D sponsor itself, that performs any of the functions or activities for which reporting is required in order to clarify the scope of the regulation.

Response: We believe that we were clear in the proposed rule when we stated that this provision applies to both Part D sponsors and to entities that provide pharmacy benefits management services to Part D sponsors, for which we use the shorthand term of PBM. Further, section 1150A of the Act makes clear that a health benefits plan or any entity that provides pharmacy benefits management services on behalf of a health benefits plan is subject to all requirements and protections under this provision. Thus, we decline to introduce a definition of PBM in this regulation, but take this opportunity to emphasize that the entity's function is more important than the form of its name.

Comment: A number of commenters requested additional details regarding the proposed reporting requirements under paragraph (d)(3) of § 423.514. This provision would require reporting of the percentage of prescriptions for

which a generic drug was available and dispensed by pharmacy type, which includes an independent, chain, supermarket, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medication to the general public. Most commenters requested clarification on how to distinguish the various pharmacy types. A few commenters noted that neither plan sponsors, PBMs, nor pharmacy groups themselves differentiate among these pharmacy types. Several suggested ways for CMS either to provide crosswalks for PBMs and sponsors to help categorize the pharmacy types or to derive the data from available data sources.

Response: We agree that consistent definitions of independent, chain, supermarket, and mass merchandiser pharmacies are necessary for accurate reporting of this data element. We explored the ideas commenters submitted for CMS to provide crosswalks or to derive the data from existing data sources and determined that we could crosswalk National Provider Identifiers with a file from the National Council for Prescription Drug Programs to determine the data element in § 423.514(d)(2) (the percentage of all prescriptions that were provided through retail pharmacies as compared to mail order pharmacies). However, this approach cannot be used to categorize independent, chain, supermarket, and mass merchandiser pharmacies because they are not standard pharmacy classifications captured in industry databases or files. Thus, while we are finalizing § 423.514(d)(3) as proposed, we will issue further subregulatory guidance regarding this reporting requirement before requiring Part D sponsors to submit this information.

Comment: We received a number of comments regarding § 423.514(d)(4), under which we proposed to require reporting of the aggregate amount and type of rebates, discounts, or price concessions (excluding bona fide service fees) that a PBM negotiates that are attributable to patient utilization under the plan. In the proposed rule, we sought comment regarding whether there are differences between direct and indirect remuneration (DIR) under the Part D program and rebates, discounts, and price concessions "attributable to patient utilization." Most commenters believed that there is no difference, with a couple of commenters mentioning that DIR under the Part D program is already based on price concessions for prescription drugs that are provided to Medicare Part D beneficiaries. Another commenter suggested that DIR under the

Part D program is broader than DIR attributable to patient utilization, and thus CMS should scale back the definition in the DIR reporting requirements.

Response: We agree that there is no substantive difference between the aggregate amount of rebates, discounts, and price concessions “attributable to patient utilization” and DIR under the Part D program. Per § 423.308 and our annual DIR reporting guidance, DIR is any and all rebates, subsidies, or other price concessions from any source (including manufacturers, pharmacies, enrollees, or any other person) that serve to decrease the costs incurred by the Part D sponsor (whether directly or indirectly) for the Part D drug. Costs are incurred by the Part D sponsor when patients utilize Part D drugs, and thus we believe that “rebates, discounts, and price concessions that are attributable to patient utilization” are substantively the same as DIR under the Part D program. Further, rebates, discounts, and price concessions would not be negotiated unless Part D plan sponsors were purchasing prescription drugs from the manufacturer for use by their enrollees. Thus, we believe even rebates, discounts, and price concessions for things such as formulary placement for a particular product, administrative services, or generic dispensing incentives are indirectly attributable to patient utilization, such that they would be subject to the reporting requirements under § 423.514(d)(4).

Comment: One commenter requested that we clarify the authority under which we collect DIR and that Part D sponsors have no additional reporting requirements for DIR attributable to patient utilization.

Response: In the 2010 DIR reporting requirements, we collected PBM spread amounts aggregated to the plan benefit package level. We believe that with the addition of PBM spread amounts for retail pharmacies and PBM spread amounts for mail order pharmacies to the existing DIR reporting requirements, Part D sponsors will meet the requirements to report the elements in § 423.514 (d)(4), (5), and (6). Beyond this change, no additional DIR reporting will be required to comply with section 1150A of the Act. We clarify that sections 1150A and 1860D–15(f)(1)(A) of the Act provide us with the authority to collect DIR data.

Comment: Several commenters recommended that instead of requiring the percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate) by independent, chain, supermarket, and mass merchandiser pharmacy types, we

allow the data to be reported by different and/or more general categories, such as mail order or retail pharmacy types.

Response: Consistent with 1150A(b)(1) of the Act, we believe that we must collect the percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate) by independent, chain, supermarket, and mass merchandiser pharmacy types. Because reporting of this information is expressly required under the statute, we do not believe we have the authority to limit or change the scope of the reporting requirements. We note, however, that in implementing this requirement and all of the other reporting requirements under section 1150A of the Act, we have sought to minimize administrative burden where possible by relying on existing reporting mechanisms and avoiding duplicative reporting.

Comment: Some commenters favored greater transparency of prescription drug cost information than we proposed. Suggestions ranged from requesting that the proposed data elements under § 423.514(d) be reported with greater granularity to proposing additional reporting requirements beyond those proposed. Examples include requiring maximum allowable cost (MAC) lists for pharmacy reimbursement, requiring transparency regarding pharmacy network design, requiring reporting of a dispensing rate for when a lower cost drug could have appropriately been dispensed, requiring reporting of prompt payment rates, and requiring PBMs to report how patient data is used and disclosed.

Response: These suggestions are beyond the scope of the current rulemaking, which implements the specific reporting requirements of section 1150A. We note that some of the commenters’ requests may be more appropriate as suggestions for revisions to prompt payment and pricing standard update requirements already codified at §§ 423.505(b)(21) and 423.520. Should we determine that the reporting of additional or more detailed information or disclosure of aggregated data is necessary and appropriate for the Part D program, we may consider some of the commenters’ suggestions in the future.

Comment: Some commenters expressed concern about maintaining confidentiality of PBM-related data.

Response: We agree that maintaining the confidentiality of PBM-related data is important and are finalizing § 423.514(e) regarding the confidentiality of PBM data. The confidentiality protections under this provision are nearly identical to those in

section 1150A, and specify that information disclosed by a Part D sponsor or PBM is confidential, and shall not be disclosed by the Secretary or by a plan receiving the information. The statute and the regulation recognize limited exceptions allowing the Secretary to disclose information disclosed by a Part D sponsor or PBM for certain limited purposes. These purposes are as the Secretary determines necessary to carry out section 1150A of the Act or Part D of Title XVIII, to permit the Comptroller General to review the information provided, or to permit the Director of the Congressional Budget Office to review the information provided. (Section 1150A of the Act also permits disclosure of the information to States to carry out section 1311 of the Affordable Care Act. We have not incorporated this exception into § 423.514(e) because it is applicable to qualified health benefits plans offered through an exchange established by a State under section 1311 of the Affordable Care Act and is addressed in separate rulemaking.) Consistent with the statute, any disclosures pursuant to these exceptions, must be in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs.

Comment: A few commenters were concerned that the proposed definition of “bona fide service fee” in § 423.501 was too broad; for example, a commenter thought that the term “patient care programs” has no boundaries or limitations. Another suggested that we not qualify the definition of bona fide service fees with specific examples, while another would like us to provide not only examples of what is included in the definition of bona fide service fees but also examples of what is excluded from the definition.

Response: After considering these comments, we are modifying the proposed definition of bona fide service fees in § 423.501 by omitting the examples of bona fide services listed in the proposed definition. Bona fide services are subject to change as new ones are developed or other bona fide services are discontinued. Thus, we believe it is appropriate to elaborate on the definition of bona fide service fees in subregulatory guidance, as we have typically done in our DIR reporting guidance. We expect to provide such guidance to help Part D plan sponsors determine what is included in or excluded from the definition of bona fide service fees. We also note that by not including specific examples of such fees in the regulation, the definition of bona fide service fees in § 423.501 is

consistent with the definition of bona fide service fees used in the Medicare Part B and Medicaid programs.

Comment: A few commenters questioned how CMS will monitor compliance with reporting requirements (for example, accurate reporting of bona fide service fees) and whether we intend to audit PBMs. A commenter asked for flexibility in CMS' policy on collecting PBM transparency data until sponsors have completed their next contract negotiations with PBMs.

Response: We intend to explore whether auditing PBMs will be necessary to ensure compliance with this provision. However, we do not believe it is necessary or appropriate to delay implementation of these reporting requirements because the statute, which was effective upon enactment, directs each PBM to provide to the Part D sponsor the data elements required by this rulemaking.

Comment: A commenter urged CMS to differentiate between PBM-owned mail order pharmacies and PBMs that contract for mail order pharmacy services because they believe that the Affordable Care Act should not be interpreted as requiring PBMs that own mail order pharmacies to disclose drug acquisition costs. Another commenter recommended that CMS clarify the reporting requirement with respect to PBM-owned mail order facilities in which there is no aggregate difference in the amount collected and the amount paid to the pharmacy. A commenter claimed that Medicare contracts between PBMs and sponsors must be 100 percent pass-through.

Response: If there is no difference between the amount the Part D sponsor pays the PBM and the amount that the PBM pays mail order pharmacies (that is, if Part D sponsors use pass-through pricing for their mail order pharmacies), then the amount should be reported under § 423.514(d)(6) as zero. Thus, for the purpose of collecting this data element, we do not believe that PBM-owned mail order pharmacies present unique challenges relative to PBMs that contract for mail order pharmacy services. Moreover, because only the aggregate amount of the difference between the amount the Part D sponsor pays the PBM and the amount the PBM pays retail pharmacies is reported, the

PBM's drug acquisition costs drugs will not be disclosed.

Consistent with the discussion in our January 12, 2009 final rule, we also clarify that sponsors may use either the lock-in pricing or pass-through pricing approach when contracting with PBMs, but they must use the price ultimately received by the pharmacy (or other dispensing provider) as the basis for calculating beneficiary cost sharing, total drug spend, and cost reporting to CMS. (See § 423.100 for the definition of negotiated price and 74 FR 1505 through 1511 for more details.)

Comment: A commenter requested that CMS clarify whether the total number of prescriptions dispensed reported under § 423.514(d)(1) is based on PDEs or actual claims. If it is based on PDEs, the commenter believed CMS should clarify that it would still be the Part D sponsor's responsibility to hire a data validation auditor to evaluate the validity of the reports, as opposed to passing this responsibility to the PBM.

Response: We do not plan to institute a new requirement on plan sponsors or PBMs to collect this data element as they already report it on PDEs. We remind plan sponsors that they must maintain audit trails to PDE source data. We expect that the plan will be able to directly link any PDE to the individual claim transactions from which the PDE was extracted, and will conduct audits of PDE data to ensure the accuracy of payment. Part D sponsors have the discretion to negotiate terms with each PBM that obligate the PBM to participate in maintaining audit trails. Also, consistent with § 423.505(k), each year Part D sponsors must certify that their PDEs and DIR reports, among other data, are accurate, complete, and truthful. While Part D sponsors remain accountable for their certifications, they have the discretion to negotiate with their first tier and downstream entities concerning the entities' participation in the data validation activities that must support each certification.

Comment: A commenter suggested that CMS should provide an annual report on the best and worst plans with respect to the reporting requirements in paragraph (d).

Response: We believe that this comment is out of scope as section 1150A of the Act addresses PBM

reporting requirements, confidentiality of PBM-related data, and penalties for failure to provide pharmacy benefits manager data.

After considering the comments received, we are finalizing the policy as proposed with one modification to the definition of "bona fide service fees" in § 423.501. We have also made a minor, technical correction to the language of § 423.514(e).

B. Strengthening Beneficiary Protections

This section includes provisions aimed at strengthening beneficiary protections under Parts C and D. In our opinion, it is appropriate to provide for reinstatement of beneficiaries in the section 1876 cost plans from which they were disenrolled for failing to pay premiums when they can establish good cause for their failure to pay. We anticipate that finalizing this provision will result in uninterrupted plan coverage for eligible beneficiaries and thereby improve access to healthcare for individuals such as those with chronic conditions requiring continual monitoring and medication. Similarly, we expect that requiring sponsors to provide enrollees in MA plans with uniform ID cards which all providers will be able to easily recognize will facilitate access to health care for those beneficiaries. We also believe that calculating creditable coverage by excluding the value of additional coverage in the coverage gap and the manufacturers discount—the standard that qualifies retiree drug coverage for the retiree drug subsidy—will mean a beneficiary receiving retiree drug coverage will be less likely to be assessed a late enrollment penalty if he or she subsequently decides to enroll in a Part D plan. Enabling health care professionals to request Independent Review Entity (IRE) reconsiderations of Part D coverage determinations on behalf of enrollees without having to obtain signed appointment of representative forms will, in our opinion, lessen the burden faced by providers seeking to assist enrollees with appeals and will encourage more health care professionals to help beneficiaries access this level of the appeals process. The foregoing proposals and the changes considered are set forth in Table 3.

TABLE 3—PROVISIONS TO STRENGTHEN BENEFICIARY PROTECTIONS

Preamble section	Provision	Part 417		Part 422		Part 423		Part 483	
		Subpart	Subpart	Section	Section	Subpart	Section	Subpart	Section
II.B.1	Good Cause and Reinstatement into a Cost Plan.	Subpart K	417.460	N/A	N/A	N/A	N/A	N/A	N/A
II.B.2	Requiring MA Plans to Issue Member ID cards.	N/A	N/A	Subpart A	422.111	N/A	N/A	N/A	N/A
II.B.3	Determination of Actuarially Equivalent Creditable Prescription Drug Coverage.	N/A	N/A	Subpart K	422.56	N/A	N/A	N/A	N/A
II.B.4	Who May File Part D Appeals with the Independent Review Entity.	N/A	N/A	N/A	N/A	Subpart M	423.600 423.602	N/A	N/A

1. Good Cause and Reinstatement Into a Cost Plan (§ 417.460)

Current regulations at § 417.460(c) specify that an HMO or competitive medical plan may disenroll a member who fails to pay premiums or other charges imposed by the plan for deductible and coinsurance amounts. The cost plan must demonstrate that it made reasonable efforts to collect the unpaid amount (for example, the plan attempted to contact the member by phone or mail) and sent the enrollee written notice of the proposed disenrollment (including an explanation of the enrollee's right to a hearing under the HMO's or competitive medical plan's grievance procedures). Cost plans also have the option of not disenrolling members who fail to pay their premiums or cost-sharing. A plan may adopt either policy and must apply it consistently to all members in the plan.

Individuals who are disenrolled from an MA or Part D plan for failure to pay premiums are generally ineligible to regain MA or Part D coverage until the next Annual Election Period. However, in some of these cases, there may be extenuating circumstances that would make reinstatement appropriate. Thus, in the April 2011 final rule (76 FR 21511), we established provisions at §§ 422.74 and 423.44 that allow individuals, who are disenrolled from MA and Part D plans for failure to pay premiums, to request reinstatement into their former plan based on good cause and the ability to pay all arrearages. These MA and Part D rules provide alignment with the existing Part B policy regarding delinquent Medicare Part B premium payments.

In the October 11, 2011 proposed rule (76 FR 63036), we proposed to extend the right to request reinstatement for good cause to beneficiaries enrolled in cost plans. Specifically, we proposed to amend § 417.460(c) to allow reinstatement of enrollment for good cause following involuntary disenrollment, based on failure to pay premiums or other cost-sharing amounts, to a cost plan. Section 417.460(c) provides that—

- To be eligible for reinstatement, the enrollee would have to pay all outstanding arrearages, including premiums that accrued during the period of disenrollment;
- The standard for good cause would be similar to the standard established under MA and Part D (for example, unexpected, prolonged hospitalization or loss of home or severe impact by fire); and

- An individual who is involuntarily disenrolled within the same timeframe from both his or her cost plan and a standalone PDP (not affiliated with the cost plan), would have to seek separate good cause determinations for reinstatement into each plan.

Comment: CMS received several comments on this proposal, all of which expressed broad support and concurrence with our intent to mirror the existing MA and Part D requirements. A commenter expressed regret with our determination that good cause would not exist if the sole basis for requesting reinstatement is a change in an individual's financial circumstances. The commenter suggested that such an individual might eventually find the means to afford the plan's premiums, in which case, she or

he should not be prohibited from reinstatement and the opportunity to reestablish relationships with previous providers. In addition, the commenter believes that beneficiaries should be able to appeal a denial of reinstatement.

Response: The intent behind this provision was to give cost plan enrollees the same protections that we currently extend to MA and Part D plan enrollees. As such, we do not believe that it would be appropriate to expand these protections to include either additional factors that meet the good cause standard or appeal rights when a request for reinstatement is denied. It is important to note that denying a beneficiary's request for reinstatement does not result in the loss of Medicare coverage. Instead, individuals who are involuntarily disenrolled from a cost plan revert back to Original Medicare and are free to maintain their relationships with established providers. In addition, if an individual's financial circumstances improve over time, she he can re-enroll during the cost plan's next period of open enrollment.

We appreciate the comments that were submitted on this provision and will be finalizing this proposal without modification.

2. Requiring MA Plans to Issue ID Cards (§ 422.111)

Pursuant to section 1860D–4(a)(1) of the Act and § 423.120(c), and consistent with, common industry practice as described in the Medicare Marketing Guidelines (http://www.cms.gov/ManagedCareMarketing/03_FinalPartC_MarketingGuidelines.asp), Part D sponsors must issue and re-issue as

appropriate a card or other technology that enrollees can use to access negotiated prices for Part D covered drugs. While we have made recommendations with respect to member identification (ID) cards for Medicare Advantage (MA) Preferred Provider Organization and Private Fee-for-Service products through our Medicare Marketing Guidelines (<http://www.cms.gov/ManagedCareMarketing/>), we have issued no related regulatory requirements. Many MA organizations issue ID cards to their enrollees, but, absent such a requirement in regulation, we cannot ensure that all MA organizations issue cards to their members or that the cards contain certain information at a minimum and other information necessary for consistency of information across such documents. Thus, we believe it is important to establish requirements for the MA member ID cards to ensure that key information (such as the plan's customer service number and the member ID number) is on the card so that enrollees can access care. Specifically, we proposed to require that ID cards contain the following information: (1) For an MA PPO or PPFS plan, a statement that Medicare Limiting Charges apply; (2) an address for the plan's Web site; (3) a customer service number; and (4) the individual identification number for each enrollee, to clearly identify that he or she is a member of the plan.

We indicated that implementation of these provisions would ensure providers have easy access to the necessary information for verifying coverage and processing claims. Therefore, under our authority at section 1852(c) of the Act (to require that MA organizations disclose MA plan information upon request), at section 1856(b)(1) of the Act (to establish standards by regulation) and section 1857(e) of the Act (to specify additional contractual terms and conditions the Secretary may find necessary and appropriate), we proposed to amend § 422.111 by adding a new paragraph (i) to expressly require that MA plans issue and re-issue, as necessary, a card that contains certain information and enables enrollees to access all covered services.

Comment: Several commenters expressed support for the proposal to require MA plans to issue ID cards. Additionally, they offered suggestions for specific ID card requirements: (1) add an identifier to the card for individuals who receive Medicaid or are QMBs; and (2) adopt the Workgroup on Electronic Data Interchange (WEDI) standards for medical ID cards. In

addition, one commenter said that we should exclude the Medicare Limiting Charges statement because of card crowding.

Response: We appreciate the thoughtful comments. In light of the recommendations that we add more information to the ID card, and realizing that there is limited space in which to include such information, we will be issuing further guidance in this area based on accepted industry practice. In developing such guidance, we will also consider the commenter's concern about the possible lack of space on the card if we were to include our proposed statement regarding Medicare Limiting Charges.

Comment: A commenter questioned whether this requirement applies to section 1876 cost plans.

Response: Yes. With the final publication of these regulations, § 417.427 will be amended to require section 1876 cost plans to follow the disclosure requirements contained in § 422.111. As the ID provision is part of these disclosure requirements, as of the publication of these regulations, section 1876 cost plans will be required to issue ID cards.

After consideration of the public comments received, we are finalizing the policy with the following modification: We are removing the specific information requirements from the ID card provision (§ 422.111(i)).

3. Determination of Actuarially Equivalent Creditable Prescription Drug Coverage (§ 423.56)

Section 1860D–22 of the Act outlines the special rules for employer-sponsored programs. Subsection 1860D–22(a) of the Act establishes that the Secretary shall provide payment to sponsors of qualified retiree prescription drug plans that provide equivalent or better coverage than the actuarial value of standard prescription drug coverage. The Affordable Care Act amended section 1860D–22(a)(2)(A) of the Act by adding a provision that changed the formula for determining the actuarial equivalence of retiree prescription drug coverage to the defined standard coverage. Consistent with this provision, qualified retiree prescription plans, in their attestation of actuarial equivalence, must disregard the value of any discount or coverage provided during the coverage gap provided under standard prescription drug coverage. Thus, in the April 2011 final rule (76 FR 21478), we amended § 423.884(d) to remove the value of any discount or coverage provided during the coverage gap from the valuation of standard prescription drug coverage

when comparing the value of the retiree drug subsidy (RDS) calculation to determine valuation of the RDS coverage.

Section 1860D–13(b)(4) of the Act defines creditable prescription drug coverage to include coverage that at least meets the actuarial equivalence requirements in 1860D–13(b)(5)(A) of the Act. This provision requires the cost of prescription drug coverage to have an actuarial value that equals or exceeds the actuarial value of the standard Medicare prescription drug benefit (as determined under section 1860D–11(c) of the Act). The Affordable Care Act established two standard Medicare prescription drug benefits. Thus, there are now two calculated actuarial values for the standard prescription drug benefit—one value that would apply for standard prescription drug coverage when establishing the low-income subsidy and another value that would apply to applicable beneficiaries. As a result, we needed to clarify which actuarial equivalence standard is used for the valuation of creditable prescription drug coverage. Retiree prescription drug coverage is the most common source of creditable coverage, therefore we proposed to align the actuarial value calculation we use for purposes of section 1860D–13(b) of the Act with the actuarial value calculation used to determine the value of the retiree drug subsidy. By using the same values for both determinations, we ensure that RDS individuals, who are enrolled in plans that meet the actuarial equivalence value of defined standard prescription drug coverage as provided under § 423.884(5)(iii)(C), are not subject to the LEP under § 423.46 if they subsequently enroll in a Part D plan.

To this end, we proposed to amend § 423.56(a) to exclude the value of gap discounts or coverage, so that the definition of creditable coverage is consistent with the calculation of the actuarial value of RDS coverage in § 423.884(d). We also proposed to revise the reference to “CMS actuarial guidelines” in § 423.56(a) to read “CMS guidelines,” to provide additional flexibility in issuing interpretive guidance on the definition of creditable coverage.

Comment: All commenters who addressed this issue were in favor of the proposal. Commenters indicated that CMS' changes would ensure that more employer-sponsored plans will be determined creditable, so enrollees will not be subject to the Part D late enrollment penalty if they choose to switch from employer-sponsored coverage to Part D coverage.

Response: We appreciate the commenters' support of the proposal and agree with their position that this approach will enable beneficiaries who switch from employer-sponsored creditable prescription drug coverage to a Part D plan to do so without incurring a late enrollment penalty.

Comment: A commenter indicated support to exclude the late enrollment penalty (LEP) from the calculation of creditable coverage and requested that CMS provide employer-sponsored plans with the LEP amounts to effectuate the proper calculation.

Response: The calculation for creditable coverage for qualified retiree prescription drug plans does not include the LEP. Further, because the LEP is not part of the formula to determine and attest creditable coverage, we do not believe it is necessary to share the LEP amounts with employer-sponsored plans.

We appreciate the comments that were submitted on this provision and will be finalizing this proposal without modification.

4. Who May File Part D Appeals With the Independent Review Entity (§§ 423.600 and 423.602)

Section 1860D-4(h) of the Act directs the Secretary to establish a Part D appeals process that is similar to the appeals process used for MA appeals. The Parts C and D appeals procedures are set forth in Subpart M of Parts 422 and 423 of our regulations, respectively. In our January 12, 2009 final rule (74 FR 1494), we amended both sets of regulations to strengthen enrollee access to the Part C and Part D appeals processes. Specifically, we amended the MA appeals regulations at § 422.582 to permit physicians to request standard plan reconsiderations of pre-service requests on behalf of MA enrollees. Consistent with section 1860D-4(g) of the Act, we made a corresponding change to the Part D regulations at § 423.580, allowing prescribing physicians and other prescribers to request standard redeterminations on behalf of enrollees. Allowing prescribers to request coverage determinations and plan level appeals on behalf of enrollees has significantly enhanced enrollee access to these processes.

Subsequent program experience has taught us that these changes to the Part D appeal process may not go far enough in terms of improving access to the Part D appeals process, as explained later in this section. Consequently, we proposed to revise the Part D regulations at § 423.600 to allow prescribing physicians and other prescribers to request Independent Review Entity

(IRE) reconsiderations on behalf of enrollees. We also proposed making a corresponding change to the notice provisions at § 423.602(a).

Currently, the Part D IRE reports that approximately 46 percent of the cases it dismisses lack a valid appointment of representative (AOR) form, and that the overwhelming majority of these dismissed appeals (close to 90 percent) are initiated by prescribers. Such dismissals impede prescribers from assisting enrollees in obtaining timely independent review of their cases which creates the potential for delays in prescription drug access. Furthermore, given a prescriber's ability to act on behalf of an enrollee in requesting Part D plan level appeals, prescribers frequently express dissatisfaction with not being able to also assist patients with IRE level appeals and the perceived burden associated with becoming the enrollee's appointed representative. Clearly, this rule will significantly reduce the number of requests for review that the Part D IRE dismisses due to the lack of an AOR form. In addition, because the IRE will no longer have to seek an AOR form, it will be able to immediately initiate substantive review of these cases. Thus, we believe this change will enhance beneficiary access to the appeals process and better ensure prompt IRE decisions on whether requested drugs are covered under Part D.

Under this final rule with comment period, the regulations will continue to require a Part D enrollee, or a prescriber acting on his/her behalf, to request IRE review; adverse redeterminations will not be automatically forwarded to the IRE. We considered requiring auto-forwarding of adverse redetermination requests under the Part D program, but we continue to believe that in order to obtain IRE review, the statute requires the enrollee (or someone acting on the enrollee's behalf) to request such review. (See the January 28, 2005 final rule (70 FR 4193) for a discussion of this issue.) Although section 1860D-4(h) of the Act states that only the Part D eligible individual shall be entitled to bring an appeal to the IRE, we do not interpret this language as precluding a prescriber from acting on a Part D enrollee's behalf in requesting IRE review. As required by section 1860D-4(h) of the Act, this change makes the MA and prescription drug benefit programs' appeals processes more similar, by giving Part D prescribers a mechanism to assist enrollees in accessing IRE review. In the MA program, the regulatory requirement that adverse plan reconsiderations be auto-forwarded to the IRE essentially

gives physicians acting on behalf of enrollees direct access to the IRE reconsideration process. Also, as explained in our January 2009 final rule, allowing prescribers to request IRE appeals on behalf of enrollees does not present a conflict of interest because Part D prescribers are generally not entitled to payment from the enrollee, pharmacy, or plan for the prescribed drug, and therefore, do not have a financial interest in the outcome of appeals in the same manner as physicians requesting appeals under the MA program. Furthermore, we believe that an enrollee's prescriber has already been selected by the enrollee and occupies a position of trust. A prescriber is in a good position to know whether an independent review is warranted and is in the best interest of his or her patient.

This change should reduce administrative burdens under the IRE appeal process by eliminating the need for prescribers to routinely obtain AOR forms from enrollees and permitting prescribers to assist their patients in the appeals process without taking on the added responsibilities attendant to being an appointed representative. In contrast to the ongoing authority of appointed representatives, this change will allow a prescriber to act on an enrollee's behalf on an as-needed, case-by-case basis. A completed AOR form is not necessary or advisable for prescribers who are only seeking to assist Part D enrollees in exercising their own appeal rights under the statute. Prescribers will not have the same authority as an appointed representative, including the right to bring appeals at any level. Instead, we envision that from the time of the initial IRE appeal request, the prescriber's role will remain what it has been, providing a supporting statement or the clinical information necessary to approve coverage, if appropriate. Accordingly, we believe that this change will promote enrollee access to the Part D appeals process, reduce the burden on the prescriber community, and allow a more efficient use of appeals resources.

We are also making a corresponding change to § 423.602(a) to specify that the IRE is responsible for notifying the prescriber of its decision when the prescriber makes the request on behalf of the enrollee. The enrollee will also receive a written decision notice from the IRE, thereby ensuring that enrollees are fully informed about the review process and able to participate if they choose to do so.

As in §§ 422.582 and 423.580, prescribers must notify enrollees whenever they request IRE review on

their behalf. We intend to issue additional operational guidance with respect to how this requirement may be satisfied. Finally, we make clear that this final rule with comment period addresses only the right of a prescriber to file an appeal on behalf of an enrollee at the IRE level. Other individuals who wish to act on behalf of an enrollee in filing an appeal must continue to do so as the enrollee's representative.

Comment: Most commenters expressed support for the proposal, noting that allowing prescribers to file IRE appeal requests on behalf of enrollees without becoming that enrollee's appointed representative would reduce administrative burdens on prescribers, limit dismissals of reconsideration requests, make the appeals processes under Parts C and D more similar, and enhance beneficiary access to the Part D appeals process.

Response: We appreciate the commenters' support and are finalizing the proposed revisions without modification.

Comment: A few commenters expressed concerns that the proposed change may negatively affect plan sponsors' quality ratings because it will likely result in an increase in the number of IRE appeal requests and potentially result in a higher IRE overturn rate.

Response: We agree that this change is likely to increase the number of IRE reconsideration requests, as discussed in the regulatory impact analysis for this provision. To the extent that a plan sponsor's IRE reversal rate increases as a result of this change, plan sponsors may wish to review their internal policies and procedures to ensure compliance with CMS subregulatory guidance instructing them to conduct reasonable and diligent outreach efforts to prescribers and enrollees when supporting statements or clinical information necessary to make a coverage decision are absent or incomplete.

Comment: A few commenters believe that allowing prescribers to file IRE appeals may violate section 1860D-4(h) of the Act, which specifically states that only the enrollee can bring an appeal to the IRE. The commenters note that the statutory language differs from the language related to Part C IRE appeals, and further suggest that Congressional intent was to limit the Part D IRE appeals process to individuals acting on behalf of enrollees, disallowing individuals other than the enrollee from initiating IRE appeals absent an AOR form.

Response: We disagree with the commenters. This provision does not

give prescribers appeal rights; it merely allows them to file an appeal with the IRE on behalf of an enrollee. We believe that an enrollee's prescribing physician or other prescriber is in the best position to provide the necessary medical rationale and documentation to support a favorable coverage decision. As we stated in the proposed rule, the revised regulation will require prescribers to notify enrollees that the request is being made. We intend to issue additional operational guidance with respect to how this requirement may be satisfied in a manner similar to the notification requirements for prescriber-initiated redeterminations.

Comment: A few commenters recommended that CMS limit IRE review to include only the information provided by the prescriber at the coverage determination and redetermination levels. These commenters believe that prescribers often delay providing full clinical information until an appeal reaches the IRE level and the IRE solicits it. Commenters note that if plans received the same information they may reach the same conclusion as the IRE in less time and at a lower cost.

Response: We strongly disagree with the commenters. The proposed rule was not intended to modify the IRE review process itself in any way; it only proposed to modify who may initiate an IRE appeal. We are retaining existing regulatory and subregulatory guidance regarding the requirement that the IRE solicit the views of the prescriber and retain a written account of those views in the IRE's record.

Additionally, we have not seen any indication that prescribers are intentionally withholding applicable clinical information in either the Part D coverage determination or appeals processes. As we noted in the proposed rule, prescribers do not have independent standing in Part D appeals, and generally are not entitled to payment from the enrollee, pharmacy, or plan for the drug being requested and therefore do not have a financial interest in the outcome of Part D appeals. In these cases, the prescriber is merely trying to assist the enrollee in obtaining coverage for a drug the prescriber believes is medically necessary. Prescribers have no incentive to withhold information that would support coverage. To the extent that the IRE routinely solicits and obtains information from a prescriber that was not provided during the initial coverage determination or redetermination, plan sponsors may wish to review their internal policies and procedures to ensure compliance with our

subregulatory guidance, which instructs plan sponsors to conduct reasonable and diligent outreach efforts to prescribers and enrollees when necessary supporting statements or clinical information are absent or incomplete.

Comment: CMS received several comments related to enrollee notification of a prescriber-initiated IRE appeal requests. Some commenters recommended that CMS issue guidance requiring prescribers to notify enrollees when they file an appeal on the enrollee's behalf. One commenter expressed a belief that, under the proposed change, plan sponsors would need to exercise additional oversight such as contacting enrollees to ensure that prescribers are appropriately notifying enrollees and review any form or document the prescriber uses to make the IRE appeal request. Another commenter recommended that CMS not require plan sponsors or the IRE to obtain proof from the prescriber that the enrollee was notified of the requested IRE review made on their behalf. Finally, one commenter stated that a prescriber must obtain the enrollee's consent in order to file an appeal with the IRE.

Response: We do not require and do not expect plan sponsors to conduct any type of review or oversight to determine whether prescribers have notified enrollees that they are initiating an IRE appeal on their behalf. We intend to issue guidance to the IRE with respect to making a reasonable determination of whether the enrollee has notice of the prescriber's request for a reconsideration on the enrollee's behalf. This provision merely eliminates the requirement that a prescriber obtain an enrollee's express consent (through a properly executed AOR form) in order to initiate an IRE appeal on behalf of the enrollee.

Comment: A commenter requested that plan sponsors be informed of all IRE submissions and determinations so that they can evaluate their internal processes and provide oversight of delegated entities.

Response: We agree with the commenter. In accordance with current processing requirements, the IRE will continue to request the plan sponsors' case files subsequent to all valid requests for IRE reconsideration. The proposed change to § 423.602(a) does not change the requirement that the IRE notify all parties, including the plan sponsor, of the reconsideration decision. Thus, processes for communication with and notification to plan sponsors with respect to prescriber-initiated reconsiderations will be identical to the

current processes for enrollee-initiated reconsiderations.

Comment: Several commenters recommended that CMS require auto-forwarding of all adverse redeterminations to the Part D IRE, as is currently done with adverse plan reconsiderations in the MA program.

Response: While we understand that auto-forwarding all adverse redeterminations to the IRE would enhance enrollee access to the Part D appeals process, we believe that this practice would be inconsistent with the statute. As we stated in the proposed rule, we interpret the statutory language related to Part D appeals to require the enrollee (or someone acting on his or her behalf) to affirmatively request IRE review.

Comment: A commenter recommended that CMS include information on who may file appeals with the IRE on the Medicare Web site, in Medicare & You and in plan communications to increase awareness of appeal options.

Response: We agree with the commenter and will ensure that all relevant CMS materials are updated to reflect this change after the final rule has been published. Part D plan sponsors are also required to maintain current information regarding the Part D appeals process on their plan Web sites and in annual enrollment materials.

Comment: A commenter requested that notification of IRE decisions for appeals initiated by prescribers be provided to the enrollee either by the provider or the IRE.

Response: We agree with the commenter that enrollees must receive written notification of IRE appeal decisions. As stated previously, we are finalizing the proposed corresponding change to § 423.602(a), which specifies that in all cases the IRE is responsible for notifying the enrollee (as well as the prescriber) of its decision, including when a prescriber makes a request on behalf of the enrollee.

Comment: A commenter sought clarification on whether a prescriber still needs to be appointed by the enrollee to file a request for IRE reconsideration.

Response: The purpose of the proposed change is to eliminate the need for a prescriber to obtain representative status in order to initiate an IRE appeal on the enrollee's behalf. Therefore, we are finalizing the proposed regulation text to state that, upon providing notice to the enrollee, the prescribing physician or other prescriber may request an IRE reconsideration on behalf of the

enrollee. An "appointment" is no longer required.

Comment: A commenter noted that a prescription may be denied by a Part D plan at the point of sale for a variety of reasons, and that a coverage determination should be required before proceeding to the IRE as a majority of appeals could be resolved through plan adjudication.

Response: We agree with the commenter. The proposed change allowing prescribers to file IRE appeals on behalf of an enrollee does not eliminate the requirement to exhaust plan level reviews before requesting IRE review. Under the proposed change, enrollees, their representatives and physicians or other prescribers may make a request for IRE review only after the Part D plan sponsor has made an adverse redetermination decision.

Comment: A commenter requested clarification that "prescriber" refers only to the physician, PA or NP who wrote the order for the drug in dispute.

Response: Under our proposed change to § 423.600, the "prescribing physician or other prescriber"—the individual who wrote the order for the drug in dispute—will be the only person authorized to make an IRE appeal request on behalf of an enrollee (absent an authorized or appointed representative).

Comment: A commenter recommended that IRE appeal requests be limited to prescribing physicians and not to a physician designee.

Response: We agree that the proposed change only allows prescribing physicians and other prescribers to initiate IRE appeals on behalf of enrollees. However, we understand that medical and administrative staffs perform various functions for physicians (such as calling in prescriptions or responding to requests for medical records) these same staff should be allowed to assist prescribers in submitting Part D IRE appeal requests and providing any necessary clinical documentation. We will develop additional subregulatory guidance around this process.

Comment: A commenter stated that allowing prescribers to initiate IRE appeals on behalf of enrollees will contribute to the increasing problem of overutilization of medications caused by prescribers who continue to prescribe drugs that are not medically necessary.

Response: We understand the commenters concerns, but disagree with the suggestion that the proposed provision will lead to overutilization. We are only allowing prescribers to request coverage at the IRE level. The decision whether to overturn the

adverse redetermination will continue to be made by the IRE based on statutory and regulatory guidelines and applicable clinical documentation.

Comment: A commenter encouraged CMS to ensure that prescriber requests for IRE reconsideration are consistent throughout the Part D and MA programs.

Response: We are seeking to make the Part D and MA programs more similar through this regulatory change. However, as noted previously, we believe the statutory differences with respect to IRE reconsiderations do not allow for these processes to be identical.

Comment: CMS received a number of comments related to fees charged by prescribers who assist enrollees with Part D appeals. Several commenters urged CMS to reexamine the policy surrounding "allowable extra fees," stating that Part D and MA program appeals are rarely successful without physician support and allowing physicians to charge fees for providing letters of medical necessity or producing medical records creates an unnecessary tension in the doctor-patient relationship. Some commenters requested that CMS prohibit physicians or other prescribers who file IRE appeals on behalf of enrollees, from charging enrollees any fee for assistance unless an enrollee has agreed to the fee in writing. Other commenters requested that CMS issue guidance related to reasonable fees. A number of commenters also noted that CMS rules related to appointment of representatives include a provision that a physician representative may waive a fee for representing a beneficiary.

Response: Subpart M does not address fees charged by physicians or other prescribers; therefore, we believe these comments are outside the scope of the proposed regulation.

As stated previously, we are finalizing the proposed changes without modification. However, we are, changing the effective date of this provision from 60 days after the publication of this rule to January 1, 2013, to clarify that prescribers may not begin requesting reconsiderations on behalf of the beneficiary until the 2013 plan year.

5. Independence of LTC Consultant Pharmacists (§ 483.60)

In our October 11, 2011 proposed rule (76 FR 63038), we noted that under sections 1819(b)(4) and 1919(b)(4) of the Act, long term care (LTC) facilities must provide, either directly or under arrangements with others, for the provision of pharmaceutical services to meet the needs of each resident. This

requirement is codified in regulations at § 483.60, which require LTC facilities to employ or obtain the services of a licensed pharmacist to provide consultation on all aspects of the provision of pharmacy services in the facility, including a drug regimen review at least once a month for each facility resident. We explained that, as a result of their role in LTC facilities, LTC consultant pharmacists may exercise significant influence over the drugs that LTC facility residents receive.

We noted that nursing homes commonly contract with a single LTC pharmacy for prescription drugs for facility residents. Very often the same LTC pharmacy then also contracts with the facility to provide consultant pharmacists for required consultation on all aspects of the provision of pharmacy services in the facility, including the monthly resident drug regimen reviews. We indicated that, in verbal conversations with industry representatives, we had been informed that some LTC pharmacies provide the consultant pharmacists to nursing homes at rates that may be below the LTC pharmacy's cost and below fair market value.

We expressed our concern with the potential effect on patient safety and quality of care for nursing home residents regarding the various contractual arrangements involving LTC facilities, LTC pharmacies, pharmaceutical manufacturers and/or distributors, and the LTC consultant pharmacists that may be provided through LTC pharmacies directly or indirectly to LTC facilities. We noted these arrangements may take many forms and mentioned the practice of LTC pharmacies' providing consultant pharmacists to nursing homes at below cost or fair market value as one such type of arrangement. We noted also that any such arrangements have the potential to directly or indirectly influence consultant pharmacist drug regimen recommendations. We indicated our concern that the lack of independence of the consultant pharmacist from the interests of the LTC pharmacy or other LTC pharmacy-related organization may lead to recommendations that steer nursing homes to recommend or use certain drugs for their residents. We noted this could result in the overprescribing of medications, the prescribing of drugs that may be inappropriate for LTC or geriatric residents, or the use of unnecessary or inappropriate therapeutic substitutions. We remarked that such potential outcomes could pose serious health-related consequences to

some nursing home residents' health and safety.

In our October 11, 2011 proposed rule (76 FR 63039), we referenced the claims brought by qui tam relators under the False Claims Act and cited research findings, HHS Office of Inspector General review findings, and nursing home survey and certification data to demonstrate that our concerns were not merely theoretical. We acknowledged that our findings did not directly connect LTC pharmacy relationships with consultant pharmacists to the research findings and survey results; however, we believed it was reasonable to presume that the incentives present in the relationships among some consultant pharmacists, LTC pharmacies, and drug manufacturers could influence the prescribing practices reflected in the data. As a result, we expressed our belief that requiring the independence of consultant pharmacists was necessary and appropriate and were considering making such a change. We solicited comments on our understanding in this matter.

In our October 11, 2011 proposed rule (76 FR 63040), we stated that we believed severing the relationship between the consultant pharmacist and the LTC pharmacy, pharmaceutical manufacturers and distributors, and any affiliated entities would further protect the safety of LTC residents because it would ensure that financial arrangements would not influence the consultant pharmacist's clinical decision making to the detriment of LTC residents. Therefore, we indicated that we were considering requiring that LTC consultant pharmacists be independent of any affiliations with the LTC facilities' LTC pharmacies, pharmaceutical manufacturers and distributors, or any affiliates of these entities and believed such a requirement would be necessary to ensure that consultant pharmacist decisions were objective, unbiased, and in the best interest of nursing home residents. LTC facilities would use a qualified professional pharmacist to conduct drug regimen reviews and make medication recommendations based on the best interests of the resident. We expressed our belief that this could be achieved only if the consultant pharmacist were working without the influence of conflicting financial interests that might otherwise encourage overprescribing and overutilization, which creates health and safety risks for residents.

We noted the changes we were considering would use the authority available under sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act to require

that LTC consultant pharmacists be independent. The cited statutory provision gives the Secretary authority to establish "such other requirements relating to the health, safety, and well-being of residents * * *." We stated we were considering requiring that LTC facilities employ or directly or indirectly contract the services of a licensed pharmacist who is independent. We also noted we were considering including a definition of the term "independence" to mean that the licensed pharmacist must not be employed, under contract, or otherwise affiliated with the facility's pharmacy, a pharmaceutical manufacturer or distributor, or any affiliate of these entities.

Finally, we noted our understanding that some LTC consultant pharmacists may perform approximately 60 drug regimen reviews in a day. We indicated we suspect that this rate may be too high, given our expectation that independent consultant pharmacists would conduct more thorough drug regimen reviews, monitoring for drug side effects and efficacy. Therefore, although we did not propose to codify changes to the drug regimen review requirements, we solicited public comment on best practices related to the conduct of drug regimen reviews and stated we would use these comments to inform possible future rulemaking regarding the drug regimen review requirements.

Comment: CMS received many responses to our request for comment on our understanding of the problems associated with conflict of interest involving LTC consultant pharmacists. A significant number of commenters who identified themselves as current or former consultant pharmacists either acknowledged they had experienced conflict of interest in the past or confirmed our understanding that conflict of interest were an on-going problem. Several of these commenters claimed that conflicts of interest have been widespread and alleged that patient care suffers because of it. A number of these commenters wrote anonymously stating they feared retribution from their pharmacy employers. A commenter asserted that the rules LTC pharmacies placed on their employee consultant pharmacists strongly influenced utilization. This, they note, often resulted in a higher number of medications per resident and use of inappropriate drugs. Commenters who had witnessed or experienced conflict of interest described practices associated with it that included the following:

- Several commenters indicated their LTC pharmacy gave consultant pharmacists a list of “preferred” drugs; that is, drugs for which the LTC pharmacy receives preferred pricing or higher rebates from the pharmaceutical manufacturer, to be used for making their medication recommendations.

- A few commenters described their LTC pharmacy’s therapeutic interchange program, which involves the consultant pharmacist recommending a change from a prescribed non-preferred drug to one of the pharmacy’s preferred drugs. A commenter characterized therapeutic interchange to rebated drugs as “big business” for the pharmacy. Another commenter explained that, once a change recommendation was made by the consultant pharmacist, the LTC pharmacy automatically generated a fax notice to the prescriber requesting the he or she sign the notice to approve the therapeutic interchange. An additional commenter indicated that the consultant pharmacists’ medication change recommendations were communicated in the form of letters to the prescriber prepared by the corporate clinical department of the pharmacy.

- Several commenters explained that consultant pharmacists’ performance evaluations and bonuses were based on the market share of particular brand name drugs in the LTC facility. Thus, as the commenters noted, consultant pharmacists had financial incentives to make medication recommendations that enabled the facility market-share targets to be met.

- Many commenters stated that they had first-hand knowledge that LTC pharmacies continue to charge below-market rates for the LTC consultant services as a means of acquiring the LTC facility’s pharmacy business, noting that this remains a common practice. Some of these commenters charged that the pharmacies recovered their costs for the consultant pharmacist services by requiring the consultant pharmacists to recommend drugs that generated the highest profit for the pharmacy.

- Many commenters charged that the consultant pharmacists’ drug regimen review quotas were so high that sufficient time was not available to perform a thorough review of the residents’ medication regimens and make good recommendations. One commenter cited a minimum drug regimen review quota of 1,500 reviews per month. Another commenter reported that, when a large LTC pharmacy organization acquired the pharmacy at which the commenter had been employed, the new management required that the commenter perform the same number of drug regimen

reviews as the commenter had been performing previously, but also that the commenter spend 2 days per week dispensing. As a result, the time available for the commenter to perform the same number of medication reviews was decreased by 40 percent.

- Some commenters asserted that by limiting the time available to conduct them, the drug regimen reviews were perfunctory. Others described how the drug regimen review requirements were subverted. For example, a commenter contended that the consultant pharmacists employed by an LTC pharmacy were performing the medication reviews at the pharmacy rather than the facility and, thus, had no access to medication administration records, physician and nursing assessment notes, lab results, or other information available in the residents’ medical records. Another asserted that an LTC pharmacy organization had its consultant pharmacists review the residents’ medication administration records, not the entire medical record, thus missing lab values and other assessments and notes.

- Many commenters agreed that consultant pharmacists should be free from conflict of interest and their medication recommendations should be based solely on the residents’ best interests. Finally, however, many other commenters stated that they never experienced any pressure in the conduct of their consultant pharmacist activities, nor had they seen others pressured, and thus they believed that conflict of interest is not an issue for consultant pharmacists.

Response: We appreciate the confirmation of our understanding that conflict of interest may be a problem for many LTC consultant pharmacists. We recognize that a significant number of commenters disagreed with our understanding and, thus, the problem may not be universal. We believe the comments suggest that the problem has been addressed in some places and not in others, is more widespread in some places and therefore more evident, or is associated with a particular LTC pharmacy or pharmacies, particular LTC facilities or chains or pharmaceutical manufacturers or manufacturer representatives.

However, the reports of conflict of interest are sufficient to indicate it continues to exist and our concerns regarding its impact on the quality of care in LTC facilities are well-founded. We believe that this demonstrates that change is necessary to ensure that all LTC consultant pharmacists are free from conflicts of interest, are able to base their professional medication

recommendations on the best interest and clinical needs of LTC facility residents, and are able to advocate for the Medicare beneficiary.

Comment: CMS received a large number of comments from advocates and advocacy organizations, long term care ombudsmen, LTC consultant pharmacists, and others supporting a requirement for LTC consultant pharmacists to be independent and noting that such a policy was needed and long overdue. These commenters asserted that independence is essential to ensure that drug regimen reviews are impartial and the consultant pharmacist is able to act as an advocate for the resident without fear of financial repercussions. A commenter agreed with an independence requirement, noting that removing the financial incentives between the consultant pharmacists and the LTC pharmacy would increase transparency.

CMS also received many comments opposing a requirement that would separate LTC pharmacy consulting from dispensing services. Many of these commenters claimed the requirement would be seriously disruptive, asserting that communication and collaboration between the dispensing pharmacy and the consultant pharmacist would be diminished, consultant pharmacists would be deprived of access to proprietary LTC pharmacy systems, data and other resources critical to the performance of consultant pharmacists’ activities. Opposing commenters noted the requirement would also deprive consultant pharmacists of the significant advantages derived from pharmacy employment, including health, retirement and other benefits, and would increase costs to both the LTC facilities and consultant pharmacists. A significant number of these commenters expressed concern that independence would decrease the quality of patient care accordingly.

Many commenters requested that we finalize the requirement and not yield to those who argued against it. CMS received several comments from independent consultant pharmacists noting that, although others have argued otherwise, working independently has neither hindered access to residents’ prescription or medical information, nor diminished the residents’ quality of care.

Response: We appreciate these comments, as well as the concerns expressed by those commenters opposed to the requirement for independent consultant pharmacists. The comments supporting the independence requirement have sustained our concerns about conflict of

interest and its impact on the quality of long term care. Also, the significant advantages associated with employment described in the opposing comments serve to highlight the strong influence such financial ties can exert on pharmacy-employed consultant pharmacists and reinforce the importance of an independence requirement to ensure unbiased medication reviews. As a result, we remain convinced of the need for changes to ensure that the consultant pharmacists' recommendations are based solely on the residents' best interests and clinical needs. However, we acknowledge that an independence requirement could be highly disruptive to the industry overall, including the LTC facilities and those consultant pharmacists with current industry affiliations, and would result in higher costs to the facilities and consultant pharmacists.

Comment: A few commenters claimed we do not have the statutory authority to impose an independence requirement. These commenters asserted that we cannot use the Secretary's authority under sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act, because consultant pharmacist independence has no direct relationship to resident health and safety. Therefore, for us to require consultant pharmacists to be independent would require Congressional authorization.

Response: We disagree. We believe that the conflict of interest inherent in the employment relationship between a consultant pharmacist and an LTC facility's pharmacy undermines the ability of the consultant pharmacist to make unbiased medication recommendations that are solely in the best interests of the residents. Many of the comments previously discussed corroborate our belief.

Recommendations made on other bases, such as those reflecting the financial interests of the consultant pharmacist or the consultant pharmacist's employer, pose health and safety risks for the residents. Even in those situations in which the consultant pharmacist is able to make unbiased medication recommendations because there are no pressures to do otherwise, if the drug regimen review quota established by the consultant pharmacist's employer is so high as to permit the consultant pharmacist to perform only the most perfunctory medication reviews, then resident health and safety are at risk.

Comment: Many commenters agreed with the definition of "independence" we indicated we were considering. Some commenters disagreed with the definition, indicating that consultant

pharmacists should not be permitted to be employees of the LTC facility in order to avoid the potential conflict of interest inherent in an employment relationship. Other commenters requested that consultant pharmacists be permitted to affiliate with pharmaceutical manufacturers and distributors. These commenters argued that affiliations with these entities permit the exchange of scientific and educational information on topics, such as medications and product benefits and risks, and much of this exchange occurs at educational programs supported by the industry at professional meetings and trade shows. They noted that consultant pharmacists frequently serve on industry advisory boards and are engaged as speakers and researchers with industry financial support and contended that HHS Office of Inspector General guidance for pharmaceutical manufacturers and industry guidelines related to the healthcare professionals' decision-making provide sufficient oversight. One other commenter requested that we define the terms "affiliates" and "affiliated."

Response: We acknowledge that there may be potential conflicts of interest in an employment relationship between consultant pharmacists and LTC facilities, but note that both the LTC facility and its residents have a common interest in the facility meeting CMS standards for unnecessary drug use in the facility. We do not agree with the commenters who advocated that we allow consultant pharmacist relationships with pharmaceutical manufacturers and distributors. The relationships that these commenters describe cause us substantial concern, as we believe they represent a basis for the conflicts of interest that we seek to eliminate. We believe that consultant pharmacists who receive remuneration from pharmaceutical manufacturers/distributors for activities, such as research and speaking engagements or for serving on advisory boards, may be influenced by these relationships in the performance of their consultant pharmacist activities. Thus, if the consultant pharmacists' recommendations are to be based solely on the LTC residents' best interests, these affiliations should be prohibited.

Comment: We received many comments from those supporting the independence requirement for LTC consultant pharmacists as well as from those opposing it, noting that consultant pharmacist independence would not solve the entire problem of conflict of interest, because other agents contribute to drug overutilization and inappropriate drug use in LTC facilities.

Contributors specifically cited by commenters were LTC facility medical directors, nurse practitioners and physician assistants and the residents' attending physicians. A few commenters noted that family members, influenced by pharmaceutical advertisements, could request antipsychotics as adjuncts for depression and the prescriber could accede to these requests. Other commenters noted the LTC facilities' role citing serious understaffing, high staff turnover, and the lack of specialized staff trained in meeting the needs of dementia patients as factors contributing to inappropriate drug use in LTC facilities. Another commenter observed that others also play a contributing role, noting that a considerable number of residents admitted into LTC facilities from their homes, hospitals, and assisted living facilities are already on potentially unnecessary drugs.

Many commenters pointed out that the ultimate decision regarding what medications to prescribe and whether to accept or reject a consultant pharmacist's recommendation lies with the physician. Therefore, the commenters asserted prescribers, not consultant pharmacists, should be held accountable for overuse or inappropriate use of drugs in LTC facilities.

Commenters claimed LTC residents' physicians, as well as the facility's medical director, rarely see or examine the residents and medications are reordered without the physician reviewing the residents' condition. According to another commenter, if a resident's behavior problem escalates, such as in the case of a resident with dementia, facility staff would call the physician to increase the medication dosage, and the physician would commonly comply without seeing the resident. Several other commenters noted that prescribers, aware of potential bias, ignore the consultant pharmacists' recommendations due to uncertainty that the recommendations are in the residents' best interests.

Many of the commenters in opposition to the consultant pharmacist independence requirement noted that conflicts of interest pervade the LTC industry, affecting the facility (which imposes its own formulary requirement to contain costs for the drugs it covers), facility staff (who can encourage the use of chemical restraints to manage residents with behavioral problems), and the residents' physicians and LTC facility-based prescribers (who may have their own financial ties to the pharmaceutical industry). For these reasons, the commenters objected to a

requirement that would single out only one group of actors that contribute to this problem. Several commenters recommended that we require that all clinicians in an LTC facility be independent, or that we at least consider the role of the physicians who prescribe medications when determining how best to solve the problem. Other commenters agreed with the independence requirement, but indicated that it was only a partial solution and a more comprehensive approach would be necessary to respond effectively to the whole problem.

Response: We appreciate the many comments noting that others in the LTC industry, including facility staff and residents' attending physicians, contribute significantly to overutilization. Commenters not only implicated others as contributing to overuse of drugs in LTC facilities, but also described other factors that contribute to the problem. Therefore, we recognize that requiring consultant pharmacists to be independent will not solve the entire problem. As a result of these comments, we are better aware that the independence requirement we specifically described in the October 11, 2011 proposed rule would disproportionately target consultant pharmacists and leave the other actors to continue to operate as they do currently. This suggests that, unless the industry on its own implements steps to curtail overutilization and inappropriate drug use in LTC facilities, we must consider requiring broader changes than independence only for consultant pharmacists and propose those changes in future notice and comment rulemaking.

Comment: Several commenters mentioned the recent investigations of nursing homes conducted by the California Department of Public Health which found that LTC consultant pharmacists failed to identify and report the misuse of antipsychotic medications in 90 percent of the cases identified by investigators as involving inappropriate and potentially lethal doses of these drugs. We also received comments from an LTC pharmacy reporting that over the past 5 years its consultant pharmacists have made over 700,000 recommendations to prescribers regarding antipsychotic drug use and that more than 99 percent were recommendations to reduce dosage, discontinue or question use or recommend monitoring for side effects. (We note this commenter did not provide information on whether these recommendations were followed.) Citing these data from the LTC

pharmacy, another commenter noted that, if (as the level of antipsychotic drug use suggests) prescribers are ignoring the consultant pharmacist recommendations, it raises the question of the effectiveness of the drug regimen reviews. A commenter suggested that, over time, conflict of interest can diminish prescribers' confidence in the consultant pharmacists, eroding their effectiveness. This suggestion was supported in the comments of another who claimed that prescribers who have been practicing in LTC facilities are sensitive to the ethical conflicts faced by consultant pharmacists and are skeptical of their recommendations because of the prescribers' uncertainty as to whether the recommendations are in the residents' best interests.

Response: These comments and the data reported by the commenters suggest that the required monthly drug regimen reviews are not yielding the intended outcomes nor are they providing the expected beneficiary protections. If perceived conflict of interest has potentially eroded confidence in the recommendations of the consultant pharmacists that prescribers are ignoring them and the reviews have become merely perfunctory exercises, then we may consider changing the requirements in § 483.60(c) and explore alternative requirements and approaches. In determining whether a regulatory change is necessary, we will continue to evaluate the number of deficiency citations for unnecessary medication use and will monitor two new performance measures on the use of antipsychotics in LTC facilities. These new performance measures, based on resident assessment information reported in the Minimum Data Set (MDS 3.0), will reflect antipsychotic drug use by short-term stay and by long-term stay facility residents and will be available later in 2012 on the CMS nursing home compare Web site at <http://www.medicare.gov/NHcompare/home.asp>.

Comment: We received extensive comments expressing serious concerns about the level of overuse and inappropriate use of antipsychotic drugs in LTC facilities. A commenter stated that, "On any given day, over 350,000 nursing home residents receive powerful antipsychotics, despite FDA warnings that the drugs increase the risk of death and studies that show the drugs do not work and have terrible side effects." Many commenters noted the vast majority of those receiving these drugs are residents with dementia who are being chemically restrained when there are safe, effective, and less expensive nonpharmacological methods

to care for these residents. Another commenter stated that studies show that compassionate, person-centered care can minimize anxiety and depression and minimize the need for psychotropic medications.

Response: We share the grave concerns expressed by the commenters concerning the level of antipsychotic drug use in LTC facilities. We believe these comments also call into question the effectiveness of the consultant pharmacists' drug regimen reviews in curtailing the use and misuse of antipsychotic drugs, regardless of whether the ineffectiveness is caused by inadequate medication reviews by consultant pharmacists or prescribing physicians ignoring the recommended changes. As we indicated previously, we agree that consultant pharmacist independence will not solve the whole problem. Therefore, we challenge the entire LTC industry to do what is in the best interests of our most vulnerable beneficiaries and implement the necessary and appropriate changes to address this serious situation.

We expect that through the implementation of changes, such as placement of greater emphasis on the use of nonpharmacological methods of care as an alternative to pharmacological treatment for the behaviors associated with dementia, the industry will achieve substantial improvement in the appropriate use of these medications. Although not all non-pharmacological treatments are appropriate for all patients, some nonpharmacological interventions may have potential benefits for residents with the behavior symptoms associated with dementia, such as agitation or aggression, wandering and sleeping disturbances. These interventions include, for example, music therapy, massage therapy, behavior management techniques, and animal-assisted therapy.

Comment: A number of commenters offered recommendations for increasing transparency in order to address conflicts of interest issues in LTC facilities. Some commenters recommended that we require LTC facilities to separate contracts for LTC consulting services from contracts for other services, including drug dispensing, and require LTC facilities pay a fair market rate for consultant pharmacist services. Some commenters suggested either that we require consultant pharmacists to disclose to the facility any affiliations that would pose a potential conflict of interest or require consultant pharmacists to sign an integrity agreement. Several commenters recommended that LTC

pharmacies ensure that consultant pharmacists are empowered to make independent judgments and affirm this in a statement to the facility. One commenter suggested that, should the implementation of a requirement for consultant pharmacists to be independent be delayed, we require consultant pharmacists to disclose their affiliations and potential conflicts of interest.

Response: We continue to believe that requiring independent consultant pharmacists is part of the right approach to address our concerns regarding conflict of interest and quality of care in LTC facilities. It is an approach that was strongly supported by some consultant pharmacists who confirmed our belief that LTC pharmacies do exert pressure on the consultant pharmacists in their employ to influence the medication recommendations. It was also supported by individual commenters, advocates and advocacy organizations, Part D plan sponsors and PBMs, and consultant pharmacist organizations. However, we acknowledge that others in the industry, including LTC facility staff and prescribers, are likewise implicated in the problem of overprescribing and inappropriate drug use. Thus, an independence requirement solely for consultant pharmacists would not solve overutilization and would single out one party, but leave the others to continue unaffected. We agree with commenters that the requirement would be highly disruptive to both LTC facilities and consultant pharmacists with current industry affiliations. Because the proposed requirement does not address the role of facility staff and prescribers in driving overutilization and inappropriate use, it is unlikely to result in substantially reducing these problems that would, in our view, outweigh the costs of industry disruption.

Comment: We received several comments that noted the lack of empirical evidence linking overutilization of drugs in LTC facilities to consultant pharmacists' possible conflicts of interest. Numerous commenters suggested that we study the recommendations, drug utilization and outcomes data for independent and pharmacy employed consultant pharmacists and many of these commenters also recommended that we consult with stakeholders to better define and scope the problem and formulate a more appropriate approach for addressing it.

Response: If, as suggested by other commenters, consultant pharmacist recommendations are rarely acted upon, this calls into question the very purpose

of the consultant pharmacists' medication reviews. We expect the industry to demonstrate the value of these reviews to the LTC residents' quality of care. Therefore, we believe the industry should collect data on the number and type of interventions recommended by the consultant pharmacists and on the outcomes of those recommendations. We expect some, if not all, of these data are already being collected and we recommend the industry work with such entities as the Pharmacy Quality Alliance (PQA) and other consensus gathering organizations, to develop performance measures to assess consultant pharmacist effectiveness. Further, since the consultant pharmacists are not the only group with responsibility for ensuring the safety and efficacy of care in the LTC facility, we expect the LTC provider and medical industry to also implement changes to address the problem of overuse and misuse of medications in LTC so that we will see inappropriate prescribing of all medications, but particularly antipsychotics, decrease. Should marked improvement not occur, we will use future notice and comment rulemaking to propose requirements to address our concerns. In determining whether marked improvement has been made, we will continue to evaluate the number of deficiency citations for unnecessary medication use and will monitor the two new performance measures on the use of antipsychotics in LTC facilities.

Comment: We received comments recommending that LTC pharmacies be required to disclose their rebates and several other comments recommending the elimination of manufacturer rebates to LTC pharmacies based on utilization.

Response: Although we agree that market-share-moving rebates may provide incentives that are not in the LTC residents' best interests, we believe that these suggestions are beyond the scope of this proposal, and we are not in a position to respond to these recommendations at this time.

Comment: Several commenters recommended a requirement that facilities use qualified professional consultant pharmacists for LTC consulting services and strictly enforce compliance with that requirement. Another commenter suggested that, as an alternative, we establish an audit or other oversight process to review and evaluate all medication changes recommended by LTC consultant pharmacists and all contractual agreements that pose potential conflict of interest risk.

Response: We appreciate these comments and will consider the recommendations in the process of future rulemaking on this issue. However, as noted above, we believe the LTC industry should collect data on the number and type of interventions recommended by the consultant pharmacists and on the outcomes of those recommendations and we recommend the industry work with such entities as the PQA and other consensus gathering groups, to develop performance measures to assess consultant pharmacist effectiveness. Since the consultant pharmacists are not the only group with responsibility for ensuring the safety and efficacy of care in the LTC facility, we expect the LTC provider and medical industry to also implement changes to address the problem of overuse and misuse of medications in LTC so that we will see inappropriate prescribing of all medication.

Comment: Many commenters responded to our request for comment on permitting exceptions for unique situations involving minimal conflict of interest risk or waiving the independence requirement to permit other alternate approaches. Some commenters recommended that we grant no waivers or exceptions, arguing that there should be a level playing field and that no employment relationship was free from conflicts of interest. Other commenters agreed with allowing exceptions or waivers for alternate approaches for IHS/Tribal facilities and facilities in rural or other "hardship areas". Several commenters suggested we monitor the exception and waiver processes to ensure they are fair and equitable. Other commenters requested either exceptions or alternate approaches for facilities with in-house pharmacies, VA, and State Veterans nursing homes, and various other situations.

Response: We appreciate these comments and will consider them in the process of future rulemaking on this issue.

Comment: Several commenters recommended either coordination between consultant pharmacists' drug regimen reviews and medication therapy management (MTM) services in order to eliminate overlap/duplication between the two reviews.

Response: We agree that the potential overlap between the drug regimen reviews required in LTC and Part D MTM reviews could possibly result in conflicting reviews. As a result, in the provision on MTM in LTC facilities discussed elsewhere in this rule, we encourage plan sponsors to consider

making arrangements that include the LTC consultant pharmacist in conducting Part D MTM services for targeted beneficiaries in LTC facilities. We note such arrangements could include direct contracts between the sponsor and consultant pharmacists (or their intermediaries), or indirect contracts between the sponsor's MTM vendor or PBM and consultant pharmacists (or their intermediaries).

Comment: Several commenters recommended we establish a January 1, 2013 effective date, and other commenters requested either a delay in implementation or suggested a later effective date. Commenters provided recommendations for phasing in the requirement and for implementing the requirement initially as a demonstration program. Commenters also noted that these latter approaches would enable us to benefit from lessons learned and identify best practices for future implementation.

Response: We appreciate these comments, but, as discussed further later in this section, we are not finalizing this provision at this time.

Comment: We received numerous comments in response to our request for information concerning best practices in the conduct of drug regimen reviews. A few commenters suggested that we require consultant pharmacists be afforded adequate time for the monthly drug regimen reviews. Another suggested that we refer to the American Society of Consultant Pharmacists "Guidelines for Assessing the Quality of Drug Regimen Review in Long Term Care Facilities" which the commenter noted provides standards to evaluate the quality of the drug regimen review and to improve the process. Several other commenters asserted that establishing a specific rate would be inappropriate because the facility's case-mix could affect the rate. However, other commenters specified what they believed would be the optimal rate per day; the suggested rates varied from a low of 20 to a high of 64 per day.

Response: We appreciate the comments and suggestions and will use them to inform possible future rulemaking regarding the drug regimen review requirements.

Comment: Many commenters noted that the services performed by LTC consultant pharmacists are more extensive than the drug regimen reviews and include activities, such as destroying unused medications, checking storage areas, conducting exit conferences, providing in-service education to nursing staff, observing medication distribution, and attending meetings. Commenters stated all the full

range of consultant pharmacist services need to be considered in evaluating the impact of any new requirements.

Response: We appreciate these comments and, as we indicated in the October 11, 2011 proposed rule, we will use them to inform possible future rulemaking regarding the LTC consultant pharmacist requirements.

As a result of considering the comments we received on this issue, we now believe a more targeted and less disruptive approach, at least initially, is warranted. We considered the possibility of finalizing several of the requirements recommended by these commenters to increase transparency around current contractual arrangements and incentives. We agree with the recommendation that LTC facilities pay a fair market rate for consultant pharmacist services; we note that the OIG has stated that provision of consultant pharmacists' services by LTC pharmacies at below market rates "present[s] a heightened risk of fraud and abuse" (*OIG Supplemental Guidance Program for Nursing Facilities*, 73 FR 56832, 56838, note 53, September 30, 2008). However, we do not believe it is within our statutory authority to require provision of such services at market rates. We also considered requiring that LTC facilities separately contract for consultant pharmacist services from other pharmacy services and that consultant pharmacists disclose to the LTC facility, the medical director, ombudsmen, and residents upon request any affiliations that would pose a potential conflict-of-interest risk.

However, due to the notice and comment provisions of the Administrative Procedure Act (5 U.S.C. 553) and section 1871(a)(4) of the Act, and their respective requirements that a final rule be the logical outgrowth of a proposed rule, we believe that any such requirements cannot be finalized in this final rule with comment period, since we did not propose them initially. As a result, since a requirement for independent consultant pharmacists will not solve the entire problem, but would be significantly disruptive for much of the LTC industry, we are not finalizing this provision at this time. Instead, we are soliciting additional comments to help us determine a more comprehensive approach to eliminate overprescribing and the use of chemical restraints in LTC.

In the meantime, given our continuing conflict of interest concerns, we strongly encourage the LTC industry in general to voluntarily adopt the following changes to increase transparency: separate contracting for LTC consulting

services from dispensing and other pharmacy services; payment by LTC facilities of a fair market rate for consultant pharmacist services; and disclosure by the consultant pharmacists to the LTC facility of any affiliations that would pose potential conflicts of interest; or the execution by the consultant pharmacists of an integrity agreement. We expect the industry to use this opportunity to collect data on the number and type of interventions recommended by the consultant pharmacists and on the outcomes of those recommendations. We believe that LTC pharmacies may already collect some, if not all, of these data and would be able to work with such entities as the Pharmacy Quality Alliance (PQA) and other consensus gathering organizations, to develop performance measures to assess consultant pharmacist effectiveness.

Until the next opportunity for us to propose a regulatory change, we will closely evaluate the number of deficiency citations for unnecessary drug use and will monitor the two new performance measures to track the use of antipsychotics in LTC facilities and expect to see significant improvement. We will also continue to participate in a Department of Health and Human Services (DHHS) initiative focused on the use of antipsychotics for persons with Alzheimer's disease. As part of this effort, we are seeking to eliminate the inappropriate use of antipsychotic drugs in LTC facilities for residents with Alzheimer's disease through updated guidance on the use of these medications and stricter enforcement of current requirements. In partnership with the Alzheimer's Disease Education and Referral Center, we will work to better educate LTC facilities, prescribers and the resident's families. We believe that effort focused on eliminating the use of inappropriate chemical restraints for LTC facility residents with Alzheimer's disease may also serve to improve the quality of care for the LTC facility residents with the behavior symptoms associated with dementia.

Our expectation is that the industry will implement changes to address the problem and we will see inappropriate prescribing decrease. Should marked improvement in inappropriate utilization not occur, we will use future notice and comment rulemaking to propose requirements to address these concerns. After considering the public comments received, we are not finalizing this provision. However, we are soliciting further comment to assist us to better define the problem and frame a more comprehensive solution to address our concerns regarding

medication management and quality in LTC. Specifically, we solicit comment related to the following three issues:

• *Enhancing medication management and the effectiveness of medication review.*

We noted in the previous comment summary and responses that many commenters pointed out that besides consultant pharmacists, other parties and factors contribute to overprescribing and inappropriate drug use in LTC facilities. These commenters charged that prescribers, including facility medical directors, nurse practitioners and physician assistants as well as the residents' attending physicians, are major contributors. Others described how pharmaceutical representatives and advertising, family members, and the LTC facility's understaffing, high staff turnover, and lack of specialized staff trained in meeting the needs of dementia patients contribute to the problem. We noted, too, that commenters questioned the effectiveness of the consultant pharmacists' medication reviews, charging that drug regimen review quotas were so high that the reviews had become perfunctory and that others had described how the review requirements were subverted. Other commenters suggested that the consultant pharmacists' recommendations were being ignored by prescribers due to their lack of confidence that the recommendations were in the best interests of the residents. As a result of these comments, we are not only aware that requiring consultant pharmacists to be independent will not solve the entire problem, but also that the drug regimen reviews may not be yielding the intended outcomes or providing the expected beneficiary protections. Therefore, we seek comment in response to the following questions:

++ What actions/steps should be taken to strengthen attending physician (and other prescribers) medication management and prescribing practices to ensure the best quality of care for the nursing home resident?

++ What is and should be the role of the nursing home medical director in overseeing the attending physician (or other prescribers) medication management activities?

++ What actions, if any, should the medical director take when attending physicians (or other prescribers) fail to engage in appropriate/adequate medication management activities?

++ What actions/steps could be undertaken to establish and ensure the independence and effectiveness of a consultant pharmacist in conducting

their medication reviews on behalf of nursing home residents?

++ What training and best practice models would assist all nursing home staff to better understand behavior signs and symptoms and respond appropriately and effectively in assisting and caring for nursing home residents?

• *Data collection and use.*

As we indicated previously, in commenting on this provision, several commenters noted the lack of empirical evidence linking overuse and inappropriate use of drugs in LTC facilities to consultant conflict of interest. Numerous commenters recommended CMS conduct further study and consult with stakeholders to better define the problem and formulate a more appropriate approach for addressing it. As a result, we solicit comment in response to the following questions:

++ What data are needed to enable and support the Medicare and Medicaid programs and others in monitoring the appropriateness and adequacy of medication management activities, including the use of antipsychotics drugs?

++ What data are needed to enable CMS to study the effectiveness of consultant pharmacist medication reviews?

++ What data are needed to create public performance metrics regarding the independence of consultant pharmacists and prescribers from pharmacies and drug manufacturers/distributors?

++ Are data needed on the number and type of interventions recommended by consultant pharmacists and on the outcomes of those recommendations? If so, how could such data be used and by whom?

• *Increasing transparency.*

Finally, as noted previously, a number of commenters offered recommendations for increasing transparency in order to address conflict of interest in LTC. Many commenters on this provision charged that conflict of interest was pervasive in LTC, affecting the facility which imposed its own formulary requirements to contain costs for the drugs it covered, facility staff who encouraged the use of chemical restraints to manage residents with behavioral problems, and residents' attending physicians and facility prescribers who may have had their own ties to the pharmaceutical industry. We expressed our interest in several of the recommendations, but due to the notice and comment provisions of the Administrative Procedure Act and section 1871(a)(4) of the Act, and their

respective requirements regarding logical outgrowth, we believe that any such requirements cannot be finalized in this rule. Thus, we solicit comment in response to the following questions:

++ What specific details regarding the financial (and other) arrangements between LTC facilities, consultant pharmacists, and LTC pharmacies providing consulting and/or dispensing services should be disclosed, and to whom should this information be available?

++ Should the public be informed of the financial and other arrangements between LTC facilities, consultant pharmacists, and LTC pharmacies providing consulting and/or dispensing services? If so, what metrics could be used?

++ What information is needed to assess the independence and adequacy of physician (and other prescriber) medication management and oversight on behalf of nursing home patients? What metrics could be used to assess the adequacy and appropriateness of prescriber response to consultant pharmacist recommendations?

++ What metrics could be used to describe the adequacy and appropriateness of a LTC facility's medication management program?

++ Describe the incentives and other arrangements that create the conflict of interest in LTC that contributes to overutilization and inappropriate drug use in LTC facilities. How can the conflict of interest stemming from these incentives and arrangements be contained or eliminated?

C. *Excluding Poor Performers*

We are finalizing three proposals designed to strengthen our ability to remove poor performers from participation in the Part C and D Medicare programs. Beneficiaries will be protected through the first provision, which enables CMS to terminate or non-renew any health care prepayment plan (HCPP) which does not adhere to specified financial, reporting, and access requirements.

The next two regulatory changes we are finalizing give entities that want to administer benefits to Medicare beneficiaries strong incentives to pay attention to the star rating criteria and provide for better quality health care if they wish to stay in or join the program. See Table 4 for details of these proposals. Specifically, we are finalizing a regulation which will provide CMS the authority to terminate MA organizations and Part D sponsors that have failed to achieve, over a period of 3 years, at least a 3-star plan rating. This authority will enable us to utilize the

plan rating system, which we developed to provide beneficiaries with information about the quality and performance of health and drug plans to assist in plan selection during the open enrollment period. The plan ratings include process measures that focus on whether good medical care or drug care was provided, outcome measures that address the result of that care, and measures that relate to administrative

processes that support and direct the provision of care. It is our view that the star rating system not only provides beneficiaries/consumers with easy-to-understand information critical for making choices among sponsors, but provides a powerful tracking tool that enables us to continue to administer the Part C and D programs with the best interests of the beneficiaries in mind.

We are also finalizing a regulation that provides CMS the authority to deny applications submitted by MA organizations and Part D sponsors that have performed so poorly that CMS has terminated or non-renewed a contract with the organization in the past. We anticipate that this regulation will directly enable us to protect beneficiaries from poor care.

TABLE 4—PROVISIONS TO EXCLUDE POOR PERFORMERS

Preamble section	Provision	Part 417		Part 422		Part 423	
		Subpart	Section	Subpart	Section	Subpart	Section
II.C.1	CMS Termination of Health Care Prepayment Plans.	Subpart U	417.801	N/A	N/A	N/A	N/A
II.C.2	Plan Performance Ratings as a Measure of Administrative and Management Arrangements and as a Basis for Termination or Non-Renewal of a Medicare Contract.	N/A	N/A	Subpart K	422.504 422.510	Subpart K	423.505 423.509
II.C.3	Denial of Applications Submitted by Part C and D Sponsors with a Past Contract Termination or CMS-Initiated Non-Renewal.	N/A	N/A	N/A	422.502	Subpart K	423.503

1. CMS Termination of Health Care Prepayment Plans (§ 417.801)

Section 1833(a)(10)(A) of the Act authorizes arrangements with HCPPs, but specifies only what type of benefits are to be provided (Part B), the method of payment (reasonable cost), and limits on cost-sharing (20 percent of reasonable cost). In implementing section 1833(a)(1)(A) of the Act, we have in regulations set forth requirements relating to these three areas that parallel those imposed under section 1876 cost contracts. In addition, since section 1833(a)(1)(A) of the Act does not address appeals, and the appeals procedures in section 1869 of the Act involve specific claims payments that do not exist for HCPP enrollees, in our January 2005 final rule (70 FR 4588 through 4741), we extended fundamental features of the MA appeals process to HCPPs.

Although our current regulations at § 417.801(d) permit us to terminate a contract with an HCPP for specified reasons, we proposed to codify additional specified grounds for HCPP termination in § 417.801(d) to strengthen our oversight and enforcement capabilities. Section 417.801(d) currently provides that we may terminate or not renew a contract with an HCPP if the HCPP: (1) No longer meets the requirements for participation and reimbursement as an HCPP; (2) is not in substantial compliance with the provisions of the agreement or applicable statutory or regulatory requirements; or (3) undergoes a change

in ownership. We proposed to retain these bases for termination but to modify § 417.801(d)(ii) to include three specific circumstances in which “substantial non-compliance,” that relate to the CMS contract, applicable CMS regulations, or applicable provision of the Act may be found. As we stated in the proposed rule, we believe that specifying instances of substantial non-compliance through notice-and-comment rulemaking will ensure that all HCPPs are aware that their failure to comply with such requirements may lead to termination of their contracts.

First, in their agreements with us, HCPPs agree to provide adequate access to providers and to document such access. Accordingly, we proposed that failure to provide adequate access to providers, and provide CMS with documentation of such access, is a basis for determining that an HCPP is not in substantial compliance with applicable regulatory requirements. We proposed to expressly identify this violation as an adequate justification for termination or non-renewal in a new paragraph (d)(1)(ii)(A). Second, HCPPs are required to provide data to us and to maintain financial records and statistics related to costs payable by CMS for CMS audit or review. This requirement is currently captured in § 417.806, which cross references financial records requirements at § 417.568 of the section 1876 cost contract plan regulations. We stated in the proposed rule that we would specify, in new paragraph (d)(1)(ii)(B), that failure to provide such

data and/or to maintain records appropriately is another violation indicating that an HCPP is not in substantial compliance. Third, HCPPs must report costs to us in addition to maintaining financial records and following other financial requirements specified at § 417.568 of the cost contract program regulations. Currently, these requirements are also referenced in HCPPs’ agreements with CMS. We proposed that a new paragraph at (d)(1)(ii)(C) would specify that failure to report costs to CMS will constitute yet another basis for determining that an HCPP is not in substantial compliance.

Comment: A commenter supported the provision as specified in our proposed rule.

Response: We thank the commenter for their support.

After consideration of the public comment received, we are finalizing the policy without modification. We would also clarify that this new list is not exhaustive and CMS may still make a determination that a HCPP is not in substantial compliance absent the existence of any of these individual violations.

2. Plan Performance Ratings as a Measure of Administrative and Management Arrangements and as a Basis for Termination or Non-Renewal of a Medicare Contract (§ 422.504, § 422.510, § 423.505, and § 423.509)

Since 2007, we have developed and published annual performance ratings for all stand-alone Medicare PDPs. In 2008, we began issuing ratings for MA

plans as well. The ratings are based on measures that address a range of health and drug plan performance categories, including access to care, communication with members, and clinical quality of care. The scores in each performance category are based on data reported by MA organizations and PDP sponsors, member satisfaction, and monitoring conducted by CMS and its contractors. We rate MA organizations and Part D sponsors on a 5-star scale, with the best performers receiving a rating of 5 stars. The organizations receive a score for each performance measure, a summary score each for Part C and Part D, as well as an overall rating. Under the methodology developed and applied by CMS for its star rating process, a rating of 3 or more stars is an indication of sponsors with “average” or better performance. By contrast, organizations receiving a summary or overall score below 3 stars are among the weakest performers in the Medicare Part C and D programs.

The Medicare regulations at § 422.503(b)(4) and § 423.504(b)(4) state that, to qualify as an MA organization or Part D sponsor, an organization must have administrative and management arrangements satisfactory to CMS, including, per § 422.503(b)(4)(ii) and § 423.504(b)(4)(ii), personnel and systems sufficient for the organization to implement, control, and evaluate the activities associated with the delivery of Part C and D benefits. Once under contract with CMS as an MA organization or Part D sponsor, an organization remains obligated to maintain satisfactory administrative and management arrangements, a point we proposed to clarify by adding paragraphs § 422.504(a)(17) and § 423.505(b)(25) to the list of required elements in CMS’ contracts with MA organizations and Part D sponsors. Also, as explained later in this section, we believe that the plan ratings are a direct indicator of the ongoing effectiveness of a contracting organization’s administrative and management arrangements. Therefore, we proposed adding paragraphs § 422.504(a)(18) and § 423.505(b)(26) to require an organization to demonstrate that it maintains satisfactory administrative and management arrangements by achieving a summary plan rating of at least 3 stars each year.

We also proposed to establish the failure to achieve a 3-star summary rating consistently as a basis for contract termination. As the measures in the star ratings are based largely on Part C and D program requirements, and the plan ratings are a reflection of a sponsor’s performance across a range of program

areas, we believe that a sponsor with a low Part C or Part D summary star rating has failed in a significant way to meet its obligations as an MA organization or Part D sponsor. (As we calculate the summary rating score by taking an average of the measure-level stars, sponsors can receive scores on individual measures of less than 3 stars but still achieve a summary rating of at least 3 stars.) A sponsor that fails to achieve at least an “average” rating for 3 consecutive years has demonstrated consistently that it is unable or unwilling to take corrective action to improve its Part C or D performance.

As noted previously, to qualify as an MA organization or Part D sponsor, an organization must have effective administrative and management arrangements. Such arrangements involve the allocation and coordination of an organization’s resources to ensure that it can fulfill the entire range of its obligations related to the delivery of Medicare benefits. Of course, the importance of these arrangements only increases once an organization has entered into an MA organization or Part D contract as the quality of the arrangements is tested repeatedly by the process of actually delivering Medicare benefits in a timely and effective manner during the term of the contract. Because of the critical role administrative and management arrangements play in ensuring an organization’s compliance with its Medicare obligations, we believe it is necessary to make clear, by adding to the set of required CMS contract elements, that organizations must continue to maintain effective administrative and management arrangements even after they have entered into Medicare contracts. Accordingly, we proposed adding paragraphs § 422.504(a)(17) and § 423.505(b)(25) which state that the maintenance of effective administrative and management arrangements is a material term of the MA organization and Part D sponsor contracts. The summary rating for a plan sponsor is calculated according to the methodologies outlined in the Plan Star Ratings technical notes, and is based on a formula that factors in a sponsor’s scores on all measures pertaining to Part C to calculate the Part C summary rating and pertaining to Part D to calculate the Part D summary rating. (The Part C and D technical notes may be found on the CMS Web site at https://www.cms.gov/PrescriptionDrugCovGenIn/06_PerformanceData.asp.)

Organizations that offer both Part C and Part D benefits receive an overall rating

that combines the Part C and D star ratings results. To evaluate an organization’s administration and management capabilities accurately, it is necessary to review its performance across a range of operational areas. Because the summary Plan Rating scores are based on a sponsor’s performance of a wide range of Medicare requirements within each of the MA and Part D programs, the scores are a reliable measure of the quality of an organization’s administrative and management arrangements. Therefore, to articulate the standard by which we would measure compliance with that obligation, we proposed to establish as a requirement that organizations must achieve a summary plan rating of at least three stars for each of Part C and Part D each year by adding paragraphs § 422.504(a)(18) and adding paragraph § 423.505(b)(26). It would not be appropriate to use the overall rating for this purpose, as organizations that offer both Part C and Part D benefits must fully meet the requirements of each program independently. It is conceivable that if we exclusively rely upon the overall measure, strong performance within one program could mask poor performance in the other program, which would not be an acceptable outcome thus giving CMS an inaccurate picture of the effectiveness of a sponsor’s administrative and management arrangements.

The star ratings may also be used as a basis for contract enforcement actions (for example, termination/non-renewal or intermediate sanctions). We have the authority under section 1857(c)(2) of the Act to terminate CMS’ contract with an MA organization or a Part D sponsor when we determine that the organization has failed substantially to carry out the contract or is carrying out the contract in a manner inconsistent with the efficient and effective administration of the Part C or D programs. A summary rating of less than 3 stars can be achieved only when a sponsor demonstrates poor performance across a range of measures. Therefore, we believe that sponsors that consistently achieve poor plan ratings have demonstrated a substantial failure to comply with the terms of their Medicare contracts. Also, low-rated sponsors interfere with the efficient and effective administration of the MA and Part D programs as beneficiaries rely on us to ensure that the array of plan choices only includes offerings from sponsors that have demonstrated that they can provide at least “average” or better quality services to their members.

Accordingly, we proposed to amend the bases upon which CMS may

terminate an MA organization or Part D sponsor contract under § 422.510(a) and § 423.509(a) to include a sponsor's failure to achieve at least a 3-star summary plan performance rating for 3 consecutive contract years. We believe that 3 years is sufficient time for a sponsor to develop and implement corrective action and for improved performance to be reflected in the star ratings issued at the conclusion of the 3-year period.

We base our determinations that good plan ratings are indicative of the strength of an organization's administrative and management arrangements and that consistently poor plan ratings are a basis for contract termination on the fact that the elements of the plan ratings correlate to Part C and D requirements described in applicable statutes and regulations. While the exact measures may vary slightly from year to year, each year's plan ratings are based on similar elements from previous years, as they are developed in consultation with a workgroup of industry stakeholders and based on a review of stated Part C and D program requirements. The plan ratings issued in September 2010 (referred to as the CY 2011 plan ratings) provide a useful template for demonstrating the correlation between program requirements and the performance measured. (See 2011 Part C Technical Notes and 2011 Part D Plan Ratings Technical Notes: September 2010.)

The CY 2011 Part C plan ratings were organized into five domains—"Staying Healthy: Screenings Tests, and Vaccines;" "Managing Chronic (Long Term) Conditions;" "Ratings of Health Plan Responsiveness and Care;" "Health Plan Members' Complaints and Appeals;" and "Health Plan Telephone Customer Service." The Part C regulations at § 422.152(a)(2) state that MA organizations must conduct quality improvement projects that can be expected to have a favorable effect on health outcomes and enrollee satisfaction and address areas identified by CMS. The Staying Healthy measures evaluated the extent to which MA organizations provided screenings to their members for conditions such as breast cancer, colorectal cancer, elevated cholesterol, glaucoma, and osteoporosis, as well as monitoring to patients with long term medication and flu vaccines to plan members. As these measures have been consistently included in the Part C plan ratings over a period of several years, it is fair to say that MA organizations have known over that same timeframe that we would rate them on quality improvement projects

designed to address the identified conditions and that they should take action to improve their scores for this measure. Moreover, we have clearly fulfilled our obligation under § 422.152(a)(2) to identify areas that MA organizations need to address for this purpose by annually publishing the methodology, providing private previews for MA organizations to review their own results, and releasing the results publicly through the CMS Web site. As a result, an MA organization's score in the "Staying Healthy" domain is a fair measure of the extent to which it is complying with § 422.152(a)(2).

The "Managing Chronic (Long Term) Conditions" domain most closely mirrors the requirements at § 422.152(a)(1) which obligate MA organizations to have a chronic care improvement program that addresses populations identified by us based on a review of current quality performance. The measures in this domain concern the management of conditions such as osteoporosis, diabetes, and high blood pressure. Again, the measures have remained largely constant for a number of years, so MA organizations have had effective notice that we had identified beneficiaries with those conditions as the populations for which we would expect sponsors to implement effective chronic care improvement programs. The measures related to the "Health Plan Responsiveness and Access to Care" domain demonstrate an MA organization's compliance with its obligations under § 422.112(a)(1) to maintain a provider network sufficient to ensure its enrollees' access to covered services. The measures "Getting Needed Care" and "Getting Appointments and Care Quickly" are both based on the results of beneficiary surveys concerning their experiences in being able to get timely appointments with plan-contracted providers. The measure "Doctors Who Communicate Well" reflects enrollees' responses to a series of questions concerning the quality of their interaction with plan-contracted physicians, including the amount of time the physicians spent with an enrollee and the care with which the physicians conducted appointments, all of which indicate the extent to which those services are provided in a manner consistent with professionally recognized standards of health care, per § 422.504(a)(3)(iii).

In the "Health Plan Member's Complaints and Appeals" domain, we provide a rating of the extent to which an MA organization affords its members their coverage determination appeal rights under the Part C program. The

Part C regulations at Part 422, Subpart M, require MA organizations to adhere to standards and timeframes for issuing timely and accurate determinations concerning the coverage of health services for their members as well as the processing of their appeals of such determinations. The "Makes Timely Decisions about Appeals" rating measures the extent to which an MA organization meets the regulatory deadlines for issuing responses to member appeals while the "Reviewing Appeals Decisions" rating measures the frequency with which the MA organization determinations were overturned by the Independent Review Entity (IRE). The analysis for these measures was conducted by Maximus, Inc., with which we contracted as an IRE for Part C appeals. The remaining measures under this domain, "Complaints about the Health Plan" and "Corrective Action Plans" (CAPs) provide a more general view of an MA organization's performance from two different perspectives. The "Complaints" measure is based on a calculation of the rate (that is, complaints per 1,000 members) at which we receive complaints from beneficiaries, providers, or others affected by the MA organization's operations. The CAP measure reflects the number and type of findings made by us during an audit of an MA organization's performance. Thus, these two measures provide a snapshot of the MA organization's compliance with a range of requirements from the perspective of the members it must serve as well as CMS.

The ratings in the last Part C domain, "Health Plan Customer Service," are the product of a series of measures related to the requirement that MA organizations operate a customer service call center that is responsive to the needs of Medicare beneficiaries. In particular, the domain rating is based on the results obtained by a CMS contractor that conducts test calls to MA organization customer service lines to assess the extent to which the call centers provide accurate plan information, in languages spoken by beneficiaries residing in the plan's service area, and with limited hold times consistent with the standards stated in the Medicare Marketing Guidelines we have issued pursuant to § 422.111(g).

The four domains of the CY 2011 Part D Plan Ratings similarly correspond to the requirements with which Part D plan sponsors must comply. The Part D domains are "Drug Plan Customer Service;" "Drug Plan Member Complaints and Medicare Audit

Findings;" "Member Experience with the Drug Plan;" and "Drug Pricing and Patient Safety." The domain "Drug Plan Customer Service" includes measures concerning hold times, accuracy of information, and foreign language interpretation services and are the Part D equivalents of the measures used in the Part C plan rating. They reflect the Part D sponsor's compliance with the customer service call center requirements described in the Medicare Marketing Guidelines issued in accordance with § 423.128(d)(1). The measure related to hold times for pharmacists' calls to the sponsor are evidence of the sponsor's compliance with the requirement, stated at § 423.128(d)(1) that the sponsor operate a call center to provide technical assistance to pharmacists concerning their plan operations. This domain also contains three measures related to plan performance of its obligations related to the issuance of coverage determinations and processing of members' appeal requests, per Part 423, Subpart M. The last measure in this domain indicates the extent to which a sponsor is complying with CMS processes for ensuring that the data used by pharmacists to determine a customer's Part D plan enrollment is accurate and up to date. The provision of this data, referred to as "4Rx data" is part of Part D sponsors' obligation, stated at § 423.505(b)(2), to process enrollments in a manner consistent with the requirements stated in Part 423, Subpart B.

The second domain, "Drug Plan Member Complaints and Medicare Audit Findings," consists largely of the same kind of measures related to beneficiary satisfaction and CMS audit findings as included in the Part C plan ratings, and the discussion provided above of their bearing on a determination of a sponsor's compliance with program requirements is applicable to the Part D ratings as well.

The "Member Experience with Drug Plan" domain consists of measures related to plan members' experience in getting access to information about their Part D plan or getting prescriptions filled easily when using the plan. These measures provide evidence of a sponsor's compliance with the requirement, stated at § 423.128, that it disseminate information about its Part D plans, and that it provide benefits through a point of claims adjudication system (per § 423.505(b)(17)) operated through a contracted pharmacy network that meets Part D access requirements (per § 423.120).

The "Drug Pricing and Patient Safety" domain consists, in part, of measures

related to a sponsor's ability to maintain and transmit accurate information related to its members' LIS eligibility status and the information concerning drug prices available at network pharmacies. Under this domain, CMS assesses, by comparing its data with that of Part D sponsors, the accuracy of a sponsor's records concerning the LIS status of its members a significant part of its obligation under § 423.800 to participate in the administration of the low-income subsidy portion of the Part D benefit program. With respect to drug pricing, we compare sponsors' data reported to us, pursuant to § 423.505(f)(2), with other data sources, including prescription drug event data and data from commercially available drug pricing reference files. The remaining two measures in this domain assess the sponsor's efforts to ensure that its members are being directed away from drugs with a high risk of side effects and that those members with diabetes are treating their high blood pressure with medication appropriate for their condition. Both of these measures are indications of a sponsor's compliance with its obligation under § 423.150(c) to develop and implement drug utilization review systems that identify patterns of inappropriate care among its enrollees.

The thresholds we have established for the star ratings in each category are based on regulatory standards or our review of industry performance over several years. From that systematic review, for each regulatory standard-based measure we consider the actual contract scores in relation to a theoretical distribution of all possible measures with the regulatory standard considered a 3-star rating. (For example, in 2008 CMS announced to Part D sponsors that, after a review of industry performance during the first 2 years of the Part D program, we had established that sponsors would be required to submit 4Rx data for 99 percent of their enrollment transactions to be considered compliant with Part D enrollment processing requirements.) When an absolute performance standard has not yet been established, we assign stars for measures based on evaluating the maximum score possible for that measure, and testing initial percentile star thresholds with the actual data. The contract-level scores are grouped using statistical techniques to minimize the distance between scores within a grouping (or "cluster") and maximize the distance between scores in different groupings. Most databases that are utilized are not normally distributed, requiring further adjustments to the star

thresholds to account for gaps in the data. CMS does not force the Plan Ratings data into 5-star categories for every measure. For some measures, based on the distribution of the data, there may only be 3, 4, or 5 stars, while for other measures there may only be 1, 2, or 3 stars. In developing that methodology, we reserved 1- and 2-star ratings for performance that was significantly below what a review of industry-wide performance would show to be acceptable and achievable by competently administered sponsors. This establishment of compliance standards through the analysis of all Medicare contractors' performance to identify outliers is consistent with our regulatory authority at § 422.504(m)(2) and § 423.505(n)(2). We have previously issued guidance (for example, CY 2012 Call Letter, page 119, issued April 4, 2011) to MA organizations and Part D sponsors indicating that we considered organizations with 3 consecutive years of less than 3-star Plan Ratings to be out of compliance with Medicare program requirements. We stated there that organizations with such a Plan Rating history should expect that, prior to initiating a termination action, we would confirm that the data used to calculate the Plan Ratings did reflect an organization's substantial failure to comply with Part C or D requirements. In essence, we noted that poor Plan Rating scores were a strong indication, but not conclusive evidence, of substantial non-compliance. In applying that policy, we include Plan Ratings issued in years prior to the issuance of the guidance to identify organizations whose performance may warrant contract termination.

With the elevation of low Plan Ratings from the status of likely indicator to conclusive evidence of substantial non-compliance, we believe that the use of prospective Plan Ratings is more appropriate in our application of this authority. Therefore, we proposed that we would not begin calculating the 3-year period until after organizations have received notice through the rulemaking process of the new basis for contract termination. As we plan on this proposal to be issued as part of a final rule in the spring 2012, we expect to use only those Plan Ratings issued after the publication of the final rule. That is, we would use the contract year 2013 Plan Ratings, which we expect to issue in September 2012, as the first set of ratings in the calculation of any sponsor's 3 consecutive years of Plan Ratings. The issuance of the 2015 ratings, expected in September 2014, will present the first opportunity for

sponsors to have accumulated three consecutive years of low plan ratings that could subject them to contract termination. We invited public comment on our proposal for identifying the first set of Plan Ratings we would use in determining whether a sponsor's performance during 3 consecutive years supported a CMS decision to terminate its Medicare contract.

Comment: Several commenters expressed opposition to the proposed addition of the failure to achieve 3 stars for 3 consecutive years to the list of bases upon which CMS may terminate an MA organization or PDP sponsor contract. They maintain that the plan rating system is not sufficiently mature or stable to provide a reliable basis for determining that an organization has substantially failed to comply with its contract. The commenters maintain that the number and type of measures have changed each year that CMS has released plan ratings. These annual changes undermine the proposed termination authority in two ways. First, the variable measures and weighting over a 3-year period mean that CMS cannot fairly evaluate a sponsor's plan rating performance over 3 years because it has not applied a consistent standard of review during that period. Second, low-rated sponsors' efforts to take corrective action to raise their ratings over 3 years are impeded by CMS' annual changes to its methodology for calculating those ratings.

Response: The Medicare plan rating system and its component measures have been in place for a sufficient period of time for plan sponsors to become familiar with the correlation between their operations and the plan ratings they have achieved. MA organizations have been measured on a star system since 2008 and Part D plans since 2007. In addition, the vast majority of measures, which come from HEDIS and CAHPS, have been required of MA organizations since the late 1990s.

While we have made some changes in each of the past 3 years to the plan rating methodologies, these changes have been relatively minor and have not affected sponsors' ability to achieve and maintain at least a 3-star summary rating over a 3-year period. This history suggests that organizations have had ample time to adjust their efforts toward achieving higher quality outcomes. For the 2010 Part C ratings through the 2012 ratings, 30 of the measures remained constant, while the 2010 ratings featured a total of 33 measures, 37 in 2011, and 36 in 2012. For the Part D ratings during the same period, 13

measures remained constant, out of 19 total in 2010 and 2011 and 17 total for 2012. We have also made low-rated sponsors aware, through the issuance of compliance notices beginning in 2010, of the risk their low plan ratings pose to their status as Medicare Part C and D sponsoring organizations and the urgent need for them to take corrective action.

Comment: Several commenters expressed their strong support for the proposed provision. They also suggested ways to strengthen the termination authority by making it effective immediately upon publication of the final rule rather than after the release of the CY 2015 plan ratings in late 2014 as we had proposed. They also recommended that any reinstatement of a sponsor's contract be accompanied by a probationary period during which the sponsor's contract could be terminated if it fails in one year to achieve a 3-star rating. The commenters also urged CMS to apply our existing sanction and termination authority against low-rated plans, improve outreach to beneficiaries about the meaning and usefulness of the plan rating system to encourage their participation in HEDIS and CAHPS surveys, and to conduct ongoing evaluations of performance measures to make sure they truly drive improvement in areas important to beneficiaries.

Response: We appreciate the expressions of support for our proposal. We also appreciate the advocates' recommendation that we strengthen the termination authority, but we believe that our draft provision allows for a reasonable transition period during which sponsors can take steps, in light of the increased consequences of low plan ratings (that is, contract termination), to focus their attention and resources on quality improvement. Of course, as we have stated in recent call letters, during the transition period (that is, from the date on which this rule becomes final until CMS' publication of the CY 2015 plan ratings in late 2014) we will continue to apply a heightened scrutiny to consistently low rated contracts to determine whether they are substantially failing to meet Part C or D program requirements.

We appreciate the concern expressed by the commenters that sponsors that re-enter the Part C and D programs after a termination for consistently low plan ratings not be permitted to "game" the system by immediately repeating their previous poor level of performance. We believe, however, that our proposal already provides a sufficient safeguard against that type of conduct without requiring re-entering sponsors to operate under a probationary period during which even one year of poor

performance would be a sufficient basis for termination. In section II.C.3. of the proposed rule, we stated our intent to adopt the regulatory authority to disapprove an application for qualification as a Part C or D contract submitted by an organization for which CMS had terminated a Medicare contract within the previous 3 years. This authority, which we finalize in this rule, will apply to all terminated sponsors, including those terminated based on consistently low plan ratings. We believe the 3-year period of ineligibility for Part C or D program participation, combined with the forfeiture of their entire set of plan members, is sufficient to provide an incentive for returning sponsors to achieve 3-star ratings upon their return to the Medicare program. We also note that consistently low plan ratings will not become the exclusive basis for contract termination. We retain the authority to terminate a sponsor based on its performance within only one year if its performance during that period fails substantially to meet Medicare requirements, and we will exercise that authority where justified.

The comments concerning outreach to beneficiaries discussing participation in the survey tools whose results are used to calculate plan ratings are outside the scope of this proposal. We believe this is also true of the comments concerning the need for CMS to continue to review plan rating measures to make certain they truly evaluate plan quality. We nonetheless agree that these efforts will receive our continued attention.

Comment: Several commenters suggested that Congress did not intend for the plan ratings to be used as a basis for contract termination. One commenter also stated that the plan rating system was not designed to measure compliance, and it is more effective as a plan comparison and beneficiary education tool.

Response: While the plan ratings were originally developed by CMS as a beneficiary comparison tool, and Congress has authorized the awarding of bonus payments based on plan rating performance, those facts do not preclude the use of plan ratings as an indicator of contract compliance. To the extent that the ratings provide reliable evidence of compliance with program requirements, they may be used as a basis for contract termination. Our preamble discussion in the proposed rule and this final rule with comment period describes the connections between each plan measure and a Part C or D requirement, noting that the measures are an effective tool for capturing information on the

effectiveness of a sponsor's administrative and management arrangements as opposed to whether the arrangements are merely in place. Thus, a sponsor's failure to meet minimal performance thresholds for 3 straight years can reasonably be said to be evidence of substantial failure to meet contract requirements.

Comment: A stand-alone PDP sponsor commented that Part D sponsors are not required by statute to ensure their members' compliance with oral diabetes, hypertension, and cholesterol medication regimens. The commenter also noted that CMS announced the measures related to drug regimen compliance too late in the year for sponsors to focus their efforts on the new measures. Finally, the commenter stated that PDP sponsors are at a disadvantage in these measures because they do not coordinate care with prescribers as health plans can.

Response: All Part D sponsors are required to administer medication therapy management programs, which may be focused on beneficiaries with diabetes, hypertension, or high cholesterol. We agree that sponsors would have benefitted from an earlier announcement of the new measures, but we believe that the 3-year phase in of the plan rating-based termination authority will give PDP sponsors sufficient time to make improvements to their performance in these areas. Also, according to our plan rating methodology, a high score on these three measures is not critical to achieving a 3-star summary plan rating. Therefore, these measures do not impose a meaningful obstacle for PDP sponsors to maintain the required minimum plan rating.

Comment: A law firm that represents clients in Medicare-related matters commented that CMS does not have the authority to impose a conclusive presumption of a basis for contract termination when doing so eliminates the affected sponsor's opportunity for a hearing prior to the termination taking effect. The commenter also asserted that the use of plan ratings as a basis for termination would relieve CMS of its statutory obligation to prove that the sponsor's conduct has met the statutory criteria for contract termination and presented a regulatory construct analogous to that struck down by the U.S. Supreme Court in *Ragsdale v. Wolverine World Wide, Inc.*, 535 U.S. 81 (2002). Finally, the commenter stated that the proposed termination authority violates the requirements of the *per se* rule as discussed by the Court in *Johnson v. California*, 543 U.S. 499

(2005) and *Arizona v. Maricopa County Medical Society*, 457 U.S. 332 (1982).

Response: The new termination authority as finalized in this rule has no impact on the administrative appeal rights currently afforded any plan sponsor under Subpart N of 42 CFR Parts 422 and 423.

We do not find the Supreme Court opinions cited by the commenter to be applicable in any way to our proposal. In *Ragsdale*, the Court held that the Department of Labor could not enforce regulations that had the effect of eliminating one of the elements that an individual must prove when appealing a denial of leave from work requested under the Family and Medical Leave Act. Our use of low plan ratings as a basis for contract termination does not relieve us of our obligation to prove at least one of the three statutory bases for termination. Rather, the plan ratings are a tool that we will use to establish, consistent with the Part C and D statutes, that a sponsor has substantially failed to meet the requirements of its Part C or D contract. As noted previously and in the proposed rule, the data used to calculate the plan ratings are derived directly from a sponsor's performance of its Medicare program obligations.

The *Johnson* and *Arizona* opinions are similarly inapplicable to the proposed termination authority. The *Johnson* matter was a civil rights case involving the California Department of Corrections' (CDC) policy of segregating inmates by race. The Court there held that the lower courts should use strict scrutiny in reviewing whether the CDC policy violated prisoners' rights under the Equal Protection Clause of the 14th Amendment. The majority opinion of the Court makes no reference to a *per se* rule or to any set of criteria governing its use. The opinion involves an analysis of the law as it applies uniquely to allegations of racial discrimination and cannot be said to provide any framework for the analysis of the contract termination process in the Medicare program. *Arizona* is an antitrust case where the Court's majority opinion provides a discussion of the meaning of the *per se* rule as it applies to price fixing agreements (that is, certain practices are deemed to violate antitrust law without regard to surrounding circumstance or intent). The opinion provides no principles for assessing the legality of *per se* rules in general, nor does it state that the legitimacy of a *per se* rule is dependent on the maintenance of the exact same evaluation standards from year to year, as the commenter maintains.

Comment: Several commenters noted that plan ratings rely too much on beneficiary survey information to be used as an indicator of contract compliance because the results of the surveys may reflect factors other than a sponsor's non-compliance with program requirements (for example, high beneficiary complaints based on CMS-approved changes to plan benefit packages).

Response: In certain instances, beneficiary satisfaction is the most effective measure of an organization's contract performance. That effectiveness outweighs the risk of the measure's inaccuracy as a compliance measure presented by those rare instances when beneficiary dissatisfaction may result from factors outside the organization's control. Moreover, only a small portion of the Part C and D measures are focused on beneficiary satisfaction. In 2012, 5 of 36 total Part C measures, and 3 of 17 Part D measures, were based on beneficiaries' satisfaction with their plans. Therefore, low beneficiary satisfaction scores, while meaningful, will not by themselves cause an organization to receive a low summary plan rating.

Comment: Several commenters stated that plan ratings are an unreliable tool for measuring contract compliance because the stars are calculated based on relative performance among all Part C and D contracts. Therefore, every year, some sponsors will be rated below 3 stars regardless of the actual quality of their performance.

Response: The majority of plan rating measures are based on fixed 4-star thresholds, or 3-star thresholds for measures when an absolute regulatory standard has been established. For CY 2012, 28 of 36 Part C measures, and 9 of the 17 Part D measures, had fixed 3- or 4-star thresholds. Having a set threshold means that any entity meeting the established threshold will receive at least a 3 or 4 star rating for the measure. We determine the star cut points below 4-star (or 3-star) ratings in those measures with fixed thresholds as well as the entire range of ratings for the remaining measures through the use of statistical techniques that take into consideration the relative distribution of the data as well as the how the data clusters. For survey measures, significance testing is also used to determine the star ratings. Given the fixed thresholds for the majority of the measures, there is nothing in the Plan Ratings methodology that would prevent all sponsors achieving 4 or more stars on measures that have fixed 4-star thresholds or achieving 3 stars for measures when an absolute regulatory

standard has been set. Additionally, while some of the cut points for the individual measures may be determined by examining the distribution of collected data, for the most part, those data sets are not normally distributed, where some number of contracts would have to be assigned 1- or 2-star ratings. Indeed, in any given year, it is possible for all Part C and D sponsors to achieve at least three-star summary ratings under the scoring methodology. Furthermore, a review of the summary plan ratings over the past 3 years would reveal that there are very few 1-star contracts and that a 3-star rating or better was achieved by a strong majority of contracts.

Comment: Several commenters stated that the annual plan ratings are a flawed mechanism for determining contract compliance because the measures used to calculate the ratings are based on data from different timeframes. That is, the measures do not provide a consistent “snapshot” of performance over a uniform evaluation period.

Response: We use the most recent data available to calculate the summary plan ratings each year, and a broad range of measures are necessary to provide a comprehensive picture of a sponsor’s performance. In fact, the majority of plan ratings posted in October of a given year reflect findings from the most recent completed contract year (that is, there is a gap of only about 9 months between completion of a measure and the posting of the star rating). However, for some performance measures there is necessarily some greater lag time between data collection and analysis. The 3 consecutive year requirement should afford sponsors sufficient time to make operational changes that would be reflected in data used to calculate plan ratings by the end of the 3-year period.

We also note that in August 2010, the CMS Hearing Officer issued an opinion in favor of an organization that appealed CMS’ denial of its contract qualification application based on a review of the organization’s contract performance (including its plan ratings) during the 14 months preceding the application submission date. (In the Matter of United Healthcare Insurance Company, Docket No. 2011 C/D App 1–10.) Among its arguments, the organization asserted that CMS should not include plan ratings as a factor in assessing past contract performance because the ratings were based on conduct that occurred prior to the 14-month look-back period. The Hearing Officer addressed this argument in a footnote to the opinion where he stated that,

* * * in future similar circumstances
* * * CMS could reasonably consider an organization out of compliance for failure to meet established performance metrics, even if a portion of the data used to evaluate compliance is technically derived from instances outside the 14 month window.

Comment: Several commenters stated that CMS should provide advanced notice of each year’s plan rating measures so that plan sponsors can develop and implement operational policies that will allow the sponsor to successfully meet the performance standards of each measure. A commenter noted that CMS released the measures for the CY 2012 plan ratings in late 2011, just prior to posting the results of the CY 2012 ratings.

Response: We have already informed sponsors that we will release the plan rating measures at the start of each calendar year. For example, on December 20, 2011, CMS issued, through the Health Plan Management System (HPMS), a request to drug and health plan sponsors for comments on our proposed measures for the CY 2013 plan ratings. In the memorandum we stated that we expected to publish the final set of CY 2013 measures in April 2012 along with a discussion of proposed measures for the CY 2014 ratings.

Comment: A number of commenters noted that CMS should take into consideration the characteristics (for example, income, age, health) of each sponsor’s enrollees when assessing performance. For example, CMS should develop measures specifically tailored to account for the unique populations served by SNP plans.

Response: We have frequently considered the adoption of modifying the plan rating standards to account for unique differences in the characteristics of certain plan membership profiles. However, we have not yet found any statistical support for the special treatment of certain plans under the plan rating methodology.

The 2011 Part C and D plan rating results, for example, provide no support for the argument that MA organizations offering SNPs face special challenges in achieving good star ratings. The plan rating results for all Part D contracts, when broken down into three categories by percentage of SNP enrollment per contract (SNP enrollment less than 50 percent, SNP enrollment greater than 50 percent, and SNP enrollment 100 percent of total contract enrollment) show that approximately 15 percent to 18 percent in each category receive less than 3 stars. The Part C results are slightly more mixed but still show that contracts with SNP enrollment receiving

less than 3 stars are decidedly in the minority relative to their peers. Among the same enrollment percentage categories described for Part D, the percentage of Part C contracts with low star ratings ranged from approximately 15 percent to 29 percent. Interestingly, the rate of less than 3 star performers drops when SNP enrollment increases from 50 percent or more to exactly 100 percent. That is, contracts with only SNP members tend to have strong performance, equal to contracts with fewer than 50 percent SNP members.¹ Therefore, we can easily conclude based on these data that having SNP members in a contract does not pull down summary plan rating results for either the Part C or Part D ratings.

Comment: A few commenters noted that the regulation should exempt from termination those sponsors that are showing improvement but have not yet reached 3 stars in the third year.

Response: Such an interpretation is unworkable as sponsors could avoid termination for as long they can demonstrate improvement without meeting the 3-star standard.

Comment: A commenter stated that CMS should provide midyear reports to sponsors of their progress on plan ratings.

Response: The data collection for several of the measures are only once a year, so it is not possible to make midyear assessments of a sponsor’s plan rating performance. Sponsors should consider the plan ratings CMS issues each year to be interim reports during the 3-year period preceding possible contract termination.

Comment: A commenter stated that CMS should release plan ratings before bids are due so that sponsors about to be terminated do not expend resources on preparation for upcoming plan year.

Response: We cannot adjust our plan rating analysis and publication schedule solely to accommodate sponsors with two consecutive years of low ratings. Those organizations should review their operations and make their own assessment of the likelihood of achieving a rating of at least 3 stars after the submission of a contract qualification application.

Comment: A few commenters supported this provision, but also expressed their concern that its application will reduce the availability of low premium plans which are often low-rated. The commenters also referenced a study by Avalere Health

¹ CMS conducted this analysis based on plan enrollment data available at https://www.cms.gov/PrescriptionDrugCovGenIn/06_PerformanceData.asp and plan rating data available at <https://www.cms.gov/MCRAdvPartDEnrolData/>.

(released on October 19, 2011; <http://www.avalerehealth.net/wm/show.php?c=&id=890>) that found that 52 percent of the stand-alone PDPs eligible for LIS auto assignment and reassignment have a 2 or 2.5-star rating during 2012. None of those plans has a 5-star rating and 16 have a 4-star rating.

Response: We have analyzed the 2012 contracts rated below 3 stars and found no correlation between low rated plans and low premiums. However, to the extent that the Avalere study suggests that Part D plans to which LIS beneficiaries are assigned tend to achieve disproportionately lower ratings, we believe that the threat of termination provides the correct incentive to these plan sponsors. That is, we can force sponsors that might otherwise ignore their plan ratings, content to compete solely on price or operate in Medicare markets with little or no competition, to dedicate the resources and attention necessary to provide at least a satisfactory level of services to their members. For LIS plans in particular, this new authority makes it clear that focusing solely on bidding below the annual benchmark to keep LIS enrollment high is no longer a viable long-term Part D business strategy.

Comment: A commenter stated that CMS should add a measure based on how often the sponsor makes exceptions and appeals determinations in favor of the beneficiary.

Response: The plan ratings already include measures, based on sponsors' IRE results, of how often the IRE agrees with a sponsor's decision to deny a claim. We believe this measure is effective in achieving the same goal suggested by the comment; measuring the extent to which the plan sponsor is making correct decisions about its members' Part D drug coverage.

Comment: A commenter stated that CMS should assign dual-eligible beneficiaries only to plans rated at more than 3 stars.

Response: This comment concerns CMS' process for automatically assigning and reassigning dual-eligible beneficiaries to stand-alone PDPs with premiums set at or below the regional benchmark. It does not concern the use of the establishment of the plan ratings as a contract requirement or as a basis for contract termination and therefore is outside the scope of the proposed regulatory change.

Comment: A commenter stated that CMS should provide information on how it monitors 4Rx data and LIS status for beneficiaries.

Response: We have provided and will continue to provide this information to

sponsors through the Health Plan Management System (HPMS) related to our monitoring of 4Rx data and LIS status accuracy.

Comment: A commenter stated that it supports the inclusion of measures related to enrollment, LIS, and MTM.

Response: This comment is a recommendation for the inclusion of certain measures in the Part D plan rating methodology. As it does not have a bearing on the use of the current plan ratings as administrative and management requirements under the Part C and D programs or as a basis for contract termination, the comment is outside the scope of the proposed regulatory change.

After consideration of the public comments received, we are finalizing the policy without modification.

3. Denial of Applications Submitted by Part C and D Sponsors With a Past Contract Termination or CMS-Initiated Non-Renewal (§ 422.502 and § 423.503)

In accordance with § 422.502(b) and § 423.503(b), applicants with current or prior contracts with CMS are subject to denial of their applications if they fail to comply with the requirements of the Part C or D programs during the preceding 14 months, even if the applications otherwise demonstrate that they meet all of the Part C or D sponsor qualifications. In the April 2011 final rule (76 FR 21432), we added provisions at § 422.502(b)(2) and § 423.503(b)(2) concerning the treatment of entities submitting applications to us when the entity has operated its contract(s) with CMS for less than 14 months at the time it submits a new application or service area expansion request. In the interest of ensuring that new entrants to the Part C or Part D programs can fully manage their current contracts and books of business before further expanding, we added a provision that in the absence of 14 months' performance history, we may deny an application based on a lack of information available to determine an applicant's capacity to comply with the requirements of the Part C or Part D program, respectively.

We proposed to further refine our approach to using past performance in making application determinations. Specifically, we are concerned about entities submitting applications to us when the entity has had a previous Medicare contract terminated or non-renewed by CMS. We initiate termination or non-renewal of a contract only when the MA organization or Part D sponsor has committed extremely serious violations of the Part C or Part D program. In the past, these contract actions by CMS have been rare. The

bases for a termination are specified in § 422.510 and § 423.509, and include such serious violations as substantially failing to carry out the terms of its Medicare contract; committing fraud; and failing to carry out the requirements for beneficiary access to services by, for instance, not implementing required appeals and grievance processes or not establishing provider and pharmacy networks that meet our requirements. The bases for a CMS-initiated non-renewal are specified in § 422.506(b) and § 423.507(b), and include the same list of violations, plus several others. Nevertheless, despite the seriousness of termination and CMS-initiated non-renewal actions, and the underlying noncompliance that would have led to such a drastic step, the regulation is silent concerning when these organizations may re-enter the Part C and Part D programs. As such, we currently rely upon the past performance provisions in § 422.502(b)(1) and § 423.503(b)(2) to determine whether an application from a previously terminated or CMS-non-renewed organization is approvable. These provisions limit the period of time we can review for purposes of assessing past performance to 14 months. Fourteen months is a reasonable amount of time to review the performance of organizations with current and ongoing Medicare Part C and Part D contracts. In the case of organizations whose performance was so poor as to have their contract(s) terminated or non-renewed by CMS, we believe that a 14-month look-back is an inadequate amount of time.

In contrast to the regulation's silence on a "waiting period" for organizations whose contracts have been terminated or non-renewed by CMS, long-standing provisions at § 422.506(a)(4), § 422.508(c), § 422.512(e), § 423.507(a)(3), § 423.508(e), and § 423.510(e) require that organizations that have voluntarily non-renewed or terminated their contracts must wait 2 years before they may reenter the program. We believe that the interval between the effective date of a contract's CMS-initiated termination or non-renewal should be no less than in the case of a voluntary termination or non-renewal. Indeed, a period of greater than 2 years is appropriate, for these entities have broken faith with the program in a more significant way than in the case of a voluntary non-renewal.

As such, we proposed to modify the past performance review period to capture CMS-initiated terminations or non-renewals that became effective within the 38 months preceding the submission of a new application. The

selection of 38 months accounts for a 3-year period, plus the 2 months of the year during which applications are being prepared for submission to CMS. Three years represents 1 additional year compared to the 2 years of waiting time for voluntary non-renewals. To make this change, we proposed adding new paragraphs at § 422.502(b)(3) and at § 423.503(b)(3) to state that if CMS has terminated or non-renewed an MA organization's or Part D sponsor's contract, effective within the 38 months preceding the deadline established by CMS for the submission of contract qualification applications, we may deny an application based on the applicant's substantial failure to comply with the requirements of the Part C or Part D program even if the applicant currently meets all of the requirements of this part.

Additionally, in the April 2011 final rule, we defined "covered persons" for the purpose of determining which organizations are prohibited from re-contracting with CMS for the two years following a voluntary non-renewal. Specifically, we codified that the 2-year ban on new Part C or Part D sponsor contracts to which non-renewing organizations are subject under the regulation be expanded to include organizations owned or managed by an individual (referred to as a covered person) who served in a similar capacity for a previously non-renewed Part C or Part D organization. The requirement assists us in prohibiting and preventing each such organization from manipulating the Medicare program by reapplying for a contract as a new organization during the 2-year ban, when the applying organization has common ownership and management control with the previous non-renewing organization. In essence, this requirement helps ensure that the provisions of the 2-year application prohibition are given full effect.

For consistency and to prevent the same sort of manipulation by organizations whose contracts have been terminated or non-renewed by CMS, we proposed to add new paragraphs at § 422.502(b)(4) and at § 423.503(b)(4) to replicate the existing language concerning covered persons as currently exists for voluntarily non-renewing organizations. Specifically, the newly proposed language states that in implementing the 38-month provision, we may deny an application where the applicant's covered persons also served as covered persons for the terminated or non-renewed contract. As with the voluntary non-renewal provisions, in this instance "covered person" would mean one of the

following: (1) All owners of terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent; (2) an owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the organization; (3) a member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

The combined effect of these proposals is to ensure appropriate requirements exist concerning program re-entry subsequent to all types of terminations and non-renewals, and to strengthen the past performance review to capture the most serious types of non-compliance (resulting in CMS-initiated terminations and non-renewals) for a more reasonable period of time.

Comment: Some commenters recommended that CMS delete the proposed language authorizing CMS to deny applications from entities whose covered persons had also served as covered persons for a contract terminated or non-renewed in the prior 3 years. Commenters stated that the provision is overly broad and may unfairly cover individuals who, for example, join the board shortly before CMS terminates or nonrenews a contract.

Response: We appreciate commenters' concerns. However, it is incumbent on prospective directors and shareholders to conduct proper due diligence concerning a sponsor's Part C and D compliance history prior to accepting a board appointment or purchasing a substantial number of shares of stock. Also, as discussed in the preamble to the proposed rule, the "covered person" definition was adopted previously under the two-year ban that follows a contract's voluntary non-renewal. It is important to apply the same standard to CMS-initiated terminations and non-renewals in order to maintain consistency and prevent entities from manipulating the Part C and D contract application process.

Comment: Many commenters expressed general support for the proposed language, including the language related to "covered persons". However, several expressed concern that the 3-year look back period is too short. They suggested a 10-year look back period instead.

Response: We appreciate the commenters' support. However, we believe that extending the look back

period to 10 years would be unduly punitive, as that would effectively exclude a terminated or non-renewed sponsor from the Part C or D programs for 10 years. Our intent in adopting this provision was in part to remedy the disparity in consequences between sponsor-initiated non-renewals and CMS-initiated terminations or non-renewals. As discussed in the proposed rule, we believe that the 3-year ban on Part C or D program participation created by the 38-month past performance look-back period meets that goal by imposing some administrative penalty where none existed for operating a Medicare contract so poorly. It also makes certain that the penalty was greater than that associated with voluntary non-renewal. Three years is also a reasonable period of time during which a terminated or non-renewed sponsor could make improvements to its organization in preparation for providing quality services should it elect to re-enter the Part C and D markets. We believe that a 10-year exclusion period goes well beyond what is necessary to achieve our policy goals and could be viewed as excessively harsh by health and drug plan sponsors and the communities they serve.

Comment: Several commenters remarked that the 14-month look back period for past performance analysis was too short.

Response: The 14-month look back period for the past performance analysis of all Part C and D contract applicants was established through previous rulemaking. As the regulatory change described here concerns a modification to the length of the look back period only for applicants with previous CMS-terminated contracts, comments concerning all other types of applicants are outside the scope of the proposed rule.

Comment: A few commenters expressed concern that entities would attempt to get around the 3-year look back period for contracts terminated or non-renewed by CMS by voluntarily non-renewing their contracts before CMS terminates them.

Response: We appreciate commenters' concerns. We will be mindful of organizations attempting to avoid the consequences of the new provision by voluntarily non-renewing. However, we believe that this type of manipulation is unlikely because voluntary non-renewal already carries with it a 2-year ban.

After consideration of the public comments received, we are finalizing these provisions as proposed.

D. Improving Program Efficiencies

We believe that finalizing the regulations discussed in this section will reduce regulatory burdens for MA organizations, Part D sponsors, and cost contractors; lower transaction costs; and reduce waste and unnecessary spending—all of which will, in turn, help keep costs down and improve the quality of care received by Medicare beneficiaries. Non-renewing cost

contractors will also save money because we are finalizing a rule that eliminates the regulatory requirement to purchase print advertising announcing their non-renewals. We are also finalizing more flexible rules regarding agent/broker compensation, which means MA organizations and Part D sponsors will no longer be tied to historic agent/broker compensation amounts and may save transaction and other costs. Finalized regulations that

enable daily cost-sharing of prescription drugs will not only save money for the Part D Program and those beneficiaries who discover during their initial fills that certain drugs do not work for them, but will also result in fewer unwanted drugs that create problems of disposal or safekeeping.

The finalized proposals mentioned previously and others are outlined in Table 5.

TABLE 5—PROVISIONS TO IMPROVE PROGRAM EFFICIENCIES

Preamble section	Provision	Part 417		Part 422		Part 423	
		Subpart	Section	Subpart	Section	Subpart	Section
II.D.1	Cost Contract Plan Public Notification Requirements in Cases of Non-Renewal.	Subpart L	417.492	N/A	N/A	N/A	N/A
II.D.2	New Benefit Flexibility for Certain Dual Eligible Special Needs Plans (D-SNPs).	N/A	N/A	Subpart C	422.102	N/A	N/A
II.D.4	Clarifying Coverage of Durable Medical Equipment.	N/A	N/A	Subpart C	422.100 422.111	N/A	N/A
II.D.5	Broker and Agent Requirements	N/A	N/A	Subpart V	422.2274	Subpart V	423.2274
II.D.6	Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program.	N/A	N/A	N/A	N/A	Subpart D	423.100 423.104 423.153

1. Cost Contract Plan Public Notification Requirements in Cases of Non-Renewal (§ 417.492)

Section 1876 of the Act provides the Secretary with the authority to enter into contracts with HMOs on a cost basis. While section 1876(k)(1)(A) of the Act precludes the Secretary from entering into new cost contracts after the establishment of Part C, existing contracts are grandfathered, and subject to regulations, including § 417.492, which sets forth rules that apply to non-renewal of a cost contract.

In the event that such a contract is non-renewed, the cost plan or CMS must notify both the enrollees of the organization and the general public of the non-renewal. As specified in current § 417.492(a)(1)(iii), public notification must include “notice in one or more newspapers of general circulation in each community or county located in the HMO’s or CMP’s geographic area.” We proposed removing the current requirements at § 417.492(a)(1)(iii) and (b)(1)(iii) for non-renewing cost-contracting plans (in voluntary non-renewal situations) and for CMS (in CMS-initiated non-renewal situations) to notify the general public concerning the impending non-renewal. Our proposed removal of this requirement was motivated by the cost of newspaper advertisements and the declining rate of newspaper circulation. In addition, we believe that the requirement that cost plans provide personalized non-renewal

information is sufficient to ensure adequate non-renewal notice.

Comment: A commenter wrote that waiving the requirement for printing a public non-renewal notice would have virtually no cost savings to a plan.

Response: Although we do believe there will be some savings associated with not having to print a public notice, we also believe that the provision will reduce unnecessary burden on plans.

Comment: A commenter stated that retaining the public notification requirement could help ensure that beneficiaries have more knowledge about plan changes.

Response: Because plans are still required to contact each enrollee when non-renewing a plan for the upcoming year, we believe that beneficiaries will continue to have sufficient notification.

After consideration of the public comments received, we are finalizing the policy without modification.

2. New Benefit Flexibility for Certain Dual Eligible Special Needs Plans (D-SNPs) (§ 422.102)

Section 2602(c) of the Affordable Care Act charged us with making Medicare and Medicaid work together more effectively to improve patient care and lower costs. In our October 11, 2011 proposed rule (76 FR 63018), we proposed to give certain SNPs additional flexibility with respect to plan design as a means of furthering this

goal of better integrating care for dual eligible beneficiaries.

Section 1852(a)(3) of the Act and our regulations at § 422.2, § 422.100(c)(1), and § 422.102 allow us considerable discretion in deciding what benefits beyond those covered under Medicare Parts A, B, or D can be offered to MA enrollees as a “mandatory supplemental benefit” that is included in an MA plan for every enrollee who joins the plan, as opposed to optional supplemental benefits which are offered to all enrollees, but for which coverage is only provided to enrollees who choose to pay for the optional benefit. In our October 11, 2011 proposed rule, we proposed providing certain fully integrated dual eligible SNPs (FIDE-SNPs) with the flexibility to offer additional supplemental benefits because we are interested in assessing whether certain supplemental benefits could help prevent health status decline in the dual eligible population and reduce the quantity and cost of future health care needs. In order to implement this proposal, we proposed amending § 422.102 to add a new paragraph (e) specifying that, subject to our approval, and as specified annually by us, certain fully integrated dual eligible SNPs (FIDE SNPs) may offer additional supplemental benefits beyond those other MA plans may offer, where CMS finds that the offering of such benefits could better integrate care provided under Medicare and Medicaid for the

dual eligible population. All such benefits would also have to otherwise be consistent with the rules for supplemental benefits under Part 422, including § 422.2, § 422.100(c)(1), and § 422.102.

We proposed limiting the new supplemental benefits flexibility offered under this provision to FIDE SNPs defined at § 422.2 that are currently operational, operated in the previous contract year, and meet certain CMS criteria including, but not limited to, being of high quality (as defined by CMS in future guidance). We believed that this approach would be most consistent with the objective of keeping beneficiaries at risk of institutionalization in their homes and preventing health status decline that results in additional utilization of health services, and lowering costs for the Medicaid and Medicare programs. We also proposed to further limit the additional benefit flexibility under the proposed rule to those qualified SNPs that serve only full-benefit dual eligible beneficiaries. We requested comment on whether extending supplemental benefit flexibilities under our proposed § 422.102(e) to eligible SNPs that are SNP types other than FIDE SNPs could measurably reduce unnecessary utilization and improve beneficiary outcomes in an equivalent manner.

In our proposed rule, we also requested comment on what specific categories and types of supplemental benefits we should consider for the purposes of extending benefit flexibility to qualified FIDE SNPs that would be participating in this initiative, as well as on the circumstances under which plans should be permitted to offer these additional supplemental benefits. We also requested comment on additional restrictions that should govern plans' ability to offer these additional benefits, and how we might be able to expand the scope of approved supplemental benefits in a manner that allows plans to serve their dual eligible enrollees effectively and efficiently. We additionally requested comment on ways to minimize this proposed provision's cost impact on dual eligible beneficiaries, while ensuring that States, SNPs, and providers can feasibly provide additional supplemental benefits to a dual eligible population.

No commenters opposed our overall policy proposal to offer new supplemental benefits flexibility to certain SNPs. We also received no comments on our planned approach to further implement this policy through guidance in our final Annual Call Letter and in Chapter 4 of the *Medicare Managed Care Manual*.

Comment: In our proposed rule, we requested comment on whether the benefit flexibility under this provision should be limited to FIDE SNPs, as defined at 42 CFR 422.2, or whether we should extend it to other SNP types. Most of the comments that we received on this issue recommended that we extend this flexibility to all SNP types so that SNPs could target additional supplemental benefits to special needs individuals enrolled in chronic SNPs (C-SNPs) and institutional SNPs (I-SNPs). Some commenters recommended that we extend this benefit flexibility to all dual eligible SNPs (D-SNPs) so that a larger number of dual eligible beneficiaries, including those dual eligible beneficiaries residing in geographic areas without an operational FIDE SNP, could access additional supplemental benefit offerings. A few commenters supported our proposal to limit this new supplemental benefit flexibility to FIDE SNPs only, because they believed that FIDE SNPs were best positioned to deliver integrated services that prevent enrollee institutionalization.

Response: After considering the comments we received, we are finalizing our proposed provision with modification to allow new supplemental benefit flexibility for certain D-SNPs that meet a high standard of integration and minimum performance and quality based standards, where CMS finds that the offering of such benefits would better integrate care for the dual eligible population. We outline these integration, contract design, performance, and quality-based criteria for a D-SNP that would meet this standard in the final CY 2013 Annual Call Letter. We plan to update these criteria annually, as necessary. We believe that expanding the new supplemental benefit flexibility to a larger pool of D-SNPs that meet certain standards in accordance with State policies is consistent with our goal of better integrating care for dual-eligible beneficiaries. By expanding this supplemental benefit flexibility beyond FIDE SNPs, more dual eligible beneficiaries will have access to additional supplemental benefits that are designed to bridge the gap between Medicare and Medicaid services. By limiting this flexibility to qualified D-SNPs—all of which must contract with the State starting in 2013—rather than allowing the flexibility for all SNP types, we can better ensure that plans will use this benefits flexibility to increase integration and care coordination.

Furthermore, we believe that, because D-SNPs must adhere to the State

contract requirements at § 422.107, limiting this new benefit flexibility to D-SNPs rather than extending it to all SNP types (C-SNPs and I-SNPs) would not provide an incentive to MA organizations to create SNPs for the purposes of qualifying for this new benefit flexibility. Therefore, we are finalizing our proposed rule with modification to afford all D-SNP types that meet a high standard of integration and meet minimum performance and quality-based standards the opportunity to qualify for this new supplemental benefit flexibility, even if they are not FIDE SNPs. We are modifying our regulations at § 422.102 to add a new paragraph (e) specifying that, subject to CMS approval, D-SNPs that meet a high standard of integration and minimum performance and quality-based standards may offer additional supplemental benefits beyond those other MA plans may offer where CMS finds that the offering of such benefits would better integrate care for the dual eligible population.

Comment: The majority of comments we received on our supplemental benefit flexibility proposal related to the types and categories of supplemental benefits that plans would be permitted to offer under this flexibility. A large number of commenters requested that we include adult day care services as a category of supplemental benefits that plans would be permitted to offer under this new supplemental benefit flexibility. The commenters noted that adult day care services are not covered by either Medicare or Medicaid in most states. They further noted that many plans that have experienced reduced utilization of long-term care services attribute this reduction to their enrollees' use of adult day care services. Other commenters suggested that we include assistive devices, nutritional supplements, incontinence supplies, and primary and secondary prevention services as permissible types of supplementary benefits under this provision.

Response: We appreciate the commenters' suggestions. We believe that the additional supplemental benefits that will be available under this provision may be appropriate to the extent that they assist Medicare-Medicaid beneficiaries with activities of daily living, (ADLs), (for example, eating, drinking, dressing, bathing, grooming, toileting, transferring, and mobility) and/or instrumental activities of daily living, (IADLs), (for example, managing a home, transportation, grocery shopping, preparing food, financial management, and medication management). Additionally, we believe

that the additional supplemental benefits afforded under this provision should be those benefits that bridge the gap between Medicare and Medicaid services and that have the potential to decrease unnecessary utilization of health care services by the dual eligible population. We have considered comments that we received in response to our proposed rule according to the standard we describe previously. We outline supplemental benefit categories that plans may offer under this provision, as well as guidance on the scope of these additional supplemental benefits, in our final CY 2013 Annual Call Letter. We also note that we will provide qualified D-SNPs with operational guidance on the bid submission process in future guidance.

Comment: In the proposed rule, CMS requested comment on whether it should limit this benefit flexibility to D-SNPs that only enroll dual eligible beneficiaries with full Medicaid benefits. A few commenters supported the limitation to full-benefit dual eligibles, noting that these individuals would receive the most benefit from additional supplemental benefits that are designed to enhance Medicare and Medicaid service integration. A significant number of commenters felt that limiting the additional supplemental benefit flexibility to full-benefit dual eligibles was needlessly restrictive, and would not allow plans to offer supplemental benefits designed to prevent partial dual eligibles (that is, dual eligible beneficiaries that do not qualify for full Medicaid benefits) from declining to full-benefit status.

Response: We agree with commenters' statements that the additional supplemental benefits that we will allow D-SNPs to offer under this provision could help prevent partial dual eligible beneficiaries from spending down to full dual status. We also recognize the potential value of supplemental benefits for dual eligibles that cycle in and out of full Medicaid eligibility during the year. We believe that allowing plans to offer additional supplemental benefits to partial duals would further our goal of aligning Medicare and Medicaid benefits to prevent health status decline and prevent unnecessary utilization of acute and long term care services. Consequently, as noted previously, we are permitting certain, D-SNPs to offer additional supplemental benefits even if they are not FIDE SNPs.

Comment: In our proposed rule, we requested comment on how our proposal would impact costs for dual eligible beneficiaries. All commenters that commented on this issue

recommended that we require SNPs that offer new supplemental benefits under this provision to provide these benefits to dual eligible enrollees at zero cost-sharing and with no increase in premium. Many commenters also recommended that we prohibit plans from creating new supplemental benefits offerings that duplicate Medicaid services because plans that offer supplemental benefits that are identical to Medicaid benefits could modify their supplemental benefits in a manner that would leave enrollees liable for higher cost-sharing. These commenters suggested that CMS require SNPs to describe how the new Medicare supplemental benefits and existing Medicaid benefits will differ and work together, as a condition of participating in this new benefit flexibility initiative.

Response: We share commenters' concerns that duplication of Medicaid benefits in plans' supplemental benefit offerings has the potential to put dual eligible beneficiaries at risk for higher cost-sharing. We do not intend for the new supplemental benefits offered under this provision to duplicate or supplant Medicaid benefits. In response to such concerns and comments received on the draft CY 2013 Call Letter, our final CY 2013 Call Letter requires qualifying D-SNPs, to attest, at the time of bid submission, that the additional supplemental benefit(s) that the SNP describes in its plan benefit package (PBP) do not inappropriately duplicate an existing service(s) that enrollees are eligible to receive under a waiver, the State Medicaid plan, Medicare Part A or B, or through the local jurisdiction in which they reside. Additionally, in order to evaluate how D-SNPs are implementing this new benefit flexibility, we indicate that we will require D-SNPs that participate in this new benefit flexibility initiative to submit a mandatory quality improvement project (QIP) under § 422.152(a)(2) on measures related to the goals of this initiative, as determined by CMS. Finally, in response to the previous comments urging that benefits offered under the new benefit flexibility be made available without cost sharing or additional premium charges, we have added language to § 422.102(e) requiring that benefits be offered to the beneficiary at no additional cost (that is, zero-cost sharing and with no attributable premium increase).

Comment: Several commenters recommended that CMS establish a means of assessing whether the new supplemental benefits offered under this provision lower costs, reduce unnecessary utilization, and improve

integration of Medicare and Medicaid services.

Response: We agree with commenters' recommendations. CMS will develop a means for evaluating the effectiveness of this new supplemental benefit flexibility and will detail our evaluative methodology in future guidance. We will also provide qualified D-SNPs with operational guidance at that time.

Comment: A commenter requested clarification on the years that SNPs must have a State contract in order to qualify under the definition of "currently operational," as discussed in the CY 2012 Annual Call Letter and the preamble to our proposed rule. Another commenter suggested that we revise our requirement that SNPs must have operated in the previous contract year, in order to allow new SNPs to qualify for this new supplemental benefit flexibility.

Response: We reject the commenter's suggestion that SNPs that have not operated in the previous contract year should qualify for this new supplemental benefit flexibility. We are maintaining our requirement that D-SNPs must have operated in CY 2012 and be operating in CY 2013 in order to qualify to participate in this supplemental benefit flexibility initiative because, without a record of operation in the prior contract year, CMS would be unable to determine whether a D-SNP would meet the minimum eligibility requirements (that is, contract design, integration, performance, and quality-based requirements) for this new benefit flexibility. We are updating our regulations at § 422.102(e) to reflect the prior year operation requirement. Furthermore, we believe that D-SNPs that have not operated for at least one year would lack the experience necessary to identify supplemental benefits that would effectively serve the specific needs of their dual eligible enrollees. D-SNPs must have a State contract in order to qualify to participate in this initiative. In our final 2013 Annual Call Letter, we clarify additional operational and contract design requirements for D-SNPs participating in this benefits flexibility initiative. Unless otherwise stated, these contract design requirements apply to the specific SNP plan (that is, SNP plan benefit package), and not the larger MA contract.

Based on our review of the public comments, we have modified our proposal as discussed in the previous responses and we have also modified § 422.102(e).

3. Application of the Medicare Hospital-Acquired Conditions and Present on Admission Indicator Policy to MA Organizations (§ 422.504)

In the October 11, 2011 proposed rule (76 FR 63049 and 63050), we proposed to require by regulation that MA organizations provide in their contracts with hospitals that they will reduce payments for Part A hospital services for serious events that could be prevented through evidence-based guidelines, in accordance with the hospital-acquired conditions (HACs) and present on admission indicator (POA) policy that is currently required for hospitals paid under the Original Medicare Acute Care Hospital Inpatient Prospective Payment System (IPPS). We believed this proposed change was appropriate in order to bring MA requirements in line with current HAC-POA policy in the original Medicare program, as well as—in the near future—to the Medicaid program.

The HAC-POA policy aims to reduce medical errors, improve quality of care for beneficiaries, and reduce Medicare expenditures for poor quality care. We proposed to specifically apply the HAC-POA policy in the MA program by requiring MA organizations to include appropriate payment provisions in their contracts with hospital providers. We believed this would be consistent with the agency goal to further align the MA and original Medicare programs and the ACA requirements to expand the HAC-POA policy further to Medicaid and Medicare and to continue development of value-based purchasing programs.

We proposed to amend § 422.504(i)(3) by adding a new paragraph (iv) to require that, beginning in CY 2013, MA organizations provide in their contracts with hospitals that payment will not be made to contracting hospitals in the case of serious preventable events and hospital-acquired conditions in accordance with section 1886(d)(4)(D) of the Act and all applicable Medicare policies. We solicited comments and recommendations on what other issues to consider in finalizing our proposal to require a payment reduction where payment would be reduced under the current IPPS HAC-POA policy to MA plans.

Comment: We received 17 comments on the proposal. All commenters expressed support for the goals of the policy, that is, to ensure quality within hospitals and reduce costs for unnecessary or poor care. However, reactions were mixed to the proposal to implement this goal through the contracting process.

Several commenters representing beneficiaries and health care professionals expressed support for the proposal and encouraged CMS to continue efforts to more closely align the MA program with original Medicare and other public program initiatives consistent with the National Quality Strategy. A commenter discussed specific HAC conditions and requested that CMS remove healthcare-associated infections from the existing HAC policy.

Several commenters representing the MA industry supported the proposal, stating that implementation would not be burdensome and expressed their belief that their organization's existing contract provisions would be sufficient to implement the policy for CY 2013 as proposed. A commenter requested affirmation of the sufficiency of their plan's specific contract language. A commenter also recommended that the HAC-POA payment adjustment should also apply to non-contract hospital providers.

Response: We thank all commenters for expressing their support and their concerns and raising important questions for CMS to consider. We agree with commenters that reducing costs, while striving for high-quality healthcare for seniors is an important goal of this agency and for the DHHS. We appreciate the encouragement for CMS to continue efforts to more closely align the MA program with original Medicare and other public program initiatives consistent with the National Quality Strategy. We also recognize that, while many plans may already have payment systems or contract provisions in place that would accommodate immediate application of this policy, other payment models, and contractual structures may not, and would have to be amended to implement a reduction in payment for occurrences of HAC.

With regard to the comment requesting that CMS remove healthcare-associated infections from the existing HAC policy, we note that this comment is not within the scope of this rule. Specific HAC conditions are considered through public comment annually in the IPPS rule.

With regard to the comment that the HAC-POA policy should also apply to non-contract providers, we indicated in the October 11, 2011 proposed rule (76 FR 63049 and 63050), that the payment reduction is already required for payments to non-contract providers. MA plans must pay non-contract acute care hospital claims the same rate that they would be paid under the IPPS, and this includes adjustments for HACs and any other IPPS payment adjustments. This is specified in the MA Payment Guide for

Out-of-Network Payments, available at: <https://www.cms.gov/MedicareAdvtgSpecRateStats/Downloads/oon-payments.pdf>.

Comment: Some commenters supported application of the policy with extra time allowed to understand requirements, modify contracts, redesign payment approaches, and incorporate POA reporting into claims processing systems. Several commenters requested that CMS set the deadline for implementation at January 1, 2014.

Response: We appreciate the support for the policy and fully recognize concerns about the additional time that would be needed in order to implement the policy. However, we are also cognizant of concerns expressed by other commenters regarding the operational implications of the policy, given, for example, the varied payment structures in place, and the need to modify and execute new contracts. We will need to fully understand such implications before we are able to establish a reasonable timeframe for implementing the policy. Therefore, at this time, we will not finalize the policy as proposed with a definitive implementation date. Instead, we intend to further study the implications of extending the HAC-POA policy to the MA program and, potentially, consider other ways to achieve the goals of the policy.

Comment: Several commenters were concerned about their ability to reasonably apply these requirements to non-DRG or fee schedule-based payment approaches, such as capitated, per diem or percentage-based models. They were concerned about the burden of “dissecting” every claim in order to calculate a payment and were concerned that every claim payment would be subject to negotiation with hospitals. Similarly, a commenter urged CMS to allow MA organizations flexibility to implement the policy in a way that would not require significant additional resources.

A commenter stated that MA organizations should not have to negotiate with hospitals on methodology, (that is, the methodology should instead be industry standard). Another commenter requested clarification that this policy would only apply to acute care inpatient hospitals. A few commenters expressed concerns with ensuring hospital compliance with reporting of serious adverse events and HACs.

Some commenters requested that plans with capitated payment models be exempt, stating that, under the capitated payment structure, the risk has already been placed on providers to reduce

costly medical errors. A commenter stated that this proposal would stifle innovation of creative payment arrangements that the private healthcare industry uses to promote quality and efficiency and could result in increased costs for beneficiaries. A few commenters claimed to have specific recommendations for applying the HAC-POA policy goals to these types of payment structures, but did not provide them in their comments.

Response: We appreciate the thorough responses from commenters. As we indicated in the proposed rule, we recognize that there may be operational challenges to implementing the HAC-POA policy under varied payment models, which is why we requested specific suggestions and ideas to consider in order to find the best approach within the MA program to reduce the occurrence of HAC conditions and encourage efforts by hospitals to increase quality of care. We believe that exempting some MA organizations based on their existing payment structures with hospitals would result in inconsistent application of the policy and, consequently, failure to advance the goal of reducing these preventable medical errors. However, we do recognize the operational concerns expressed by the commenters. Therefore, we believe that the most prudent approach at this time is to continue to study the implications of extending the HAC-POA policy to the MA program in order to determine how best to incorporate the HAC-POA policy and other quality initiatives into the MA program.

Comment: With respect to the proposal to add this policy as a contractual requirement through § 422.504(i)(3), a commenter requested greater transparency and full disclosure to the public with respect to the types of contractual flexibility that CMS would allow. Other commenters were concerned about CMS over-regulating MA contracts, setting precedent for regulating MA financial arrangements and the burden of contract negotiations. Several commenters stated that hospital contracting is a multi-year process and that opening the contract for one provision would subject the entire contract to renegotiation, potentially resulting in increased costs to MA organizations, enrollees, and CMS. A commenter was concerned that smaller MA organizations might be disadvantaged in negotiating this payment reduction with hospitals.

A few commenters recommended that we revise the proposed rule to effectuate the policy goals through NCDs or other coverage requirements, rather than

contracting/payment provisions. They argued that this would allow MA organizations to implement in a manner that is most appropriate to their provider networks without requiring MA organizations to make changes to their existing contracts, (for example through manual provisions). A commenter requested a model notice for MA plans to issue to hospitals describing the revised coverage policy for HACs and POA indicator reporting.

Several other commenters requested that CMS withdraw the proposal and engage in a collaborative effort with MA organizations to develop alternative approaches to achieve the policy goal of reducing HACs and securing higher-quality hospital care for beneficiaries in the MA program.

Response: We thank commenters who offered alternative solutions and we appreciate the comments expressing concern about opening up potentially lengthy and costly contract negotiations. We also understand, based on comments received, that some MA organizations may already have sufficient contract provisions in place to implement the policy without further negotiations. However, we agree with commenters that the proposal requires further consideration and discussion. Therefore, after consideration of the public comments received, we are not finalizing the proposed policy at this time. However, we will continue to explore alternative approaches to achieve a reduction in HACs, reduce costs for unnecessary medical care and ensure high-quality hospital care for beneficiaries in the MA program.

4. Clarifying Coverage of Durable Medical Equipment (§ 422.100 and § 422.111)

MA organizations and other stakeholders have asked for our guidance on whether MA organizations can limit enrollees to specified durable medical equipment (DME) manufacturers and brands. Some MA organizations have also asked us whether they could offer lower cost-sharing for “preferred” DME products or brands versus “non-preferred” DME products or brands. In section 50.1 of Chapter 4 of the Medicare Managed Care Manual, “Benefits and Beneficiary Protections” (see <http://www.cms.gov/manuals/downloads/mc86c04.pdf>), we specified that, beginning in CY 2011, plans could establish several cost-sharing levels (that is, tiers) for DME items, supplies, and Part B drugs, provided that: (1) The highest cost-sharing tier is at or below the relevant cost-sharing threshold established by CMS for DME and Part B drugs; and (2)

plans ensure access to all products through the established network of providers. However, we have not specified in regulation or guidance whether network-based MA plans may, within a specified category of DME, limit coverage to the DME brands, items and supplies of specific (preferred) manufacturers.

Since we understand that some MA organizations are currently limiting DME coverage to certain brands and manufacturers, we believe it is important to establish a regulatory framework for the protection of beneficiaries by ensuring appropriate and adequate MA enrollee access to DME brands, items, and supplies. Additionally, we believe that MA plans working with MA clinicians are positioned to increase MA program efficiencies by allowing plans to negotiate bulk discounts for high-quality items.

Accordingly, under our authority in section 1856(b)(1) of the Act, to establish MA standards by regulation, and in section 1857(e) of the Act, to specify additional contractual terms and conditions the Secretary may find necessary and appropriate, we proposed the requirements discussed later in this final rule with comment period, followed by a discussion of any applicable comments we received on the proposal.

We received 43 comments in response to our proposed requirements. Commenters included MA organizations and other industry representatives, beneficiary advocacy groups, DME manufacturers and representatives of DME manufacturers, and certain pharmacy groups. The majority of the comments focused on our proposed beneficiary protections. We have provided a brief summary of each of the proposed beneficiary protections to be required of MA plans that elect to limit provision of DME to specific brands and manufacturers. Each proposed beneficiary protection is followed by a discussion of applicable comments on that proposal, if any. Subsequent to this discussion, we address several additional comments associated with more general issues related to the proposed rule.

a. Access to Preferred DME Items and Supplies

We proposed requiring that MA organizations wishing to limit coverage within a specific category of DME to specific brands, items and supplies of “preferred” manufacturers take necessary steps to ensure that enrollees have access to all preferred manufacturer items and brands through

their contracts with their network of DME suppliers. We reflected this change in proposed § 422.100(l)(2)(i). We received no comments on this proposal.

b. Medical Necessity Requirements for DME Items and Supplies

In accordance with § 422.112(a)(6)(ii) of the MA program regulations, MA organizations must have established policies and procedures that allow for individual medical necessity determinations if there is a question about whether a service or item, considered medically necessary by an enrollee's provider, should be covered. MA organizations making medical necessity determinations must have a medical director, who is a physician, ensuring the accuracy of organization determinations and reconsiderations as per § 422.562(a)(4). Therefore, we proposed requiring MA organizations—to the extent that they elect to limit coverage of DME brands, items and supplies to preferred manufacturers—to provide coverage of any DME brands, items and supply deemed medically necessary, including DME brands, items, and supplies made by non-preferred manufacturers. We reflected this change in proposed § 422.100(l)(2)(ii).

Comment: Several commenters were concerned about the burden of the medical necessity process for enrollees and their providers. A commenter pointed to our mention of § 422.112(a)(6)(ii) and § 422.562(a)(4) which requires MA organizations to have a medical director and established policies and procedures that allow for individual medical necessity determinations at the MA organizational level. These citations suggested that a formal petition from the plan is required for medical necessity. Several commenters explicitly asked that the enrollee's provider have the right to determine medical necessity. Several commenters requested clarification on the specific process for a medical-necessity determination; for example, whether the enrollee petitions the plan for a non-preferred brand and, if so, within what timeframe response can be expected.

Response: We wish to clarify that the medical necessity process concerning brand/manufacture of DME items is the same as that for any health care service offered by a plan. As we stated in the proposed rule, we are not adding an exceptions process for DME similar to the Part D formulary exceptions process. While medical necessity requests are the same for DME as any other health care service offered by a plan (that is, they must follow the requirements for

medical necessity at § 422.112(a)(6)(ii), § 422.562(a)(4) and, more generally, the requirements for organizational determinations at § 422.566), we do want to clarify that medical-necessity status may be initiated by the enrollee's provider if the provider believes that a particular brand of DME is medically necessary. Our purpose in citing § 422.112(a)(6)(ii) and § 422.562(a)(4) was to clarify that plans are not unconditionally bound by an enrollee provider's medical-necessity declaration. That is, plans have the right to deny medical-necessity requests made by the enrollee's provider. However, the enrollee has the right to an appeal or expedited appeal if the plan denies the provider's medical-necessity determination. We are also reinforcing that, as specified in § 422.112(a)(6)(i), requests for medically-necessary items must be responded to in a timely fashion.

c. Transition Period for Coverage of Non-Preferred DME Items and Supplies

As provided under § 423.120(b)(3), MA organizations offering an MA-PD plan and Part D sponsors are required to provide for an appropriate process for enrollees transitioning from other coverage who are currently prescribed Part D drugs not on the new Part D plan's formulary. The purpose of this period is to transition the new enrollee to a therapeutically-substitutable formulary drug or, alternatively, to obtain a formulary exception whereby the new Part D plan would continue to cover the non-formulary drug for the remainder of the plan year for reasons of medical necessity.

Similarly, we proposed requiring MA organizations to continue to ensure access to DME brands, items and supplies of non-preferred manufacturers—such as diabetic test strips—for a transition period comprising the first 90 days of coverage under the plan, as specified by CMS. Similar to the Part D transition process, we expect that MA organizations would provide one refill during the 90-day transition period. We also propose requiring that, during this 90-day transition period, MA organizations cover repairs to DME brands, items, and supplies of non-preferred manufacturers such as wheelchairs, feeding pumps, and hospital beds. More specifically, the enrollee, during this 90-day transition period, could elect to have the MA plan continue to provide the DME brand, item or supply from the non-preferred manufacturer as well as provide all necessary repairs to DME items, including providing a loaner. Alternatively, the enrollee could

immediately switch to a brand, item, or supply of a preferred manufacturer. We reflected this change in proposed § 422.100(l)(2)(iii)(A) and § 422.100(l)(2)(iii)(B).

Comment: In the proposed rule we recommended a 90-day transition period to enable beneficiaries who had used one brand of DME and had to change brands because their current plan no longer supplies this brand, to adjust to the change. We solicited comments on the duration of the transition period. While we received comments that indicated no transition period was necessary, other commenters agreed with the 90-day transition period, others suggested durations of 120 days and 6 months.

Response: We believe that the proposed 90-day transition period, similar to the transition period in the Part D program, strikes the appropriate balance between ensuring an enrollee's smooth transition to a new plan while taking into account the ability of the plan to offer preferred DME items for its enrollees.

Comment: We also received several comments on the appropriateness of a transition period. A commenter pointed out that it should not be required for enrollees to continue a former DME brand if new brands were more efficacious. Another commenter asked if the use of a brand, item, or supply from a non-preferred manufacturer based on a medical-necessity determination only applies to the transition period.

Response: Our requirement that plans continue to furnish non-preferred DME brands that they had formerly was not intended to prevent a plan enrollee from switching to a different brand, should she or he so desire. If the enrollee wants to continue using the former brand, item, or supply, the new plan must furnish it for 90 days. Alternately, the enrollee may decide to change brands immediately. We also note that the medical necessity exception and the transition exception are independent of one another. An enrollee is permitted a 90-day transition period for a currently non-preferred brand that was used in the former plan year even if that non-preferred brand is not considered medically necessary for that individual.

Furthermore, if deemed medically required, the new plan is required to furnish the specific DME brand, item, or supply regardless of whether the product was used previously.

d. Midyear Changes to Preferred DME Items and Supplies

We proposed prohibiting MA organizations from making “negative changes,” that is, eliminating coverage

of a Medicare-covered DME brand, item or supply of a preferred manufacturer, midyear. However, plans would not be responsible for involuntary negative changes such as those due to supplier terminations or sanctions. We also proposed allowing MA organizations to make “positive changes,” that is, adding coverage of Medicare-covered DME brands, items or supplies, midyear. Examples of allowable positive midyear changes include: Adding new manufacturers’ products, providing substitute DME brands, items and supplies for DME products that are no longer available, considering new DME technologies, and complying with national and local coverage determinations for new DME brands, items and supplies. Plans could also add suppliers midyear. We believe this strikes the appropriate balance between allowing flexibility for plans to designate preferred products, while ensuring that changes to the list of DME brands, items and supplies of preferred manufacturers are not disruptive to enrollees. We reflected this change in proposed § 422.100(l)(2)(iv).

Comment: We received several comments on midyear changes to DME. A number of commenters criticized the proposed rule on the grounds that it would not be sensitive to midyear changes in technology. Other commenters raised the issue of the effect of supplier termination or supplier sanctions. Still other commenters asked if suppliers as well as products could be added midyear.

Response: In the proposed rule we allow the addition, but not the deletion, of brands and manufacturers midyear. Consequently: (1) Plans may add DME with innovative new technologies midyear; and; (2) plans may add midyear suppliers as this would increase brands and manufacturers available to enrollees. Note, that if a midyear supplier termination or supplier sanction deprives enrollees of access to certain brands, items or supplies of preferred manufacturers, the plan has an obligation to add suppliers midyear in order to maintain enrollee access.

Comment: A commenter requested that plans be allowed to withdraw midyear brands and manufacturers based on safety issues.

Response: We agree that plans must exclude items from their preferred DME list if recalled by a Federal agency, for example, the FDA, or if CMS determines there is a safety concern. Additionally, if a plan has concerns regarding the safety of a certain brand or manufacturer, it should immediately contact the FDA’s Center for Devices

and Radiological Health Ombudsman to whom such concerns should be directed.

e. Appeals

As indicated previously, a medical necessity determination is initiated by the enrollee’s provider. The plan’s subsequent denial could then lead to an appeal or expedited appeal. We proposed to clarify at § 422.100(l)(2)(v) that a plan’s non-coverage of a particular manufacturer’s product or brand of a DME constitutes an organization determination under § 422.566.

Comment: Several commenters requested that to ensure a proper balance between costs and access, CMS must incorporate safeguards around the use of DME formularies similar to those of Part D drug formularies. These commenters specifically identified the following Part D safeguards as examples of safeguards that should apply to DME: (1) Annual review and approval of DME formularies established by Medicare Advantage Plans by the plans’ respective Pharmacy and Therapeutics Committees; (2) a formal exceptions process for non-formulary DME items deemed medically necessary for a particular patient, similar to that employed for Part D drugs pursuant to § 423.578; and, (3) the right of patients to seek review of adverse determinations related to requested DME brands, items or supplies by an independent review entity in a manner similar to that utilized for adverse determinations made by Part D Plans related to Part D drugs.

Response: As indicated in the proposed rule, we studied the possibility of establishing an exceptions process for DME similar to the one established for non-formulary Part D drugs under § 423.578(b) and decided that the safeguards we proposed, along with the ability to appeal brand/manufacturer decisions as coverage determinations, were the most efficient means to implement this provision in the context of the MA program. The Part D appeal process adds an additional level of review to the established appeal process under subpart M of Part 422 to account for the fact that Part D drugs in a category of prescription drugs are frequently prescribed based on the individual’s unique requirements and disputes about medical necessity are more likely. We believed such a process is unnecessary for DME brands, items and supplies because, unlike Part D drugs, DME is generally not specific to individuals and, as a result, appeal of coverage determinations based on brand/manufacturer are infrequent.

Comment: A few commenters requested that, in addition to the right to appeal non-coverage of non-preferred, medically-necessary DME, CMS issue guidance on differential cost-sharing between preferred and non-preferred brands.

Response: As specified in § 422.100(f)(2), MA plans are already prohibited from designing cost-sharing structures that inhibit access. We annually publish detailed guidance on acceptable cost-sharing criteria.

Comment: Several commenters requested that we provide guidance, similar to guidance in the Part D program, on the criteria for making an Independent Review Entity (IRE) determination. These commenters also recommended that access to DME and medical necessity be guiding principles as part of the IRE determination process.

Response: We agree that access and medical necessity should be two primary principles guiding IREs in making determinations. For this reason, we strongly encourage MA plans when formulating their medical-necessity requirements, as specified at § 422.112(a)(6), to specifically address how medical-necessity determinations by enrollee providers should be communicated and addressed. We do not believe it necessary, however, that IREs be given additional guidance regarding how to determine claims based on the brand/manufacturer of DME.

Comment: In the proposed rule, CMS supported our decision not to have a formal exception process for DME denials by citing the following statistic: Of 12,500 appeals on wheelchairs reviewed by the IRE since the inception of the IRE appeals process in 2006, only seven related to brand-specific issues. A commenter suggested that the small number of brand-specific appeals could be due to our not formerly allowing plans to limit DME items, such as wheelchairs, by brand and manufacturer.

Response: As indicated in the proposed rule, we have anecdotal evidence that plans are already limiting DME by brand and manufacturer. Consequently, we believe this statistic to be supportive of our proposal.

f. Disclosure of DME Coverage Limitations

As provided under § 422.111(b)(2), MA plans must notify enrollees—at the time of enrollment and annually thereafter—of the benefits offered under the plan, including applicable conditions and limitations, premiums, and cost-sharing, and any other conditions associated with receipt of

benefits. This requirement has been operationalized as the annual notice of change/evidence of coverage (ANOC/EOC). We would require, under proposed § 422.100(l)(2)(vi), that MA plans that choose to limit DME coverage to brands, items, and supplies of preferred manufacturers, be required to include, in the description of benefits required under § 422.111(b)(2) and under § 422.111(h)(2)—which requires the provision of specific information via a toll-free customer service call center and Internet Web site, and in writing upon request—disclosures about these DME coverage restrictions and enrollee rights to the Part C appeals process for requests to obtain medically necessary DME brands, items, and supplies from non-preferred manufacturers.

Comment: Several commenters requested clarification on how MA organizations should disclose the list of DME brands, items, and supplies of preferred manufacturers. For example, several commenters asked whether they should be listed in the bid or EOC. These commenters pointed out that the EOC is a template and consequently a template change would be required for additional disclosures. Other commenters asked whether these materials should be listed on plan Web sites or in the plan finder.

Response: As specified in § 422.111(b)(2) and § 422.111(h)(2), MA plans must disclose all conditions, limitations, premiums, and cost-sharing for benefits they provide, including DME. There are already several vehicles for such disclosure in place. We propose modeling the disclosure requirements for DME by applying similar disclosure requirements currently used for the Part D formulary. More specifically, a plan choosing to limit certain DME products to specific brands and manufacturers would have to maintain a Web site with current information on DME access. We would also require that the list of DME brands, items, and supplies of preferred manufacturers be included in the EOC packet. We will issue guidance on these matters along with other guidance for proper bid submission.

Comment: A commenter requested that disclosure requirements apply to any changes in provision of DME such as midyear changes. Another commenter asked if providing access to only two brands is a limitation for which notification is required.

Response: We are modeling the disclosure requirements for DME on the disclosure requirements for the Part D formulary. Consequently, in addition to the list of brands, items, and supplies of preferred manufacturers that should be mailed in the EOC packet along with the

Part D formulary, MA plans must have dedicated Web sites listing all current information on DME provision, including any midyear changes. Plans must notify enrollees of any contractual limitation in DME brands, items, supplies, and manufacturers.

Comment: A commenter requested a 60-day notification for any midyear changes in DME.

Response: The notification requirements for midyear changes specified in the Medicare Marketing Guidelines are applicable to midyear changes in DME.

Comment: A commenter asked whether plans must submit their DME formularies, that is, their list of brands, items, and supplies of preferred manufacturers, to CMS for prior approval.

Response: As indicated in the proposed rule, we are not applying the formulary requirements of the Part D program in our DME policies. Consequently, the submission of bids that includes all supporting documentation as part of the annual bid review cycle will suffice.

g. Flexibility

Based on comments we received on the proposed rule, and which we discuss later in this final rule with comment period, we are providing additional flexibility at 422.100(l)(2)(vii) for CMS to annually review DME categories. We would also review complaint data and appeals and grievances data. This would allow us to require full coverage of certain categories of DME without limitation in brand and manufacturer. Additionally, such flexibility would allow us to consider and respond to emerging new technologies, as well as to require full coverage of categories of DME items typically tailored to meet individual needs.

Comment: Several commenters requested that we exclude orthotics and prosthetics from the items that MA organizations could limit purchase of to specific brands and manufacturers. Several commenters requested a general exclusion of orthotics and prosthetics while other commenters requested exclusion of specific orthotics and prosthetics. In particular, several commenters pointed to our use, in the proposed rule, of ostomy bags as an example of an item that could be subject to limitation based on brand or manufacturer. One of the commenters asked if we had intended to include ostomy bags, as they are actually prosthetics. The other commenters on this issue, while not identifying ostomy bags as prosthetics, stated that these are

not, in fact, examples of items that are interchangeable and, thus, should not be subject to limitation based on brand or manufacturer.

Response: When discussing the transition requirement, we mistakenly included ostomy bags, which are prosthetic devices, in our example of DME that would be subject to limitation—and thus the transition requirement—based on brand or manufacturer. In discussing the transition requirement, a better example would be diabetic supplies. In this final rule with comment period, we are clarifying that the ability of MA organizations to limit DME brands, items, and supplies to specific manufacturers does not apply to orthotics and prosthetics. Section 1860(s) of the Act specifically distinguishes the authorities for provision of DME, prosthetics and orthotics. Consequently, our proposal to allow plans to limit provision of DME brands, items, and supplies to specific manufacturers would not affect prosthetics and orthotics. MA organizations must still provide to their enrollees all medically-necessary prosthetics and orthotics covered under Original Medicare, Part B. The principal reason for not including orthotics and prosthetics in the scope of this requirement is that the provision of orthotics and prosthetics requires clinical care by specially educated and trained practitioners who utilize those skills to design, fabricate, and fit custom orthoses and prosthesis. DME, however, primarily refers to equipment such as wheelchairs (manual and electric), walkers, scooters, canes, crutches, and home oxygen therapy. A standard cane from a supplier, for example, is qualitatively different from receiving a custom-fit orthotic brace molded specifically for the patient by a skilled provider. We already recognize this distinction between DME and prosthetics and orthotics in its quality and supplier standards.

Comment: There was support for the notion that brands of certain DME such as canes are essentially interchangeable. However, over half the commenters mentioned specific categories of DME whose brands are less likely to be interchangeable in terms of quality, consistency in performance, and ease in repair. Among the 43 comments received, 7 categories of DME were identified for which commenters requested full coverage without plan limitation: (1) Wheelchairs; (2) diabetic supplies; (3) Continuous Positive Airway Pressure (CPAP) devices; (4) patient lifts; (5) speech generating devices; (6) oxygen; and (7) paddings

(such as foam mattresses). Additionally, a commenter questioned the classification of speech-generating devices as DME, rather than orthotics and prosthetics, citing the Department of Defense and VA classifications.

Response: We agree that certain categories of DME include items which are tailored to the individual and are not interchangeable. For this reason, we intend to conduct an annual review to ascertain which categories or subcategories of DME require full coverage without allowance for plan limitation by brand or manufacturer. In making our decisions, we will identify categories of DME not subject to limitation, based on a variety of sources. Sources include, but are not limited to—

- Comments on the proposed rule;
- Discussions with DMEPOS staff;
- Advice from the Chief Medical Officer Center for Medicare, CMS and DME MAC medical directors; and
- Experience from the DMEPOS competitive bidding program and other Medicare programs.

Based on our review of public comments, we have modified our proposal by adding new paragraph (l)(2)(vii) to § 422.100 to specify that plans must comply with CMS' designation of DME items not subject to limitation based on brand or manufacturer.

We have made two other changes to the regulatory text: (1) at 422.100(l)(2)(iii) we have clarified that transition coverage changes are at the enrollee's request; and (2) throughout the regulatory text we use the phrase "DME brands, items, and supplies of preferred manufacturers." The enrollee's request for transition coverage is initiated when he or she fills a script and generates a claim for a particular brand. Our purpose in using the phrase "DME brands, items, and supplies of preferred manufacturers," is to emphasize that plans can limit both items and supplies and plans can limit by either: brand, manufacturer, or both.

Following this discussion are several comments that address more general issues related to the proposed rule.

Comment: A few commenters were opposed to the proposed rule on general grounds. They cite section 1801 of the Act which prohibits supervision over the practice of medicine and section 1802 of the Act which guarantees basic freedom of choice. Another commenter disagreed with our authority to allow plans to limit brands and manufacturers, arguing that section 1852(a)(1)(A) of the Act, allowing MA plans to contract with networks of providers, specifically applies to providers, not suppliers.

Response: In the proposed rule—and as clarified further in this final rule with comment period—we have specifically indicated that a medical-necessity determination by the enrollee's provider initiates a process that could allow enrollees access to DME brands, items, and supplies of non-preferred manufacturers. Hence, we have not interfered with the practice of medicine. Furthermore, section 1852(a)(1)(A) of the Act specifically allows plans in the MA program to limit the providers from which services may be obtained, provided adequate access is ensured. The statute is silent on limitations of supplier networks. As we stated in the proposed rule, we believe it is consistent with the goals of the statute to allow MA plans to contract with networks of suppliers and to restrict brands and manufacturers provided access is ensured and are thus exercising our authority under 1856(b)(1) of the Act, to establish MA standards by regulations, and section 1857(e)(1) of the Act to impose additional terms and conditions found necessary and appropriate.

Comment: A commenter believed that the proposed regulation had given plans arbitrary power and would unnecessarily limit beneficiary choices. The commenter also believed that MA plans do not have the necessary knowledge to make decisions about limits on brands, items, supplies, and manufacturers of DME. Another commenter asked how CMS would define access to non-preferred brands.

Response: In developing our proposal, we took deliberate steps to ensure that an MA organization's DME policies not be instituted arbitrarily and that such policies are fair and transparent to enrollees. In the proposed rule, we specifically mentioned our goal to strike "the appropriate balance between allowing flexibility for plans to designate preferred products, while ensuring that changes to preferred DME products are not disruptive to enrollees." Furthermore, we explicitly proposed at § 422.100(l)(2)(ii), that MA organizations—to the extent that they elect to limit coverage of DME items and supplies to specific manufacturers' products or brands—ensure access to DME by providing coverage of any medically-necessary DME brand, item, and supply, including DME brands, items, and supplies made by non-preferred manufacturers. Other requirements, such as the transition period and the prohibition on removing DME items midyear, also help ensure that enrollees will continue to have full access to DME.

Comment: A few commenters requested that we offer the proposed rule as guidelines rather than regulations. These commenters suggested that, aside from specific requirements to ensure adequate access, we should not impose requirements or otherwise oversee functions that have traditionally been left to the discretion of plans.

Response: We have already given plans much flexibility in choosing DME; we must also ensure that enrollees continue to have access to necessary DME. Plans must develop their own medical necessity criteria and methods for addressing provider determinations of medical necessity. However, the requirements delineated in the proposed rule, including disclosure, beneficiary appeal rights and access, have traditionally been regulatory areas and part of CMS' oversight of plans. In the proposed rule, we proposed requirements in three other areas—medical necessity, transition periods, and midyear changes—and believe these to be important beneficiary protections.

Comment: A commenter pointed out that, although the proposed rule focuses on reducing out-of-pocket costs for beneficiaries, this concept could also affect costs for plans.

Response: In the proposed rule we pointed out that some organizations are already limiting DME to specific brands; consequently, our proposal would not adversely affect the costs incurred by these organizations. As we stated in the proposed rule, we believe this provision will give more flexibility to plans when making DME choices; if plans wish to offer multiple brands of DME in a category, this provision would in no way prohibit this. As we also stated in the proposed rule, we believe this additional flexibility may permit MA organizations to negotiate bulk discounts with preferred manufacturers.

Comment: Several commenters pointed out that cost savings was the only reason mentioned in the proposed rule to allow plans the right to limit furnishing DME to specific brands and manufacturers. Another commenter mentioned an MA plan that is currently selecting manufacturers and brands of diabetic supplies, based on consultation with clinicians and, consequently, is able to offer products at zero cost-sharing to its enrollees.

Response: We agree that a variety of factors—including cost, access, diverse patient needs, convenience, and medical necessity—should be part of benefit considerations and overall plan design. We believe the beneficiary protections we have specified concerning enrollee access to all

categories of DME will help ensure that cost is not the sole driving factor of a plan's DME choices. In addition, we believe that quality requirements, a robust appeals process, and plan oversight are important factors in ensuring that enrollees have continued access to necessary DME.

Comment: Several commenters requested that if an individual requires multiple DME brands, items, or supplies and one brand, item, or supply that he or she requires is only available through a supplier of brands, items, and supplies from non-preferred manufacturers, the individual should be allowed to obtain all the medically-necessary brands, items, and supplies from the non-preferred manufacturer. This would promote efficiency and ease of obtaining brands, items, and supplies.

Response: The implication of this comment is that it is inconvenient for the enrollee to have to purchase brands, items, and supplies from multiple suppliers. We do not agree. Furthermore, since MA organizations contract with suppliers, they can communicate in advance the brands and manufacturers that are preferred and nonpreferred so that suppliers can stock up on these.

Based on our review of public comments, we are finalizing our proposed provisions with the modifications previously discussed.

5. Broker and Agent Requirements (§ 422.2274 and § 423.2274)

Regulations setting forth rules for agent and broker compensation promulgated in our November 10, 2008 interim final rule with comment (73 FR 67406 through 67414) required MA organizations and Part D plan sponsors ("plan sponsors") to submit historical agent/broker compensation data from years 2006 and 2007. In addition, we requested that plan sponsors submit information in 2008 that would indicate their 2009 compensation schedules for agents selling Medicare health plans on their behalf. We conducted an analysis of the historical compensation information submitted by plan sponsors and published fair market value cut-off (FMV) amounts during the spring of 2009. Later that year, plan sponsors were given the opportunity to adjust their compensation amounts to any amount at or below the FMV. These adjusted 2009 amounts became the baseline amount for compensation adjustments in future years. Subsequent to our initial compensation guidance, plan sponsors have expressed concerns about the validity of continuing to base future compensation on amounts which

were selected in 2009 and based on data from 2006 and 2007.

We have also heard that current economic conditions have drastically changed local markets such that, even as adjusted, the 2009 compensation amounts do not accurately reflect the current market rates. We have been advised by plan sponsors that have been in the market since 2009 that they are at a competitive disadvantage as compared to newly entering plans as the new entrants may set compensation at current-day FMV rates and are not tied to 2009 compensation amounts. Therefore, we proposed to modify paragraph (a) and add a new paragraph (f) to § 422.2274 and § 423.2274 to allow plan sponsors to annually select their compensation amounts to reflect rates which are at or below FMV as annually established by CMS. Under these proposed changes, plan sponsors would also be required to report their intentions to use independent agents and/or brokers in the upcoming plan year, along with the amounts that they will be paid, if applicable.

Comment: Many commenters expressed support for the proposal to allow sponsors to annually select agent/broker compensation amounts which reflect rates at or below the CMS established FMV.

Response: We appreciate the many comments received in support of this provision.

Comment: A commenter asked whether this provision applies to section 1876 cost plans.

Response: This provision does apply to section 1876 cost plans pursuant to § 417.428, Marketing Activities, which states that the marketing regulations found in subpart V of part 422, which include this specific requirement, apply to section 1876 cost plans.

Comment: A commenter expressed a concern that the compensation regulations were driving agents/brokers away from MA and encouraging them to sell Medigap.

Response: We appreciate the comment and will consider it as we continue to refine and improve our managed care programs. However, this comment is beyond the scope of these regulations.

Comment: Several commenters expressed a concern that CMS should be evaluating its current marketing rules against the Affordable Care Act and considering the impacts.

Response: We appreciate the comment and will consider it as we implement the provisions under the Affordable Care Act. However, these comments are beyond the scope of this regulation.

After consideration of the public comments received, we are finalizing the provision without modification.

6. Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program (§ 423.100, § 423.104, and § 423.153)

Pursuant to our authority under section 1860D-4(c) of the Act, which requires PDP sponsors to have cost-effective drug utilization management and a fraud, abuse, and waste control program in place, we proposed that Medicare Part D sponsors be required to provide their enrollees access to a daily cost-sharing rate for prescriptions dispensed by a network pharmacy for less than a 30 days' supply of certain covered Part D drugs that: (1) Are for an initial fill of a new medication; (2) are intended to allow the enrollee to synchronize refill dates of multiple drugs; or (3) are dispensed in accordance with § 423.154 (which sets forth the requirements placed on Part D sponsors with respect to dispensing of prescription drugs in long-term care facilities beginning January 1, 2013).

As we explained in the proposed rule, current prescribing patterns and pharmacy benefit management (PBM) payment practices result in most prescriptions being written by providers, and dispensed by retail pharmacies, in 30-or-more days quantities. When the full amount dispensed is not utilized by a beneficiary due to adverse medication reaction or interaction, or due to failure of beneficiary therapeutic adherence because of cost, inconvenience, death, or other reason for discontinuation, it comes at an unnecessary and wasteful cost to the beneficiary, the Medicare program, Part D sponsors, and the environment.

We believe that if Part D enrollees and their prescribers had the option of shorter days' supplies of initial fills of new prescriptions, without the disincentive of the enrollee having to pay a full month's (or longer) copayment or coinsurance, a significant portion of the current costs to the program of chronic medications discontinued after initial fills could be avoided. In addition, the avoidance of unused drugs would contribute to diminishing the environmental issues² caused by disposal of unused medications, and opportunities for

² See <http://www.epa.gov/ppcp> for information about Pharmaceuticals and Personal Care Products as Pollutants (PPCPs) on the Web site of the U.S. Environmental Protection Agency.

criminal activities and substance abuse³ caused by diversion of unused medications, all of which are growing concerns in the United States.

We observed that, currently, Part D enrollees' cost-sharing generally is the same whether they receive a 7, 14, or 30 days' supply of a medication. A daily cost-sharing rate requirement imposed on Part D sponsors would encourage enrollees and their prescribers to limit days' supplies, when appropriate, by reducing the enrollees' out-of-pocket costs. More specifically, under our proposal, Part D sponsors would be required to establish and apply a daily cost-sharing rate, such that an enrollee requesting a trial fill of a prescription for a new chronic medication, for example, would pay only a portion of the established cost-sharing amount under his or her Part D benefit plan that corresponds to the actual number of days supply that was dispensed. This would be the case whether it was for a 7- or 14-days' supply, or some other quantity less than 30 days, and this decision would primarily be at the discretion of the prescriber. Thus, although a daily cost-sharing rate requirement would be mandatory for Part D sponsors, actually taking advantage of it would be voluntary for enrollees and their prescribers. Neither sponsors nor the Federal government would determine whether a beneficiary should receive less than a month's supply of a new medication. Rather, such a decision should be made solely by the beneficiary and his or her prescriber.

Through the establishment and application of a daily cost-sharing rate requirement on Part D sponsors, we believe an enrollee would be especially incentivized to inquire of his or her prescriber whether a fill of less than a month's supply would be appropriate when first prescribed a chronic medication. We also believe enrollees would be most likely to inquire about such a trial fill when faced with high cost-sharing for such a medication, due to the expense of the drug, such as when purchasing a drug in the deductible phase of the benefit or in the coverage gap. We further believe prescribers

would be most likely to concur as to the appropriateness of a trial fill when the prescription is for a drug that has significant side effects and/or is frequently poorly tolerated.

In such a case, we suggested that the prescriber could write either one prescription for the initial fill at the prescriber's discretion, or two prescriptions (for example, one for an initial fill and a second prescription for a 30 or 90 days' supply; the latter prescription would be utilized if the enrollee and the prescriber agreed the drug therapy should be continued after the trial period). Because the two prescriptions could be written during one office visit, or could be refilled by the prescriber directly with the beneficiary's pharmacy after the trial period, as permitted by applicable law, additional visits to the prescriber would not necessarily be required and would not need to cause a burden to the beneficiary. We assumed the two-prescriptions option would be most convenient for the beneficiary and the prescriber (when appropriate), but sought specific comment on this assumption. If a beneficiary would have difficulty returning to the pharmacy, presumably he or she would not inquire about a trial fill. Furthermore, since prescribers would determine whether or not medication being prescribed should or could be dispensed in a trial fill, we stated that we would not expect our proposal to have any adverse effects on beneficiaries' health. However, if the medication were discontinued after use of the initial fill, the enrollee, as well as the sponsor, would have avoided the net costs associated with the unused quantity that would be dispensed under current standard practices.

While we envisioned, as described previously, beneficiaries primarily requesting less than a full month's supply when prescribed a drug for the first time for a chronic condition that is known to have significant side effects, to be frequently poorly tolerated and expensive, we did not limit the requirement for Part D sponsors to establish and apply a daily cost-sharing rate to such medications. Rather, in the proposed rule, we also identified an additional benefit of a daily cost-sharing rate requirement, which is the ability to allow for synchronization of prescriptions. The ability to synchronize medications should assist beneficiaries in adhering to prescription treatment regimens that involve multiple medications, and we noted that at least one study supports this belief. In addition, we believe the ability to synchronize medications will be convenient for both those beneficiaries

who take advantage of it and their prescribers by enabling fewer trips to the pharmacy and fewer prescription refill requests of prescribers from beneficiaries through the ability to consolidate pharmacy trips and prescriber office visits and phone calls. We also stated that daily cost-sharing rates also may permit pharmacies, as opposed to prescribers, to facilitate synchronization of a beneficiary's medications upon his or her request, and we sought specific comment as to this possibility, as well as to any issues we may need to address to facilitate this possibility.

We noted in the proposed rule that we do not expect long-term care (LTC) beneficiaries to request to synchronize medications, as this was not our understanding of the LTC environment with respect to prescribing, and the LTC dispensing rules at § 423.154 require 14 days or less dispensing in LTC facilities in certain instances, beginning January 1, 2013. However, as noted in the April 2011 final rule (76 FR 21432), we expected the LTC dispensing requirements "would likely lead to a change in copayment methodology * * * [and] anticipate[d] the implementation of particular copayment methodologies will be dependent on the billing and dispensing methodologies used, and as a result * * * copayment methodologies within the same plan may vary depending on the LTC facility where the beneficiary resides. Copayment may be collected at the first dispensing event in a month, the last dispensing event in a month, or prorated based on the number of days a Part D drug was dispensed in a month. However, due to the relatively small copayments for low-income subsidy (LIS) beneficiaries, copayments for LIS beneficiaries should be billed with the first or last dispensing event of the month." Because Part D sponsors would have to address copayment methodology in connection with the LTC dispensing requirements, we proposed to supersede our quoted guidance in the April 2011 final rule (76 FR 21432), and thus proposed that the daily cost-sharing rate requirement would apply to prescriptions dispensed in LTC facilities, beginning January 1, 2013.

In the proposed rule, we urged the industry to develop coding to be used by network pharmacies to communicate to sponsors whether a less than month's fill is to align refill dates, or for that matter, is an initial fill of a new medication, or in the case of the LTC setting, is to communicate the dispensing methodology employed. We stated such coding would allow

³ See Office of National Drug Control Policy, 2008 "Prescription for Danger", January 24, 2008, and 2009 National Drug Survey on Drug Use and Health (NSDUH), September 2010, for more information on the growing problem of nonmedical use of prescription drugs in the United States, particularly among teenagers. See also <http://www.deadiversion.usdoj.gov/index.html> for more information from the Drug Enforcement Administration about the problems associated with drug abuse resulting from legitimately made controlled substances being diverted from their lawful purpose into illicit drug traffic.

sponsors to be able to monitor the prevalence and appropriateness of the dispensing of prescriptions in shorter than a month's supply to ensure that a pharmacy does not dispense a prescription for 30 days' supply in stages in order to increase dispensing fees.

We recognized in the proposed rule that establishing and applying a daily cost-sharing rate to the already small copayments for LIS beneficiaries would cause such copayments to be the same or even smaller. We also stated that, while there may be additional waste generated by multiple fills when medications are continued or synchronized (for example, more plastic bottles and paper inserts, additional trips to pharmacies), the harmful effects on the environment from unused drugs, particularly the biological implications, likely have a much greater impact on the environment than additional recyclables.

We acknowledged in the proposed rule that realized savings from our daily cost-sharing rate proposal may be partly offset by additional dispensing fees, and that Part D sponsors would also incur some costs to program their systems to establish and apply a daily cost-sharing rate to prescriptions dispensed to enrollees for less than a 30 days' supply. We cited in the proposed rule a previous review of 2009 PDE data by us that suggested that just under 32 percent of approximately 78.6 million first fills for chronic medications are not refilled by Medicare Part D enrollees. We assumed for purposes of estimating savings to the Part D program that the lack of refills indicates the prescribed medications were discontinued. The estimated total cost of these discontinued medications was approximately \$1.6 billion (70 percent for brands and 30 percent for generics). However, since this review did not distinguish between community and institutional settings, to estimate the costs of discontinued medications in community settings only, we reduced the total costs by approximately 13 percent in accordance with CMS data on gross drug costs in the Part D program in 2009 in the community and institutional settings to remove a proportion representing long-term care expenses. (We did not estimate the costs of discontinued medications in the LTC environment since the daily cost-sharing rate requirement proposed here does not further change the dispensing requirements in the long-term care setting, which are applicable January 1, 2013). Consequently, we arrived at an adjusted total estimated cost of 2009 community-based discontinued first

fills of maintenance chronic medications was estimated at roughly \$1.4 billion.

As noted previously and in the proposed rule, potential savings of a daily cost-sharing requirement on Part D sponsors would come from a reduction of these costs which would be offset by some additional dispensing fees. In order to estimate the savings, we made assumptions about how many initial fills for new maintenance medications for chronic conditions will be dispensed in quantities of less than a 30 days' supply, and what the average quantity of such initial fills will be. We pointed out that these assumptions were highly uncertain, because it is very difficult to predict beneficiaries' behavioral response. Having noted this caveat, we assumed 20 percent of initial fills in 2013 will be for a supply of less than 30 days, trending to almost 50 percent by 2018, and that the average of such fills will be for a 15 days' supply. We also applied a dispensing fee rate of approximately \$2 in our estimation. Assuming 32 percent of these first fills are discontinued, we estimated the potential savings to the Part D program to be \$140 million in FY 2013 alone, and over \$2.4 billion total by 2018. However, because we are revising the applicable date of this requirement to January 1, 2014, as explained later in this final rule with comment period, we are revising the cumulative savings in 2018 to roughly \$1.8 billion.

We noted in the proposed rule that we considered proposing a requirement similar to the Fifteen Day Initial Script program introduced in Maine in the summer of 2009. In this program, specific medications that were identified by the MaineCare program with high side effect profiles, high discontinuation rates, or frequent dose adjustments, were phased in by class and required to be dispensed in a 15-day initial script to ensure cost effectiveness without wasting or discarding of dispensed, but unused, medications. We have learned through representatives of the program that MaineCare has achieved overall savings for 2 consecutive State fiscal years with respect to both brand and generic drugs through this program, despite the additional dispensing fees. The representatives have also reported that there has been very good acceptance of the program and very little confusion upon implementation. While we acknowledged the savings benefits of the mandatory MaineCare approach, we stated that leaving the decision to obtain less than a month's supply of a prescription with the beneficiary and his or her prescriber and pharmacist is

a better approach in light of the voluntary nature of the Medicare Part D program.

We recognized in the proposed rule that certain medications are universally accepted in the health care community as not suitable to be dispensed in amounts less than a 30 days' supply (for example, lotions and other drugs not in solid form). Therefore, we proposed to further limit the requirement that sponsors establish and apply a daily cost-sharing rate to solid oral doses of drugs, except antibiotics or drugs which are dispensed in their original containers as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance (for example, steroid dose packs). However, unlike the long-term care dispensing requirements, we proposed that the daily cost-sharing rate requirement would apply to both brand and generic drugs.

Comment: Some commenters were strongly supportive of our proposal, recognizing as we do that, for Part D plans that use a copayment structure, there is currently no direct cost incentive for enrollees to obtain a less than 30 days' supply, and lauding the potential cost-savings to enrollees and the reductions of waste as a result of our proposal. A commenter fully endorsed our proposal, stating that its data led to the MaineCare program, and that after significant effort was put into addressing initial prescriber confusion, there were virtually no complaints by either prescribers or patients. This commenter disagreed, however, that a voluntary approach is the preferred method, asserting that clinical inertia for continuation of past prescribing habits and practices may erode our expectations on savings. A commenter estimated that our proposal could eliminate 1.5 billion pounds of pharmaceutical waste at its source (the preferred method for improving environmental health) and \$1 million in waste management cost savings, in addition to improving dispensing efficiencies in terms of time spent. A commenter asserted that an analysis of our proposal regarding the harmful effects on the environment should include recognition that humans are part of the environment and are adversely affected by the diversion, misuse, and abuse of unused drugs.

Response: We appreciate these supportive comments and estimates and agree that a daily cost-sharing requirement will lead to significant cost-savings and waste reduction in the Part D program. We have taken the

comments on prescriber education under advisement, but we continue to believe that the voluntary method is the best way to approach less-than-30-days' supply dispensing outside the LTC setting in the Part D program, although we acknowledge our opinion could change after experience with the voluntary method. We agree that reducing medication waste will reduce opportunities for medications to be diverted for misuse and abuse.

Comment: Some commenters stated that we should complete a more thorough, and prospective assessment of the potential impact of our proposal to understand the tradeoffs and implications before we proceed with it. Several commenters, while supporting our proposal's goal to reduce cost and waste, countered that it would increase dispensing fees and administrative and programming costs, some suggesting that these fees/costs would completely or more than offset any realized savings from the proposal. Another commenter stated that calculating the daily cost-sharing rate for each enrollee is tremendously burdensome by necessitating system changes at a substantial cost, stating that the administrative costs to Part D sponsors are the same regardless of whether the prescriber writes a prescription for a trial fill or a 30 days' fill, such that administering a trial fill differently than a complete fill will double the cost to Part D sponsors.

Response: We believe that we have sufficiently accounted for the tradeoffs and implications of the potential impact of our requirement, both in the proposed rule and in this final rule with comment period. In the preamble and the Regulatory Impact Analysis section of the proposed rule and this final rule with comment period, we specifically accounted for the additional dispensing fees, as well as the administrative and programming costs that we believe Part D sponsors will incur in implementing this requirement. Despite these costs, we continue to estimate savings in the hundreds of millions each year to the Part D program.

Comment: Some commenters, while also supportive of our proposal's goal to reduce fraud, waste and abuse in the Medicare Part D program, raised various operational concerns in implementing the proposal and requested a delay or phased-in approach. A commenter requested more clarification of what constitutes a trial fill. Some commenters recommended that we simplify our proposal by requiring the application of the daily cost-sharing rate whenever less than a month's supply of a covered Part D drug is dispensed (unless an

exception applies due to the type of drug involved), regardless of the reason, which would obviate the need to document the reason. Some commenters stated that applicable law permits pharmacists to dispense lesser quantities than written on certain prescription. Other commenters indicated that standard identifiers/fields would be needed for physicians, pharmacies, and plans to communicate regarding initial fills of new medications, beneficiary synchronization request and daily cost-sharing amounts. Some commenters pointed out that pharmacies have no reliable way to learn that a prescription is an initial trial supply of a new medication, since such information is not routinely conveyed on a prescription, and pharmacies would not be in a position to notify sponsors of this fact, even if coding were available.

Another commenter believed that having to capture information from enrollees could be difficult to reliably implement. Some commenters thought that our proposal would result in more frequent "refill too soon" DUR edits, including additional PDEs identified as duplicate, requiring review and justifications, which would result in greater workload for Part D plans. Commenters also noted that daily cost-sharing is not an industry standard in prescription drug coverage, and complications could arise in coordinating benefits with other prescription drug plans, such as in the case of Employer Group Waiver Plans (EGWPs). A commenter stated that our proposal may result in multiple prior authorizations for the same medication. A commenter noted that our proposal may complicate partial fill straddle claims and have PDE and TrOOP implications. A few of these commenters noted that lessons may be learned from implementation of the long-term care dispensing requirements at § 423.154, which are effective January 1, 2013.

Response: We were persuaded by these commenters that more time is needed for Part D sponsors, PBMs, their network pharmacies, and industry standard development organizations to work through the details of implementation of our requirement. We believe that proper programming will be crucial to address the technical issues that the commenters referenced, such as how to calculate cost-sharing when multiple payers are involved. For these reasons, we have delayed implementation of the daily cost-sharing rate requirement until January 1, 2014. In addition, we will work with the industry to develop subregulatory

guidance, if and as needed, to address technical questions arising upon implementation of the requirements, such as the implications for PDE submissions.

However, to the extent Part D sponsors wish to implement daily cost-sharing rates for contract year 2013, they may do so on a voluntary basis before then, for instance, if such implementation would assist them in complying with the LTC dispensing requirements, rather than waiting for any lessons that may be learned from such implementation, since Part D sponsors will have to address cost-sharing with respect to LTC dispensing in 2013.

In deciding to delay implementation of these requirements for 1 year, we were also persuaded by comments that we should simplify our requirement and apply it to all drugs dispensed for less than a month's supply. Without this simplification of the requirement, we agree that extraordinary processes would have to be created to obtain information about the reasons less than a month's supply is being dispensed. For instance, the parties involved in the prescription transaction (for example, health plans, PBMs and pharmacies) may not know when a prescription is an initial fill of a new medication, and this information is not necessarily readily available from the beneficiary or physician, whereas the days' supply is available from the prescription. Therefore, we are revising our requirement such that Medicare Part D sponsors will be required to provide their enrollees access to a daily cost-sharing rate for prescriptions dispensed by a network pharmacy for less than a 30-days' supply of covered Part D drugs (unless an exception applies due to the type of drug involved) regardless of the reason the prescriptions are so dispensed. This will obviate the need for health plans, PBMs, pharmacies, physicians, and beneficiaries to communicate the reasons for the less-than-30-day supply, and also make it unnecessary to specifically define "trial fill." This revision also takes into account our understanding that pharmacists, under applicable law, can currently dispense a smaller quantity than is written on certain prescriptions at a customer's request, and thus there may occasionally be other reasons for less than a month's supply to be dispensed than the three reasons we identified in the proposed rule. To be clear, the industry can still decide to develop coding in order to best manage these transactions, but none is required by this final rule with comment period.

Comment: A few commenters suggested we adopt a “copayment by days’ supply” structure with respect to plans that have a copayment structure, whereby Part D enrollees would be charged a set copayment amount based on a range of days dispensed, for example, a \$10 copayment for 1–10 days, and a \$20 copayment for 11–20 days and so on. These commenters asserted that, for a variety of reasons, this structure would be simpler to implement, including: (1) It would dovetail with the LTC dispensing requirements at § 423.154; (2) it would not require the maintenance of an exception drug list; and (3) it would enable Part D plans to more accurately model and predict drug costs.

Response: We decline to revise our requirement in the manner suggested by the commenters. We do not believe it would necessarily dovetail better with the LTC dispensing requirements than our requirement, as those requirements require the implementation of 14 days’ supply or less dispensing, and thus under the commenters’ suggested approach, copayments in an LTC facility could still vary. In addition, we do not believe our requirement will necessitate an exception drug list, as we discuss later in this section. Finally, we believe that creating additional multiple “copay tiers” based on the days’ supply dispensed, as suggested, would significantly increase beneficiary confusion in evaluating benefit packages, which already contain copayment tiers based on the type of drug.

Comment: Some commenters stated that Part D sponsor and network pharmacy interests should be aligned in terms of quality of patient care, reduction of waste and the associated savings with our proposal, such that the stakeholders should be able to work together to ensure that certain pharmacies do not game our proposal. Other commenters stated that pharmacies may dispense a prescription in multiple stages, even when it is not so prescribed, to generate additional dispensing fees, and that the net value of any anticipated offsets should include such manipulation.

Response: The proposed rule recognized the possibility of manipulation by network pharmacies to increase dispensing fees, and as noted previously, we urged the industry to develop appropriate coding so that the pharmacies could communicate the reason for dispensing less than a month’s supply, even though the reason is not required under our revised, simplified requirement, as described previously. Although we will not

mandate such coding, we do not think it would be unreasonable for sponsors to ask pharmacies to attest as to why a prescription was dispensed for less than a month’s supply. We would also expect that sponsors will implement contractual terms and auditing and other internal controls to detect and prevent fraud, waste, and abuse and to ensure that pharmacies are not inappropriately splitting prescriptions to increase dispensing fees, and thus costs to beneficiaries and the program. We further note that if pharmacies dispense prescriptions in stages merely in order to increase dispensing fees, they would have to have the cooperation of the affected beneficiaries, and we do not anticipate beneficiaries desiring less than a month’s supply of a medication, absent the recommendation of their physicians, to any significant degree, particularly given the potential inconvenience involved. Additionally, engaging in this activity may constitute fraud by the network pharmacy against the Part D sponsors involved and the Federal government, and we would expect sponsors to take action appropriate against such activity, such as terminating the pharmacy from its network. Consequently, we agree with the commenter that stakeholders’ interests should be aligned under our requirement, and we do not agree that potential additional dispensing fees would completely or even significantly offset potential savings associated with this requirement.

Comment: A commenter stated that the purpose of cost-sharing obligations is to provide beneficiaries with a financial connection with the health care service they receive, which assists in countering potential overutilization, and implied that reduced cost-sharing would be less effective in this regard.

Response: While we agree that cost-sharing obligations create a financial connection between beneficiaries and the health care services they receive, we disagree that our requirement would engender overutilization. On the contrary, under our requirement as revised, a beneficiary will pay the same cost-sharing for a month’s supply of medication dispensed in multiple stages that the beneficiary would otherwise pay.

Comment: Other commenters were concerned that Part D enrollees would be incentivized to obtain a lesser quantity of a medication than written by their physicians at the pharmacy counter in cases where the physician would not want the enrollee to take the medication on a trial basis, which would negatively affect the beneficiary’s

medication adherence. A commenter acknowledged that plans that utilize coinsurance structures already accommodate the concept of assessing a lower cost share when less than a month’s supply is dispensed, and did not indicate that this causes problems with adherence today.

Response: We are unclear what scenario the commenter is envisioning, but we presume it to be that a beneficiary who currently takes a medication will begin to take less because he or she will be able to pay lower cost-sharing for less than a month’s supply. We do not believe our requirement would cause more instances of this scenario than currently may be the case. As noted previously, it is our understanding that, if permitted under applicable law, pharmacists currently may dispense a lesser quantity than prescribed at a customer’s request, and we are not aware that this possibility negatively affects medication adherence today. In contrast to lower cost-sharing incentivizing beneficiaries to take less medication than they already do, we think lower cost-sharing is just as likely, if not more likely, to incentivize beneficiaries to begin taking medications they have avoided altogether due to cost-sharing.

Comment: A commenter stated that physicians are currently allowed to write prescriptions for a less than a month’s supply, and that reducing Part D enrollees’ copayments for such prescriptions will not incentivize physicians to do so more frequently.

Response: As noted previously, our requirement is directed at incentivizing beneficiaries, who actually pay the cost-sharing, to consider along with their prescribers, whether a less-than-30-days’ supply of a new medication would be appropriate. Indeed, we believe that prescribers are generally unaware of the copayments that their patients pay for prescriptions. To the extent that prescribers are aware of cost-sharing today, we would argue that prescribing patterns are currently influenced by the inflexible cost-sharing arrangements in prescription drug plans today, so it would not make sense for prescribers to write for shorter days’ supplies if the industry standard is to charge a whole month’s cost-sharing.

Comment: A commenter noted that Part D plans currently have in place member-friendly provisions that permit members to pay the lesser of the copayment amount or the cost of the particular Part D covered drug. Accordingly, if a prescriber were to write a prescription for a less than a month’s supply and the total cost were less than the member’s copayment, the

member would only be responsible for the lesser amount. The commenter asserted such provisions are a more appropriate way to ensure that members receive the benefit of a less than a month's supply option without increasing administrative burden to plans.

Response: We see these policies as complementary, not alternatives. We believe the lesser of copayment or cost will generally result in lower cost-sharing than monthly copayments for relatively less expensive drugs.

Comment: A commenter requested clarification on support in member documents, assuming that Plan Finder, Evidence of Coverage, and Summary of Benefits, would not include detailed information on daily cost-sharing rates, since they are not the norm.

Response: We intend to include language in future Medicare & You and the Part D Evidence of Coverage (EOC) documents on availability of daily cost-sharing rates and on when beneficiaries should consider taking advantage of them. We are currently reviewing the level of detail that we think is appropriate to be included in Summaries of Benefits, as daily cost-sharing rates are optional for the beneficiary under this requirement. At this point, we do not think that Plan Finder needs to add this level of complexity, since its purpose is to help beneficiaries compare costs of their current medications in different plans—not to price shortened days' supplies of new prescriptions.

Comment: A commenter was concerned that the proposal would be very confusing to beneficiaries, and that it is predicated on the belief that prescribers have actual knowledge if patients fill or refill prescriptions, and that there is an opportunity for these parties to have meaningful conversations about a medication's relative cost.

Response: As we noted in the preamble to the proposed rule, the decision to try a medication for less than a month's supply would generally be made by the Medicare Part D enrollee and his or her prescriber, and if an enrollee would have difficulty returning to the pharmacy, or even broaching the subject with his or her prescriber, then we believe he or she would not seek to obtain a smaller supply of a medication.

Comment: Some commenters believed our proposal would result in better adherence, specifically referencing that our proposal would greatly facilitate current efforts by community pharmacists to achieve better adherence through refill synchronization. Other commenters believed that medication

adherence would be negatively affected if Part D enrollees did not return to the pharmacy to pick up the next supply of a medication, when it was determined by their prescriber that the medication should be continued after an initial trial fill, for example. A commenter stated that our proposal seems to run counter to using adherence rates as a 5-star metric to measure the quality of a plan's clinical services, and that there is data in the literature that shows patients may not return to the pharmacy to fill the remainder of a prescription under circumstances envisioned by our proposal.

Response: We were persuaded by the comments that our requirement would assist pharmacists in synchronizing Part D medication refill dates. Also, as noted previously, the policy behind our requirement is to incentivize the appropriate elimination of unused medication that our data shows is already present in the Part D program. That is, a certain percentage of initial fills of maintenance medications for chronic conditions are not refilled by enrollees, and this indicates that the medications were not effective, tolerated, or continued, for whatever reason, and therefore presumably, a portion of the initial supply was not used, either. The commenter did not specify the referenced literature, so we are unable to review it, and we would note that, since daily cost-sharing rates are not the current industry standard, we are unclear on what data the literature would be based. We address star ratings later in this section.

Comment: A commenter stated that the prescriber writing two prescriptions is the method generally employed by community pharmacists to assist patients in synchronizing the refill dates of multiple prescriptions and would work for trial fills, as well.

Response: We appreciate the confirmation that this practice is already familiar to many prescribers and pharmacies.

Comment: A commenter disputed that many beneficiaries would be willing to undertake the analysis necessary to synchronize multiple prescriptions and coordinate with their prescribers' offices. Another commenter stated that beneficiaries can currently synchronize multiple medications over months, and that allowing refill-too-soon edits to be overridden could contribute to fraud, waste, and abuse. Another commenter requested additional clarification from CMS in terms of medications that beneficiaries are permitted to synchronize, how many times this may occur per year, what documentation would be needed, and what safeguards

plans may implement at point-of-sale to review such claims for fraud, waste, and abuse issues, etc.

Response: Our proposal acknowledged that Part D enrollees could take advantage of daily cost-sharing rates to synchronize multiple prescriptions on a voluntary basis, likely with pharmacists playing a role in assisting them, so we do not believe that our requirement should be modified because some enrollees will not take advantage of it to synchronize their medications. While beneficiaries may be able to synchronize medications currently, they are disincentivized from doing so under current cost-sharing structures that generally assume at least a month's supply will be dispensed. Under our revised, simplified requirement, as described previously, Medicare Part D sponsors will be required to provide their enrollees access to a daily cost-sharing rate for prescriptions dispensed by a network pharmacy for less than a 30 days' supply of covered Part D drugs (unless an exception applies due to the type of drug involved), regardless of the reason, unless fraud is suspected. We believe that beginning this requirement on January 1, 2014 will give sponsors sufficient time to appropriately program their systems to account for changes to refill-too-soon and other similar edits. Despite eliminating the requirement to apply a daily cost-sharing rate only in specific circumstances, such as for synchronization, we note that our policy does not prevent sponsors from developing coding requirements or other internal controls to ensure pharmacists are not splitting prescriptions to increase dispensing fees.

Comment: A commenter requested that additional information should be provided on the methodology that will apply when prescribers take advantage of our proposal to synchronize the dispensing dates of multiple medications, as this would impact the Adherence Measure in the Patient Safety Reports because of the different dispensing dates and alterations in days' supply of the medications, and classify a patient as not adherent, which would affect Star Rating Measures.

Response: Comments about the star ratings are outside the scope of this rulemaking, but we do not believe a daily cost sharing rate requirement would have any negative impact on our ability to measure medication adherence because, for example, if a Part D enrollee does not return to the pharmacy for the second fill, he or she will not be captured in the measure calculation (which requires at least two

fills of a drug in the classes measured for adherence). Also, we account for multiple fills for the same drug when the days supply overlap.

Comment: A commenter stated that our proposal should not apply to controlled substances because prorating cost-shares is not permitted. More specifically, this commenter stated that multiple prescriptions for the same controlled substance may not be permitted under state law, including post-dating one for future dispense, and that pharmacists cannot change quantities dispensed on prescriptions for controlled substances.

Response: To the extent that applicable Federal and/or State law prohibits two prescriptions from being written simultaneously for the same medication, a prescription from being refilled by a physician directly with the pharmacy, and/or a lesser quantity than was prescribed from being dispensed, our requirement would not supersede such law. Therefore, we have revised the regulation text so that the daily cost-sharing rate requirement applies to a prescription presented by an enrollee at a network pharmacy for a covered Part D generic or brand drug that may be dispensed for a supply less than 30 days under applicable law.

Comment: A commenter supported application of our proposal to LTC dispensing, asserting it would create consistency in the claims and billing processes, which could otherwise be chaotic if inconsistent approaches are adopted by Part D sponsors. Another commenter was opposed, stating strong concerns that LTC pharmacies would have to expend considerable staff time and cost creating paper invoices for extremely nominal amounts and collecting LIS fees, many of which go uncollected anyway.

Response: As noted previously, based on comments received, this requirement will not begin until January 1, 2014. However, Part D sponsors can voluntarily choose to apply a daily cost-sharing rate in the LTC setting in 2013 or not, or for that matter, in the retail setting or not. Beginning January 1, 2014, under our revised, simplified requirement, as described previously, Medicare Part D sponsors will be required to provide their enrollees with access to a daily cost-sharing rate when the covered Part D drug may be dispensed by a network pharmacy for less than a 30 days' supply (unless an exception applies due to the type of drug involved), regardless of the reason, unless fraud is suspected. Thus, there is no longer any reference to the LTC dispensing requirements in the regulation text. We note that, because

Part D sponsors must offer a uniform benefit, we are unable to exempt Part D enrollees residing in LTC facilities from the requirement. Moreover, we agree with the commenter who stated that a consistent approach among Part D sponsors in the LTC setting with respect to cost-sharing is ideal and note that our requirement does not address when daily cost-sharing amounts would have to be collected from LTC beneficiaries. Thus, LTC pharmacies and facilities may implement consolidated monthly cost-sharing collection irrespective of the cost-sharing methodology assessed on claims. We also note that the majority of Part D enrollees in LTC have no copays.

Comment: A commenter stated that LTC customers routinely request synchronization of patient medications for their residents and asked that we clarify that the ability to synchronize refills is available to LTC customers.

Response: Under our revised, simplified requirement, as described previously, the ability to synchronize refills will be available in LTC settings.

Comment: A commenter expressed support for LIS beneficiaries to continue making nominal copayments for prescriptions filled for less than a month and recommended that we consider capping total cost-sharing amounts for such beneficiaries who take multiple medications, since the combined cost of daily-cost-sharing could jeopardize the ability to comply with such prescription drugs regimens.

Response: Under our requirement, LIS enrollees would not pay any more in cost-sharing for a month's supply of medication than they would otherwise. However, we are revising our proposed definition of "daily cost-sharing rate" to make this clearer, as indicated by the underlining later in this final rule with comment period. Thus, with respect to copayments, "daily cost-sharing rate" is defined as "the established monthly copayment under the enrollee's Part D plan, divided by 30 or 31 and rounded to the nearest lower dollar amount, *if any*, or to another amount, but in no event to an amount *which would require the enrollee to pay more for a month's supply of the prescription* than would otherwise be the case." We have added the "if any" language specifically in recognition that some daily cost-sharing rates may be below \$1. We do not have authority under the statute to cap aggregate LIS cost-sharing, except as provided after the out-of-pocket threshold has been met.

Comment: Some commenters expressed concern about the effect of our proposal on the already very low cost-sharing payments of some Part D

enrollees. Commenters noted that, because many plans have cost-sharing on the preferred generic tier that is lower than the LIS brand cost-sharing, our proposal would cause the copayments of enrollees other than just LIS enrollees to be nominal, particularly with respect to generic medications, and with respect to some dual-eligibles, and the copayments might even round down to \$0, depending upon on the days supply prescribed by the prescriber. Several commenters asserted that generics should be exempted from our proposal due to their low-cost-sharing and the cost associated with dispensing them. A commenter offered an alternate proposal for LIS enrollees, which was to require Part D sponsors to offer a 15 days' supply for half the normal copayment since dividing their already nominal copayments by 30 days could be impractical.

Response: While we recognize that generics are generally associated with low cost-sharing, not all generics may be, and we believe our requirement should apply to all medications (unless an exception applies due to the type of drug involved). Moreover, the MaineCare program cited previously achieved savings even with the inclusion of generic drugs. We also remind stakeholders that our requirement applies to Part D sponsors, but beneficiaries are not required to avail themselves of this option. Therefore, if beneficiaries are not sufficiently incentivized by the lowered cost-sharing applicable to a less-than-month's supply of medication, they presumably will not ask their prescribers to write a prescription for less than a month's supply or their pharmacists to dispense one. Even if beneficiaries do ask in some instances, the volume of unused drugs that must be discarded will be reduced, even if the costs are not less. Nevertheless, we expect this requirement, even as revised, to be most attractive to enrollees when their drugs are relatively more expensive and for maintenance medications for chronic conditions. We do not believe that that these nominal cost-sharing scenarios would occur very often. However, recognizing that this requirement may result in nominal cost-sharing amounts for a less than month's supply, or none, if Part D sponsors choose to round the applicable copayment down to \$0, we have added, "if any" after "rounded to the nearest lower dollar amount," in the definition of "daily cost-sharing rate." This change recognizes that, in the case of LIS enrollees, or other enrollees for that matter, there will not be a "lower dollar

amount” when making the calculation required by the definition if the “established monthly copayment” is lower than the \$30 to \$31 range.

Comment: A commenter stated that if a plan’s preferred generic cost share is \$2, the pro-rated cost share would be \$.46 for a 7 days’ supply of the medication, which would be rounded up to \$1, so the enrollee would be paying half the regular cost-share for a 1 week supply.

Response: The commenter is not correct. Under our proposed definition of “daily cost-sharing rate,” as applied to a monthly copayment, \$2 would be divided by 30 (or 31) and then rounded to the nearest lower dollar amount (\$0), or to another amount (for example, \$0.06), but in no event to an amount which would require the enrollee to pay more for a month’s supply than would otherwise be the case. In other words, the Part D sponsor can alternatively choose to round to \$0.06 or \$0, since another figure, for instance \$0.07, is a daily cost-sharing rate (or any higher amount) that, when applied to a 30 days’ supply, would cause the enrollee to pay \$2.10 (or more) for a 30 days’ supply, which is not permitted under the proposed definition. Thus, the copayment for a 7-day supply in this example (based on 30 days being a month’s supply) would be \$0.42 or \$0. We note that this definition also does not allow for rounding to the higher dollar amount, as was done in the example given by the commenter. However, for further clarity, we have further revised the regulation text to add the word “lower.”

Comment: Some commenters requested that we provide more rounding guidance.

Response: We will consider addressing rounding in more detail in guidance, and we will consider suggestions from the industry as appropriate in the development of any such guidance.

Comment: A commenter stated that including the coinsurance calculation in the definition of “daily cost-sharing rate” is incorrect and unnecessary, because a coinsurance percentage already applies to the allowed amount (for example, sum of ingredient cost, dispensing fee, vaccine administration fee, and sales tax). A commenter requested clarification that for drug tiers using coinsurance, the proposal would result in no change in the coinsurance percentage as enrollee cost-sharing would simply be determined via mathematics, as well as our expectations on “daily cost-sharing rates” for plan designs that include

coinsurance with a minimum, maximum, or both.

Response: We agree and have revised § 423.100 and § 423.153(b) accordingly so that, with respect to coinsurance, “daily cost-sharing rate” is defined as the established coinsurance percentage under the enrollee’s Part D plan, and so that it is not multiplied by the days supply actually dispensed. We also confirm that coinsurance percentages would not change under our requirement, nor would minimum or maximum coinsurance amounts be affected, if applicable to an enrollee’s Part D plan.

Comment: A commenter asked for clarification on whether 30 or 90 days should be used to calculate the daily cost-sharing rate for copayments for Part D LIS enrollees.

Response: Since a month’s supply is typically a 30 to 31 days’ supply, the proposed definition of “daily cost-sharing rate” is based on a month’s supply which consists of 30 or 31 days, regardless of whether the enrollee is an LIS enrollee or not.

Comment: Several sponsors asked how dispensing fees would be prorated.

Response: If the dispensing fee is included in the copayment, it will be “prorated” by virtue of the copayment being divided under the calculation in § 423.100 (definition of daily cost-sharing rate) to establish a daily cost-sharing rate in case of a copayment. With respect to coinsurance, § 423.100 defines the daily cost-sharing rate as the established coinsurance percentage under the enrollee’s Part D plan. Thus, to the extent that the established coinsurance percentage is applied to the dispensing fee, the beneficiary will be liable for the specified coinsurance percentage of the dispensing fee for each fill. Therefore, beneficiaries may have a higher liability under a shorter fill for a given month if the beneficiary has to pay his/her share of a dispensing fee multiple times under a coinsurance arrangement.

Comment: Several commenters asked how they should account for daily-cost sharing in their annual bids.

Response: We believe that Part D sponsors have the requisite actuarial expertise to adequately estimate the potential effects on utilization and costs generated by our requirement for their annual bids. Previously, we stated that our savings assumptions were highly uncertain, because it is very difficult to predict beneficiaries’ behavioral response. However, we were able to estimate savings based on our data on first fills for chronic medications that are not refilled, removing costs associated with the LTC setting, and

then making some assumptions about beneficiaries’ response to the daily cost-sharing rate requirement, while accounting for additional dispensing fees, which we described previously. We believe sponsors’ actuaries will undertake a similar analysis to account for the daily cost-sharing rate requirements in Part D plan bids.

Comment: A few commenters requested that a list of drugs excepted from the daily cost-sharing rate requirement be provided by CMS or claims processors.

Response: As we noted previously, we do not believe our requirement will cause the need for an exception drug list. The daily cost-sharing rate requirement would apply to solid oral doses of drugs that may be dispensed for a supply less than 30 days under applicable law, except antibiotics or drugs which are dispensed in their original containers as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance (for example, steroid dose packs). However, unlike the long-term care dispensing requirements which apply only to brand drugs, we are proposing here that the daily cost-sharing rate requirement would apply to both brand and generic drugs. We believe the industry has the expertise to administer this policy without our assistance.

Comment: A commenter stated that certain drug therapies in solid oral dosage forms are inappropriate for dispensing in less than 30 days’ supplies, because they take longer to be effective.

Response: We believe prescribers will know when writing for a limited days supply is appropriate and will not do so when not clinically appropriate.

After consideration of the public comments received, we are finalizing our daily cost-sharing rate proposal with the following modifications previously noted. Therefore, we have revised the definition of “daily cost-sharing rate” in § 423.100. “Daily cost-sharing rate” means, as applicable, the established—(1) monthly copayment under the enrollee’s Part D plan, divided by 30 or 31 and rounded to the nearest lower dollar amount, if any, or to another amount, but in no event to an amount that would require the enrollee to pay more for a month’s supply of the prescription than would otherwise be the case; or (2) coinsurance percentage under the enrollee’s Part D.

In addition, we will revise § 423.104 by adding a paragraph (i) to state that a Part D sponsor is required to provide its

enrollees access to a daily cost-sharing rate in accordance with § 423.153(b)(4). Section 423.153(b) currently requires a Part D sponsor to establish a reasonable and appropriate drug utilization management program. We will revise § 423.153(b) by adding a new paragraph (4). Paragraph (4)(i) will require a drug utilization management program to establish and apply a daily cost-sharing rate to a prescription presented to a network pharmacy for a covered Part D drug that is dispensed for a supply of less than 30 days, and in the case of a monthly copayment, multiplied by the days supply actually dispensed. Paragraph (b)(4)(i)(A) would limit the

requirement to drugs that are in the form of solid oral doses and may be dispensed for a supply less than 30 days under applicable law. Paragraph (b)(4)(i)(B) would state that the requirements of (b)(4)(i) would not apply to antibiotics or drugs dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance.

E. Clarifying Program Requirements

We have worked with MA organizations and Part D sponsors to

implement the Medicare Advantage and Prescription Drug Benefit Programs since the inception of these programs. As part of this partnership, we have implemented operational and/or policy guidance via HPMS memoranda or manuals instruction to assist MA organizations and Part D sponsors in ensuring the proper and efficient administration of the Part C and D programs. In this section, we are finalizing provisions that codify some of that guidance and provide other definitive direction on policy issues in order to address requests from stakeholders. These proposals appear in Table 6.

TABLE 6—PROVISIONS TO CLARIFY PROGRAM REQUIREMENTS

Preamble Section	Provision	Part 417		Part 422		Part 423	
		Subpart	Section	Subpart	Section	Subpart	Section
II.E.1	Technical Corrections to Enrollment Provisions.	Subpart K	417.422 417.432	Subpart B	422.60	Subpart B	423.56
II.E.2	Extending MA and Part D Program Disclosure Requirements to Section 1876 Cost Contract Plans.	Subpart K	417.427	N/A	N/A	N/A	N/A
II.E.3	Clarification of, and Extension to Local Preferred Provider Plans, of Regional Preferred Provider Organization Plan Single Deductible Requirement.	N/A	N/A	Subpart C	422.101	N/A	N/A
II.E.4	Technical Change to Private Fee-For-Service Plan Explanation of Benefits Requirements.	N/A	N/A	Subpart E	422.216	N/A	N/A
II.E.5	Application Requirements for Special Needs Plans.	N/A	N/A	Subpart K	422.500 422.501 422.502 422.641 422.660	N/A	N/A
II.E.6	Timeline for Resubmitting Previously Denied MA Applications.	N/A	N/A	Subpart K	422.501	N/A	N/A
II.E.7	Clarification of Contract Requirements for First Tier and Downstream Entities.	N/A	N/A	Subpart K	422.504	Subpart K	423.505
II.E.8	Valid Prescriptions.	N/A	N/A	N/A	N/A	Subpart C	423.100 423.104
II.E.9	Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings.	N/A	N/A	N/A	N/A	Subpart D	423.153
II.E.10	Employer Group Waiver Plans Requirement to Follow All Part D Rules Not Explicitly Waived.	N/A	N/A	N/A	N/A	Subpart J	423.458
II.E.11	Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers.	N/A	N/A	N/A	N/A	Subpart C	423.120

1. Technical Corrections to Enrollment Provisions (§ 417.422, § 417.432, § 422.60, and § 423.56)

In our October 11, 2011 proposed rule we proposed a number of technical corrections to our enrollment regulations (76 FR 63056). Specifically we proposed the following changes:

- At § 417.422(d) (Eligibility to enroll in an HMO or CMP) and § 417.432(d) (Conversion of enrollment) we proposed to remove references to signatures thereby ensuring that all of our regulations conform with allowing cost

plans to utilize alternate enrollment mechanisms.

- At § 422.60(c) (Election process) we proposed to revise an outdated cross-reference.

- At § 423.56 (Procedures to determine and document creditable status of prescription drug coverage) we proposed to remove an outdated reference to the Annual Coordinated Election Period.

We received no comments on these proposals, and therefore, are finalizing this provision without modification.

2. Extending MA and Part D Program Disclosure Requirements to Section 1876 Cost Contract Plans (§ 417.427)

In our April 2010 final rule (75 FR 19783 through 19785), we exercised our authority under sections 1876(c)(3)(C) and 1876(i)(3)(D) of the Act to extend the MA marketing requirements to section 1876 cost contract plans. Under section 1876(c)(3)(C) of the Act, we may regulate marketing of plans authorized under section 1876 of the Act to ensure that marketing material is not misleading. Section 1876(i)(3)(D) of the

Act gives the Secretary the authority to impose “other terms and conditions” under contracts authorized by the statute that the Secretary finds “necessary and appropriate.” As a result, since contract year 2010, cost plan contractors have been required to follow all marketing requirements specified in Subpart V of Part 422, with the exception of § 422.2276, which permits an MA organization to develop marketing and informational materials specifically tailored to members of an employer group who are eligible for employer-sponsor benefits through the MA organization, and waives requirements to review such materials. In our April 2010 final rule (75 FR 19785), in which we discuss extending MA marketing requirements to cost contracts, we note that the statutory authority under section 1857(i)(1) of the Act, which permits the Secretary to waive certain requirements for employer group plans under the MA program, does not apply to cost plans.

In extending the marketing requirements to cost contract plans in our April 2010 final rule, we neglected to extend the MA organization and Part D sponsor disclosure requirements, at § 422.111 and § 423.128, respectively, to cost contract plans. As we specified in the proposed rule, we believe that extending these provisions would also be appropriate, given the close relationship between the marketing requirements in Subpart V of Parts 422 and 423 and the disclosure requirements at § 422.111 and § 423.128. These provisions require MA organizations and Part D sponsors to disclose to enrollees, at the time of enrollment and annually thereafter (in the form of an annual notice of change/evidence of coverage, or ANOC/EOC mailing), certain detailed information about plan benefits, service area, provider and pharmacy access, grievance and appeal procedures, quality improvement programs, and disenrollment rights and responsibilities. They also require the provision of certain information and establish requirements with respect to: (1) The explanations of benefits notice, (2) customer service call centers, and (3) Internet Web sites. Thus, these requirements are closely tied to the marketing requirements of Subpart V of Parts 422 and 423. In order to ensure that cost contract plan enrollees have all the information they need about their health care benefits, we believe that cost contract plans should also be subject to all the same disclosure requirements as MA organizations and Part D sponsors. Therefore, we proposed to extend the

disclosure requirements in § 422.111 and § 423.128 to cost contract plans by adding a new § 417.427.

Comment: A commenter supported the provision as specified in the proposed rule.

Response: We thank the commenter for its support.

Comment: A few commenters believe the effective date of 60 days after publication of the final rule does not allow enough time for Medicare cost contract plans to implement the new requirements and that the requirements instead should become effective no sooner than for the 2013 annual election period (that is, in the Fall of 2012).

Response: Although the provisions of the rule are effective 60 days after publication of the rule, the disclosure requirements are primarily carried out through the ANOC/EOC, so we would indeed expect that the disclosure requirements would be implemented during the 2013 annual election period (Fall of 2012), the first such period after the effective date of the regulations.

Comment: A commenter stated that changing the ANOC/EOC delivery date from December 1 to 15 days prior to the beginning of the annual election period would not be appropriate for cost contract plans that include only Medicare benefits, (that is, no supplemental benefits). The commenter stated that CMS may not have released the applicable deductible amounts for the following contract year at the time the ANOC is required to be distributed, which is a significant issue because some cost plans mirror Original Medicare cost-sharing amounts.

Response: We will continue to require that cost plans not offering Part D send the ANOC for member receipt by December 1. It was not our intention to change this date for cost plans. We will clarify this in forthcoming plan guidance. All cost plans offering Part D must currently follow the MA ANOC timelines, and must send the ANOC for member receipt 15 days before the beginning of annual coordinated election period.

Comment: A commenter notes that, contrary to the MA disclosure language at § 422.111(b)(7), which states that non-contract providers submit claims to the MA organization, non-contract providers would submit claims to the Medicare administrative contractor (MAC), not the cost contract plan. The commenter asks that we address this issue in the regulation by establishing a waiver process for MA provisions that do not apply to cost contract plans.

Response: We will clarify in the cost contract plan EOC that, in most instances, non-contract providers

should submit claims to the MAC, and not directly to the cost contract plan. Therefore, we do not believe that it is necessary to establish a general exceptions process to waive MA requirements.

After consideration of the public comments received, we are finalizing the policy without modification.

3. Clarification of, and Extension to Local Preferred Provider Plans, of Regional Preferred Provider Organization Plan Single Deductible Requirement (§ 422.101)

Section 1858(b) of the Act provides that, to the extent RPPO plans use a deductible, any such deductible must be a single deductible, rather than separate deductibles for Parts A and Part B benefits. This single deductible may be applied differentially for in-network services and may be waived for preventive or other items and services. Our regulations at § 422.101(d)(1) track the language in the statute closely. They require that RPPO plans, to the extent they apply a deductible, apply only a single deductible related to combined Medicare Part A and Part B services. They also allow the single deductible to apply only to specific in-network services and to be waived for preventive services or other items and services, at the plan's option. However, both the statute and our regulations are silent with respect to any deductible requirements for local preferred provider organization (LPPO) plans. Consequently, in practice, LPPO plans may have a variety of deductible designs, including separate in-network and out-of-network deductibles.

We proposed to make three changes to our regulations at § 422.101(d)(1) to both clarify current requirements with respect to the application of a single deductible and to level the playing field between LPPO and RPPO plans by extending the RPPO rules to LPPOs. Specifically, we proposed to clarify the application of the single deductible differential for in-network services and modify our current regulations to take into account recent rulemaking under which MA plans must provide certain Medicare-covered preventive services at zero cost sharing. We proposed to rely upon our authority at section 1856(b)(1) of the Act to establish MA standards by regulation, and in section 1857(e)(1) of the Act to impose additional terms and conditions, found necessary and appropriate, to extend the RPPO single deductible requirements by regulation to LPPOs. We believe that having the same rules for LPPOs and RPPOs supports transparency and comparability of options for

beneficiaries when they evaluate and select plans for enrollment. In previous rulemaking, we took steps to align the plan design requirements for RPPOs and LPPOs. For example, in our April 2010 final rule (76 FR 21507 through 21508) that made revisions to the MA and Part D programs for CY 2012, we extended the same maximum out-of-pocket (MOOP) and catastrophic limits we had previously codified for LPPOs (75 FR 19709 through 19711) to RPPOs. In the interest of transparency, alignment in benefit design between RPPO and LPPO plans, and comparability for beneficiaries making health care coverage elections, we proposed to extend to LPPOs the single deductible requirements at § 422.101(d)(1). We would clarify the rules that would now apply to both LPPO and RPPO plans as set forth later in this section.

As discussed previously, we proposed to clarify at § 422.101(d)(1) that an LPPO or RPPO single deductible “may be applied differentially for in-network services,” as provided under section 1858(b) of the Act. We currently furnish interpretive guidance and examples of the application of the single deductible in section 50.3 of Chapter 4 of the Medicare Managed Care Manual, “Benefits and Beneficiary Protections” <http://www.cms.gov/manuals/downloads/mc86c04.pdf>). However, we believe there may still be confusion with respect to how these requirements are articulated in our regulations and therefore proposed amending § 422.101(d)(1) to add paragraphs (i) through (iii) clarifying that an RPPO or LPPO that chooses to apply a deductible may both—

- Specify different deductibles for particular in-network Parts A and B services, provided that all of these service-specific deductibles are applied to the overall, single plan deductible; and
- Choose to exempt, that is, exclude, specific plan-covered items or services from the deductible. That is, the LPPO or RPPO may choose to always cover specific items or services at plan-established cost-sharing levels regardless of whether the deductible has been met. For example, under our regulations, an LPPO or RPPO could establish a single combined deductible of \$1,000 but limit the amount of the deductible that applies to in-network inpatient hospital services to \$500, and the amount that applies to in-network physician services to \$100. This LPPO or RPPO could also choose to exclude particular in-network services from application of the deductible altogether; for example, all in-network home health

services would not be subject to the deductible.

In our April 2011 final rule (76 FR 21475 and 21476), we established a new requirement for MA organizations to provide certain in-network Medicare-covered preventive benefits at zero cost sharing. As provided under § 422.100(k), MA organizations, including those offering PPO plans, may not charge deductibles, copayments, or coinsurance for in-network Medicare-covered preventive services specified in § 410.152(l). Therefore, we will now require both LPPO and RPPO plans to exclude preventive services from the single deductible at § 422.101(d)(1), and will add a new paragraph § 422.101(d)(1)(iv) that explicitly requires LPPO and RPPO plans to exclude certain Medicare-covered preventive services (as defined in § 410.152(l)) from the single, combined deductible.

Comment: A commenter supported CMS’ proposed clarification of the rules for RPPO plans with a deductible.

Response: We thank the commenter for its support.

After consideration of the public comment received, we are finalizing the proposed clarifications of the RPPO deductible and extension of deductible rules to local PPO plans without modification.

4. Technical Change to Private Fee-for-Service Plan Explanation of Benefits Requirements (§ 422.216)

In our April 15, 2011 final rule (76 FR 21504 through 21507) implementing changes to the MA and Medicare Prescription Drug Programs for Contract Year 2012, we finalized regulations at § 422.111(b)(12) giving us the authority to require MA organizations to furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits, when benefits are provided under this part. We expressed our intention to work with MA organizations, Part D sponsors, and beneficiary advocates to develop an Explanation of Benefits (EOB) for Part C benefits and to test the EOB in CY 2012 through a small, voluntary pilot program. In our April 2011 final rule (76 FR 21505), we also stated our intention to finalize a model EOB in the future, based on the results of the pilot program and to require all MA organizations to periodically send an EOB to enrollees for Part C benefits.

We did not specifically discuss private fee-for-service (PFFS) plans in our April 2010 final rule because section 1852(k)(2)(c) of the Act and § 422.216(d)(1) already require PFFS

plans to provide an EOB to enrollees. Our current regulations at § 422.216(d)(1) specify that PFFS plans must provide an appropriate EOB to plan enrollees for each claim filed by the enrollee or the provider that furnished the service. The explanation must include a clear statement of the enrollee’s liability for deductibles, coinsurance, copayment, and balance billing. In the interest of consistency for beneficiaries and MA organizations, we proposed—in our October proposed rule—to amend § 422.216(d)(1) to state that the EOB requirement for PFFS plans will be consistent with the MA EOB requirements of § 422.111(b)(12). The standard EOB that we are currently developing and piloting for most of the other MA plan types will include the same information as currently required for PFFS plans, as well as plan maximum out-of-pocket (MOOP) cost information. Adding this cross-reference to § 422.216(d)(1) would provide consistency in EOB requirements as well as submission and approval of marketing materials across plan types. Since the pilot program is in progress during the CY 2013 rule development cycle and we would not have finalized EOB requirements based on the pilot prior to publication of the CY 2013 final rule, we proposed that PFFS plans would continue to furnish EOBs as they have been, in accordance with § 422.216(d)(1), until we finalize and implement EOB models for all MA plans.

We did not receive any comments on this provision in the proposed rule; therefore, we are finalizing this technical change as proposed.

5. Application Requirements for Special Needs Plans (§ 422.500, § 422.501, § 422.502, § 422.641, and § 422.660)

Section 1859(f) of the Act and its implementing regulations specify several requirements for Special Needs Plans (SNPs). MA organizations that would like to offer a SNP are required to engage in an intensive application process to demonstrate that they meet these SNP specific requirements, including the requirement in § 422.101(f) that MA organizations offering a SNP implement an evidence based model of care (MOC) to be evaluated by NCQA; the requirement in § 422.107 that Dual Eligible SNPs (D-SNPs) have a contract with the State Medicaid Agencies in the States in which they operate; and the requirement in § 422.152(g) that SNPs conduct a quality improvement program. SNP applicants follow the same process in accordance with the

same timeline as applicants seeking to contract as MA organizations.

Accordingly, we proposed to broaden the regulations on Medicare Advantage (MA) Application Requirements and Evaluation and Determination Procedures, in accordance with section 1859(f) of the Act, to apply to SNP applicants. Specifically, we proposed to revise the language in § 422.500(a) and § 422.501(a) to specify that the scope of these provisions include the specific application requirements for SNPs. We also proposed to add paragraph (iii) to § 422.501(c)(1) to specify the documentation SNP applicants must provide to complete an application. Furthermore, we proposed to revise § 422.502(a) and § 422.502(c) to specify that our regulations on application evaluations and determinations apply to SNP applications.

Additionally, in accordance with section 1859(f) of the Act, we proposed to provide explicit appeal rights to each applicant that has been determined unqualified to offer a SNP for failure to meet the requirements in section 1859(f) of the Act and its implementing regulations. To do so, we proposed adding a new paragraph (d) to § 422.641, a new paragraph (a)(5) to § 422.660, and a new paragraph (b)(5) to § 422.660. We believe these proposed changes will ensure that only MA organizations capable of meeting the requirements to serve Special Needs Individuals are able to target their enrollment to this vulnerable population, while also affording each MA organization that has been determined unqualified to offer a SNP the opportunity to have this decision reviewed by an impartial hearing officer.

Comment: Commenters expressed their support for our proposals to ensure that SNP applicants have the same rights and responsibilities as other MA contract applicants. A commenter specifically noted its support for consistent rules for all MA options.

Response: We appreciate the commenters' support for this provision, which makes the rules and appeal rights for SNP applicants consistent with the rules governing the MA contract application and appeals process.

Comment: A commenter recommended that we add language to our application regulations to ensure that an entity that has applied as a SNP is presumed to have applied as an MA plan. The commenter thought that such language would be necessary so that the MA organization could operate an MA plan in the event that the MA organization is not able to meet the SNP application requirements necessary to operate a SNP.

Response: It has been CMS' longstanding policy that, in order to offer a SNP, an MA organization must also apply and be approved to offer an MA Coordinated Care Plan (CCP) in the service area in which it would like to offer a SNP. (Please note that a prior year's MA application approval is sufficient to meet this requirement. The plan is not required to submit a new MA application if it has been previously approved to offer a CCP in the service area in which it is applying to offer a SNP.) Accordingly, if an approved MA organization's SNP application is denied, the plan is nonetheless still authorized to bid to offer an MA plan for the upcoming contract year. If an MA organization is applying to offer an MA CCP that is also a SNP, and the SNP application is denied, the MA organization's MA application must still be approved. As such, the language requested by the commenter will not be added to the regulatory text and we will finalize the policy without modification.

Comment: A commenter requested that we modify our substantive regulations on the SNP MOC approvals to specify that SNPs can be approved for multiple years. Another commenter encouraged CMS to provide States with operational support and regulatory guidance regarding the D-SNP State contract requirements.

Response: While we appreciate these suggestions, the MOC approval regulations and D-SNP State contract requirements are outside the scope of this regulation. We will consider these suggestions as we develop future rulemakings and guidance.

After review of the public comments, we are finalizing our proposal without modification.

6. Timeline for Resubmitting Previously Denied MA Applications (§ 422.501)

Section 1857(a) of the Act requires organizations that wish to participate in the MA program enter into a contract with the Secretary under which the organization agrees to comply with all applicable MA program requirements and standards. In order for us to determine whether these program requirements and standards have been met, the organization must complete an application in the manner described at Subpart K of part 422. Section 422.501 sets forth the required elements of such an application. Under § 422.501(e), entities that are seeking to contract with the Secretary as an MA organization may not resubmit an application that has been denied by CMS for 4 months following CMS' denial. This 4-month prohibition on resubmitting a previously-denied application is

obsolete and inconsistent with current agency practices, as we presently operate on an annual application cycle. In order to align § 422.501 with current procedures, we proposed revising paragraph (e) to clarify that every organization seeking to become an MA organization must wait until the application cycle for the following contract year to resubmit an application that was previously denied in the current contract year's application cycle.

Comment: A commenter recommended that if a SNP application is denied, the plan should be presumed to have applied for an MA plan; thus, if the application meets MA requirements, the plan will not have to reapply as such.

Response: We have addressed the commenter's concern that a SNP application shall be presumed to be an MA application and approvable if it meets the MA requirements in the comment and response for our provision on applications for SNPs in section II.E.5. of this final rule with comment period.

Comment: The commenter also expressed its support for extending appeal rights to denied SNP applications.

Response: SNP application requirements and appeal rights are outside the scope of this provision.

After consideration of the public comments received, we are finalizing the policy without modification.

7. Clarification of Contract Requirements for First Tier and Downstream Entities (§ 422.504 and § 423.505)

The regulations at § 422.504(i) and § 423.505(i) require MA organizations and Part D sponsors to require all of the first tier, downstream, and related entities to which they have delegated the performance of certain Part C or D functions to agree to certain obligations. In particular, the regulations require sponsors to have "contracts or written arrangements" that provide, for example: (1) For the delegated entity to carry out its contract in a manner consistent with the sponsor's Medicare contract obligations; (2) that the sponsor may revoke the contract if the sponsor determines that the delegated entity has not performed satisfactorily; and (3) that the sponsor on an ongoing basis monitors the performance of the delegated entity. We believed it was clear that the language of § 422.504(i) and § 423.505(i) required that all contracts governing the relationships among a sponsor and all of its delegated entities (that is, those between the

sponsor and its first tier entity; those between the first tier entity and any downstream entity; and those between downstream entities) contain provisions specifically addressing each of the required elements stated in the respective paragraphs. That is, each contract was required to contain “flow down” clauses through which each delegated entity would become legally obligated to honor the provisions of § 422.504(i) and § 423.505(i).

In the solicitations for applications for qualification of MA organizations and Part D sponsors, we instructed applicants that all contracts with delegated entities provided for our review must include language addressing all of the elements stated in § 422.504(i) and § 423.505(i). We took this position because: (1) We believed that the requirement was clearly stated in the regulation; and (2) as the sponsor cannot enforce a contract to which it is not a party (that is, it has no privity of contract with its downstream entities), the only way to give the provisions of § 422.504(i) and § 423.505(i) full effect is to require that each subcontract specifically describe the delegated entity's obligations to the sponsor.

This interpretation was challenged in 2010 by an organization whose Part D sponsor qualification application was denied when we determined, among other things, that the contract between the applicant's first tier and downstream entities incorrectly made reference to the rights of the first tier entity, rather than the applicant, in the contract sections the applicant intended to meet the requirements of § 423.505(i). While the hearing officer upheld CMS' denial of the application, in the interest of providing transparency and clarity for the healthcare industry, we have decided to amend the regulation. The changes to the regulation will help future applicants avoid confusion about the requirements related to contracts with first tier and downstream entities, thus helping to streamline the application process.

We believe that the most legally effective and direct way to ensure that the MA organizations and Part D sponsors retain the necessary control and oversight over their delegated entities is by requiring all contracts among those entities to specifically reference each party's obligations to the sponsor, as enumerated in § 422.504(i) and § 423.505(i). Documents or “written arrangements” other than contracts can be ambiguous as to the nature of an obligation and who has agreed to perform it. They are unreliable tools for the protection of the rights of sponsors with respect to the performance of their

Medicare obligations by their delegated entities. Assurances from delegated entities that they will provide necessary instructions to other downstream entities should the need arise are equally ineffective as they provide no evidence that the downstream entity could be compelled to follow such instructions. Therefore, we proposed to make explicit that sponsors can fulfill the requirements of § 422.504(i) and § 423.505(i) only by providing evidence that the contract of every first tier or downstream entity contains provisions stating clearly that the parties have agreed to recognize and give effect to the sponsor's rights as listed in those subsections. Accordingly, we proposed to delete the term “written arrangements” throughout § 422.504(i) and § 423.505(i) and in each instance replace it with “each and every contract.”

Comment: An MA organization expressed its concern about the use of the term “contract” throughout the proposed regulatory change. The organization noted that the term was too narrow and appeared to exclude less formal arrangements that sponsors use to meet their Part C and D obligations. For example, some organizations use related parties (for example, another subsidiary of their parent organization) to perform delegated functions and those relationships may be governed by something other than a contract.

Response: We believe that the term “contract” best expresses the nature of the arrangements sponsors must have in place to meet the requirements of § 422.504(i) and § 423.505(i). Therefore, we are retaining the proposed language in the final rule. Nonetheless, we acknowledge that organizations may meet the requirements through the use of documents that may not be expressly labeled as “contracts.” These may include letters of agreement or intercompany agreements. Sponsors must simply make certain that the documents they use to memorialize the functions delegated to their first tier, downstream, or related entities contain language that clearly describes an enforceable set of plan sponsor rights and subcontractor obligations to the sponsor, regardless of whether the sponsor is a party to the agreement.

Comment: An MA organization asked that CMS provide more information about the deficiency that led to the application denial discussed in the proposed rule.

Response: More discussion of the facts of the application denial appeal is provided in the CMS Hearing Officer's opinion, *In the Matter of Stonebridge Life Insurance Company, Inc., Denial of*

Application, S3502, Docket No. 2010 C/D App. 7. The opinion is posted on the CMS Web site at https://www.cms.gov/Medicare-Advantage-Prescription-Drug-Plan-Decisions/downloads/2010_CD_App_7.pdf.

Comment: A commenter requested that CMS clarify that sponsors are not required to directly monitor the performance of all downstream entities to which they have delegated functions but with which they do not directly contract.

Response: The commenter is technically correct that the regulations only require that the contracts that govern the delegated functions among the sponsor's first tier, downstream, and related entities contain provisions expressly granting the sponsor the authority to perform oversight of the activities of the subcontractors. The regulations do not require the sponsor to exercise that authority. That said, we remind sponsors that the Part C and D regulations require them to adopt and implement an effective compliance program which provides for, among other things, the sponsor to establish an effective system for monitoring and auditing its first tier and downstream entities to ensure their compliance with our requirements. We encourage all sponsors to review their compliance program activities to make certain that their methods for oversight of their subcontractors are effective in holding them accountable for Part C and D functions performed on the sponsors' behalf.

Comment: A commenter requested that CMS provide model contracting language that meets the subcontracting requirements discussed in the proposed provision.

Response: The arrangements between a plan sponsor and its first tier, downstream and related entities are subject to considerable variation from sponsor to sponsor. Accordingly, the contracts governing the arrangements must be tailored to reflect their particular features. For example, some arrangements may require a unique contract where the plan sponsor is specifically named in the document while others can be served through a contract template used by a subcontractor that serves multiple plan sponsors and the sponsors are identified by proper reference to another document. We believe that it would be, at best, not useful for CMS to provide model language and at worst, counterproductive as it could create the temptation for sponsors to use the model language in their contracts when a specially-tailored set of terms is needed to properly govern their unique

arrangements and to meet the Part C and D program requirements.

Comment: A commenter requested that CMS require MA organizations to provide to their first tier and downstream entities a copy of the organization's Part C contract with CMS. The commenter stated that such a requirement would be useful to subcontractors perform their delegated functions in a manner consistent with the MA organization's contract with CMS.

Response: The subject of this comment is technically outside the scope of our proposal. However, we note that our contracts with Part C and D sponsors consist of uniform terms and conditions for each type of plan offering. Therefore, we have already responded to this request by posting on our Web site all of the current Part C and D contract templates. Subcontractors can now obtain the Medicare plan sponsor contact terms and conditions directly from CMS.

After consideration of the public comments received, we are finalizing the policy without modification.

8. Valid Prescriptions (§ 423.100 and § 423.104)

Since the inception of the Part D program, we have consistently maintained that drugs cannot be eligible for Part D coverage unless they are dispensed upon prescriptions that are valid under applicable State law. Using our authority in section 1860D–12(b)(3)(D), we proposed in our October NPRM to codify this policy to remove any doubt as to the appropriate source of law to consult when determining whether a prescription is valid.

We proposed, first, to add a definition of the term “valid prescription” to § 423.100 to mean a “prescription that complies with all applicable State law requirements constituting a valid prescription.” This would make clear the need to consult State law to determine whether a prescription is valid.

We underscore, as we did in the proposed rule, that we do not intend to impose any State law requirements that do not otherwise apply. Rather, our proposal is that prescriptions must comply with applicable State law requirements; there is no need to comply with State law requirements to the extent that they do not apply. The two following examples illustrate our intent. Some States require that insulin syringes be dispensed upon prescription only, while other States do not. We would not require prescriptions for coverage of insulin syringes under Part D in those States that do not mandate

prescriptions, but would require prescriptions for Part D coverage in States that require insulin be dispensed only upon prescription. The second example involves the Indian Health Care Improvement Act (IHCIA), which: (1) Provides that licensed health professionals employed by a tribal health program need not be licensed in the State in which the program performs services; and (2) exempts specified health facilities from obtaining State licenses provided they otherwise meet State law requirements. The proposed changes would not necessitate either that these licensed professionals obtain additional State licenses or that the specified facilities obtain initial State licenses.

We also proposed to add a new paragraph (h) to § 423.104 stating that, for every Part D drug that requires a prescription, Part D sponsors may only provide benefits when that drug is “dispensed upon a valid prescription”. In tandem with the proposed definition of the term valid prescription discussed previously, these changes would ensure that, for drugs and other items that must be prescribed (including biological products and some insulin and specified associated supplies), Part D coverage would be limited to those dispensed upon valid prescriptions under applicable State law.

At this time, we are not aware of any State that requires that each electronic or written prescription include the prescriber's individual NPI in order for that prescription to be valid. But as is discussed in section II.E.11. of this final rule with comment period (Access to Covered Part D Drugs through Use of Standardized Technology and National Provider Identifiers), we believe that linking individual NPIs to specific prescriptions may provide law enforcement agencies with information that could be essential to identifying and prosecuting the particular individuals committing or abetting fraud, waste, or abuse. Accordingly, we once again would like to take this opportunity to encourage States to require that every prescription include the individual NPI of the prescriber in order to be valid under State law.

Comment: A few commenters indicated they supported or agreed with the provision.

Response: We appreciate the commenters' support of this codification of our long standing policy.

Comment: A few commenters questioned whether the proposed regulation would change existing responsibilities and asked CMS to provide additional guidance. A commenter first pointed out that

pharmacies, not plans, are required by State pharmacy laws to ensure that prescriptions meet minimum State requirements and should not be held accountable if a pharmacy fails to fill a prescription pursuant to applicable laws. The commenter then requested that CMS (1) “reiterate” that pharmacies must ensure that prescriptions are valid; and (2) direct pharmacies to ensure that CMS mandates like NPIs are included in prescription claims sent to plans.

Response: This regulation does not in any way preempt existing State requirements or create new Federal requirements. Rather, our codification of longstanding policy merely specifies in regulation that applicable State law applies in determining whether a prescription is valid. Therefore, we disagree with the commenter's suggestion that our policy takes any position with respect to which parties are responsible for ensuring prescriptions are valid under applicable State law—the parties should look to applicable State law on that issue. However, we would like to note, as has always been the case, that it is up to each Part D sponsor to determine through its contracting management how to best ensure that its network pharmacies are complying with the Part D requirement that prescriptions be valid under applicable State law.

Comment: Several commenters asked CMS to clarify the limits on audits as related to this proposal. One of these commenters believed that prescriptions cannot be audited using more strict guidelines than State law requires and requested that CMS instruct sponsors to stop “egregious audit practices” against pharmacies for violations of requirements not found in State law. Requesting that CMS clarify that LTC pharmacies being audited should not be required to produce documentary proof of prescriptions under applicable State laws, another commenter expressed concern that LTC pharmacies would not be able to provide sponsors, auditors, and/or CMS with such proof valid under State law because such prescriptions are typically kept with patient charts at the LTC setting.

Response: As discussed previously, our proposal was intended to codify our longstanding policy that applicable State law applies in determining what constitutes a valid prescription and that Part D benefits should be available only for otherwise covered drugs that are dispensed upon a valid prescription. We did not propose rules governing the conduct of audits by any entities—including plan sponsors.

Comment: A commenter appreciated that CMS encouraged States to require

individual NPIs for valid prescriptions. But, after observing that no States required NPIs for valid prescriptions, the commenter indicated that pharmacists would be challenged by a large number of prescriptions lacking appropriate NPIs.

Response: For a response addressing this issue, please see section II.E.11 of this final rule with comment period (Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers).

We are finalizing this provision without modification.

9. Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings (§ 423.153)

Section 1860D–4(c)(2) of the Act requires medication therapy management (MTM) programs to be designed to ensure that, with respect to targeted beneficiaries described in section 1860D–4(c)(2)(A)(ii) of the Act (individuals as specified with multiple chronic diseases, taking multiple covered Part D drugs, and likely to incur certain annual Part D drugs costs), covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events. Section 10328 of the Affordable Care Act further amended section 1860D–4(c)(2)(ii) of the Act to require prescription drug plan sponsors as part of the MTM services furnished to targeted beneficiaries to offer, at a minimum, an annual comprehensive medication review (CMR) that must be furnished person-to-person or via telehealth technologies. The comprehensive medication review must include a review of the individual's medications, which may result in the creation of a recommended medication action plan with a written or printed summary of the results of the review provided to the targeted individual.

As we reiterated in the preamble to the October 11, 2011 proposed rule, we first explained in our April 2011 final rule (75 FR 21476 through 21478) that beneficiaries residing in long term care (LTC) facilities who have cognitive impairments may not be able to participate in CMRs. The current regulations at § 423.153(d)(1)(vii)(B), which were amended in the April 2011 final rule to reflect certain requirements of the Affordable Care Act, continue to exempt sponsors from offering interactive, person-to-person consultations to targeted beneficiaries who reside in LTC settings. However, the Act, as amended by section 10328 of

the Affordable Care Act, does not provide a basis for creating an exception to the requirement to offer a CMR based on the setting of care. Since the Affordable Care Act provision for MTM programs was not effective until January 1, 2013, in the April 2011 final rule, we indicated that we would undertake further rulemaking to clarify the requirements for MTM programs to offer CMRs to targeted beneficiaries in LTC settings.

In the October 11, 2011 proposed rule, we proposed to revise the regulation at § 423.153 to require sponsors to offer the annual CMR to targeted beneficiaries in an LTC facility—but when the beneficiary cannot accept the offer to participate—the pharmacist or other qualified provider must perform a CMR without the beneficiary. When the beneficiary is cognitively impaired and cannot make decisions regarding his or her medical needs, we recommended that the pharmacist or qualified provider reach out to the beneficiary's prescriber, caregiver, or other authorized individual, such as the resident's health care proxy or legal guardian, to take part in the beneficiary's CMR.

Comment: Several commenters questioned how to determine whether a beneficiary residing in an LTC setting is cognitively impaired or able to participate in the CMR and suggested that this determination should be made by or coordinated with the LTC facility or LTC consultant pharmacist. One of these commenters questioned if documentation of this determination should be maintained and another suggested revising the Part D reporting requirements to require Part D sponsors to report the beneficiaries who opted out of the CMR due to cognitive impairment.

Response: We agree that LTC consultant pharmacists are positioned to help plan sponsors work with the LTC facility staff to identify cognitively impaired beneficiaries in LTC settings and determine whether beneficiaries are capable of participating in a CMR. We recommend that plan sponsors coordinate with LTC consultant pharmacists to make these determinations. If asked, plan sponsors should be able to present documentation or a rationale for these determinations. Any changes to the Part D reporting requirements are outside the scope of this regulation.

Comment: A few commenters are opposed to the proposed policy, and a commenter argued that the CMR requirement in the LTC setting should be the responsibility of the LTC facility, not plan sponsors, because LTC

facilities are paid to provide care to their patients and have their own physicians and pharmacists who order and fill the drugs.

Response: The statute specifies that “prescription drug plan sponsors shall offer medication therapy management services to targeted beneficiaries” and requires interventions “to increase adherence to prescription medications or other goals deemed necessary” and includes at a minimum “an annual comprehensive medication review furnished person-to-person or using telehealth technologies.” Further, the Act, as amended by section 10328 of the Affordable Care Act, does not provide a basis for distinguishing the offering of a CMR based on the setting of care.

Comment: Several commenters urged CMS that in order to maximize the efficient use of healthcare resources, the CMR should be performed in the LTC setting by an LTC consultant pharmacist or that plan sponsors should coordinate with the consultant pharmacists performing monthly drug regimen review (DRR) before intervening to resolve potential medication-related problems identified through the CMR or other MTM services. Other commenters requested clarification and additional guidance on the pharmacist or other qualified provider who will perform the CMR on behalf of the targeted beneficiary in LTC settings and how this would be implemented. Another commenter questioned if the pharmacist or other qualified provider performing the CMR is permitted to be employed by the sponsor or its Pharmacy Benefits Manager (PBM) and if it is common for the MTM provider to be the PBM, and not the plan sponsor.

Response: Sponsors may utilize in-house resources or make arrangements with other resources (such as PBMs, MTM vendors, or individual pharmacists or other qualified providers) to provide MTM services and administer their MTM program to targeted beneficiaries. We agree that LTC consultant pharmacists would be a valuable resource for the delivery of CMRs to targeted beneficiaries in LTC settings, and also acknowledge that the potential overlap between the DRR reviews required in LTC settings and Part D MTM reviews could possibly result in conflicting reviews. To maximize efficient use of healthcare resources, we encourage plan sponsors to consider making arrangements that include the LTC consultant pharmacist in conducting Part D MTM services for targeted beneficiaries in LTC. Such arrangements could include direct contracts between the sponsor and consultant pharmacists (or their

intermediaries), or indirect contracts between the sponsor's MTM vendor or PBM and LTC consultant pharmacists (or their intermediaries). We would like to hear from any parties who may currently be doing this and how such arrangements have improved care coordination or created efficiencies. You may contact CMS at partd_mtm@cms.hhs.gov.

Comment: A commenter argued that when the targeted beneficiary in the LTC setting is unable to participate in the CMR, there should be an exemption from the CMR standardized format requirements.

Response: Section 423.153(d)(1)(vii)(D) of the regulations requires standardized format action plans and summaries that comply with requirements as specified by CMS for the standardized format, to be provided following each CMR. This applies whether the CMR is provided to the beneficiary, or to the authorized representative or prescriber who may take part in the CMR if the beneficiary cannot participate. If the commenter meant to suggest that no written summary be provided, we would respond that the need for a CMR is certainly no less vital when individuals are cognitively impaired and these summaries can serve to coordinate care.

Comment: A few commenters suggested that CMS consider alternative approaches to disseminating MTM recommendations in the LTC setting by, for instance, providing: (1) The findings or recommendations related to drug therapy to the attending physician and/or nursing staff at the LTC facility; (2) CMR written summaries and standardized action plans to the LTC facility; or (3) medication review results to the beneficiary's medical power of attorney, if applicable.

Response: We appreciate these recommendations. Plan sponsors and MTM providers may, but are not required to, provide copies of the CMR written summaries and medication action plans to other HIPAA-covered entities to coordinate care. Also, a HIPAA covered entity may share a beneficiary's health information (such as medication review results) with the beneficiary's personal representative, which includes a person with medical power of attorney, where that information is relevant to such personal representation.

Comment: Several commenters focused on outreach to individuals to participate in the CMR aside from the targeted beneficiary. A commenter suggested that, even when the beneficiary can participate, the provider conducting the CMR still should be able

to reach out to individuals, such as the family caregiver, other authorized individual, and beneficiary's prescriber, to participate in the CMR. A few commenters suggested that when impairment prevents a targeted LTC beneficiary from participating in the CMR, CMS should require the provider arranging the CMR to provide written notice to the individual's health care proxy or legal representative, while another asked whether telephone or mail contact was acceptable. Another commenter recommended that if the targeted beneficiary in the LTC setting is unable to participate, the caregiver or surrogate should be engaged first, and then the prescriber, to ensure that the patient's best interests are protected.

Response: While we certainly appreciate an approach that would allow the beneficiary to be joined by, for instance, family members for a CMR, we believe it best, when a beneficiary is able to participate, to leave the decision as to whom he or she wishes to invite to his or her discretion. In these instances the pharmacist or other qualified provider may ask the beneficiary for permission to invite other individuals to the CMR. As to the form of the outreach, sponsors are responsible for choosing the outreach method, and are expected to use more than one approach when possible to reach all eligible targeted beneficiaries, regardless of setting, so they are able to receive MTM services and a CMR versus only reaching out via passive offers. These expectations also apply to any outreach to a beneficiary's prescriber, caregiver, or other authorized individual. Lastly, we do not believe it would be appropriate to burden the pharmacist or qualified provider arranging the CMR by specifying the order in which to contact individuals to represent a beneficiary who cannot participate in the CMR. This decision should be at the discretion of the provider and is dependent on the individual beneficiary's needs and situation.

Comment: A commenter recommended that CMS recognize that MTM services focused on the use of the most appropriate and cost-effective medications should be the primary goal of MTM in the LTC population.

Response: This comment is outside the scope of this rulemaking, and therefore, we will not address it in this rule.

Comment: A few commenters suggested that beneficiaries in other settings may be cognitively impaired or unable to participate in the CMR (such as hospice patients, beneficiaries being cared for in an assisted living facility, or

at home) and the proposed rule should not be limited to targeted beneficiaries in the LTC setting.

Response: Targeted beneficiaries in other health care settings are not excluded from the Part D MTM requirements, and must be offered MTM services if eligible. The proposal to eliminate the exception to the requirement to offer a CMR for beneficiaries residing in LTC settings was necessary in order to bring the existing regulation into compliance with requirements of section 10328 of the Affordable Care Act. Accordingly, the proposed revisions to the language of § 423.153(d) would require Part D sponsors to offer CMRs to all targeted beneficiaries in all settings. We acknowledge that beneficiaries in settings other than LTC may suffer cognitive impairments. Therefore, we encourage MTM programs to adopt similar approaches to furnishing MTM services to these beneficiaries who may be unable to accept an offer of a CMR and recommend outreach to the beneficiary's prescriber, caregiver, or other authorized individual.

Comment: A commenter questioned whom the plan sponsor can contact to act on behalf of the beneficiary if a call to an LTC facility results in the plan not being able to reach a beneficiary. The commenter questioned if the plan sponsor should assume that the prescriber and/or LTC consultant pharmacist on staff can be called and a CMR can be completed.

Response: We recommend that when a targeted beneficiary moves to an LTC facility, Part D plan sponsors should identify the appropriate contact for each beneficiary, which could be the prescriber, caregiver, or authorized representative. Alternatively, sponsors could include this requirement in any arrangements that may be made with the LTC consultant pharmacist in the conduct of Part D MTM services.

Comment: Several commenters requested clarification about distinguishing services provided through the existing LTC consultant pharmacist monthly DRR and those required for targeted LTC beneficiaries through Medicare Part D MTM and commented that the efforts are duplicative. Some commenters suggested that plan sponsors should rely on the consultant pharmacists' review or, alternatively, sponsors should not be required to conduct CMRs for beneficiaries in the LTC setting.

Response: As mandated by section 10328 of the Affordable Care Act, sponsors are required to offer CMRs to all targeted beneficiaries, including those in LTC settings. While there is

some potential overlap between the LTC consultant pharmacist monthly DRR and MTM required for targeted LTC beneficiaries through Part D, Part D sponsors remain subject to the requirement to furnish MTM services to all targeted beneficiaries consistent with section 1860D–4(c)(2) and the regulations at § 423.153(d). Thus, services required for MTM, such as offering a CMR, which must include an interactive, person-to-person, or telehealth consultation, are required for all targeted beneficiaries, including those in LTC settings. In light of the potential overlap, and to maximize efficient use of healthcare resources, we encourage plan sponsors to consider making arrangements that include the LTC consultant pharmacist in the conduct of Part D MTM services for targeted beneficiaries in LTC settings. We will provide guidance on the implementation of the MTM requirements and set service level expectations where necessary.

Comment: Several commenters felt that the recommendation that MTM providers reach out to the beneficiary's prescriber, caregiver, or other authorized individual to participate in the CMRs is administratively burdensome and costly given that plan sponsors cannot easily identify the LTC resident's health care proxy or authorized representative, or primary care physician (and their contact information), and question if this contact information is consistently captured or reported.

Response: As indicated in an earlier response, we recommend but do not require that when a beneficiary moves to an LTC facility, Part D plans identify the appropriate contact for each beneficiary, which could be the prescriber, caregiver, or authorized representative. Alternatively, sponsors could include this requirement in any arrangements that may be made with the LTC consultant pharmacist regarding the conduct of Part D MTM services. LTC consultant pharmacists are positioned to help plan sponsors work with LTC facility staff to identify the resident's authorized representative or prescriber, particularly in cases where this information is not part of the Part D enrollment information. We recommend that plan sponsors coordinate with LTC consultant pharmacists to obtain this information.

Comment: A few commenters requested clarification to distinguish between an interactive and non-interactive CMR and how it differs from the current MTM and interactive CMR processes.

Response: The October 11, 2011 proposed rule inappropriately referred to “non-interactive CMRs.” By definition, a CMR is an interactive consultation with the beneficiary or an authorized individual, such as their prescriber or caregiver, to review the beneficiary's medications and must be a real-time interaction. Per the regulation at § 423.153(d)(1)(vii)(B)(i), the annual comprehensive medication review with written summaries must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider. While providers are required to offer a CMR to all beneficiaries, regardless of setting, in the event the beneficiary is cognitively impaired, the MTM provider is encouraged to reach out to other appropriate parties to participate in a CMR. However, in the event the MTM provider is unable to identify another individual who is able to participate in the CMR, or a beneficiary in any setting refuses to participate in the CMR, a CMR cannot be performed, but sponsors are required to perform targeted medication reviews at least quarterly with follow-up interventions when necessary and perform prescriber interventions. To make the distinction clear, we are adding the word “comprehensive” before “medication review” in § 423.153(d)(1)(vii)(B)(2). We are also revising § 423.153(d)(1)(vii)(B)(2) to remove the reference to beneficiaries residing in LTC settings and to state that if a beneficiary is offered the annual CMR and is “unable to” accept the offer to participate, the pharmacist or other qualified provider “may” perform the CMR “with the beneficiary's prescriber, caregiver, or other authorized individual” to clarify that a CMR is voluntary and that a CMR cannot be performed without participation by the beneficiary, or an individual authorized to represent the beneficiary.

Comment: A commenter requested that we delay implementation due to potential bid and cost implications that would impact contract negotiations with LTC facilities or even the pharmacy providers for LTC facilities.

Response: We cannot delay implementation of this requirement because the statute mandates that we implement section 10328 of the Affordable Care Act by January 1, 2013. Additionally, sponsors were put on notice regarding this deadline in our April 2011 final rule in which we stated our plans to undertake additional rulemaking to clarify the CMR requirements for targeted beneficiaries in LTC settings. However, we thank the commenter for highlighting that we

incorrectly stated in the proposed rule that we did not anticipate any costs associated with this change. This was an oversight, and we have revised the regulatory impact and estimate to acknowledge that there will be a modest increase in costs to offer CMRs to beneficiaries residing in LTC settings with written summaries in a standardized format that complies with the requirements specified by CMS.

After consideration of the comments received in response to this final rule with comment period, we are adopting the revisions to § 423.153(d)(1)(vii)(B) as proposed with the clarifying changes discussed previously. The revisions will become effective January 1, 2013.

10. Employer Group Waiver Plans Requirement To Follow All Part D Rules Not Explicitly Waived (§ 423.458)

The Secretary has the statutory authority to waive or modify requirements that hinder the design of, the offering of, or the enrollment in, employer/union sponsored prescription drug plans (PDPs). Both employers/unions that contract directly with CMS, as well as PDP sponsors that contract with employers/unions and CMS, may offer customized employer group PDPs which are referred to collectively as employer/union-only group waiver plans (EGWPs). The statutory authority, set forth in section 1860D–22(b) of the Act, provides that the provisions of section 1857(i) of the Act shall apply with respect to prescription drug plans in relation to employment-based retiree health coverage in a manner similar to that in which they apply to an MA plan in relation to employers, including authorizing the establishment of separate premium amounts for enrollees in a prescription drug plan by reason of such coverage and limitations on enrollment to Part D eligible individuals enrolled in such coverage.

Under this statutory authority, in order to facilitate the offering of PDPs to employer/union group health plan sponsors, we may grant waivers and/or modifications to PDP sponsors. In general, each waiver or modification that we grant is conditioned upon the PDP sponsor meeting a set of defined circumstances and complying with a set of conditions. PDP sponsors offering EGWPs must comply with all Part D requirements unless those requirements have been specifically waived or modified.

It has come to our attention that some EGWPs that provide Part D benefits to their members may not be affording their members appropriate Medicare beneficiary protections put in place by CMS regulations or guidance. Based

upon discussions we have had with sponsors of EGWPs, some sponsors believe they are exempt from Part D requirements when providing Part D benefits because of the CMS waiver of the requirement that EGWP sponsors submit plan benefit packages for CMS review (see section 20.9 of Chapter 12 of the Medicare Prescription Drug Benefit Manual). Regardless of whether plan benefit packages are submitted for review, Part D sponsors of EGWPs must meet all Part D requirements (regulatory or legislative) unless such requirements are specifically waived or modified by CMS. Therefore, in order to emphasize the importance of providing EGWP members with beneficiary protections put in place by Part D requirements, we proposed to revise § 423.458 by adding a new paragraph (paragraph (c)(3)) to clearly state that in the absence of a CMS approved waiver, all Part D requirements apply and, in the case of a CMS approved waiver that modifies the application of Part D requirements, such requirements must be met as modified by the waiver.

Comment: While supporting the clarification, a commenter opined that significant operational challenges exist for EGWPs as they try to meet Part D requirements in areas including enrollment, formulary requirements, and transition fill policy. The commenter requested that CMS establish a forum and process for stakeholders such as EGWPs and employer groups to raise these issues and re-evaluate the current Part D requirements in consultation with stakeholders. In calling for transparency and efficiency, it further requested that CMS publish the outcome of waiver requests.

Response: We thank the commenter for the support and appreciate that EGWPs and EGWP sponsors face unique operational issues. We have already established a forum for stakeholders to raise Part C and D concerns—the biweekly Part C & D user call—and we would welcome any questions or concerns that EGWPs, EGWP sponsors, employer groups, or other interested stakeholders might care to raise. Stakeholders can email inquiries to the Part C & D user call at PartDBenefitImpl@cms.hhs.gov.

As to the suggestion that we publish the outcome of waiver requests, Chapter 12 of the Prescription Drug Benefit Manual (and Chapter 9 of Medicare Managed Care Manual) describes approved waivers current as of the date of publication; we also post Part D waivers when approved by CMS through HPMS. We will take the suggestion to publish requests for

waivers that are denied under consideration.

We are finalizing the provision as proposed with one modification. In § 423.458, the new paragraph will be designated as paragraph (c)(4) instead of (c)(3).

11. Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (§ 423.120)

Every time a beneficiary fills a prescription under Medicare Part D, a sponsor must submit to CMS an electronic summary record called a prescription drug event (PDE). We require that Part D sponsors obtain and submit a prescriber identifier on PDE records. Every prescriber has at least one identifier that can be submitted. These identifiers include the National Provider Identifier (NPI), Drug Enforcement Administration (DEA) number, uniform provider identification number (UPIN), or State license number. In a June 2010 report titled, “Invalid Prescriber Identifiers on Medicare Part D Drug Claims,” the OIG reported the findings of its review of prescriber identifiers on 2007 Part D PDE records. The OIG reported finding 18.4 million PDE records that contained 527,749 invalid identifiers, including invalid NPIs, DEA registration numbers, and UPINs. Payments by Part D drug plans and enrollees for these PDE records totaled \$1.2 billion.

In light of this report, we signaled in the Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Letter issued on April 4, 2011 (“CY 2012 Call Letter”) that we were considering a regulatory change in the Part D program that would limit acceptable prescriber identifiers on claims and PDE records in 2013 to only the individual NPI. We indicated that since all practitioners who are authorized to prescribe Part D drugs under applicable U.S. State laws, including foreign prescribers whose prescriptions are valid in certain States, can acquire an individual NPI from HHS, we do not believe such a change would present a significant access barrier to needed Part D drugs for Medicare beneficiaries.

Not only can all practitioners who are authorized to prescribe Part D drugs under applicable U.S. State laws acquire an NPI from HHS, but most are required to do so. Pursuant to HIPAA, HHS adopted the NPI as the standard for uniquely identifying health care providers in electronic transactions in the final rule published on January 23,

2004 (69 FR 3434), which was effective May 23, 2005, the date on which all health care providers, broadly defined in 45 CFR 160.103, became eligible for NPIs. By May 23, 2008, all covered health care providers, defined in 45 CFR 162.402, must have obtained an NPI. Covered health care providers must disclose their NPI to other entities that need the NPI for use in standard transactions.

Health care providers who are not covered entities are not required to obtain and disclose NPIs, but HHS encourages them to do so in the NPI final rule (January 23, 2004, 69 FR 3445). Therefore, we believe there are very few prescribers who do not already have an individual NPI that they will disclose to Part D sponsors and/or their network pharmacies who need it for standard transactions, with the exception of foreign prescribers, whom we discussed in greater detail later in this section of the final rule with comment period. In addition, for those health care providers who do not already have an NPI, obtaining one is not a burdensome endeavor and is free of charge.

As a measurable indicator, approximately 90 percent of Medicare Part D claims as reported in 2011 prescription drugs events (PDEs) submitted to CMS contain valid individual prescriber NPIs—a uniform identifier—even though CMS permits alternate prescriber IDs at this time. However, while the vast majority of Medicare Part D claims contain individual NPIs as of coverage year 2011, 10 percent still do not, and CMS believes it is important for prescribers to be identified in a consistent, verifiable manner in order to conduct appropriate oversight of the program.

The consistent use of a single validated identifier would enable us to provide better oversight over possible fraudulent activities. More specifically, CMS, MEDICs, and oversight agencies would be able to more efficiently identify patterns of unusual prescribing that may be associated with fraudulent activities. When multiple prescriber identifiers, not to mention default, dummy or invalid identifiers, are used, authorities must take an additional step in their data analysis before even achieving a refined data set to use for further analysis to identify possible fraud. For example, having to cross-reference multiple databases that update on different schedules to be certain of the precise prescribers involved, when multiple identifiers were used, would necessitate several additional steps of data pre-analysis and also would

introduce potential errors in correctly matching prescribers among databases.

In light of the foregoing, we proposed to amend § 423.120(c) to require, effective January 1, 2013, that Part D sponsors must submit an active and valid individual prescriber NPI on any PDE record submitted to CMS. This requirement would enhance our efforts to use claims data to identify fraud in furtherance of section 1893 of the Act, which established the Medicare Integrity Program and the Secretary's obligations with respect thereto. In addition to supporting CMS fraud and abuse activities, accurate data on prescriptions through the consistent use of valid NPIs on PDEs allows CMS to serve beneficiaries when using data in various initiatives whose purpose is to foster higher quality and more efficient coordination of care for individuals and groups of individuals.

We also proposed that sponsors may not reject a pharmacy claim solely on the basis of the lack of a valid prescriber NPI, unless the issue can be resolved at point-of-sale (POS), in order not to impede Medicare beneficiary access to needed medications. In other words, we proposed that Part D sponsors may not reject pharmacy claims at point of sale without prompt follow-up to ensure that the claim has been resubmitted by the network pharmacy with a corrected and valid individual prescriber NPI, or new information has been otherwise received to correct the sponsor's information.

Our proposal meant that if a correct and valid individual prescriber NPI is not included in the pharmacy claim, and it is determined that the prescriber does not have one and the claim is otherwise payable (for example, no indication of fraud, such as a prescription written by a provider excluded from the Medicare program, or no question regarding coverage), the sponsor must pay the claim, but cannot submit the PDE to CMS. Thus, if an active and valid prescriber ID is not included on the Part D claim, either the sponsor, or the pharmacy if in accordance with the contractual terms of the network pharmacy agreement, must follow up retrospectively to acquire an active and valid ID before the PDE may be submitted to CMS. As noted previously, we believe prescribers' NPIs will be widely available to Part D sponsors.

We reminded Part D sponsors that the requirements proposed were on sponsors, whose responsibility it would be to submit PDEs to CMS with individual prescriber NPIs. Therefore, we stated that we would expect that network pharmacies will be permitted to correct any invalid data before

payment for a claim is reversed, if the contract allows such a reversal. Additionally, we stated that we would expect that any requirement by a plan sponsor or its contracted PBM on a pharmacy to acquire and utilize its own automated validation capability will be arrived at only through mutual agreement, since such a requirement may be unaffordable for many smaller pharmacy organizations. For the reasons discussed in the following comment and response section, in response to comments, we are modifying the regulation text to better accomplish these policy goals.

With respect to requests for reimbursement submitted directly by Medicare beneficiaries, we proposed that requests for reimbursement from Medicare beneficiaries be handled in the same manner by Part D sponsors as claims from pharmacies. Thus, we proposed that sponsors may not make payment to the beneficiary dependent upon the sponsor's acquisition of an active and valid individual prescriber NPI, unless there is an indication of fraud. If the sponsor is unable to retrospectively acquire an active and valid NPI in connection with a request for reimbursement submitted by a beneficiary, we proposed that the sponsor may not seek recovery of the payment from the beneficiary solely on that basis, unless there is an indication of fraud.

We had learned from stakeholders through a contractor to CMS that a key barrier to improved NPI reporting on Part D PDEs is that CMS does not currently require NPI reporting, and our proposal was thus responsive to those observations. In addition, some pharmacy representatives have offered that certain States require or accept other prescriber identifiers, which impedes NPI reporting at the pharmacy level. It is unclear to us whether the latter observation was in the context of States as regulators of prescriptions or as payers of claims or both, and which alternate identifiers are required or accepted by these States. Therefore, we sought specific comment on this issue to assist us in understanding and confirming any State-imposed barriers to the standardization of prescriber identifiers to the individual NPI for the Medicare Part D program. We did not receive any such comments.

We stated that we considered exercising the discretionary authority granted pursuant to section 6405(c) of the Affordable Care Act so that prescriber NPIs would be required on Part D claims and PDEs. However, such an approach would require prescribers to also enroll in the Medicare program,

which is a provider credentialing process. Thus, we were concerned that requiring such enrollment could impede Part D beneficiary access to needed medications, because the process involves more effort on the part of prescribers, who are not reimbursed for prescriptions, compared to obtaining an NPI, which involves a three page application form that primarily seeks only identifying and location information and is free of charge. We stated that since we know that prescribers will also be concerned about beneficiary access to medications, we believed virtually all prescribers who do not already have an NPI would actually obtain one, but we are not certain this would be the case with respect to Medicare enrollment.

Regarding foreign prescribers, we stated our understanding that seven States (Arizona, Florida, Maine, North Dakota, Texas, Vermont, and Washington) currently permit pharmacies to fill prescriptions from foreign prescribers, to varying degrees. We stated our belief that foreign prescribers may not have sufficient incentives in terms of patient base or familiarity with health care reimbursement in the United States, particularly with respect to the Medicare program and Part D benefits, to obtain individual NPIs. Thus, unlike our guidance in the CY 2012 Call Letter, and in contrast to our proposal with respect to domestic prescribers, we did not propose to require Part D sponsors to cover claims involving foreign prescribers without an active and valid individual prescriber NPI. The motivation for our individual prescriber NPI proposal stems in large part from our need for consistent data to conduct better oversight over possible fraudulent activities in the Medicare Part D program. Since the Federal government has no jurisdiction over foreign prescribers, we proposed an exception to our proposal that the sponsor must pay an otherwise payable claim for a prescription, but cannot submit the PDE to CMS, without an individual prescriber NPI, when the claim involves a foreign prescriber who does not have an individual NPI. Thus, we proposed a Part D sponsor could reject a claim involving a foreign prescriber who does not have an NPI at point-of-sale without additional follow-up requirements.

In fact, in light of our lack of jurisdiction over foreign prescribers and our motivation to conduct better oversight over possible fraudulent activities, we stated that we were considering whether the proposal with respect to foreign prescribers was broad enough and whether we should instead

revise the Medicare Part D rules to prohibit sponsors from paying claims that involve prescriptions written by foreign prescribers, regardless of whether the foreign prescribers obtain an individual NPI. We noted that we were not making such a proposal, but solicited specific comments on foreign prescribers and the Part D program. However, we received no comments on this alternative to the foreign prescriber issue, and therefore we are finalizing our original proposal as to foreign prescribers.

Comment: Some commenters acknowledged the need for a single, validated prescriber identifier on PDEs. A commenter elaborated that our proposal would streamline prescriber identifier validation and enhance the ability to more effectively track and validate prescription activity at the individual prescriber level, which will assist in the identification of potentially fraudulent or inappropriate claims, as well as in improve the quality of patients' therapeutic outcomes.

Response: We agree with these comments. In addition to assisting us, we believe our proposal will result in a more streamlined prescriber validation process for Part D sponsors, PBMs, and network pharmacies. Routine use of a single identifier will minimize validation costs and efforts for all entities that collect, review and utilize this data.

Comment: Some commenters reiterated our observation that not all prescribers have to obtain an NPI and use it, in particular medical interns and residents, and these commenters stated that interns and residents have often used group or supervisor NPIs on prescriptions. Other commenters stated it was unfair for Part D sponsors to shoulder the burden of claims for which there is not an active and valid prescriber NPI. Another commenter stated conversely that, due to the standards described in the CY 2012 Call Letter regarding prescriber identifiers, nearly all claims submitted by pharmacies to Part D sponsors will contain prescriber NPIs by 2013.

Response: As part of our observations in the proposed rule, we stated that we believe there are actually very few prescribers who either do not have, or would be unwilling to obtain, an individual NPI that they will disclose to Part D sponsors and/or their network pharmacies who need it for standard transactions in order to facilitate their Medicare patients' access to needed medications. Moreover, nothing prevents a sponsor from requesting a prescriber to obtain and disclose an NPI to facilitate a delayed submission of a

PDE. Nevertheless, other strategies are being explored which would require prescribers who are not currently required to obtain NPIs to be required to obtain them. We agree with the commenter that there will be very few instances in which a Part D sponsor would not be able to submit a PDE to CMS due to the lack of an active and valid individual prescriber NPI.

Comment: A commenter stated that our request that payers not reject a claim from a network pharmacy for lack of an active and valid NPI (unless the issue can be resolved at point of sale) and retrospectively obtain one, could result in a retroactive denial of the claim, and that this scenario would not adhere to NCPDP's definition of a paid response. That is, if the sponsor has or should have had reason to believe that the identifier on the submitted claim is invalid or not active, but submits a paid response in such circumstances, this response would be inconsistent with HIPAA transaction standards, pursuant to which a paid response may be sent only when the claim satisfies the payer's requirements for payment. Another commenter stated that the "unless the issue can be resolved at point-of-sale" standard is very unclear.

Other commenters, while acknowledging the beneficiary access issue should still be considered, requested that we modify the final rule to allow Part D plans greater flexibility to implement measures to address claims lacking an active and valid NPI, such as claim rejection at POS, in order to alert the pharmacy of this fact, and to allow for two-way communication between the parties when there is an inconsistency between prescriber identifier databases at the time when the inconsistency is most readily resolved.

Some commenters expressed appreciation and support for our statements regarding the fact that the requirement to obtain an active and valid NPI is imposed on sponsors and our expectation that sponsors would provide opportunities for network pharmacies to correct any invalid data before recouping any payment. These commenters also appreciated and supported our statements regarding any requirements by Part D sponsors/PBMs for the pharmacies to acquire automated validation capability to be mutually negotiated. However, these commenters stated that the practical effect of our proposal not to allow claims rejection at POS would be that network pharmacies will be forced to bear recoupment of claims paid by Part D sponsors, when active and valid NPIs cannot be obtained retrospectively, even when they have done nothing wrong. These

commenters further stated that pharmacies must generally dispense a medication if the Part D plan provides coverage under their contract, and they are furthermore not in a position to refuse these Part D plan/PBM terms, nor terms requiring pharmacies to obtain a valid NPI for the claim to be payable, which will impose additional costs on many pharmacies, particularly smaller ones. A commenter stated that some Part D plans are already imposing requirements above and beyond current Federal regulations by recouping pharmacy reimbursement unless the underlying claims contain a valid individual NPI.

Response: Our proposed policy that payers not reject a claim from a network pharmacy for lack of an active and valid NPI (unless the issue can be resolved at point of sale) and to retrospectively obtain one was to ensure beneficiary access to needed medications in cases when the NPI issue could not be resolved at point-of-sale. We believed this scenario would be rare, and that most NPI issues could and would be resolved at point-of-sale. We have been even more persuaded by commenters that real time notification of a possible NPI issue or error is the most efficient process, since the pharmacy is in the best position to acquire corrected information from the beneficiary and/or prescriber when filling the prescription. This is because we believe the pharmacy representative is most motivated to check available data or contact the prescriber in order to get the claim adjudicated. Similarly, a prescriber is most motivated to disclose a missing NPI when the pharmacy is trying to dispense the drug prescribed to his or her patient.

In addition, in light of the comments received that our proposal did not allow for claim rejection at POS (even though this is a misunderstanding of our proposal), we are concerned that this proposed provision would be implemented by Part D sponsors in such a manner that sponsors will not undertake efforts at POS to resolve the NPI issue. We are concerned that sponsors will indicate to network pharmacies that claims lacking an active and valid individual prescriber NPI are payable, when the sponsors actually have reason to believe that the NPI is not active and valid, and then later recoup payment from the pharmacies pursuant to their agreements. We were especially persuaded by the commenter who stated that such a scenario would not adhere to NCPDP's definition of a paid response. That is, if the sponsor has reason to believe that the identifier on the submitted claim is invalid or not

active, but submits a paid response in such circumstances, this response would be inconsistent with HIPAA transaction standards, pursuant to which a paid response may be sent only when the claim satisfies the payer's requirements for payment.

For these reasons, and in response to comments, we are revising our policy and the regulation text to require a Part D sponsor to ensure that the lack of an active and valid individual prescriber NPI on a network pharmacy claim does not unreasonably delay a beneficiary's access to a covered Part D drug. Sponsors will be required to so ensure in the following manner: (1) A sponsor must communicate at point-of-sale whether or not the prescriber NPI is active and valid; (2) if the sponsor communicates that the prescriber NPI is not active and valid, the sponsor must permit the pharmacy to confirm that the NPI is active and valid, or in the alternative, to correct it; (3) if the pharmacy confirms that the prescriber NPI is active and valid or corrects it, the sponsor must pay the claim if it is otherwise payable; and (4) if the pharmacy cannot or does not correct or confirm that the prescriber NPI is active and valid, the sponsor must require the pharmacy to resubmit the claim (when necessary), which the sponsor must pay, if it is otherwise payable, unless there is an indication of fraud or the claim involves a prescription written by a foreign prescriber (where permitted by State law).

We would expect the back-and-forth between a sponsor and network pharmacy described previously to take no more than 24 hours, which means that sponsors will have to have controls in place to make sure network pharmacies resubmit claims where the sponsor has communicated an issue with the NPI and a pharmacy cannot or does not correct or confirm that the NPI is active and valid. We note that in practice today, pharmacy customers are not infrequently asked to return to the store later the same day or the next to pick up a prescription to allow time to resolve a claim adjudication or stock replenishing issue. Thus, we would consider a 24-hour timeframe to be timely access to outpatient medications. We also note that it is standard retail pharmacy practice to dispense a few doses of medication when these delays occur if the customer needs immediate access to the drug.

We believe these revisions preserve our policy that beneficiaries not be denied access to needed medications, while making it clearer that the requirement to obtain active and valid prescriber NPIs is imposed on Part D

sponsors. At the same time, we believe these revisions respond to commenters' concerns by clarifying what we meant when we stated that NPI issues must be resolved at point-of-sale. In addition, in response to commenters' concerns that pharmacies will be unscrupulously subjected to payment recoupment for claims that do not contain an active and valid NPI when the requirement to obtain one is on sponsors, we are further revising the regulation text to state that a Part D sponsor must not later recoup payment from a network pharmacy for a claim that does not contain an active and valid individual prescriber NPI on the basis that it does not contain one, unless the sponsor: (1) Has complied with the POS requirements previously described; (2) has verified that a submitted NPI was not in fact active and valid; and (3) the agreement between the parties explicitly permits such recoupment. We believe that this revision will further ensure that Part D sponsors engage in the point-of-sale NPI validation that we are requiring for the reasons stated previously.

Comment: A commenter requested that we instruct Part D plans that they are not allowed to mandate the use of individual NPIs on Part D claims. Other commenters requested that CMS do just that.

Response: Because this rule requires Part D sponsors to submit an active and valid prescriber NPI with a PDE, Part D sponsors may require that the NPI be submitted on claims by network pharmacies. However, as described previously, Part D sponsors will be required to communicate at the point-of-sale about the status of the NPI and will, under certain circumstances, be required to pay an otherwise payable claim, even if it does not contain an active and valid prescriber NPI.

Comment: Some commenters stated that following up with prescribers to obtain NPIs creates an administrative burden on plans, especially when considering CMS PDE submission requirements.

Response: We agree that this requirement imposes a new administrative burden on Part D sponsors. However, as we have stated previously, we believe that it is important to ensure that we have active and valid individual prescriber NPIs to allow us to better combat fraud and abuse. Therefore, we believe the benefit of this requirement outweighs the burden. Moreover, we expect that prescribers will readily respond to both pharmacy and sponsor activities to correct invalid data, and that any corrective action needed will substantially and rapidly decline over

time, thus decreasing the burden on all parties. In light of the revision to our proposal to require NPI validation by sponsors at point-of-sale, as described previously, we believe there will be relatively little additional follow-up administration effort required on the part of sponsors that would interfere with timely PDE submission to CMS.

Comment: A few commenters requested clarification of the meaning of "active and valid."

Response: By an "active and valid" NPI, we mean that the NPI number is in the expected format/sequencing for such numbers and is listed as an active identifier in the National Plan and Provider Enumeration System (NPPES).

Comment: A commenter stated that we should prohibit group NPIs from being used on Part D prescriptions. Other commenters stated that prescribers should have to use individual NPIs on their prescriptions.

Response: Prescriptions are regulated by State law as noted in section II.E.8. of this final rule with comment period. We do not regulate prescriptions. At this time, we are not aware of any State that requires each electronic or written prescription to include the prescriber's group or individual NPI in order for that prescription to be valid. However, we would again like to take this opportunity to encourage States to require that every prescription include the individual NPI of the prescriber in order to be valid under State law.

Comment: Some commenters stated that CMS should notify all prescribers that pharmacies cannot fill Part D prescriptions unless they provide an active and valid individual NPI.

Response: We encourage sponsors not to permit their network pharmacies to refuse to accept prescriptions when a prescriber has not disclosed an active and valid NPI, although we cannot prohibit a pharmacy from independently doing so. However, we do not anticipate that pharmacies will engage in this practice, as we have revised this requirement so that sponsors must provide information at POS regarding whether a submitted NPI is not active and valid, and to prohibit recoupment by the sponsor if it has not provided this information. Thus, since pharmacies will have an opportunity to correct or resolve apparent discrepancies concerning the validity of NPIs, and if they do, will not be subject to recoupment, we believe pharmacies will be able to manage the risk of nonpayment by sponsors and will not refuse prescriptions. Also, options are being explored to require NPIs for those few prescribers who are not currently required to obtain NPIs, and who do not

voluntarily do so, in order to facilitate their patient access to Part D drugs, even though we believe there are very few prescribers in this category.

Comment: A commenter believed that our proposal would actually undermine its purpose to achieve better oversight over possible fraudulent activities, as well as other program oversight objectives, since PDE records would no longer constitute a comprehensive database of drugs covered under the Part D program. In other words, we understood this commenter to assert that plans will not submit significant numbers of PDEs for lack of an active and valid prescriber NPI.

Response: We disagree. As noted previously, most prescribers already have and disclose NPIs, and we believe that number will increase after current efforts in 2012 to correct invalid prescriber identifiers on file with pharmacies. Also, options are being explored to require NPIs for those few prescribers who are not currently required to obtain NPIs, and who do not voluntarily do so, in order to facilitate their patient access to Part D drugs. Thus, we believe the commenter's projected risk of sponsors not submitting PDE records due to missing or invalid NPIs, leading to incomplete Part D drug utilization records on file with CMS, will not materialize.

Comment: Several commenters stated that there is no single, thorough, complete, and accurate database that contains up to date and validated prescriber NPIs, including NPPES, which also lacks all the data elements needed, such as DEA numbers, which causes editing issues in a real-time adjudication environment. One of the commenters stated that NPPES information should be disseminated and available to plans on a weekly basis, with deactivated NPIs noted, including the rationale for and date of deactivation. This commenter also stated that CMS should work with HHS Office of Inspector General (OIG) to ensure excluded individuals are identified in NPPES, as well as to create an NPI reference on the HHS-OIG excluded provider list.

Response: The primary purpose of the NPPES is to collect information needed to uniquely identify individual and organization health care providers, assign NPIs to those health care providers, maintain and update the information about the health care providers, and disseminate the information according to the NPPES Data Dissemination Notice. NPPES data is available to the public via the NPI Registry and is updated daily. In addition to the NPI Registry, CMS

provides a monthly NPPES downloadable file.

NPPES was designed in a way to meet its intended purpose in the most feasible way and was not intended to be a one-stop database for all prescriber identifiers. Also, sanction data were not included in the data element list published in the final NPI rule published January 23, 2004, and therefore, are not included in the NPPES data element list today. However, we do acknowledge the advantages of the additional information desired by sponsors, such as the date and reason for deactivation of an NPI, and we are exploring the feasibility of improving the information available regarding the deactivated NPIs.

Comment: A commenter stated that a grace period should be allowed to address the processing of claims with deactivated NPIs, such as when a prescriber has retired or passed away. This commenter suggested that rather than rejecting the claims, sponsors could send an information edit to notify pharmacies of the time period when it will begin to reject claims that contain the prescriber NPI, and pharmacies could then inform beneficiaries to find a new prescriber with an active individual NPI.

Response: An informational edit during a grace period for an NPI deactivated due to death or retirement might be a prudent practice, since we understand some States permit refills when the prescription was written before the prescriber's retirement or death. We will provide additional guidance in the future, if necessary on this point. We take no position on whether a pharmacy should encourage a beneficiary to find a new prescriber with an active NPI.

Comment: A commenter supported the proposal to not permit recovery of beneficiary payment on beneficiary-submitted requests for reimbursement when retroactive acquisition of the prescriber NPI has not been successful, as a means to protect beneficiary access to drug therapy prescribed by his or her physician. Another commenter was pleased that beneficiaries will not be negatively impacted by such lack of an NPI for a PDE.

Response: We appreciate the support for our proposal.

Comment: A commenter was pleased that we chose not to require Medicare Part D prescribers to enroll in Medicare which supports beneficiary access and obviates the need for physicians to engage in a credentialing process for which they are not compensated.

Response: We appreciate the support for our proposal.

Comment: A few commenters supported our proposal regarding foreign prescribers. Another commenter stated the proposal was essential for prohibiting claims payment on prescriptions involving foreign prescribers. One commenter noted that there is no database of foreign prescribers.

Response: We thank the commenters for their support. Under our proposal, as revised in response to other comments, if a foreign prescriber has an active and valid NPI that is submitted on the claim, a Part D sponsor must pay the claim, if it is otherwise payable and applicable State law permits prescriptions from foreign prescribers. However, if the NPI is not active and valid and the pharmacy cannot correct the NPI for a foreign prescriber, then the sponsor does not have to require the pharmacy to resubmit the claim (when necessary) and is not required to pay it (if it is otherwise payable). This is consistent with our proposal that sponsors could not reject a claim lacking an active and valid NPI unless the claim involved a prescription written by a foreign prescriber. We acknowledge that there is no database of foreign prescribers; however, we do not believe the lack of such a database would hinder sponsors' compliance.

Comment: Some commenters requested a delay in the NPI requirement.

Response: We were not persuaded by the comments we received that we should delay the prescriber NPI requirement for PDEs. In particular, we considered that ninety percent of PDEs as of coverage year 2011 already contain prescriber NPIs, according to CMS data, and weighed that against the importance of a single prescriber identifier to assist in fighting potential fraud in the Part D program.

After consideration of the public comments received, we are finalizing our proposal with the modifications noted previously.

Section 423.120(c) sets forth the responsibilities of Part D plan sponsors with regard to the use of standardized technologies and compliance with the HIPAA standards at 45 CFR 162.1102. We are adding a new paragraph (c)(5)(i) which requires Part D plan sponsors to submit to CMS only PDE records that contain an active and valid individual prescriber NPI. However, new paragraph (c)(5)(ii) will require a Part D plan sponsor to ensure that the lack of an active and valid individual prescriber NPI on a network pharmacy claim does not unreasonably delay a beneficiary's access to a covered Part D drug by taking the steps described in a new

paragraph (c)(5)(iii). New paragraph (c)(5)(iii) requires that the sponsor communicate at point-of-sale whether or not a submitted NPI is active and valid; paragraph (c)(5)(iii)(A)(1) and (2) will require, if the sponsor communicated that the NPI is not active and valid, that the sponsor must permit the pharmacy to confirm that the NPI is active and valid, or in the alternative, to correct it. If the pharmacy confirms that the NPI is active and valid or corrects the NPI, paragraph (c)(5)(iii)(B)(1) will require the sponsor to pay the claim, if it is otherwise payable. Paragraph (c)(5)(iii)(B)(2) will require, if the pharmacy cannot or does not correct or confirm that NPI is active and valid, that the sponsor must require the pharmacy to resubmit the claim (when necessary), which claim the sponsor must pay, if it is otherwise payable, unless there is an indication of fraud or the claim involves a prescription written by a foreign prescriber (where permitted by State law).

New paragraph (c)(5)(iv) will prohibit a Part D sponsor from later recouping payment to a network pharmacy for a claim that does not contain an active and valid individual prescriber NPI on the basis that it does not contain one unless the sponsor: (1) Complied with paragraph (c)(5)(ii) and (iii); (2) verified that a submitted NPI was not in fact active and valid; and (3) the agreement between the parties explicitly permits such recoupment.

New paragraph (c)(5)(v) will prohibit a Part D sponsor, with respect to requests for reimbursement submitted by Medicare beneficiaries, from making payment to the beneficiary dependent upon the sponsor's acquisition of an active and valid individual prescriber NPI, unless there is an indication of fraud. It will further prohibit a Part D sponsor from seeking recovery of any payment to the beneficiary on the basis that the sponsor was unable to retrospectively acquire an active and valid individual prescriber NPI, unless there is an indication of fraud. As noted previously, these changes would be effective for PDEs submitted by Part D sponsors on January 1, 2013 or later.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB,

section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The following sections of this document contain paperwork burden but not all of them are subject to the PRA for reasons noted.

A. ICRs Regarding the Coverage Gap Discount Program (§ 423.100, § 423.505(b), § 423.1002, and Part 423 Subpart W)

Section 1860D–14(d)(6) of the Act exempts this section from PRA requirements.

B. ICRs Regarding the Inclusion of Benzodiazepines and Barbiturates as Part D Drugs (§ 423.100)

In accordance with section 175 of MIPPA, which amended section 1860D–2(e)(2)(A) of the Act, we proposed to revise the definition of Part D drug at § 423.100 to include barbiturates when used for the medical indications of epilepsy, cancer, or a chronic mental health disorder, and benzodiazepines, effective January 1, 2013.

Part D plan sponsors will be required to submit information in their formulary files indicating that they will cover these drugs. The collection of information burden on Part D sponsors imposed by this proposed regulation is negligible. Any burden associated with the requirement on sponsors relates to the required data entry in the formulary file software, and will be included in the PRA package entitled, Formulary Submission for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP) for Contract Year (CY) 2013 (OCN 0938–0763).

Comment: A few commenters believed that they would be burdened because they would need to apply prior authorization to determine whether barbiturates covered specific indications. A commenter pointed to an increased number of appeals, while the other foresaw an increased number of documents related to indication determinations. A commenter also noted that the change would impact SNPs because these medications are typically available without prior authorization under their medical assistance benefit.

Response: It is outside of the scope of this proposed rule to comment on the use of prior authorization for this purpose. However, we do not believe that this inclusion will increase the burden of any plan in any significant way because sponsors must always ensure that they cover drugs only when used for medically accepted indications. Making this determination is no different for barbiturates than for other drugs. As to the SNP concerns, we are complying with the statutory requirement, and because Part D coverage requirements for SNPs are not different from those for other MA–PDs, this requirement applies consistently across plan types.

After considering the public comments received, we are finalizing the policy without modification.

C. ICRs Regarding Pharmacy Benefit Manager's Transparency Requirements (§ 423.514)

Consistent with the statutory requirements under section 1150A(b)(3), we proposed to add an additional data element to the DIR data reporting requirements: aggregate amount of the difference between the amount the Part D sponsor pays the PBM and the amount the PBM pays retail and mail order pharmacies, also known as PBM spread. In the 2010 DIR reporting requirements, we collected PBM spread amounts aggregated to the plan benefit package level. We believe that with the addition of PBM spread amounts for retail pharmacies and PBM spread amounts for mail order pharmacies to the existing DIR reporting requirements, Part D sponsors will meet the requirements to report the elements in § 423.514(d)(4) through (6). Beyond this change, no additional DIR reporting will be required pursuant to section 1150A of the Act. We did not receive any comments on increased burden due to reporting PBM spread. We are finalizing as proposed reporting of this data element, also known as PBM spread.

In addition, section 1150A(b)(1) of the Act requires PBMs and Part D sponsors to report the percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies and the percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate) by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy). We explored the ideas commenters submitted for CMS to provide crosswalks or derive the pharmacy type data from existing data sources and

determined that we could crosswalk National Provider Identifiers with a file from the National Council for Prescription Drug Programs to determine the percentage of all prescriptions that were provided through retail pharmacies as compared to mail order pharmacies as required under § 423.514(d)(2). However, this approach cannot be used to categorize independent, chain, supermarket, and mass merchandiser pharmacies because they are not standard pharmacy classifications captured in industry databases or files. Thus, while we are finalizing § 423.514(d)(3) as proposed, we will issue further subregulatory guidance regarding this reporting requirement before requiring Part D sponsors to submit this information.

D. ICRs Regarding Good Cause and Reinstatement Into a Cost Plan (§ 417.460)

Our proposal in § 417.460 extends reinstatement rights currently in place for members of MA and Part D plans to members of cost plans. Because good cause determinations would be made by CMS (or its contractor), we believe that this rule would not impose any new information collection requirements. We received no comments on the cost burden of the collection of information requirements related to this proposal and therefore are finalizing this provision without modification.

E. ICRs Regarding Requiring MA Plans Issuance of Member ID Cards (§ 422.111)

Under our authority at section 1852(c) of the Act to require that MA organizations disclose MA plan information upon request, as well as our authority under section 1857(e) of the Act to specify additional contractual terms and conditions the Secretary may find necessary and appropriate, we proposed to expressly require MA plans issue and re-issue as necessary a MA member ID card that enables enrollees to access all covered services. While this requirement is subject to the PRA, we believe this burden is exempt as defined in 5 CFR 1320.3(b)(2). That is, the time, effort, and financial resources necessary to comply with the requirement would be incurred by MA organizations in the normal course of their business activities.

F. ICRs Regarding Determination of Actuarially Equivalent Creditable Prescription Drug Coverage (§ 423.56)

We are amending a calculation at § 423.56 to be consistent with the calculation of the actuarial value of qualified retiree prescription drug

coverage found at § 423.884(d) and to change the term “CMS actuarial guidelines” to read “CMS guidelines” to allow CMS further flexibility in issuing interpretive guidance on these requirement. There is no new information collection burden on organizations.

We received no comments on the cost burden of the collection of information requirements related to this proposal and therefore are finalizing this provision without modification.

G. ICRs Regarding Who May File Part D Appeals With the Independent Review Entity (§ 423.600 and § 423.602)

The information collection requirements referenced in this section are exempt from the PRA in accordance with 5 CFR 1320.4(a)(2) which excludes collection activities during the conduct of administrative actions, such as redeterminations, reconsiderations, and/or appeals.

H. ICRs Regarding CMS Termination of Health Care Prepayment Plans (§ 417.801)

This section does not impose any new information collection requirements.

I. ICRs Regarding Termination or Non-Renewal of a Medicare Contract Based on Consistent Poor Plan Performance Ratings (§ 422.510 and § 423.509)

It is our position that 3 years' worth of low-star ratings constitutes a sufficient basis for us to terminate a sponsor's Part C or D contract under our authority under section 1857(c)(2) of the Act. The regulation has been changed to reflect that.

Regarding ICRs, we are not imposing any new reporting requirements. We are merely harnessing and putting to use internal data that has already been collected. We do not believe that our proposal would result in an additional burden; therefore, we have not incorporated a burden increase.

J. ICRs Regarding Denial of Applications Submitted by Part C and D Sponsors With a Past Contract Termination or CMS-Initiated Non-Renewal (§ 422.502 and § 423.503)

We have modified the past performance review period described in § 422.502(b) and § 423.503(b) (by adding new paragraphs at § 422.502(b)(3) and at § 423.503(b)(3) as well as § 422.502(b)(4) and at § 423.503(b)(4)) to include among the factors that may support a CMS denial of a contract application those CMS-initiated terminations or non-renewals that became effective within the 38 months preceding the submission of a new application.

We are not imposing any new reporting requirements. We are merely further refining our intended approach to using past performance in making application determinations. We do not believe that our proposal would result in an additional burden; therefore, we have not incorporated a burden increase.

K. ICRs Regarding New Benefit Flexibility for Certain Dual Eligible Special Needs Plans (SNPs) (§ 422.102)

Under § 422.102(e), we would allow certain dual SNPs meeting a high standard of integration and minimum performance and quality based standards, the flexibility to offer supplemental benefits beyond those that we allow for all other MA plans. We would review each qualified SNP's proposed supplemental benefit offerings as part of our review of plan bids, and we would approve additional supplemental benefit offerings for these qualified SNPs as we deem necessary. The burden associated with this proposed requirement is the time and effort necessary for SNPs to submit their benefit designs, including cost-sharing amounts, via the PBP software. The collection of benefit design information via PBP software is currently approved under OCN 0938–0944. We are seeking to revise this control number to incorporate the additional use of this information that is described in this section of the final rule with comment period.

Additionally, in order to evaluate how D–SNPs are implementing this new benefit flexibility, we indicate that we will require D–SNPs that participate in this new benefit flexibility initiative to submit a mandatory quality improvement project (QIP) on measures related to the goals of this initiative, as determined by CMS. The burden associated with this requirement is the time and effort that qualifying D–SNPs would put forth to develop and submit a QIP, which is currently approved under OCN 0938–1023 (CMS form #10209). We are assuming that this process would be completed by one MA organization staff person receiving a median hourly wage rate of \$37.58, which is equivalent to the median hourly wage rate that the BLS currently reports for a management analyst. Adding the standard OMB figures of 12 percent for overhead and 36 percent for benefits, respectively, we estimate an hourly cost of \$55.61 to comply with this requirement. Based on our existing estimates of the QIP submission burden, we estimate that it would take each SNP approximately 15 hours to complete each QIP, resulting in an aggregate

burden of 1,095 hours (15 hours multiplied by 73 D-SNPs) for the 73 D-SNPs that we believe may qualify to offer additional supplemental benefits under this new benefit flexibility initiative. Therefore, we estimate that D-SNPs participating in this initiative will incur an aggregate cost of \$60,892 (\$55.61 per hour multiplied by 1,065 hours) in order to comply with this additional QIP submission requirement. We are seeking to revise our collection approved under OCN 0938–1023 to account for this new requirement for certain D-SNPs participating in this benefits flexibility initiative.

L. ICRs Regarding Clarifying Payment to Providers in Instances of Hospital-Acquired Conditions (HACs) (§ 422.504)

We proposed to require MA organizations provide in their contracts with hospitals that payments for Part A hospital services will be reduced for serious events that could be prevented through evidence based guidelines, in accordance with the HACs and POA policy that is currently required for hospitals paid under the Original Medicare IPPS. We believe that plans already have some operational systems in place to facilitate implementation of the requirement. For example, MA organizations are already required to pay non-contract provider hospitals the amount that they will receive for services under original Medicare, including any applicable reductions for HACs. Also, beginning January 3, 2012, MA plans will be required to collect and submit encounter data for each item and service provided to MA enrollees in accordance with risk adjustment policies required in § 422.310(d). This information is collected using the HIPAA 5010, which is already in use by hospital providers for FFS claims and contains fields for POA indicator reporting. While this requirement is subject to the PRA, the diagnosis, POA indicator information, and other claims information is already collected as part of the encounter data collection process, and this burden is currently approved under OCN 0938–1054.

Additionally, we expressed our belief that hospitals will already be familiar with POA reporting and will not require additional education. Therefore, the burden associated with this provision would be the time and effort necessary for MA plans to modify their claims processing to recognize the POA indicators, if they do not already do so, and to adjust payment to contracted hospitals for the HAC events accordingly. Plans usually update their claims processing systems regularly for changes such as, payment logic for new

national and local coverage determinations, updating HCPCS code information, and other changes to their payment calculations. Therefore, we believe this burden is exempt from the PRA as defined in 5 CFR 1320.3(b)(2), because the time, effort, and financial resources necessary to comply with this requirement will be incurred by plans in the normal course of their business activities.

We received no comments on the information collection requirements associated with this proposal. However, based on the comments received on the proposed policy, we are not finalizing this proposal. We will continue to not only consider alternate strategies for reducing hospital-acquired conditions in hospitals that provide care to MA enrollees, but also strive toward aligning quality initiatives in the Medicare and Medicare Advantage programs.

M. ICRs Regarding Clarifying Coverage of Durable Medical Equipment (§ 422.101(a) and § 422.112(a))

Under § 422.100(l), we proposed to permit MA plans to limit coverage of DME to specific manufacturers' products or brands. Furthermore, in order to ensure that MA enrollees have adequate access to their DME benefits, our proposed regulatory changes establish requirements with respect to access, midyear changes to preferred DME items and supplies, appeals, and disclosure of DME coverage limitations to enrollees. The burden associated with this requirement is the time and effort necessary for MA organizations to submit their benefit designs via the PBP software. While this requirement is subject to the PRA, the burden associated with it is currently approved under OCN 0938–0763. With respect to disclosing DME coverage limitations, this requirement is captured in the burden associated with the annual notice of coverage/evidence of coverage which must be completed at the time of the beneficiary's enrollment and at least annually thereafter. The MA program disclosure requirement is at § 422.111 and the burden associated with it was formerly approved under OCN 0938–0753 which expired November 30, 2011. We are seeking to reinstate this collection in order to account for the new DME disclosure requirement.

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

At § 422.2274 and § 423.2274, we proposed that plans can choose any agent/broker compensation amount at or below the fair market value amount annually. We require MA organizations

to submit and/or update and attest to their compensation amount (or range) in the HPMS. This web-based system in HPMS allows new plans to submit information and, for existing plans, automatically updates, based on changes in MA payment rates, organization compensation information. We proposed to allow plans to annually adjust their base compensation rates to reflect fair market value. Plans would continue to be required to annually submit and attest to this information to CMS through HPMS. While this proposed requirement is subject to the PRA, it does not impose any new information collection requirement on plans. The burden associated with the proposed requirement was formerly approved under OMB control number (OCN) 0938–0753 which expired November 30, 2011. We are seeking to reinstate this collection.

O. ICRs Regarding the Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program (§ 423.100, § 423.104 and § 423.153)

In accordance with section 1860D–4(c) of the Act, we are revising § 423.153 at paragraph (b)(4) to provide that a Medicare Part D sponsor's drug utilization management program must establish and apply a daily cost-sharing rate, under certain circumstances, to a prescription presented by an enrollee at a network pharmacy for a covered Part D generic or brand drug that is dispensed for a supply of less than 30 days. Under this requirement, the enrollee and his or her prescriber generally will decide if a medication supply of less than 30 days will be appropriate, and if so, the cost-sharing for the medication will be prorated by the Part D sponsor based on the days supply dispensed. Since obtaining a supply of a medication for less than 30 days is optional for the enrollee and his or her prescriber, the collection of information burden imposed by these regulations on either Part Medicare D enrollees or their prescribers is negligible. Moreover, any burden associated with this proposal on sponsors related to the required data entry in the PBP software will be included in the revised PRA package entitled Plan Benefit Package (PBP) and Formulary Submission for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP) for Contract Year (CY) 2014, since we are delaying the effective date of this requirement until January 1, 2014.

After consideration of the public comments received, none of which

specifically addressed this collection of information burden section, we are modifying this requirement as discussed in section II.D.6. of this final rule with comment period (Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program (§ 423.100, § 423.104 and § 423.153)). However, we are not modifying these ICRs, since the collection of information burden imposed by this final rule with comment period will still be negligible, and any burden associated with it will still be captured elsewhere.

P. ICRs Regarding Technical Corrections to Enrollment Provisions (§ 417.422, § 417.432, § 422.60, and § 423.56)

At § 417.422, § 417.432, § 422.60, and § 423.56 we are proposed technical changes that correct cross-references that should have been updated in previous rulemaking. These changes do not establish any new rules or requirements for cost or Part D plans. They merely update regulatory cross-references that were overlooked in previous rulemaking. As a result, these changes do not impose any new information collection requirements.

Q. ICRs Regarding Applying MA and Part D Disclosure Requirements to Cost Contract Plans (§ 417.427)

We proposed to extend the disclosure requirements in § 422.111 and § 423.128 to cost contract plans. Our regulations at § 422.111 and § 423.128 require MA organizations and Part D sponsors to disclose to enrollees, at the time of enrollment and annually thereafter (in the form of an annual notice of change/evidence of coverage, or ANOC/EOC mailing), certain detailed information about plan benefits, service area, provider and pharmacy access, grievance and appeal procedures, quality improvement programs, and disenrollment rights and responsibilities. Sections 422.111 and § 423.128 also require the provision of certain information about requests and establish requirements with respect to dissemination of explanations of benefits, customer service call centers, and Internet Web sites.

The burden associated with this requirement is the time and effort associated with completing an ANOC/EOC at the time of a beneficiary's enrollment and at least annually thereafter, as specified in § 422.111(a)(2) of the MA program regulations and § 423.128(a)(3) of the Part D program regulations. For each entity, we estimate that it will take 12 hours to develop and submit the required information. This

includes 1 hour to read CMS' published instructions, 6 hours to generate the standardized document, 1 hour to submit the materials, 4 hours to print and disclose to the beneficiaries. This package is currently approved under OCN 0938-0753 with a November 30, 2011 expiration date to account for this burden as detailed in Table 7. We estimate 20 cost contractors would be affected annually by this requirement, resulting in a total annual burden of 240 hours. We estimate, based on an hourly wage of \$29.88 (hourly salary for a compliance officer/cost estimator according to Bureau of Labor Statistics) plus 48 percent for fringe benefits and overhead, that this requirement will result in a total annual burden of \$10,613 (240 burden hours multiplied by \$44.22 per hour). We are revising the PRA package currently approved under OCN 0938-0753 with a November 30, 2011 expiration date.

R. ICRs Regarding Clarification of and Extension of Regional Preferred Provider Organization Plan Single Deductible Requirements to Local Preferred Provider Plans (§ 422.101)

This section does not impose any new information collection requirements.

S. ICRs Regarding Modifying the Current PFFS Plan Explanation of Benefits (EOB) Requirements (§ 422.216(d)(1))

Section 1852(k)(2)(c) of the Act and § 422.216(d)(1) require PFFS plans to provide an EOB to enrollees for each claim filed by the enrollee or the provider that furnished the service. In the interest of consistency for beneficiaries and MA organizations, we proposed to amend § 422.216(d)(1) to state that the EOB requirement for PFFS plans would be consistent with the MA EOB requirements of § 422.111(b)(12). The standard EOB that we are currently developing and piloting in CY 2012 for most other MA plan types would include the same information as currently required for PFFS plans, as well as plan MOOP cost limit information. Adding this cross-reference to § 422.216(d)(1) would provide consistency in EOB requirements and submission and approval of marketing materials across plan types. Since the pilot program is in progress and we would not have finalized EOB requirements during this rulemaking, we proposed that PFFS plans would continue to furnish EOBs as they have been, in accordance with § 422.216(d)(1), until we finalize and implement EOB models for all MA plans. While this proposed requirement is subject to the PRA, the information collection has been approved under

CMS form CMS-10349, the information collection approved for the Part C EOB at § 422.111(b)(12).

T. ICRs Regarding Authority To Deny SNP Applications and SNPs Appeal Rights (§ 422.500)

Our proposed amendments to § 422.500(a), § 422.501(a), § 422.501(c)(1)(iii), § 422.502(a) and § 422.502(c) would give CMS the authority to deny SNP applications that fail to demonstrate that the MA organization meets the requirements of § 422.2, § 422.4(a)(1)(iv); § 422.101(f); § 422.107, if applicable; and § 422.152(g). The burden associated with this requirement is the time and effort required by an MA organization offering a SNP to complete a SNP application. While these requirements are subject to the PRA, we do not expect the burden to change from the existing burden estimate, as currently approved under OCN 0938-0935, with a January 31, 2012 expiration date. We are seeking to renew this collection.

Our proposed amendments to § 422.641 provide the procedures for making and reviewing certain contract determinations, while our proposed amendments to § 422.660 establish the circumstances under which an MA organization may request a hearing before a CMS hearing officer. We proposed these amendments to our existing regulations so that each applicant that we determine not to be qualified to offer a SNP has the right to request an administrative review of CMS' determination. The burden associated with these requirements is the time and effort of the SNP applicant in developing and presenting their case to a CMS hearing official, and ultimately the CMS Administrator, to demonstrate that they qualify to offer a SNP.

We expect the burden associated with this provision to be incurred by the small number of SNP applicants that we expect would receive application denials, and the small percentage of denied applicants that we expect would appeal our denial decision. We estimate that the total annual hourly burden for developing and presenting a case for us to review is equal to the number of organizations likely to request an appeal multiplied by the number of hours for the attorneys of each appealing SNP to research, draft, submit, and present their arguments to CMS. Based on SNP application denials from contract year 2012, out of the approximately 400 SNP applications received, 8 of these applications were denied and all 8 denials were appealed. In contract year 2011, 8 SNP applications were denied and none of these denials were

appealed. Taking the average of the last 2 years, we estimate that approximately 4 denied applicants would appeal the denial of the SNP application. We further estimate that one attorney working for 8 hours could complete the documentation to be submitted for each application denial, resulting in a total burden estimate of 32 hours (8 hours \times 4 SNP application denials = 32 hours). The estimated annual cost to all MA organizations, in the aggregate, that have been denied to offer a SNP associated with this provision (assuming an attorney billing \$250 per hour) is \$8,000 (32 hours \times \$250 = \$8,000) as detailed in Table 7. We are revising the PRA package currently approved under OCN 0938–0935, with a January 31, 2012 expiration date, to account for this burden. We are seeking to renew this collection.

U. ICRs Regarding Timeline for Resubmitting Previously Denied MA Applications (§ 422.501)

This section does not impose any new information collection requirements.

V. ICRs Regarding Contract Requirements for First Tier and Downstream Entities (§ 422.504 and § 423.505)

We proposed to modify the regulations at § 422.504(i) and § 423.505(i) by deleting the term “written arrangements” throughout and in each instance replacing it with “each and every contract,” thus ensuring that the MA organizations and Part D sponsors retain the necessary control and oversight over their delegated entities by requiring that all contracts among those entities specifically reference their obligations to the sponsor.

Regarding ICRs, we are not imposing any new reporting requirements. We are simply clarifying a requirement with which MA organizations and Part D sponsors must already comply concerning their contracts with first tier and downstream entities. We do not believe that our proposal would result in an additional burden; therefore, we have not incorporated a burden increase.

W. ICRs Regarding Valid Prescriptions (§ 423.100 and § 423.104)

Our proposed definition of “valid prescription” in § 423.100 and requirement of a “valid prescription” in § 423.104 would codify our longstanding policy of deferring to State laws when applicable to determine whether a prescription is valid such that

the drug may be eligible for Part D coverage. We are not imposing any new reporting requirements. Prescribers and pharmacies remain subject to applicable State laws regarding valid prescriptions. Furthermore, private contracts regarding Part D drugs (such as those between MA organizations or Part D sponsors and pharmacies) likely also require valid prescriptions. Given these realities, we do not believe that codifying our practice of limiting Part D coverage to items dispensed upon applicable State law requirements for valid prescriptions could necessitate any more action than that already required on the part of stakeholders—be they prescribers taking steps to ensure they write valid prescriptions or MA organizations, Part D sponsors, PBMs, or pharmacies trying to ascertain that prescriptions are valid.

X. ICRs Regarding Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings (§ 423.153)

Current regulations require that unless a beneficiary is in a LTC setting, the comprehensive medication review (CMR) must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider, and may result in a recommended medication action plan. Section 10328 of the Affordable Care Act amended section 1860D–4(c)(2) of the Act to require that all targeted beneficiaries be offered a CMR. Accordingly, we proposed a change to § 423.153 permitting the sponsor to allow the pharmacist or other qualified provider to perform the CMR without the beneficiary in cases when the beneficiary is in a LTC facility and is cognitively impaired and thus, cannot accept the sponsor's offer of a CMR. We anticipated that the impact of this proposed revision would clarify the CMR process for sponsors by allowing pharmacists and other qualified providers to ascertain whether the patient is willing and able to participate in a CMR before administering it.

We incorrectly stated in the proposed rule that we did not anticipate any costs or savings associated with this change. However, there will be a modest increase in costs based on the requirement to offer CMRs to beneficiaries residing in LTC settings with written summaries and provide the summaries and action plans for these beneficiaries in a standardized format that complies with the requirements specified by CMS. We estimate that 215,000 beneficiaries in LTC settings are eligible for MTM services and 10

percent (21,500) of those beneficiaries will receive an annual CMR. We also estimate that the 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. Therefore, the estimated total annual cost of providing CMRs in LTC settings is \$1,504,140 (21,500 CMRs \times 0.583 hours/CMR \times \$120/hour). The estimate reflects costs previously calculated in the OCN 0938–1154.

Y. ICRs Regarding Coordination of Part D Plans With Other Prescription Drug Coverage (§ 423.458)

We proposed a change to simply strengthen our policy regarding EGWP sponsor responsibilities, there is no additional burden on the part of sponsors or other entities associated with the regulation. This section does not impose any new information collection.

Z. ICRs Regarding Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (§ 423.120)

The inconsistent use of identifiers that have not been validated has hindered efforts to combat fraud and abuse. Therefore, we will require, effective January 1, 2013, that Part D sponsors must include active and valid individual prescriber NPIs as identifiers in PDEs submitted to CMS. Since Part D sponsors are already required to include a prescriber identifier on PDEs submitted to CMS, there is no new collection of information burden imposed by this proposed regulation. Furthermore, the change does not impose any new collection of information burden on Medicare beneficiaries enrolled in the Part D program with respect to requests for reimbursement they may submit, since the requirement is imposed on Part D sponsors. After consideration of the public comments received, none of which specifically addressed this collection of information burden section, we are modifying this requirement as discussed in section II.E.11. of this final rule with comment period, Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (§ 423.120). However, we are not modifying these ICRs since, again, no new collection of information burden is imposed by this requirement.

TABLE 7—ESTIMATED FISCAL YEAR REPORTING, RECORDKEEPING AND COST BURDENS

Regulation sections	OMB control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total labor cost (\$)	Total capital/maintenance costs (\$)	Total cost (\$)
417.427	0938-0753	20	20	12	240	44.22	10,613	N/A	10,613
422.102	0938-1023	73	73	15	1,095	55.61	60,893	N/A	60,893
422.500	0938-0935	4	4	8	32	250.00	8,000	N/A	8,000
423.153	21,500	21,500	0.583	12,534.5	120.00	1,504,140	N/A	1,504,140
Total	21,597	21,597	13,901.5	N/A	1,583,646

Note: Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2010 wage data from the U.S. Department of Labor, Bureau of Labor Statistics.

AA. Additional Information Collection Requirements—Independence of LTC Consultant Pharmacists

In the proposed rule we imposed collection of information requirements as outlined in the regulation text and specified earlier in this section. However, we also made reference to associated information collection requirements that were not presented in the regulation text of the proposed rule. In our October 11, 2011 proposed rule (76 FR 63067), we discussed the information collection requirements related to the changes we considered that would require each LTC facility to employ or obtain the services of a consultant pharmacist who was not employed, under contract, or otherwise affiliated with the facility's pharmacy, a pharmaceutical manufacturer or distributor, or any affiliate of these entities.

Comment: Many commenters noted that the services performed by LTC consultant pharmacists are more extensive than the drug regimen reviews and include activities such as destroying unused medications, checking storage areas, conducting exit conferences, providing in-service education to nursing staff, observing medication distribution, and attending meetings. Commenters stated the full range of consultant pharmacist services need to be considered in determining the burden associated with the new requirements.

Response: We appreciate these comments and will use them to inform possible future rulemaking regarding the LTC consultant pharmacist requirements. However, after considering the public comments received, we are not finalizing this provision at this time.

V. Regulatory Impact Analysis

A. Statement of Need

The purpose of this final rule with comment period is to make revisions to the MA Part C and Part D programs to

implement provisions specified in the statute and make other changes to the regulations based on our continued experience in the administration of the Parts C and Part D programs. The final rule with comment period will—(1) Implement statutory provisions; (2) strengthen beneficiary protections; (3) exclude plan participants that perform poorly; (4) improve program efficiencies; and (5) clarify program requirements.

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 with comment period has been designated an “economically significant” rule under section 3(f)(1) of Executive Order 12866. Accordingly, we have prepared a regulatory impact analysis that details the anticipated

effects (costs, savings, and expected benefits), and alternatives considered by proposed requirement. Details regarding the burden associated with the requirements of this final regulation are located in the Collection of Information section (section IV. of this final rule with comment period).

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than \$7.0 million to \$34.5 million in any 1 year). Individuals and States are not included in the definition of a small entity. This final rule does not directly impact, health care providers, suppliers and State governments since it amends the current requirements for MA organizations and Parts D sponsors, and adds requirements for pharmaceutical manufacturers consistent with the statutory requirements of the new manufacturer drug discount program. Part D sponsors and pharmaceutical manufacturers, the entities that will largely be affected by the provisions of this rule, are not generally considered small business entities. Part D sponsors must meet minimum enrollment requirements (5,000 in urban areas and 1,500 in nonurban areas) and because of the revenue from such enrollments, these entities are generally above the revenue threshold required for analysis under the RFA. We determined that there were very few Part D sponsors that fell below the size thresholds for “small” businesses established by the Small Business Administration (SBA). Currently, the SBA size threshold is \$7 million in total annual receipts for health insurers (North American

Industry Classification System, or NAICS, Code 524114) and CMS has confirmed that most Part D sponsors have Part D receipts above the \$7 million threshold. We also determined that there were very few pharmaceutical manufacturers participating in the Medicare prescription program drug discount program that fell below the size thresholds for small businesses using the SBA size threshold of 750 employees (NAICS code 32541). Total jobs data for manufacturers support the fact that the pharmaceutical industry is dominated by large businesses.

While the NAICS lists 1,555 business in the United States that represent the pharmaceutical and medicine manufacturing industry only 237 brand manufacturers currently participate in the program, and most exceed the 750 employee threshold. The majority of smaller manufacturers are either generic or specialty pharmaceutical manufacturers that are unlikely to participate in the Medicare discount program. We reviewed some of the employment statistics for the smaller specialty pharmaceutical manufacturers that participate in the discount program, and found that the number of employees typically exceeds the SBA 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. Similarly, manufacturers are not normally considered small business entities. However, there are manufacturers that have minimal revenue, primarily because their emphasis is on the development of products rather than sales or they are not focused on large markets. A fraction of MA organizations and sponsors are considered small businesses because of their non-profit status. HHS uses as its measure of significant economic impact on a substantial number of small entities, a change in revenue of more than 3 to 5 percent. We do not believe that this threshold 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 with comment period 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 with comment period will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year by State, local, or tribal governments in the aggregate, or by the private sector of \$100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold was approximately \$136 million. This final rule with comment period is expected to reach this spending threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Based on CMS Office of the Actuary estimates, we do not believe that this final rule with comment period imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

After considering the public comments received, we are not finalizing two of the provisions included in the proposed rule—Application of Medicare Hospital-Acquired Conditions and Present on Admission Indicator Policy to MA organizations, and Independence of LTC Consultant Pharmacists. We estimated that the impact of the former provision would be negligible and received no comments on our estimate. We estimated the costs and savings associated with the consultant pharmacist independence provision and stated that we believed the costs and benefits would be offsetting. Some commenters disagreed with our estimates. However, we agree with the many commenters who claimed that the requirement for consultant pharmacists to be independent would be highly disruptive to the industry, but would not solve drug overutilization and inappropriate prescribing in LTC, because others, such as LTC facility staff and physicians, contribute significantly to the problem. Therefore, although we believe changes are necessary and a requirement for consultant pharmacist independence is part of the right

approach, we are not finalizing the requirement in this rule. Since we are not finalizing these two provisions, they have no impact on this final rule with comment period.

In Table 8, we estimate total costs to the Federal government, States, Part D sponsors, MA organizations, pharmaceutical manufacturers and other private sector entities as a result of various provisions of this final rule with comment period. The provisions with the most significant costs (costs greater than \$100 million from FY 2013 through FY 2018) in this final rule with comment period are the Medicare Coverage Gap Discount Program (Discount Program), and the Inclusion of Benzodiazepines, and Barbiturates as Covered Part D drugs.

The total costs of the Discount Program for the periods beginning FY 2013 through FY 2018 are estimated to be \$31.1 billion, and the total costs of the inclusion of benzodiazepines and barbiturates is \$1.9 billion.

Tables 9, 10, and 11 detail the costs by cost-bearing entity. Specifically, Table 9 describes costs and savings to the Federal government, Table 10 describes costs to MA organizations and/or PDP sponsors and third party entities, Table 11 describes costs to pharmaceutical manufacturers, and Table 12 describes savings to States.

As a result, when considering both the costs and savings associated with the provisions of this final rule with comment period, we conclude with a net cost estimate of \$31.3 billion for FY 2013 through FY 2018.

C. Anticipated Effects

1. Medicare Coverage Gap Discount Program

The Discount Program makes manufacturer discounts available at the point-of-sale to applicable Medicare beneficiaries receiving applicable drugs while in the coverage gap. In general, the discount on each applicable drug is 50 percent of an amount equal to the negotiated price of the drug (less any dispensing fee). In general, manufacturers must agree to provide these discounts by signing an agreement with CMS in order for their applicable drugs to continue to be covered under Medicare Part D.

a. Required Payment of Gap Discounts

We believe that there will be significant costs to manufacturers from paying the required discounts to beneficiaries while in the coverage gap. We estimate that aggregate discounts from pharmaceutical manufacturers will be \$29.7 billion during FY 2013 through

FY 2018. That estimate is based upon historical patterns of claims dispensed during the coverage gap and the dollar amount of those claims trended forward by enrollment growth and price increase.

In addition, the Discount Program will increase Medicare costs by inducing additional use of more expensive brand name drugs by improving beneficiary adherence as a result of the lower out-of-pocket costs by increasing use of brand name instead of generic drugs. The increased use of brand name drugs will increase Medicare costs by increasing the number of beneficiaries reaching the Part D catastrophic threshold and thereby, increasing the cost of plan benefits. We estimate that the Discount Program will increase Medicare costs by \$1.3 billion during FY 2013 through FY 2018.

It is important to note that these estimated Medicare costs do not include costs related to the Affordable Care Act provisions that revised the Part D benefit structure to close the coverage gap. These provisions not only revised the coinsurance amount, but also reduced the growth in the annual out-of-pocket threshold. The costs to the Federal government associated with these provisions, as scored in the April 15, 2011 final rule (76 FR 21432), were estimated to total \$3.6 billion during FY 2011 through FY 2016.

b. Other Manufacturer Costs

We believe that manufacturers will also incur costs as a result of specific obligations under the Discount Program Agreement. The Discount Program Agreement must be signed by all participating manufacturers and provides the terms and conditions for timely payment of discounts, disputes and appeals, penalties, and termination of the Agreement. In order to comply with the Discount Program Agreement, manufacturers will need to analyze and pay quarterly invoices, notify CMS about labeler code changes, notify FDA about NDC changes and maintain records for potential audit by CMS. This will require them to establish connectivity with the Discount Program third party administrator (TPA) to receive quarterly invoices and file disputes, and obtain access to the CMS Health Plan Management System (HPMS) to update and maintain contact and labeler code information. However, manufacturers already have existing systems and perform similar activities as a result of their experience with Medicaid and Tricare. We estimate that analyzing and paying the quarterly invoices will require 0.5 FTEs. We

estimate that the cost to manufacturers will be \$73,380 (annual salary for a Pharmaceutical Manufacturing Compliance Officer according to Bureau of Labor Statistics) plus 48 percent for fringe benefits and overhead $\times 0.5$ FTE $\times 240$ manufacturers $\times 6$ years for a total cost of \$78.2 million over the complete period FY 2013 through FY 2018.

2. Payment Processes for Part D Sponsors

We believe that there will be a minor impact on Part D sponsors from receiving and reconciling estimated rebates advanced by CMS with subsequent payments by manufacturers. Part D sponsors have experience and existing systems to accept and reconcile funds with CMS, including a LICS subsidy and a reinsurance subsidy. We believe that there will be a marginal increase in resources focused on accounting and computer system operations and maintenance. We estimate that the additional resources required will be 0.5 FTEs, on average, per Part D sponsor. We estimate that the total cost to Part D sponsors will be \$63,360 (annual salary for insurance carrier compliance officer according to Bureau of Labor Statistics) plus 48 percent for fringe benefits and overhead $\times 0.5$ FTE per Part D sponsor $\times 270$ Part D sponsors $\times 6$ years for a total of \$76.0 million over the complete period FY 2013 through FY 2018.

3. Provision of Applicable Discounts for Applicable Drugs for Applicable Beneficiaries

We believe that there will be a minor impact on Part D sponsors as a result of this provision. Part D sponsors already implement systems to adjudicate pharmacy claims. With the exception of calculating and accounting for gap discounts, those systems include similar, if not identical, tasks as the requirements in the final rule. Further, we believe that the carrying cost of distributing the discounts to beneficiaries will be offset by prospective payments from us as previously described.

We believe that the additional workload associated with this final regulation will involve modifications to existing computer programming to account for the differences between the Discount-related systems and the traditional Part D program. In addition, we expect there to be additional reporting and recordkeeping. We estimate that Part D sponsors will increase resources the equivalent of 0.5 additional FTEs to accomplish these tasks. We estimate the cost to Part D sponsors will be \$63,360 (annual salary

for insurance carrier compliance officer according to Bureau of Labor Statistics) plus 48 percent for fringe benefits and overhead $\times 270$ Part D sponsors $\times 6$ years for a total cost of \$76.0 million over the complete period FY 2013 through FY 2018.

4. Manufacturer Discount Payment Audits and Dispute Resolution

The final regulation will permit manufacturers to undertake audits of the data used to calculate quarterly invoices and to dispute the invoices themselves. We believe that the activities necessary for disputing invoices and conducting data audits will be accommodated by the additional resources that we earlier linked to the Discount Program Agreement. Therefore, we are not estimating an additional economic impact to manufacturers from this provision.

5. Beneficiary Dispute Resolution

The final rule will create the right of beneficiaries to dispute gap discounts using preexisting Part D sponsor beneficiary dispute resolution mechanisms. We believe that the potential increase in beneficiary dispute volume will not require additional Part D sponsor resources. We have made significant efforts to ensure that the data used to calculate the discounts are accurate. We believe that the accuracy of the data, coupled with the automation of the dispute calculation, will result in accurate discounts that will generate few beneficiary appeals and will be accommodated within existing resources.

6. Compliance Monitoring and Civil Money Penalties

The final regulations require CMS to impose penalties if a manufacturer does not pay gap discounts that are owed according to the terms of the Discount Program Agreement. We believe that, in general, manufacturers will pay the quarterly invoice according to the terms within the Discount Program Agreement and, therefore; we expect very few instances where manufacturers are levied a civil money penalty. Accordingly, we assume that monetary penalties will be levied on only a very small percent of all discount payments, estimated to be approximately 0.03 percent, for a total of \$9.64 million in civil money penalties imposed over the period FY 2013 through FY 2018.

7. Termination of Discount Program Agreement for Part D Program

We believe that we will rarely find it necessary to terminate an agreement. Upon termination, covered Part D drugs

of the manufacturers will be excluded from the Part D program and the manufacturer potentially will suffer a significant reduction in revenue. We have experience with similar programs and believe that the potential reduction of revenue will encourage manufacturers to resolve our concerns. This will tend to avoid terminations and the associated fiscal effects.

Consequently, we estimate that there will be no material costs to manufacturers due to potential agreement terminations during the period FY 2013 through FY 2018.

8. Inclusion of Benzodiazepines and Barbiturates as Part D Drugs

In accordance with section 175 of the MIPPA that amended section 1860D-2(e)(2)(A) of the Act (42 U.S.C. 1395w-102(e)(2)(A)), we proposed to revise the definition of Part D drug at § 423.100, by including barbiturates when used for the medical indications of epilepsy, cancer, or a chronic mental health disorder, and benzodiazepines class drugs as covered under Part D effective January 1, 2013.

Under this provision, Part D plan sponsors will be required to submit information in their formulary files indicating that they will cover these drugs. We estimated that the cost to the Federal Government to be \$1.9 billion over the 2013 through 2018 period. We assumed the cost of benzodiazepines and barbiturates as 0.4 percent of total drug cost, and that the inclusion of both these drugs will increase proportional to the current overall Part D level.

9. Good Cause and Reinstatement Into a Cost Plan

At § 417.460(c)(3) we proposed to allow beneficiaries who have been disenrolled from their cost plans for nonpayment of premium or other charges imposed by the plan for deductible and coinsurance amounts the opportunity to be reinstated into their plan if they can establish good cause for nonpayment of cost-sharing. CMS (or its designee) will evaluate cost-plan enrollees' requests for reinstatement based on good cause and make the "good cause" determinations. We anticipate that there would be no cost impact on cost plans. We received no comments on the regulatory impact analysis of this proposal and therefore are finalizing this provision without modification.

10. Determination of Actuarially Equivalent Creditable Prescription Drug Coverage

We are clarifying our regulations at § 423.56 to define creditable

prescription drug coverage consistent with the calculation of the actuarial value of qualified retiree prescription drug coverage found at § 423.884(d). Since this is a clarification to an existing calculation that is already being utilized by organizations providing creditable coverage, there will be no cost impact on these organizations.

We received no comments on the regulatory impact analysis of this proposal and are finalizing this provision without modification.

11. Who May File Part D Appeals With the Independent Review Entity

The changes to § 423.600 will allow prescribing physicians and other prescribers to request IRE reconsiderations on behalf of Part D plan enrollees and the corresponding change to § 423.602(a) specifies that the IRE must also notify the prescribing physician or other prescriber of its decision when the prescriber makes the request on behalf of the enrollee. The quantifiable burden associated with these provisions is the cost of processing Part D reconsiderations (which includes providing notice of the decision). While this provision is expected to increase the number of reconsiderations processed and completed by the IRE, it will also significantly reduce the number of appeals that have to be dismissed because the AOR form would no longer be required in cases when a prescriber is requesting a reconsideration on behalf of an enrollee. In 2010, the IRE dismissed approximately 2,500 reconsideration requests submitted by prescribers due to the lack of a properly executed AOR form, at an estimated cost of \$215,000. We estimate the cost of issuing a substantive reconsideration decision in cases that are currently subject to dismissal to be \$540,000, assuming an estimated cost of about \$216 per case. However, this added cost would be offset by the reduction in dismissed cases, for an estimated annual cost increase of \$325,000 (\$540,000 less \$215,000).

We also believe that eliminating the AOR requirement will result in about a 15 percent increase in the total number of IRE reconsiderations requests. Based on the percentage of plan level appeals currently filed by prescribers on behalf of enrollees (approximately 85 percent), we estimate an increase in prescriber-initiated IRE appeals, which would be partially offset by a decrease in enrollee-initiated IRE appeals. Based on 2010 reconsideration data, we estimate there would be an additional 3,000 reconsideration requests, with an estimated increase in annual costs of

about \$648,000. The estimated increased cost associated with issuing substantive reconsideration decisions (as opposed to dismissals) and the increased cost associated with the increase in the reconsideration workload, results in total estimated annual increased costs to the Federal government of approximately \$973,000 or a total of \$5.84 million for FYs 2013 through 2018.

The increase in reconsideration requests would result in additional costs to plan sponsors based upon additional time and effort to assemble case files and documentation associated with these requests and shipping to the IRE for processing. We assume a cost of approximately \$25.00 per reconsideration to print, copy, compile, and mail the case file to the IRE. This results in an additional annual cost to all Part D plan sponsors of approximately \$75,000 (\$25 per file × 3,000 additional files = \$75,000), or a total of \$450,000 from FYs 2013 through 2018.

Comment: CMS received a few comments on the regulatory impact analysis of this proposal. A commenter, citing the greater number of IRE reconsideration requests under the MA program and linking that in part to providers' ability to initiate appeals, urged CMS to consider additional administrative costs associated with this change. Another commenter specifically noted the increased burden placed on plan sponsors' appeals departments as a result of having to prepare a larger number of case files for the IRE.

Response: We agree that compared to the Part D program, the MA program has a significantly higher number of IRE appeal requests. However, this is not a result of provider appeals, because in the MA program, providers do not technically have a right to appeal an adverse plan reconsideration to the IRE. Instead, in MA, all adverse plan reconsiderations are auto-forwarded to the IRE for review. We are not proposing that all adverse redeterminations in the Part D program be auto-forwarded to the IRE. The burden estimate already includes a discussion of the burden associated with the increased number of reconsiderations as a result of the proposed change and the increased number of cases that plan sponsors will need to prepare for shipment to the IRE. Thus, we believe that we have accurately accounted for the estimated burden increase related to this provision, both for the government and plan sponsors, and are finalizing this provision without modification.

12. Termination for Continued Lower-Than-3-Star-Ratings

We have the authority under section 1857(c)(2) of the Act to terminate contracts with a MA organization or a Medicare PDP sponsor when we determine that the organization has failed substantially to carry out the contract or is carrying out the contract in a manner inconsistent with the efficient and effective administration of the Part C or D program. We believe that a sponsor that fails to achieve at least a 3-star rating for 3 consecutive years has demonstrated consistently that it is unable or unwilling to take corrective action to improve its Part C or D performance. Therefore, we are proposing to revise the regulation to reflect our position that 3 years' worth of low star ratings constitutes a sufficient basis for CMS to terminate a sponsor's Part C or D contract.

The changes made to this regulation will not result in any additional costs. MA organizations and Part D sponsors already incur costs as a result of needing to be in compliance with existing regulatory requirements. This change merely clarifies our authority to use sustained poor performance rating results (which are already being produced annually) as a basis for termination.

13. Exclusion for Sponsors of Contracts Terminated for Cause

We have modified the past performance review period described in § 422.502(b) and § 423.503(b) (by adding new paragraphs at § 422.502(b)(3) and at § 423.503(b)(3) as well as § 422.502(b)(4) and at § 423.503(b)(4)) to include among the factors that may support a CMS denial of a contract application those CMS-initiated terminations or non-renewals that became effective within the 38 months preceding the submission of a new application.

The changes made to this regulation will not result in any additional costs since we are not imposing any new requirements. Rather, we are merely extending the period of time that we can review for purposes of application qualification determinations when an organization has had a prior contract terminated or non-renewed by CMS. Thus, there are no additional costs involved.

14. Independence of Long Term Care Consultant Pharmacists

In our October 11, 2011 proposed rule (76 FR 63071), we discussed the anticipated effects of the changes we considered that would require each LTC facility to employ or obtain the services

of a consultant pharmacist who was not employed, under contract, or otherwise affiliated with the facility's pharmacy, a pharmaceutical manufacturer or distributor, or any affiliate of these entities.

Comment: Some commenters disagreed with our belief that the costs and benefits associated with this provision would be offsetting. Instead, they contended that the requirement for independent consultant pharmacists would create a financial burden for facilities and consultant pharmacists and that the requirement would cost, not save, money.

Response: We are not finalizing the requirement for consultant pharmacists to be independent in this rule. However, we appreciate the comments on our impact analysis and will consider the information provided in the process of possible future rulemaking on this issue.

15. New Benefit Flexibility for Certain Dual Eligible Special Needs Plans (D-SNPs) (§ 422.102)

We estimate that our modification of § 422.102(e) to allow certain D-SNPs to offer additional supplemental benefits beyond those other MA plans—subject to CMS approval, and as specified annually by CMS—will result in aggregate savings to both States and the Federal government of approximately \$137.7 million between FY 2013 and FY 2018. These Federal and State savings estimates are based on our assumption that, based on the eligibility standards we establish, approximately 73 D-SNPs will qualify to participate in this initiative, representing a total of approximately 507,000 enrollees in 2011. We estimate that D-SNPs participating in this initiative will incur a small cost of approximately \$0.07 million annually in order to comply with the QIP reporting requirements that we are requiring for eligible D-SNPs as a condition of participating in this initiative. Accounting for these administrative costs to MA organizations, we estimate this provision will result in an aggregate savings to the health care sector of \$137.22 million between FY 2013 and FY 2018.

While we acknowledge that the current authority for all SNPs, including D-SNPs, to restrict enrollment to special needs individuals (under section 1859(f)(1) of the Act), expires at the end of the 2013 contract year, we report the impact of this provision from FYs 2013 through 2018, to be consistent with the scoring of other provisions of this rule. We note that this impact may vary based on Congressional action.

We are basing our analysis of the potential cost impacts of the D-SNP benefit flexibility initiative on our experience with HMO integrated care model demonstrations for Medicare-Medicaid dual eligibles and on our observation of enrollment increases that resulted from these demonstrations.

From 1997 through 2006, we conducted demonstrations that pooled Medicare and Medicaid payments to the Minnesota Senior Health Options (MSHO), Wisconsin Health Partnership Program (WPP) and Massachusetts Senior Care Organization (MSCO) HMOs to deliver Medicare and Medicaid-covered primary, acute, and long-term care services to voluntarily enrolled elderly dual eligibles. The plans participating in the demonstration were responsible for delivering Medicaid community care services, developing managed care coordination models, and arranging for the delivery of the full range of acute and long-term care services and developing care coordination models—characteristics that we believe are essential for the provision of comprehensive, integrated care. The demonstrations also used Medicaid funds to cover community care services (for example, personal care, homemaking, transportation, personal emergency response systems, home-delivered meals, adaptive equipment, home modifications, incontinence supplies, and respite care that support independence and avoid inappropriate institutionalization). At the start of the demonstrations, concern that marketing additional supplemental benefit offerings would attract a significant number of new enrollees led us to cap enrollment in the demonstration. However, States in the demonstration never came close to reaching this enrollment cap. The only major enrollment increase was in 2006, when the demonstration programs were converted to D-SNPs, and the D-SNPs were able to passively enroll enrollees.

The MSHO demonstration, the most extensively analyzed integrated care demonstration program for dual eligible enrollees, received a Medicare and a Medicaid capitation payment for the provision of acute and long-term care services, but reimbursed providers directly for nursing home services on a fee-for-service basis. Therefore, Federal and State government costs under this capitated program were not related to actual utilization, with the exception of fee-for-service nursing home costs. Utilization data from the MSHO demonstration show that MSHO enrollees had significantly fewer short-stay nursing home admissions as compared to dual eligibles both within

and outside of the MSHO demonstration area.

We believe that plans have incentives to generate higher rebates to fund these extra supplemental benefits and have assumed that they will reduce their margins by 1 percent. Taking into account expected growth rates in bids and benchmarks, and projected rebate shares, we expect that D-SNPs that participate in this benefit flexibility initiative will reduce their bids by 2 percent on average—1 percent medical and 1 percent margin—as a result of our proposed changes to § 422.102(e).

Applying the per-capita savings to the projected enrollment for these qualified D-SNPs, we project \$131.6 million savings to the Medicare program for the 6-year period between FY 2013 and FY 2018.

We also believe that, when delivered in a prudent manner, the additional benefits that qualified D-SNPs will be permitted to offer under our proposed changes to § 422.102(e) will allow some high-risk patients to remain in their home and out of institutions. We estimate that the new flexibility will generate modest reductions in Medicare program expenditures, due to a 1 percent savings of Medicare-covered medical benefits stemming from these enhanced flexibilities.

Additionally, based on the evidence from the studies in Massachusetts, Minnesota, and Wisconsin demonstrations, we believe that the flexibility for D-SNPs to offer additional supplemental benefits will modestly impact nursing facility utilization rates and Medicaid costs. Our assumptions regarding the effectiveness of these services in preventing nursing facility entry are consistent with assumptions we have used for other legislative and regulatory proposals aimed at reducing nursing facility use and encouraging home and community based long term care. Applying the per-capita savings to the projected enrollment for D-SNPs that would qualify to participate in this initiative, we estimate Federal and State Medicaid savings of \$6.12 million for the 6-year period between FY 2013 and FY 2018 as a result of this provision.

Finally, as detailed in the section III. Information Collection Requirements, of this final rule with comment period, we estimate an annual cost of \$60,893 to MA organizations as a result of this provision's requirements. This cost reflects the administrative cost, including burden hours and staff wage rates, that participating D-SNPs would incur in order to complete and submit the additional QIP that we are requiring as a condition of participating in this benefits flexibility initiative. We

estimate that these requirements will cost MA organizations approximately \$0.36 million from FYs 2013 through 2018.

16. Application of the Medicare Hospital-Acquired Conditions and Present on Admission Indicator Policy to MA Organizations (§ 422.504)

We proposed to require MA organizations to reduce reimbursements for Part A hospital services for contract provider hospitals for serious events that could be prevented through evidence based guidelines, in accordance with the HACs and POA policy that is currently required for hospitals paid under the Original Medicare IPPS. MA organizations are already required to pay non-contract provider hospitals the amount that they will receive for services under Original Medicare, including any applicable reductions for HACs. This requirement is outlined in the MA Payment Guide for Out of Network Payments.

Based on the comments received, we are not finalizing this proposal, but will continue to consider alternate strategies for reducing hospital-acquired conditions in hospitals that provide care to MA enrollees and strive toward aligning quality initiatives in the Medicare and Medicare Advantage programs.

17. Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse, and Waste Control Program

As discussed in section II.D.6. of this final rule with comment period, Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program, a previous review of 2009 PDE data suggested that the adjusted total estimated cost of 2009 community-based discontinued first fills of chronic medications was roughly \$1.4 billion. In light of this cost, we proposed to revise § 423.153(b)(4) to provide that a Medicare Part D sponsor's drug utilization management program must establish and apply a daily cost-sharing rate, under certain circumstances, to a prescription presented an enrollee at a network pharmacy for a covered Part D generic or brand drug that is dispensed for a supply of less than 30 days. Under this proposal, the enrollee and his or her prescriber generally will decide if a medication supply of less than 30 days will be appropriate, and if so, the daily cost-sharing rate for the medication will be applied by the Part D sponsor based on the days supply dispensed.

Potential savings of a daily cost-sharing rate requirement on Part D sponsors will come from a reduction of the estimated \$1.4 billion in costs noted above which will be offset by some additional dispensing fees. We previously estimated the potential savings to the Part D program to be \$140 million in 2013 alone, and over \$2.4 billion total by 2018 as described in section II.D.6. of this final rule with comment period. However, because we are revising the applicability date of this requirement to January 1, 2014, we have updated the cumulative savings in 2018 to roughly \$1.8 billion, as also noted in section II.D.6. of this final rule with comment period.

Aside from the additional dispensing fees, we expect the other regulatory impact costs imposed by the proposed provisions to be the one-time costs for the industry to reprogram PBM systems to apply a daily cost-sharing rate. In this regard, we estimate that the number of hours for 28 PBMs and 12 plan organizations to reprogram their systems to establish and apply a daily copayment rate is 80 hours per processor or plan organization, for a total one-time burden of 3,200 hours (40 × 80). The estimated cost associated with such reprogramming is the estimated number of hours multiplied by the estimated hourly rate of \$145.37 (Department of Labor, Bureau of Labor Statistics, Computer Software Engineers-Applications), which equals \$465,184.

We did not receive any comments on this specific section, and are finalizing the requirement as discussed in section II.D.6. of this final rule with comment period.

18. Technical Corrections to Enrollment Provisions

We proposed technical changes that correct cross-references that should have been updated in previous rulemaking. These changes are technical corrections and do not represent a burden for small businesses, rural hospitals, States, or the private sector. We received no comments on the regulatory impact analysis of this proposal and, therefore, are finalizing this provision without modification.

19. MA and Part D Disclosure Requirements to Cost Contract Plans

We are proposing to extend the disclosure requirements in § 422.111 and § 423.128 to cost contract plans. Our regulations at § 422.111 and § 423.128 require MA organizations and Part D sponsors to disclose to enrollees, at the time of enrollment and annually thereafter (in the form of an annual

notice of change/evidence of coverage, or ANOC/EOC mailing), certain detailed information about plan benefits, service area, provider and pharmacy access, grievance and appeal procedures, quality improvement programs, and disenrollment rights and responsibilities. They also require the provision of certain information about request and establish requirements with respect to dissemination of explanations of benefits, customer service call centers, and Internet Web sites.

For each entity, we estimate that it will take 12 hours to develop and submit the required information. This includes 1 hour to read CMS' published instructions, 6 hours to generate the standardized document, 1 hour to submit the materials, and 4 hours to print and disclose information to the beneficiaries. We estimate 20 cost contractors will be affected annually by this requirement, resulting in a total annual burden of 240 hours. We estimate, based on an hourly wage of \$21.93 (hourly rate for a GS-10 step 1) plus 48 percent for fringe benefits and overhead, that this requirement will result in a total annual burden of \$7,789 rounded. We did not receive public comments on the regulatory impact for this provision but are revising it to more accurately reflect the labor associated with the provision. In the October 2011 proposed rule, we based costs on the activities of a compliance officer instead of those of a GS-10 step 1.

20. Denials of SNP Applications and SNP Appeal Rights

We estimate that the proposed provision will have a minimal impact resulting from administrative costs incurred by the small number of SNP applicants that we expect will receive application denials and the small percentage of denied applicants that we expect will appeal our denial decision. For those organizations that do appeal the denial of their SNP application, a minimal number of professional staff working over a short period of time will be required to prepare and present the organization's appeal.

We estimate that the total annual hourly burden for developing and presenting a case for us to review is equal to the number of organizations likely to request an appeal multiplied by the number of hours for the attorneys of each appealing SNP to research, draft, submit, and present their arguments to CMS. Based on SNP application denials from contract year 2012, out of the approximately 400 SNP applications received, 8 of these applications were denied and all 8 denials were appealed. In contract year 2011, 8 SNP

applications were denied and none of these denials were appealed. Taking the average of the last 2 years, we estimate that approximately 4 denied applicants will appeal the denial of the SNP application. We further estimate that 1 attorney working for 8 hours could complete the documentation to be submitted for each application denial. The estimated annual cost to all of the MA organizations, the aggregate, that have been denied to offer a SNP associated with this provision (assuming an attorney billing \$250 per hour) is \$8,000 (32 hours × \$250) or when rounded, to approximately \$0.01 million per year.

21. Contract Requirements for First Tier and Downstream Entities in Subcontracts

The regulations at § 422.504(i) and § 423.505(i) require MA organizations and Part D sponsors to require all of the first tier, downstream, and related entities to which they have delegated the performance of certain Part C or D functions to agree to certain obligations. We believe that the most legally effective and direct way to ensure that the MA organizations and Part D sponsors retain the necessary control and oversight over their delegated entities is by requiring all contracts among those entities to specifically reference each party's obligations to the sponsor, as enumerated in § 422.504(i) and § 423.505(i). Thus, the regulation has been changed to address this need. Specifically, we deleted the term "written arrangements" throughout § 422.504(i) and § 423.505(i) and in each instance replace it with "each and every contract."

The proposed changes will not result in any additional costs since these types of contracts are already in use and required by regulation. Thus, the strengthening of the language to ensure that the sponsor is responsible for downstream entities is merely clarifying an existing requirement and eliminating potential loopholes.

22. Valid Prescriptions

In the § 423.100 proposed definition of "valid prescription" and the § 423.104 requirement of a "valid prescription," we will codify our longstanding policy of deferring, when applicable, to State law to determine whether a prescription is valid such that the prescribed drug may be eligible for Part D coverage.

The changes made to this regulation will not result in any additional costs. Not only have we expected that prescriptions will be valid under applicable State law since the beginning

of the Part D program, but also prescribers and pharmacies remain subject to applicable State laws regarding valid prescriptions. Furthermore, private contracts regarding Part D drugs (such as those between MA organizations or Part D sponsors and pharmacies) likely also require valid prescriptions. In light of the above realities, it is not unreasonable to presume that MA organizations, Part D sponsors, PBMs, and pharmacies are already taking steps to write prescriptions that are valid under applicable State law. Accordingly, we do not believe codifying the valid prescription requirement will change current practices.

23. Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings

Current regulations require that unless a beneficiary is in a LTC setting, the comprehensive medication review (CMR) must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider, and may result in a recommended medication action plan. Section 10328 of the Affordable Care Act amended section 1860D-4(c)(2) of the Act to require that all targeted beneficiaries be offered a CMR. Accordingly, we proposed a change to § 423.153 to require that Part D sponsors offer a CMR to beneficiaries in LTC settings, but permitting the sponsor to allow the pharmacist or other qualified provider to perform the CMR without the beneficiary in cases when the beneficiary is in a LTC facility and is cognitively impaired and thus, cannot accept the sponsor's offer of a CMR. We anticipated that the impact of this proposed revision would clarify the CMR process for sponsors by allowing pharmacists and other qualified providers to ascertain whether the patient is willing and able to participate in a CMR before administering it. We incorrectly stated in the October 2011 proposed rule that we did not anticipate any costs or savings associated with this change. However, there will be a modest increase based on the requirement to offer CMRs to beneficiaries residing in LTC settings with written summaries and provide the summaries and action plans in a standardized format that complies with the requirements specified by CMS. We estimate that 215,000 beneficiaries in LTC settings are eligible for MTM services and 10 percent of those beneficiaries will receive an annual CMR. We also estimate that the 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 LTC settings is \$1,524,565 ($\$70.91/\text{CMR} \times 21,500 \text{ CMRs}$). The estimate reflects costs previously calculated in the OCN 0938–1154.

24. Coordination of Part D Plans With Other Prescription Drug Coverage

The regulation will be explicit that sponsors, when providing Part D benefits to enrollees of EGWPs, are subject to the same requirements as sponsors providing Part D coverage in the individual market unless such requirements are explicitly waived. Since this change is being made to clarify an existing policy, we do not anticipate any effect on costs or savings on any specific entity.

25. Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (NPIs)

The inconsistent use of identifiers by prescribers on Part D claims has hindered some of our efforts to combat fraud and abuse activities. Therefore, we proposed to require, effective January 1, 2013, that Part D sponsors include only active and valid individual prescriber NPIs as identifiers in PDEs submitted to CMS.

The impact associated with these proposed regulations is: (1) The annual cost for PBMs and plan organizations to contract with a commercial vendor or with network pharmacies to provide prescriber ID validation services; or (2) the annual cost required for PBMs and plan organizations to build their own databases of active and valid prescriber NPIs. We estimated a one-time burden for an estimated 28 PBMs and 12 plan organizations to negotiate and execute a contract with a commercial vendor to provide prescriber ID validation services to be negligible, particularly since PBMs and plan organizations typically have in-house counsel or law firms on retainer. The estimated annual cost of such a contract is \$160,000, which is the mid-point of estimates we have seen for such a contract. Therefore, the estimated annual cost of such a contract for 40 PBMs and plan organizations is \$6,400,000 ($40 \times 160,000$). However, preliminary results of an analysis of coverage year 2011 PDEs submitted to date conducted by a contractor to CMS indicate that approximately 90 percent already contain valid individual NPIs. Therefore, this estimation should be reduced to reflect that a certain amount of cost associated with prescriber ID validation has already been absorbed by the industry. Therefore, we assume that 80 percent of the industry needs to acquire additional prescriber ID validation capacity in order to submit only PDEs that contain active and valid individual prescriber NPIs to CMS. Thus, the estimated annual cost to

PBMs and plan organizations of a contract with a commercial vendor to perform prescriber NPI validation services is \$5,120,000 ($6,400,000 \times 0.8$).

With respect to PBMs and plan organizations that decide to build their own databases of active and valid prescriber NPIs (or to contract with network pharmacies for prescriber validation services), we assume that they will only do so if the cost is equal to or less than contracting with a commercial vendor for such services, and therefore, no estimation of the costs to do so is necessary.

Since approximately 90 percent of PDEs for coverage year 2011 submitted to CMS already contain valid individual NPIs, an estimated 95 percent of physicians have an NPI, and prescribers may voluntarily obtain an NPI to facilitate coverage of their patients' prescriptions, we estimate negligible costs associated with any PDE that cannot be submitted to CMS for lack of an NPI.

After consideration of the public comments received, we are modifying this requirement as discussed in section II.E.11. of this final rule with comment period (Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (§ 423.120)). However, we are not modifying this regulatory impact analysis, since none of the comments received specifically addressed this analysis, and we believe our modifications do not necessitate a change to this analysis.

TABLE 8—ESTIMATED AGGREGATED COSTS TO THE HEALTH CARE SECTOR BY PROVISION FOR FISCAL YEARS 2013 THROUGH 2018

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TABLE 8—ESTIMATED AGGREGATED COSTS TO THE HEALTH CARE SECTOR BY PROVISION FOR FISCAL YEARS 2013 THROUGH 2018—Continued

Provision(s)	Regulation section(s)	Fiscal year (\$ in millions)						Total (\$ in millions) FYs 2013– 2018
		2013	2014	2015	2016	2017	2018	
Total Impact (\$ in millions)	3,977.03	4,408.71	4,875.83	5,437.57	5,979.95	6,570.19	31,249.28

Note: Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2010 wage data from the U.S. Department of Labor, Bureau of Labor Statistics.

TABLE 9—ESTIMATED COSTS AND SAVINGS TO THE FEDERAL GOVERNMENT BY PROVISION FOR FYs 2013 THROUGH 2018

Provision(s)	Regulation section(s)	Fiscal year (\$ in millions)						Total (\$ in millions) FYs 2013– 2018
		2013	2014	2015	2016	2017	2018	
Medicare Coverage Gap Agreement	423.2315	160.00	190.00	210.00	260.00	260.00	260.00	1,340.00
Inclusion of Benzodiazepines and Barbiturates as Part D Covered Drugs	423.100	200.00	280.00	300.00	330.00	360.00	390.00	1,860.00
Who May File Part D Appeals with the Independent Review Entity	423.600	0.97	0.97	0.97	0.97	0.97	0.97	5.84
Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program	423.100 423.104 423.153	0.00	– 150.00	– 260.00	– 360.00	– 460.00	– 580.00	– 1,810.00
Benefit Flexibility for Certain Dual Eligible Special Needs Plans (SNPs)—Medicare	422.102	– 29.80	– 27.63	– 20.76	– 19.08	– 17.16	– 17.13	– 131.56
Benefit Flexibility for Certain Dual Eligible Special Needs Plans (SNPs)—Federal Medicaid	422.102	– 0.67	– 0.64	– 0.59	– 0.55	– 0.52	– 0.53	– 3.50
Total (\$ in millions)	330.50	292.70	229.62	211.34	142.29	53.31	1,260.78

Note: Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2010 wage data from the U.S. Department of Labor, Bureau of Labor Statistics.

TABLE 10—ESTIMATED COSTS TO MA ORGANIZATIONS AND PART D SPONSORS BY PROVISION FOR FYs 2013 THROUGH 2018

Provision(s)	Regulation section(s)	Costs per fiscal year (\$ in millions)						Total FYs 2013– 2018 (\$ in millions)
		2013	2014	2015	2016	2017	2018	
Payment Processes for Part D Sponsors	423.2320	12.66	12.66	12.66	12.66	12.66	12.66	75.96
Provision of Applicable Discounts	423.2325	12.66	12.66	12.66	12.66	12.66	12.66	75.96
Who May File Part D Appeals with the Independent Review Entity	423.600	0.08	0.08	0.08	0.08	0.08	0.08	0.45
Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program	423.100 423.104 423.153	0.5	0	0	0	0	0	0.5
Benefit Flexibility for Certain Dual Eligible Special Needs Plans (SNPs)—Medicare	422.102	0.06	0.06	0.06	0.06	0.06	0.06	0.36
Apply MA and Part D Disclosure Requirements to Cost Contract Plans	417.427	0.01	0.01	0.01	0.01	0.01	0.01	0.06
Add language specific to SNP applications to give CMS the clear authority to deny SNP applications and to give SNPs appeal rights	22.500	0.01	0.01	0.01	0.01	0.01	0.01	0.06
Access to covered Part D drugs through the use of standardized technology and NPIs	423.120	5.12	5.12	5.12	5.12	5.12	5.12	30.72
MTM Comprehensive Medication Reviews in LTC Settings	423.153	1.52	1.52	1.52	1.52	1.52	1.52	9.12
Total (\$ in millions)	32.62	32.12	32.12	32.12	32.12	32.12	193.19

Note: Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2010 wage data from the U.S. Department of Labor, Bureau of Labor Statistics.

TABLE 11—ESTIMATED COSTS TO MANUFACTURERS BY PROVISION FOR FISCAL YEARS 2013 THROUGH 2018

Provision(s)	Regulation section(s)	Costs per fiscal year (\$ in millions)						Total FYs 2013– 2018 (\$ in millions)
		2013	2014	2015	2016	2017	2018	
Medicare Coverage Gap Agreement	423.2315	3,600.00	4,070.00	4,600.00	5,180.00	5,790.00	6,470.00	29,710.00
Other Manufacturer Costs	423.2315	13.03	13.03	13.03	13.03	13.03	13.03	78.18
Compliance and Civil Money Penalties	423.2340	1.18	1.32	1.48	1.67	1.88	2.11	9.64

TABLE 11—ESTIMATED COSTS TO MANUFACTURERS BY PROVISION FOR FISCAL YEARS 2013 THROUGH 2018—Continued

Provision(s)	Regulation section(s)	Costs per fiscal year (\$ in millions)						Total (FYs 2013– 2018) (\$ in millions)
		2013	2014	2015	2016	2017	2018	
Total (\$ in millions)	3,614.21	4,084.35	4,614.51	5,194.70	5,804.91	6,485.14	29,797.82

Note: Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2010 wage data from the U.S. Department of Labor, Bureau of Labor Statistics.

TABLE 12—ESTIMATED SAVINGS TO STATES BY PROVISION FOR FISCAL YEARS 2013 THROUGH 2018

Provision(s)	Regulation section(s)	Savings per fiscal year (\$ in millions)						Total savings (FYs 2013– 2018) (\$ in millions)
		2013	2014	2015	2016	2017	2018	
Benefit Flexibility for Certain Dual Eligible Special Needs Plans	422.102	–0.50	–0.48	–0.44	–0.41	–0.39	–0.40	–2.62

Note: Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2010 wage data from the U.S. Department of Labor, Bureau of Labor Statistics.

D. Expected Benefits

1. Medicare Coverage Gap Discount Program Agreement

The rule codifies a number of requirements that must be included in the manufacturer Discount Program Agreement that generally must be signed by a manufacturer to allow Part D coverage of the manufacturers applicable drugs. These requirements are fundamental to ensuring that participating manufacturers pay all applicable discounts for applicable drugs received by applicable beneficiaries while in the coverage gap. We believe that a well-implemented Discount Program will increase beneficiary adherence to medication regimens that can improve their health by lowering their pharmaceutical costs at the point-of-sale.

2. Payment Processes for Part D Sponsors

The rule requires CMS to facilitate distribution of the applicable discount to beneficiaries by requiring that CMS provide an interim discount payment to Part D sponsors. That interim discount payment will be subsequently reconciled against manufacturer payments for discounts provided to beneficiaries. This provision will help Part D sponsors maintain operations with minimal, if any, effect on cash flow. This will help ensure that Part D sponsors provide the applicable discount to applicable beneficiaries at point-of-sale.

3. Provision of Applicable Discounts on Applicable Drugs for Applicable Beneficiaries

The rule requires Part D sponsors to calculate the applicable discount that should be provided to applicable beneficiaries in the coverage gap.

Applicable beneficiaries will, therefore, have minimal need to determine when they qualify for the gap discount and when they are no longer in the gap. In addition, Part D sponsors will likely automate discount calculations, potentially reducing errors and the need for beneficiaries to file an appeal that challenges the discount amount.

4. Manufacturer Discount Payment Audits and Dispute Resolution

We believe that the audit and dispute programs will both contribute to the stable operation of the Discount Program. Both programs are intended to provide an equitable means to resolve manufacturer concerns, enhance program integrity and, therefore, program stability. A predictable and stable Discount Program will help beneficiaries plan their finances and health care costs over time.

5. Beneficiary Dispute Resolution

The traditional Medicare program provides a means for beneficiaries to challenge Medicare decisions to ensure they receive needed benefits. We believe that beneficiaries will gain the same benefit from a dispute resolution program associated with the Discount Program. Further, extending the existing Part D beneficiary dispute resolution process to the Discount Program will reduce the need for beneficiaries to learn a new set of dispute procedures.

6. Compliance Monitoring and Civil Money Penalties

Our expectation is that manufacturers will generally comply with the terms of the Discount Program Agreement and the Discount Program. We understand that manufacturers may still err and that such errors can disrupt program operations. Our intention is to use compliance actions, including penalties,

to encourage reduced manufacturer errors and maintain a predictable program for beneficiaries.

7. Termination of Agreement

We believe that CMS' ability to terminate the Agreement upon extreme non-compliance by manufacturers will likely encourage manufacturers to address issues quickly. We believe that prompt resolution of significant concerns will create minimal disruption to the program and inconvenience of beneficiaries.

8. Inclusion of Benzodiazepines and Barbiturates as Part D Covered Drugs

Part D coverage of benzodiazepines and barbiturates potentially improves beneficiary access to these drugs and reduces beneficiary out-of-pocket costs for non-Part D covered drugs. In addition, State costs are reduced in those States that have been paying for these drugs.

9. Determination of Actuarially Equivalent Creditable Prescription Drug Coverage

This final rule with comment period requirement to change the actuarial value calculation for creditable coverage to exclude the additional value of gap coverage consistent with the determination of the RDS actuarial value of prescription drug coverage will enable beneficiaries who switch from an RDS plan or other creditable prescription drug coverage to a Part D plan to do so without incurring a late enrollment penalty.

10. Who May File Part D Appeals With the Independent Review Entity

The changes to § 423.600 and § 423.602 will allow physicians and other prescribers to request IRE reconsiderations on behalf of Part D plan enrollees. These changes will

reduce the burden on enrollees and their prescribers because they will no longer have to submit a properly executed AOR form in cases where the prescriber wishes to request a reconsideration on behalf of a Part D plan enrollee. Additionally, physicians and prescribers are in the best position to anticipate and provide the appropriate medical documentation needed to support coverage for Part D enrollees' medications. We believe that by allowing a physician or other prescriber to request a reconsideration on an enrollee's behalf, it will further improve the enrollee's access to the Part D appeals process and assist enrollees in obtaining coverage of medically necessary medications.

11. Termination for Lower-Than-Three-Star-Performance Ratings

The benefit of this change is that we will leverage the annual performance ratings to remove from the MA and Part D programs poor performing organizations, thereby strengthening the programs and protecting Medicare beneficiaries.

12. Exclusion for Sponsors of Contracts Terminated for Cause

The benefit of this change is that we will ensure that organizations that demonstrated extremely poor performance have their performance history reviewed as part of the application process for an appropriate amount of time, thereby strengthening the programs and protecting Medicare beneficiaries.

13. Benefit Flexibility for Certain Dual Eligible Special Needs Plans (SNPs)

We believe that allowing certain dual eligible SNPs that meet high integration and performance based standards to offer supplemental benefits beginning contract year 2013 will advance our overall goal of better integrating care for dual eligible beneficiaries, keeping beneficiaries at risk of institutionalization in their homes, lowering dual eligible beneficiaries' utilization of health services, and lowering costs for the Medicaid and Medicare programs.

14. Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse, and Waste Control Program

Requiring Part D sponsors to establish and apply a daily cost-sharing rate as previously described facilitates the ability of Medicare Part D enrollees to obtain trial fills of chronic medications, particularly those with higher cost-sharing and that are known to

frequently be poorly tolerated. As noted previously, we believe trial fills will result in the avoidance of unused drugs, reduce drug costs, diminish the environmental issues caused by disposal of unused medications, and reduce opportunities for criminal and substance abuse caused by diversion of unused medications, all of which are growing concerns in the United States. While there may be additional waste generated by multiple fills when medications are continued after a trial fill or synchronized (for example, more plastic bottles and paper inserts, additional trips to pharmacies), we believe the harmful effects on the environment from unused drugs, particularly the biological implications, likely have a much greater impact on the environment than additional recyclables.

With respect to synchronization of medication refills specifically, we also note that at least one study supports the notion that synchronization may assist enrollees in adhering to prescription treatment regimens that involve multiple prescriptions. In addition, we believe the ability to synchronize medications will be convenient for those enrollees who take advantage of the opportunity and their prescribers, by enabling fewer trips to the pharmacy and fewer prescription requests of prescribers by enrollees through the ability to consolidate pharmacy trips and prescriber office visits and phone calls.

We received no specific comments on this section.

15. Apply MA and Part D Disclosure Requirements to Cost Contract Plans

We believe that our requirement that cost contract plans disclose to enrollees, at the time of enrollment and annually thereafter (in the form of an annual notice of change/evidence of coverage, or ANOC/EOC mailing), certain detailed information about plan benefits, service area, provider and pharmacy access, grievance and appeal procedures, quality improvement programs, and disenrollment rights and responsibilities, and an explanation of benefits will ensure that the beneficiaries have information to help them make best choices for their health care needs.

16. Denial of SNP Applications and SNPs Appeal Rights

Our intent in proposing this provision is to give us the explicit authority to deny SNP applications that demonstrate that the applicant does not meet the requirements to operate a SNP, which have been incorporated into the MA

application. This proposed change will ensure that the only MA organizations that are able to offer a SNP are those that meet CMS' SNP specific requirements and are capable of serving the vulnerable special needs individuals who enroll in SNPs, thereby strengthening the program and protecting Medicare beneficiaries. Additionally, to ensure a fair and comprehensive review of these SNP applications, we propose to allow applicants who have been determined unqualified to offer a SNP the right to an administrative review process.

17. Clarification of Contract Requirements for First Tier and Downstream Entities

This clarification ensures that the MA organizations and Part D sponsors retain the necessary control and oversight over their delegated entities, thereby strengthening the programs and protecting Medicare beneficiaries.

18. Valid Prescriptions

By removing any doubt as to the appropriate source of law to consult when determining whether a prescription is valid, this regulation will benefit federal law enforcement agencies. We do not believe, however, that there is a quantifiable monetary value to easing prosecutions in this manner.

19. Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings

The expected benefits of the revisions to § 423.153 are that Part D sponsors will be required to offer all targeted beneficiaries in LTC facilities the opportunity to participate in a CMR, but in the event the beneficiary is cognitively impaired and unable either to respond to the offer or to participate in a CMR, the pharmacist or qualified provider may proceed with a CMR that is informative for the beneficiary's prescriber and/or caregiver without interacting with the beneficiary.

20. Coordination of Part D Plans With Other Prescription Drug Coverage

We are clarifying the regulation at § 423.458 regarding the application of waivers to EGWPs. We expect that this clarification will benefit Medicare beneficiaries enrolled in such plans by ensuring them the same protections as those afforded Medicare beneficiaries enrolled in individual market Part D plans where such protections have not been explicitly waived.

21. Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (NPIs)

In addition to supporting our fraud and abuse activities, accurate data on prescriptions through the consistent use of valid NPIs on PDEs allows us to serve beneficiaries when using data in various initiatives whose purpose is to foster higher quality and more efficient coordination of care for individuals and groups of individuals.

We received no specific comments on this section, and therefore are not modifying our policy based on such comments. However, we are modifying our proposal, as described in section II.E.11. of the final rule with comment period, Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (§ 423.120), based on general comments we received.

E. Alternatives Considered

1. Affordable Care Act AND MIPPA Provisions

We did not consider alternatives for the following provisions, as their implementation was mandated by the Affordable Care Act and MIPPA:

- Inclusion of Benzodiazepines and Barbiturates
- Pharmacy Benefit Manager's Transparency Requirements

2. Coverage Gap Discount Program

The Affordable Care Act mandated implementation of the Coverage Gap Discount Program and further specified that the associated manufacturer discounts had to be made available at point-of-sale. An alternative model for point-of-sale administration of the discount will involve a third party administrator directly adjudicating the discount payment to pharmacies. In this model, the pharmacy will submit the Part D claim to the Part D sponsor and receive information on the response that will direct the pharmacy to bill the third party for applicable claims. However, while this model initially showed promise, neither the current HIPAA electronic pharmacy claims billing standard nor the next HIPAA approved version of the billing standard could support the transfer of information from the Part D sponsor that will be necessary to specify the appropriate claims and appropriate discount amounts to be billed to the third party administrator, or allow for accurate coordination of benefits among payers.

3. Determination of Actuarially Equivalent Creditable Prescription Drug Coverage

We clarified our regulations at § 423.56 to define creditable prescription drug coverage consistent with the calculation of the actuarial value of qualified retiree prescription drug coverage found at § 423.884(d). This is a clarification to an existing calculation that is already being used by organizations providing creditable coverage, therefore, there is no cost impact on these organizations.

4. Who May File Part D Appeals With the Independent Review Entity

As previously mentioned, the changes to § 423.600 and § 423.602 will allow physicians and other prescribers to request IRE reconsiderations on behalf of Part D plan enrollees. We considered maintaining the status quo, which would require physicians and other prescribers to obtain an AOR form in order to request a reconsideration by the IRE on behalf of their patients. However, given our program experience since the inception of the Part D program, we realize that this approach results in an undue burden on both enrollees and their prescribing physicians or prescribers and can create an unintended barrier to enrollees accessing the appeals process. Consequently, we are finalizing the change previously highlighted in this rule.

5. Termination or Non-Renewal of a Medicare Contract Based on Poor Plan Performance Ratings

We did not consider alternatives for this regulation since it is necessary to ensure compliance.

6. Exclusion for Sponsors of Contracts Terminated for Cause

We considered keeping the look-back period at 14 months, but we determined it will be insufficient to accomplish our needs and thus a longer look-back period was necessary. We also considered longer look-back periods, but we deemed them to be excessive.

7. New Benefit Flexibility for Certain Dual Eligible Special Needs Plans (SNPs)

In our proposed rule, we considered affording this benefit flexibility only to those plans that met the definition of a fully integrated dual eligible special needs plan (FIDE SNP) as defined at 42 CFR 422.2. We also proposed limiting this benefit flexibility to only those FIDE SNPs that enrolled dual eligible beneficiaries that received full Medicaid benefits. In this final rule with comment

period, we are not limiting this benefit flexibility to FIDE SNPs, but are instead allowing D-SNPs that meet integration and performance-based standards established by CMS to qualify for this benefit flexibility. We believe that expanding this flexibility to a larger pool of D-SNPs that are integrating care for dual eligible beneficiaries is still consistent with our overall objective of preventing institutionalization, and will give more dual eligible beneficiaries across the country access to these additional supplemental benefits.

8. Establishment and Application of Daily Cost-Sharing Rates as Part of Drug Utilization Management and Fraud, Abuse, and Waste Control Program

We considered proposing a requirement similar to the Fifteen Day Initial Script program introduced in Maine in the summer of 2009. In this program, specific medications that were identified by the MaineCare program with high side effect profiles, high discontinuation rates, or frequent dose adjustments, were phased in by class and must be dispensed in a 15-day initial script to ensure cost effectiveness without "wasting" or "discarding" of used medications. We have learned through representatives of the program that MaineCare has achieved overall savings for the two consecutive state fiscal years with respect to both brand and generic drugs through this program, despite the additional dispensing fees. The representatives have also reported that there was very good acceptance of the program and very little confusion upon implementation. While we acknowledge the savings benefits of the MaineCare approach, we believe that leaving the decision to obtain less than a month's supply of a prescription with the enrollee and his or her prescriber and pharmacist may be better suited for the Medicare Part D program, but we sought specific comment on this belief.

Comment: A few commenters offered a "copayment by days supply" alternative.

Response: For these reasons discussed in section II.D.6. of this final rule with comment period (Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program), we decline to adopt this alternative.

9. Clarification of Contract Requirements for First Tier and Downstream Entities

We did not consider alternatives for this regulation since it is necessary to ensure compliance and is the most

effective “no-cost” means to achieving it.

10. Valid Prescriptions

We did not consider alternatives for this regulation as it reflects existing state laws.

11. Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings

Section 10328 of the Affordable Care Act requires that a CMR be offered to all targeted beneficiaries, regardless of setting. Thus, the only alternative to this revision would be to have the pharmacist or provider attempt to perform a CMR with a LTC resident who is not capable of participating. However, by requiring a CMR to be offered to all targeted beneficiaries residing in LTC our revisions to the regulations will give these beneficiaries, who typically have chronic conditions that are managed by medication, the opportunity to participate in the CMR and comprehend the medication action plan as a result of the CMR. In cases when the beneficiary is unable to accept the offer of a CMR, the beneficiary will still benefit from having a CMR performed by a pharmacist or other qualified provider

with the beneficiary’s prescriber and/or caregiver without interacting with the beneficiary.

12. Coordination of Part D Plans With Other Prescription Drug Coverage

We considered the alternative, which was to remain silent in regulation. However, we believe that in order to facilitate beneficiary protections it is better to be clear that, unless waived, the same Medicare rules apply to sponsors of EWGPs as they do to sponsors of individual market plans. This ensures Medicare beneficiaries enrolled in EGWPs receive the same patient protections as beneficiaries enrolled in individual market plans.

13. Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (NPIs)

We considered requiring prescribers to enroll in Medicare in order for their prescriptions to be covered by the Part D program, but were concerned about the potential impact of such a requirement on enrollee access to needed medications. We also considered permitting any 1 of 4 types of prescriber identifiers to be submitted

on PDEs, but we believe this option is not in line with Congressional intent regarding the use of NPIs as provider identifiers.

Comment: A commenter supported our policy to not require physicians to enroll in Medicare in order for their prescriptions to be covered by the Part D program.

Response: We appreciate the commenter’s support.

After consideration of the other public comments received, we are modifying this requirement as discussed in section II.E.11. of this final rule with comment period, (Access to Covered Part D Drugs Through Use of Standardized Technology and National Provider Identifiers (§ 423.120)).

F. Accounting Statement

As required by OMB Circular A–4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), in Table 13, we have prepared an accounting statement showing the classification of the expenditures, costs, and savings associated with the provisions of the proposed rule for FY 2013 through 2018.

TABLE 13—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS AND SAVINGS, FROM FY 2013 TO FY 2018
[\$ In millions]

Category	Transfers		
	Units discount rate		Period covered
	7%	3%	
Annualized Monetized Transfers	\$220.3	\$214.5	FYs 2013–2018
From Whom To Whom?	Federal Government to MA Organizations and Part D Sponsors		
Annualized Monetized Transfers	–\$0.44	–\$0.44	FYs 2013–2018
From Whom To Whom?	States to Medicaid Providers		
	Costs (All other provisions)		
	Units discount rate		Period covered
	7%	3%	
Annualized Costs to MA organizations and Part D Sponsors	\$32.2	\$32.2	FYs 2013–2018
Annualized Costs to Manufacturers	\$4,853.7	\$4,916.9	FYs 2013–2018

(* Monetized figures in 2011 dollars.)

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget reviewed this final rule with comment period.

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.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 1. The authority citation for part 417 continues to read as follows:

Authority: Sec. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), 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 § 417.422 is amended by revising paragraph (d) to read as follows:

§ 417.422 Eligibility to enroll in an HMO or CMP.

* * * * *

(d) During an enrollment period of the HMO or CMP, completes the HMO's or CMP's application form or another CMS-approved election mechanism and gives whatever information is required for enrollment;

* * * * *

■ 3. Subpart K is amended by adding § 417.427 to read as follows:

§ 417.427 Extending MA and Part D program disclosure requirements to section 1876 cost contract plans.

(a) The procedures and requirements relating to disclosure in § 422.111 and § 423.128 apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(b) In applying the provisions of §§ 422.111 and 423.128, references to part 422 and part 423 of this chapter must be read as references to this part, and references to MA organizations and Part D sponsors as references to HMOs and CMPs.

■ 4. Section 417.432 is amended by revising paragraph (d) to read as follows:

§ 417.432 Conversion of enrollment.

* * * * *

(d) *Application form.* The individual who is converting must complete an application form or another CMS-approved election mechanism as described in § 417.430(a).

* * * * *

■ 5. Section 417.460 is amended by adding paragraphs (c)(3) and (4) to read as follows:

§ 417.460 Disenrollment of beneficiaries by an HMO or CMP.

* * * * *

(c) * * *

(3) *Good cause and reinstatement.* When an individual is disenrolled for failure to pay premiums or other charges imposed by the HMO or CMP for deductible and coinsurance amounts for which the enrollee is liable, CMS may reinstate enrollment in the plan, without interruption of coverage, if the individual shows good cause for failure to pay and pays all overdue premiums within 3 calendar months after the disenrollment date. The individual must establish by a credible statement that failure to pay premiums was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

(4) *Exception for reinstatement.* A beneficiary's enrollment in the plan will not be reinstated if the only basis for such reinstatement is a change in the individual's circumstances subsequent to the involuntary disenrollment for non-payment of premiums.

* * * * *

§ 417.492 [Amended]

■ 6. Section 417.492 is amended as follows:

■ A. In paragraph (a)(1)(i), “;” is removed and “; and” is added in its place.

■ B. In paragraph (a)(1)(ii), “; and” is removed and “.” is added in its place.

■ C. By removing paragraph (a)(1)(iii).

■ D. By removing paragraph (b)(1)(iii).

■ 7. Section 417.801 is amended by revising paragraph (d)(1)(ii) to read as follows:

§ 417.801 Agreements between CMS and health care prepayment plans.

* * * * *

(d) * * *

(1) * * *

(ii) The HCPP is not in substantial compliance with the provisions of the agreement, applicable CMS regulations, or applicable provisions of the Medicare law. This includes, but is not limited to, the following:

(A) Failure to provide for and document adequate access to providers.

(B) Failure to comply with CMS requirements concerning provision of data and maintenance of records.

(C) Failure to comply with financial requirements specified at § 417.806; or

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 8. 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).

§ 422.60 [Amended]

■ 9. In § 422.60, paragraph (c)(1) is amended by removing the reference “§ 422.80” and adding in its place the reference “§ 422.2262”.

■ 10. Section 422.100 is amended by adding paragraph (l) to read as follows:

§ 422.100 General requirements.

* * * * *

(l) Coverage of DME. MA organizations—

(1) Must cover and ensure enrollees have access to all categories of DME covered under Part B; and

(2) May, within specific categories of DME, limit coverage to certain DME brands, items, and supplies of preferred manufacturers provided the MA organization ensures all of the following:

(i) Its contracts with DME suppliers ensure that enrollees have access to all DME brands, items, and supplies of preferred manufacturers.

(ii) Its enrollees have access to all medically-necessary DME brands, items, and supplies of non-preferred manufacturers.

(iii) At the enrollees' request, it provides for an appropriate transition process for new enrollees during the first 90 days of their coverage under its MA plan, during which time the MA organization will do the following:

(A) Ensure the provision of a transition supply of DME brands, items, and supplies of non-preferred manufacturers.

(B) Provide for the repair of DME brands, items, and supplies of non-preferred manufacturers.

(iv) It makes no negative changes to its DME brands, items, and supplies of preferred manufacturers during the plan year.

(v) It treats denials of DME brands, items, and supplies of non-preferred manufacturers as organization determinations subject to § 422.566.

(vi) It discloses DME coverage limitations and beneficiary appeal rights in the case of a denial of a DME brand, item, or supply of a non-preferred manufacturer as part of the description of benefits required under § 422.111(b)(2) and § 422.111(h).

(vii) It provides full coverage, without limitation on brand and manufacturer,

to all DME categories or subcategories annually determined by CMS to require full coverage.

■ 11. Section 422.101 is amended by revising paragraph (d)(1) to read as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(d) * * *

(1) *Single deductible.* MA regional and local PPO plans, to the extent they apply a deductible as follows:

(i) Must have a single deductible related to all in-network and out-of-network Medicare Part A and Part B services.

(ii) May specify separate deductible amounts for specific in-network Medicare Part A and Part B services, to the extent these deductible amounts apply to the single deductible amount specified in paragraph (d)(1)(i) of this section.

(iii) May waive other plan-covered items and services from the single deductible described in paragraph (d)(1)(i) of this section.

(iv) Must waive all Medicare-covered preventive services (as defined in § 410.152(l)) from the single deductible described paragraph (d)(1)(i) of this section.

* * * * *

■ 12. Section 422.102 is amended by adding paragraph (e) to read as follows.

§ 422.102 Supplemental benefits.

* * * * *

(e) *Supplemental benefits for certain dual eligible special needs plans.*

Subject to CMS approval, dual eligible special needs plans that meet a high standard of integration and minimum performance and quality-based standards may offer additional supplemental benefits, consistent with the requirements of this part, where CMS finds that the offering of such benefits could better integrate care for the dual eligible population provided that the special needs plan—

(1) Operated in the MA contract year prior to the MA contract year for which it is submitting its bid; and

(2) Offers its enrollees such benefits without cost-sharing or additional premium charges.

■ 13. Section 422.111 is amended by adding paragraph (i) to read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(i) *Provision of information required for access to covered services.* MA plans must issue and reissue (as appropriate) member identification cards that

enrollees may use to access covered services under the plan. The cards must comply with standards established by CMS.

■ 14. Section 422.216 is amended by revising paragraph (d)(1) to read as follows:

§ 422.216 Special rules for MA private fee-for-service plans.

* * * * *

(d) * * *

(1) *General information.* An MA organization that offers an MA private fee-for-service plan must provide to plan enrollees, an appropriate explanation of benefits consistent with the requirements of § 422.111(b)(12).

* * * * *

■ 15. Section 422.500 is amended by revising paragraph (a) to read as follows:

§ 422.500 Scope and definitions.

(a) *Scope.* This subpart sets forth application requirements for entities seeking a contract as a Medicare organization offering an MA plan, including MA organizations offering a specialized MA plan for special needs individuals. MA organizations offering prescription drug plans must, in addition to the requirements of this part, follow the requirements of part 423 of this chapter specifically related to the prescription drug benefit.

* * * * *

■ 16. Section 422.501 is amended as follows:

■ A. By revising paragraph (a).

■ B. In paragraph (c)(1)(i) by removing “; or” and adding in its place “.”.

■ C. By adding paragraph (c)(1)(iii).

■ D. By revising paragraph (e).

The addition and revisions read as follows:

§ 422.501 Application requirements.

(a) *Scope.* This section sets forth application requirements for entities that seek a contract as an MA organization offering an MA plan and additional application requirements for MA organizations seeking to offer a Specialized MA Plan for Special Needs Individuals.

* * * * *

(c) * * *

(1) * * *

(iii) For Specialized MA Plans for Special Needs Individuals, documentation that the entity meets the requirements of §§ 422.2; 422.4(a)(1)(iv); 422.101(f); 422.107, if applicable; and 422.152(g) of this part.

* * * * *

(e) *Resubmittal of an application.* An application that has been denied by CMS for a particular contract year may

not be resubmitted until the beginning of the application cycle for the following contract year.

* * * * *

■ 17. Section 422.502 is amended as follows:

■ A. In paragraph (a)(1), by removing the phrase “MA contract solely” and adding in its place the phrase “MA contract or for a Specialized MA Plan for Special Needs Individuals solely”.

■ B. In paragraph (b)(1), by removing the phrase “If an MA organization” and adding in its place “Except as provided in paragraphs (b)(2) through (b)(4) of this section, if an MA organization”.

■ C. By adding paragraphs (b)(3) and (4).

■ D. In paragraph (c) introductory text, by removing the phrase “MA contract under this part” and adding in its place the phrase “MA contract or to be designated a Specialized MA Plan for Special Needs Individuals under this part”.

■ E. By revising paragraphs (c)(2) and (c)(3)(i).

The additions and revision read as follows:

§ 422.502 Evaluation and determination procedures.

(b) * * *

(3) If CMS has terminated, under § 422.510, or non-renewed, under § 422.506(b), an MA organization's contract, effective within the 38 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application based on the applicant's substantial failure to comply with the requirements of the Part C program even if the applicant currently meets all of the requirements of this part.

(4) During the same 38-month period as specified in (b)(3) of this section, CMS may deny an application where the applicant's covered persons also served as covered persons for the terminated or non-renewed contract. A “covered person” as used in this paragraph means one of the following:

(i) All owners of terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(iii) A member of the board of directors or board of trustees of the

entity, if the organization is organized as a corporation.

(c) * * *

(2) *Intent to deny.* (i) If CMS finds that the applicant does not appear to be able to meet the requirements for an MA organization or Specialized MA Plan for Special Needs Individuals, CMS gives the applicant notice of intent to deny the application for an MA contract or for a Specialized MA Plan for Special Needs Individuals a summary of the basis for this preliminary finding.

(ii) Within 10 days from the intent to deny, the applicant must respond in writing to the issues or other matters that were the basis for CMS' preliminary finding and must revise its application to remedy any defects CMS identified.

(iii) If CMS does not receive a revised application within 10 days from the date of the notice, or if after timely submission of a revised application, CMS still finds that the applicant does not appear qualified or has not provided CMS enough information to allow CMS to evaluate the application, CMS will deny the application.

(3) * * *

(i) That the applicant is not qualified to contract as an MA organization under Part C of title XVIII of the Act and/or is not qualified to offer a Specialized MA Plan for Special Needs Individuals;

* * * * *

■ 17. Section 422.504 is amended as follows:

■ A. By adding paragraphs (a)(17) and (18).

■ B. By revising paragraphs (i)(3)(iii), (i)(4)(i), (ii), (iii), (iv) introductory text and (i)(5).

The additions and revisions read as follows:

§ 422.504 Contract provisions.

* * * * *

(a) * * *

(17) To maintain administrative and management capabilities sufficient for the organization to organize, implement, and control the financial, marketing, benefit administration, and quality improvement activities related to the delivery of Part C services.

(18) To maintain a Part C summary plan rating score of at least 3 stars. A Part C summary plan rating is calculated by taking an average of a contract's Part C performance measure scores.

* * * * *

(i) * * *

(3) * * *

(iii) A provision requiring that any services or other activity performed by a first tier, downstream, and related entity in accordance with a contract are consistent and comply with the MA organization's contractual obligations.

(4) * * *

(i) Each and every contract must specify delegated activities and reporting responsibilities.

(ii) Each and every contract must either provide for revocation of the delegation activities and reporting requirements or specify other remedies in instances where CMS or the MA organization determine that such parties have not performed satisfactorily.

(iii) Each and every contract must specify that the performance of the parties is monitored by the MA organization on an ongoing basis.

(iv) Each and every contract must specify that either—

* * * * *

(5) If the MA organization delegates selection of the providers, contractors, or subcontractor to another organization, the MA organization's contract with that organization must state that the CMS-contracting MA organization retains the right to approve, suspend, or terminate any such arrangement.

* * * * *

■ 18. Section 422.510 is amended by adding paragraph (a)(14) to read as follows:

§ 422.510 Termination of contract by CMS.

(a) * * *

(14) Achieves a Part C summary plan rating of less than 3 stars for 3 consecutive contract years. Plan ratings issued by CMS before September 1, 2012 are not included in the calculation of the 3-year period.

* * * * *

■ 19. Section 422.641 is amended by adding paragraph (d) to read as follows:

§ 422.641 Contract determinations.

* * * * *

(d) A determination that an entity is not qualified to offer a Specialized MA Plan for Special Needs Individuals as defined in §§ 422.2 and 422.4(a)(1)(iv).

■ 20. Section § 422.660 is amended by adding paragraphs (a)(5) and (b)(5) to read as follows:

§ 422.660 Right to a hearing, burden of proof, standard of proof, and standards of review.

(a) * * *

(5) An applicant that has been determined to be unqualified to offer a Specialized MA Plan for Special Needs Individuals.

(b) * * *

(5) During a hearing to review a determination as described at § 422.641(d) of this subpart, the applicant has the burden of proving by a preponderance of the evidence that

CMS' determination was inconsistent with the requirements of §§ 422.2; 422.4(a)(1)(iv); 422.101(f); 422.107, if applicable; and 422.152(g) of this part.

* * * * *

■ 21. Section 422.2274 is amended as follows:

■ A. By revising paragraph (a)(1)(i).

■ B. By removing and reserving paragraph (a)(1)(ii).

■ C. By revising paragraph (a)(1)(iii).

■ D. By adding paragraph (f).

The revisions and addition read as follows:

§ 422.2274 Broker and agent requirements.

* * * * *

(a) * * *

(1) * * *

(i) The compensation amount paid by plan sponsors to an independent broker or agent:

(A) For an initial enrollment of a Medicare beneficiary into an MA plan, must be at or below the fair market value (FMV) cut-off amounts published annually by CMS.

(B) For renewals, must be an amount equal to 50 percent of the initial compensation in paragraph (a)(1)(i)(A) of this section.

(ii) [Reserved].

(iii) The independent broker or agent is paid a renewal compensation for each of the next 5 years that the enrollee remains in the plan in an amount equal to 50 percent of the initial year compensation amount (creating a 6-year compensation cycle).

* * * * *

(f) A plan sponsor must report annually, as directed by CMS—

(1) Whether it intends to use independent agents or brokers or both in the upcoming plan year; and

(2) If applicable, the specific amount or range of amounts independent agents or brokers or both will be paid.

PART 423—MEDICARE PROGRAM; MEDICARE PRESCRIPTION DRUG PROGRAM

■ 22. The authority citation for part 423 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–43, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–153, and 1395hh).

■ 23. Section 423.56 is amended by revising paragraphs (a) and (f)(3) to read as follows:

§ 423.56 Procedures to determine and document creditable status of prescription drug coverage.

(a) *Definition.* Creditable prescription drug coverage means any of the following types of coverage listed in

paragraph (b) of this section only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage under Part D in effect at the start of such plan year, not taking into account the value of any discount or coverage provided during the coverage gap, and demonstrated through the use of generally accepted actuarial principles and in accordance with CMS guidelines.

* * * * *

(f) * * *

(3) Prior to the commencement of the Annual Coordinated Election Period as defined in § 423.38(b); and

* * * * *

■ 24. Section 423.100 is amended as follows:

■ A. By adding in alphabetical order the definition of “Daily cost-sharing rate.”

■ B. By revising paragraph (2)(iii) of the definition of “Incurred costs.”

■ C. In paragraph (2)(ii) of the definition of “Part D drug,” by removing the phrase “smoking cessation agents” and adding in its place the phrase “smoking cessation agents; barbiturates when used to treat epilepsy, cancer, or a chronic mental health disorder; and benzodiazepines”.

■ D. By revising the definition of “Supplemental benefits.”

■ E. By adding in alphabetical order the definition of “Valid prescription.”

The additions and revision read as follows:

§ 423.100 Definitions.

* * * * *

Daily cost-sharing rate means, as applicable, the established—

(1) Monthly copayment under the enrollee’s Part D plan, divided by 30 or 31 and rounded to the nearest lower dollar amount, if any, or to another amount, but in no event to an amount that would require the enrollee to pay more for a month’s supply of the prescription than would otherwise be the case; or

(2) Coinsurance percentage under the enrollee’s Part D.

* * * * *

Incurred costs * * *

(2) * * *

(ii) Under State Pharmaceutical Assistance Program (as defined in § 423.464); by the Indian Health Service, an Indian tribe or tribal organization, or urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act) or under an AIDS Drug Assistance Program (as defined in part B of title XXVI of the Public Health Service); or by a manufacturer as payment for an applicable discount (as defined in § 423.2305) or under the

Medicare Coverage Gap Discount Program (as defined in § 423.2305); or

* * * * *

Supplemental benefits means benefits offered by Part D plans, other than employer group health or waiver plans, that meet the requirements of § 423.104(f)(1)(ii).

* * * * *

Valid prescription means a prescription that complies with all applicable State law requirements constituting a valid prescription.

■ 25. Section 423.104 is amended by adding paragraphs (h) and (i) to read as follows:

§ 423.104 Requirements related to qualified prescription drug coverage.

* * * * *

(h) *Valid prescription*. A Part D sponsor may only provide benefits for Part D drugs that require a prescription if those drugs are dispensed upon a valid prescription.

(i) *Daily cost-sharing rate*. Beginning January 1, 2014, a Part D sponsor is required to provide its enrollees access to a daily cost-sharing rate in accordance with § 423.153(b)(4).

■ 26. Section 423.120 is amended by adding paragraph (c)(5) to read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

(c) * * *

(5)(i) A Part D sponsor must submit to CMS only a prescription drug event (PDE) record that contains an active and valid individual prescriber NPI.

(ii) A Part D sponsor must ensure that the lack of an active and valid individual prescriber NPI on a network pharmacy claim does not unreasonably delay a beneficiary’s access to a covered Part D drug, by taking the steps described in paragraph (c)(5)(iii) of this section.

(iii) The sponsor must communicate at point-of-sale whether or not a submitted NPI is active and valid in accordance with this paragraph (c)(5)(iii).

(A) If the sponsor communicates that the NPI is not active and valid, the sponsor must permit the pharmacy to—

(1) Confirm that the NPI is active and valid; or

(2) Correct the NPI.

(B) If the pharmacy—

(1) Confirms that the NPI is active and valid or corrects the NPI, the sponsor must pay the claim if it is otherwise payable; or

(2) Cannot or does not correct or confirm that the NPI is active and valid, the sponsor must require the pharmacy

to resubmit the claim (when necessary), which the sponsor must pay, if it is otherwise payable, unless there is an indication of fraud or the claim involves a prescription written by a foreign prescriber (where permitted by State law).

(iv) A Part D sponsor must not later recoup payment from a network pharmacy for a claim that does not contain an active and valid individual prescriber NPI on the basis that it does not contain one, unless the sponsor—

(A) Has complied with paragraphs (c)(5)(ii) and (iii) of this section;

(B) Has verified that a submitted NPI was not in fact active and valid; and

(C) The agreement between the parties explicitly permits such recoupment.

(v) With respect to requests for reimbursement submitted by Medicare beneficiaries, a Part D sponsor may not make payment to a beneficiary dependent upon the sponsor’s acquisition of an active and valid individual prescriber NPI, unless there is an indication of fraud. If the sponsor is unable to retrospectively acquire an active and valid individual prescriber NPI, the sponsor may not seek recovery of any payment to the beneficiary solely on that basis.

* * * * *

■ 27. Section 423.153 is amended as follows:

■ A. In the introductory text for paragraph (b) by removing the phrase “that -” and adding in its place the phrase “that address all of the following:”.

■ B. In paragraph (b)(1) by removing “;” and adding in its place “.”.

■ C. In paragraph (b)(2) by removing “; and” and adding in its place “.”.

■ D. By adding paragraph (b)(4).

■ E. By revising paragraph (d)(1)(vii)(B).

The addition and revision read as follows:

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

* * * * *

(b) * * *

(4)(i) Establishes a daily cost-sharing rate and applies it to a prescription presented to a network pharmacy for a covered Part D drug that is dispensed for a supply less than 30 days, and in the case of a monthly copayment, multiplies the daily cost-sharing rate by the days supply actually dispensed—

(A) If the drug is in the form of a solid oral dose, subject to paragraph (b)(4)(i)(B) of this section and may be dispensed for a supply less than 30 days under applicable law;

(B) The requirements of this paragraph (b)(4)(i) do not apply to either of the following:

(1) Solid oral doses of antibiotics.
 (2) Solid oral doses that are dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance.

(ii) [Reserved]

* * * * *

(d) * * *

(1) * * *

(vii) * * *

(B) *Annual comprehensive medication review with written summaries.* (1) The beneficiary's comprehensive medication review—

(i) Must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider; and
 (ii) May result in a recommended medication action plan.

(2) If a beneficiary is offered the annual comprehensive medication review and is unable to accept the offer to participate, the pharmacist or other qualified provider may perform the comprehensive medication review with the beneficiary's prescriber, caregiver, or other authorized individual.

* * * * *

■ 28. Section 423.458 is amended by adding paragraph (c)(4) to read as follows:

§ 423.458 Application of Part D rules to certain Part D plans on or after January 1, 2006.

* * * * *

(c) * * *

(4) Employer-sponsored group prescription drug plans must comply with all applicable requirements under this part that are not specifically waived or modified in accordance with in paragraph (c)(3) of this section.

* * * * *

■ 29. Section 423.501 is amended by adding the definition of “Bona fide service fees” in alphabetical order to read as follows:

§ 423.501 Definitions.

* * * * *

Bona fide service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

* * * * *

■ 30. Section 423.503 is amended as follows:

■ A. In paragraph (b)(1), by removing the phrase “If a Part D” and adding in its place “Except as provided in paragraphs (b)(2), (3), and (4) of this section, if a Part D”.

■ B. Adding paragraphs (b)(3) and (4).
 The additions read as follows:

§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.

* * * * *

(b) * * *

(3) If CMS has terminated, under § 423.509, or non-renewed, under § 423.507(b), a Part D plan sponsor's contract, effective within the 38 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application based on the applicant's substantial failure to comply with the requirements of the Part D program even if the applicant currently meets all of the requirements of this part.

(4) During the same 38-month period as specified in (b)(3) of this section, CMS may deny an application where the applicant's covered persons also served as covered persons for the terminated or non-renewed contract. A “covered person” as used in this paragraph means one of the following:

(i) All owners of terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

* * * * *

■ 31. Section 423.505 is amended as follows:

■ A. By adding paragraphs (b)(24) through (26).

■ B. By revising paragraphs (i)(3) introductory text, (i)(3)(iii), (i)(3)(v), and (i)(4)(i) through (iv).

The addition and revisions read as follows:

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(24) Provide applicable beneficiaries with applicable discounts on applicable drugs in accordance with the requirements in subpart W of Part 423.

(25) Maintain administrative and management capabilities sufficient for the organization to organize, implement, and control the financial, marketing, benefit administration, and quality assurance activities related to the delivery of Part D services.

(26) Maintain a Part D summary plan rating score of at least 3 stars. A Part D summary plan rating is calculated by taking an average of a contract's Part D performance measure scores.

* * * * *

(i) * * *

(3) Each and every contract governing Part D sponsors and first tier, downstream, and related entities, must contain the following:

* * * * *

(iii) A provision requiring that any services or other activity performed by a first tier, downstream, and related entity in accordance with a contract are consistent and comply with the Part D sponsor's contractual obligations.

* * * * *

(v) Each and every contract must specify that first tier, downstream, and related entities must comply with all applicable Federal laws, regulations, and CMS instructions.

* * * * *

(4) * * *

(i) Each and every contract must specify delegated activities and reporting responsibilities.

(ii) Each and every contract must either provide for revocation of the delegation activities and reporting responsibilities described in paragraph (i)(4)(i) of this section or specify other remedies in instances when CMS or the Part D plan sponsor determine that the parties have not performed satisfactorily.

(iii) Each and every contract must specify that the Part D plan sponsor on an ongoing basis monitors the performance of the parties.

(iv) Each and every contract must specify that the related entity, contractor, or subcontractor must comply with all applicable Federal laws, regulations, and CMS instructions.

* * * * *

■ 32. Section 423.509 is amended by adding paragraph (a)(13) to read as follows:

§ 423.509 Termination of contract by CMS.

* * * * *

(a) * * *

(13) 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.

* * * * *

■ 33. Section 423.514 is amended as follows:

■ A. By redesignating paragraphs (d) through (g) as paragraphs (g) through (j), respectively.

■ B. By adding new paragraphs (d), (e), and (f).

The additions read as follows:

§ 423.514 Validation of Part D reporting requirements.

* * * * *

(d) *Reporting requirements for pharmacy benefits manager data.* Each entity that provides pharmacy benefits management services must provide to the Part D sponsor, and each Part D sponsor must provide to CMS, in a manner specified by CMS, the following:

(1) The total number of prescriptions that were dispensed.

(2) The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies.

(3) The percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medication to the general public), that is paid by the Part D sponsor or PBM under the contract.

(4) The aggregate amount and type of rebates, discounts, or price concessions (excluding bona fide service fees as defined in § 423.501) that the PBM negotiates that are attributable to patient utilization under the plan.

(5) The aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed.

(6) The aggregate amount of the difference between the amount the Part D sponsor pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies.

(e) *Confidentiality of pharmacy benefits manager data.* Information disclosed by a Part D sponsor or PBM as specified in paragraph (d) of this section is confidential and must not be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs, for the following purposes:

(1) As the Secretary determines necessary to carry out section 1150A of the Act or Part D of Title XVIII.

(2) To permit the Comptroller General to review the information provided.

(3) To permit the Director of the Congressional Budget Office to review the information provided.

(f) *Penalties for failure to provide pharmacy benefits manager data.* The provisions of section 1927(b)(3)(C) of the Act are applicable to a Part D sponsor or PBM that fails to provide the required information on a timely basis or knowingly provides false information in the same manner as such provisions apply to a manufacturer with an agreement under section 1927 of the Act.

* * * * *

■ 34. Section 423.600 is amended by revising paragraphs (a) through (c) to read as follows:

§ 423.600 Reconsideration by an independent review entity (IRE).

(a) An enrollee who is dissatisfied with the redetermination of a Part D plan sponsor has a right to a reconsideration by an independent review entity that contracts with CMS. The prescribing physician or other prescriber (acting on behalf of an enrollee), upon providing notice to the enrollee, may request an IRE reconsideration. The enrollee, or the enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee) must file a written request for reconsideration with the IRE within 60 calendar days of the date of the redetermination by the Part D plan sponsor.

(b) When an enrollee, or an enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee) files an appeal, the IRE is required to solicit the views of the prescribing physician or other prescriber. The IRE may solicit the views of the prescribing physician or other prescriber orally or in writing. A written account of the prescribing physician's or other prescriber's views (prepared by either the prescribing physician, other prescriber, or IRE, as appropriate) must be contained in the IRE record.

(c) In order for an enrollee or a prescribing physician or other prescriber (acting on behalf of an enrollee) to request an IRE reconsideration of a determination by a Part D plan sponsor not to provide for a Part D drug that is not on the formulary, the prescribing physician or other prescriber must determine that all covered Part D drugs on any tier of the formulary for treatment of the same

condition would not be as effective for the individual as the non-formulary drug, would have adverse effects for the individual, or both.

* * * * *

■ 35. Section 423.602 is amended by revising paragraph (a) to read as follows:

§ 423.602 Notice of reconsideration determination by the independent review entity.

(a) *Responsibility for the notice.* When the IRE makes its reconsideration determination, it is responsible for mailing a notice of its determination to the enrollee and the Part D plan sponsor, and for sending a copy to CMS. When the prescribing physician or other prescriber requests the reconsideration on behalf of the enrollee, the IRE is also responsible for notifying the prescribing physician or other prescriber of its decision.

* * * * *

■ 36. Section 423.1000 is amended by adding paragraph (a)(3) to read as follows:

§ 423.1000 Basis and scope.

* * * * *

(a) * * *

(3) Section 1860D–14A(e)(2) of the Act specifies that the Secretary must impose a civil money penalty on a manufacturer that fails to provide applicable beneficiaries discounts for applicable drugs of the manufacturer in accordance with its Discount Program Agreement. Section 1860D–14A(e)(2)(B) of the Act makes certain provisions of section 1128A of the Act applicable to such civil money penalties imposed on manufacturers.

* * * * *

■ 37. Section 423.1002 is amended by revising the definition of “Affected party” to read as follows:

§ 423.1002 Definitions.

* * * * *

Affected party means any Part D sponsor or manufacturer (as defined in § 423.2305) impacted by an initial determination or, if applicable, by a subsequent determination or decision issued under this part, and “party” means the affected party or CMS, as appropriate.

* * * * *

■ 38. Section § 423.2274 is amended as follows:

■ A. By revising paragraph (a)(1)(i).

■ B. By removing and reserving paragraph (a)(1)(ii).

■ C. By revising paragraph (a)(1)(iii).

■ D. By adding paragraph (f).

The revisions and addition read as follows:

§ 423.2274 Broker and agent requirements.

* * * * *

- (a) * * *
(1) * * *

(i) The compensation amount paid by plan sponsors to an independent broker or agent—

(A) For an initial enrollment of a Medicare beneficiary into a PDP must be at or below the fair market value (FMV) cut-off amounts published annually by CMS; or

(B) For renewals, must be an amount equal to 50 percent of the initial compensation in paragraph (a)(1)(i)(A) of this section.

* * * * *

(iii) The independent broker or agent is paid a renewal compensation for each of the next 5 years that the enrollee remains in the plan in an amount equal to 50 percent of the initial year compensation paid (creating a 6-year compensation cycle).

* * * * *

(f) Plan sponsor must report annually, as directed by CMS the following:

(1) Whether it intends to use independent agents or brokers or both in the upcoming plan year.

(2) If applicable, the specific amount or range of amounts independent agents or brokers or both will be paid.

■ 39. Subpart W is added to read as follows:

Subpart W—Medicare Coverage Gap Discount Program

Sec.

- 423.2300 Scope.
423.2305 Definitions.
423.2310 Condition for coverage of drugs under Part D.
423.2315 Medicare Coverage Gap Discount Program Agreement.
423.2320 Payment processes for Part D sponsors.
423.2325 Provision of applicable discounts.
423.2330 Manufacturer discount payment audit and dispute resolution.
423.2335 Beneficiary dispute resolution.
423.2340 Compliance monitoring and civil money penalties.
423.2345 Termination of Discount Program Agreement.

§ 423.2300 Scope.

This subpart implements provisions included in sections 1860D–14A and 1860D–43 of the Act. This subpart sets forth requirements regarding the following:

(a) Condition for coverage of applicable drugs under Part D.

(b) The Medicare Coverage Gap Discount Program Agreement.

(c) Coverage gap discount payment processes for Part D sponsors.

(d) Provision of applicable discounts on applicable drugs for applicable beneficiaries.

(e) Manufacturer audit and dispute resolution processes.

(f) Resolution of beneficiary disputes involving coverage gap discounts.

(g) Compliance monitoring and civil money penalties.

(h) The termination of the Discount Program Agreement.

§ 423.2305 Definitions.

As used in this subpart, unless otherwise specified—

Applicable discount means 50 percent of the portion of the negotiated price (as defined in § 423.2305) of the applicable drug of a manufacturer that falls within the coverage gap and that remains after such negotiated price is reduced by any supplemental benefits that are available.

Applicable number of calendar days means, with respect to claims for reimbursement submitted electronically, 14 days, and otherwise, 30 days.

Date of dispensing means the date of service.

Labeler code means the first segment of the Food and Drug Administration national drug code (NDC) that identifies a particular manufacturer.

Manufacturer means any entity which is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. For purposes of the Discount Program, such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law, but includes entities otherwise engaged in repackaging or changing the container, wrapper, or labeling of any applicable drug product in furtherance of the distribution of the applicable drug from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer or user.

Medicare Coverage Gap Discount Program (or Discount Program) means the Medicare coverage gap discount program established under section 1860D–14A of the Act.

Medicare Coverage Gap Discount Program Agreement (or Discount Program Agreement) means the agreement described in section 1860D–14A(b) of the Act.

Medicare Part D discount information means the information sent from CMS or the TPA to the manufacturer along with each quarterly invoice that is derived from applicable data elements

available on prescription drug events as determined by CMS.

National Drug Code (NDC) means the unique identifying prescription drug product number that is listed with the Food and Drug Administration (FDA) identifying the product and package size and type.

Negotiated price for purposes of the Discount Program, means the price for a covered Part D drug 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) Is reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point-of-sale; and

(3) Excludes any dispensing fee or vaccine administration fee for the applicable drug.

In connection with applicable drugs dispensed by an out-of-network provider in accordance with the applicable beneficiary's Part D plan out-of-network policies, the negotiated price means the plan allowance as set forth in § 423.124, less any dispensing fee or vaccine administration fee.

Other health or prescription drug coverage means any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries, including, in the case of employer group health or waiver plans, other than basic prescription drug coverage as defined in § 423.100.

Third Party Administrator (TPA) means the CMS contractor responsible for administering the requirements established by the CMS to carry out section 1860D–14A of the Act.

§ 423.2310 Condition for coverage of drugs under Part D.

(a) *Covered Part D drug coverage requirement.* Except as specified in paragraph (b) of this section, in order for coverage to be available under Medicare Part D for applicable drugs of a manufacturer, the manufacturer must do all of the following:

(1) Participate in the Discount Program.

(2) Have entered into and have in effect an agreement described in § 423.2315(b).

(3) Have entered into and have in effect, under terms and conditions specified by CMS, a contract with the TPA.

(b) *Exception to covered drug coverage requirement.* Paragraph (a) of this section does not apply to an applicable drug if CMS has made a determination that the availability of the applicable drug is essential to the health of beneficiaries enrolled in Medicare Part D.

§ 423.2315 Medicare Coverage Gap Discount Program Agreement.

(a) *General rule.* The Medicare Coverage Gap Discount Program Agreement (or Discount Program Agreement) between the manufacturer and CMS must contain the provisions specified in paragraph (b) of this section, and may contain such other provisions as are established in a model agreement consistent with section 1860D–14A (a)(1) of the Act.

(b) *Agreement requirements.* The manufacturer agrees to the following:

(1) All the applicable requirements and conditions set forth in this part and general instructions.

(2) Reimburse all applicable discounts provided by Part D sponsors on behalf of the manufacturer for all applicable drugs having NDCs with the manufacturer's FDA-assigned labeler code(s) invoiced to the manufacturer within a maximum of 3 years of the date of dispensing based upon information reported to CMS by Part D sponsors.

(3) Pay each Part D sponsor in the manner specified by CMS within 38 calendar days of receipt of the invoice and Medicare Part D Discount Information for the applicable discounts included on the invoice, except as specified in § 423.2330(c)(3).

(4) Provide CMS with all labeler codes for all the manufacturer's applicable drugs and to promptly update such list with any additional labeler codes for applicable drugs no later than 3 business days after learning of a new code assigned by the FDA.

(5) Collect, have available, and maintain appropriate data, including data related to manufacturer's labeler codes, FDA drug approvals, FDA NDC Directory listings, NDC last lot expiration dates, utilization and pricing information relied on by the manufacturer to dispute quarterly invoices, and any other data CMS determines are necessary to carry out the Discount Program, for a period of not less than 10 years from the date of payment of the invoice.

(6) Comply with the audit and dispute resolution requirements in § 423.2330.

(7) Electronically list and maintain up-to-date electronic FDA listings of all NDCs of the manufacturer, including providing timely information about discontinued drugs to enable the

publication of accurate information regarding what drugs, identified by NDC, are in current distribution.

(8) Maintain up-to-date NDC listings with the electronic database vendors for which the manufacturer provides NDCs for pharmacy claims processing.

(9) Enter into and have in effect, under terms and conditions specified by CMS, an agreement with the TPA that has a contract with CMS under section 1860D–14(A)(d)(3) of the Act.

(10) Pay quarterly invoices directly to accounts established by Part D sponsors via electronic funds transfer, or other manner if specified by CMS, within the time period specified in paragraph (b)(3) of this section and within 5 business days of the transfer to provide the TPA with electronic documentation of such payment in a manner specified by CMS.

(11) Use information disclosed to the manufacturer on the invoice, as part of the Medicare Part D Discount Information, or upon audit or dispute only for purposes of paying the discount under the Discount Program.

(c) *Timing and length of agreement.*

(1) For 2011, a manufacturer must enter into a Discount Program Agreement not later than 30 days after the date of establishment of the model Discount Program Agreement.

(2) For 2012 and subsequent years, for a Discount Program Agreement to be effective for a year, a manufacturer must enter into a Discount Program Agreement not later than January 30th of the preceding year.

(3) Unless terminated in accordance with § 423.2345, the initial period of a Discount Program Agreement is 24 months and the agreement is automatically renewed for a 1-year period on January first each year for a period of 1 year thereafter.

(d) *Compliance with requirements for administration of the Program.* Each manufacturer with an agreement in effect under this subpart must comply with the requirements imposed by CMS or the third party administrator (as defined in § 423.2305) for purposes of administering the program.

§ 423.2320 Payment processes for Part D sponsors.

(a) *Interim payments.* CMS provides monthly interim coverage gap discount program payments as necessary for Part D sponsors to advance coverage gap discounts to beneficiaries.

(b) *Coverage Gap Discount Reconciliation.* CMS reconciles interim payments with invoiced manufacturer discount amounts made available to each Part D plan's enrollee under the Discount Program.

§ 423.2325 Provision of applicable discounts.

(a) *General rule.* On behalf of the manufacturers, Part D sponsors must provide applicable beneficiaries with applicable discounts on applicable drugs at the point-of-sale.

(b) *Discount determination.* (1) Part D sponsors must determine the following:

(i) Whether an enrollee is an applicable beneficiary (as defined in § 423.100).

(ii) Whether a Part D drug is an applicable drug (as defined in § 423.100).

(iii) The amount of the applicable discount (as defined in § 423.2305) to be provided at the point-of-sale.

(2) Part D sponsors must make retroactive adjustments to the applicable discount as necessary to reflect changes to the claim or beneficiary eligibility determined after the date of dispensing.

(3) Part D sponsors must determine whether any affected beneficiaries need to be notified by the Part D sponsor that an applicable drug is eligible for Part D coverage whenever CMS specifies a retroactive effective date for a labeler code and notify such beneficiaries.

(c) *Exception to point-of-sale requirement.* Part D sponsors must provide an applicable discount for applicable drugs submitted by applicable beneficiaries via paper claims, including out-of-network and in-network paper claims, if such claims are payable under the Part D plan.

(d) *Collection of data.* Part D sponsors must provide CMS with appropriate data on the applicable discounts provided by the Part D sponsors in a manner specified by CMS.

(e) *Supplemental benefits.* (1) An applicable discount must be applied to beneficiary cost-sharing after supplemental benefits (as defined in § 423.100) have been applied to the claim for an applicable drug.

(2) No applicable discount is available if supplemental benefits (as defined in § 423.100) eliminate the coverage gap so that a beneficiary has zero cost-sharing.

(f) *Other health or prescription drug coverage.* An applicable discount must be applied to beneficiary cost-sharing when Part D is the primary payer before any other health or prescription drug coverage is applied.

(g) *Pharmacy prompt payment.* Part D sponsors must reimburse a network pharmacy (as defined in § 423.100) the amount of the applicable discount no later than the applicable number of calendar days after the date of dispensing of an applicable drug. For long-term care and home infusion pharmacies, the date of dispensing can be interpreted as the date the pharmacy

submits the discounted claim for reimbursement.

§ 423.2330 Manufacturer discount payment audit and dispute resolution.

(a) *Third-party Administration (TPA) audits.* (1) Manufacturers participating in the Discount Program may conduct periodic audits, no more often than annually, directly or through third parties as specified in this section.

(2) The manufacturer must provide the TPA with 60 days notice of the reasonable basis for the audit and a description of the information required for the audit.

(3) The manufacturer must have the right to audit a statistically significant sample of data and information held by the TPA that were used to determine applicable discounts for applicable drugs having NDCs with the manufacturer's FDA-assigned labeler code(s). Such data and information will be made available on-site, and with the exception of work papers, such information cannot be removed from the audit site.

(4) The auditor for the manufacturer may release only an opinion of the audit results and is prohibited from releasing other information obtained from the audit, including work papers, to its client, employer, or any other party.

(b) *Manufacturer audits.* (1) A manufacturer is subject to periodic audit by CMS no more often than annually, directly or through third parties, as specified in this section.

(2) CMS provides the manufacturer with 60 days notice of the audit and a description of the information required for the audit.

(3) CMS has the right to audit appropriate data, including data related to a manufacturer's FDA-assigned labeler codes, NDC last lot expiration dates, utilization, and pricing information relied on by the manufacturer to dispute quarterly invoices, and any other data CMS determines are necessary to carry out the Discount Program.

(c) *Dispute resolution.* (1) Manufacturers may dispute applicable discounts invoiced to the manufacturer on quarterly invoices by providing notice of the dispute to the TPA in a manner specified by CMS within 60 days of receipt of the information that is the subject of the dispute.

(2) Such notice must be accompanied by supporting evidence that is material, specific, and related to the dispute in a manner specified by CMS.

(3) The manufacturer must not withhold any invoiced discount payments pending dispute resolution with the sole exception of invoiced

amounts for applicable drugs that do not have labeler codes provided by the manufacturer to CMS in accordance with § 423.2306(b)(4) of this subpart. If payment is withheld in accordance with this paragraph, the manufacturer must notify the TPA and applicable Part D sponsors within 38 days of receipt of the applicable invoice that payment is being withheld for this reason.

(4) If the manufacturer receives an unfavorable determination from the TPA, or the dispute is not resolved within 60 calendar days of the TPA's receipt of the notice of dispute, the manufacturer may request review by the independent review entity contracted by CMS within—

(i) Thirty calendar days of the unfavorable determination; or

(ii) Ninety calendar days after the TPA's receipt of the notice of dispute if dispute is not resolved within 60 days, whichever is earlier.

(5) The independent review entity must make a determination within 90 calendar days of receipt of the manufacturer's request for review.

(6)(i) CMS or a manufacturer that receives an unfavorable determination from the independent review entity may request review by the CMS Administrator within 30 calendar days of receipt of the notification of such determination.

(ii) The decision of the CMS Administrator is final and binding.

(7) CMS adjusts future invoices (or implements an alternative reimbursement process if determined necessary by CMS) if the dispute is resolved in favor of the manufacturer.

§ 423.2335 Beneficiary dispute resolution.

The Part D coverage determination and appeals process as described in §§ 423.558 through 423.638 applies to beneficiary disputes involving the availability and amount of applicable discounts under the Discount Program.

§ 423.2340 Compliance monitoring and civil money penalties.

(a) *General rule.* CMS monitors compliance by a manufacturer with the terms of the Discount Program Agreement.

(b) *Basis for imposing civil money penalties.* CMS imposes a civil money penalty (CMP) on a manufacturer that fails to provide applicable beneficiaries applicable discounts for applicable drugs of the manufacturer in accordance with the Discount Program Agreement.

(c) *Determination of the civil money penalty amounts.* CMS imposes a CMP for each failure by a manufacturer to provide an applicable discount in accordance with the Discount Program

Agreement equal to the sum of the following:

(1) The amount of applicable discount the manufacturer would have paid under the Discount Program Agreement, which will then be used to pay the applicable discount that the manufacturer had failed to provide.

(2) Twenty-five percent of such amount.

(d) *Procedures for imposing civil money penalties.* If CMS makes a determination to impose a CMP described in paragraph (c) of this section, CMS sends a written notice of its decision to impose a CMP to include the following:

(1) A description of the basis for the determination.

(2) The basis for the penalty.

(3) The amount of the penalty.

(4) The date the penalty is due.

(5) The manufacturer's right to a hearing (as specified in § 423.1006).

(6) Information about where to file the request for hearing.

(e) *Collection of civil money penalties imposed by CMS.* (1) When a manufacturer does not request a hearing, CMS initiates the collection of the CMP following the expiration of the timeframe for requesting an ALJ hearing as specified in § 423.1020.

(2) If a manufacturer requests a hearing and the Administrator upholds CMS' decision to impose a CMP, CMS may initiate collection of the CMP once the Administrator's decision is final.

(f) *Other applicable provisions.* The provisions of section 1128A of the Act (except subsections (a) and (b) of section of 1128A of the Act) apply to CMPs under this section to the same extent that they apply to a CMP or procedure under section 1128A(a) of the Act.

§ 423.2345 Termination of Discount Program Agreement.

(a)(1) CMS may terminate the Discount Program Agreement for a knowing and willful violation of the requirements of the agreement or other good cause shown in relation to the manufacturer's participation in the Discount Program.

(2) The termination must not be effective earlier than 30 days after the date of notice to the manufacturer of such termination and must not be effective prior to resolution of timely appeal requests received in accordance with paragraphs (a)(4) and (5) of this section.

(3)(i) CMS provides the manufacturer with an opportunity to cure any ground for termination for cause or to show the manufacturer is in compliance with the Discount Program Agreement within 30 calendar days of receipt of the written termination notice.

(ii) If the manufacturer cures the violation, or establishes that it was in compliance within the cure period, CMS repeals the termination notice by written notice.

(4) CMS provides upon request a manufacturer with a hearing with the hearing officer concerning such termination if requested in writing within 15 calendar days of receiving notice of the termination. The hearing takes place prior to the effective date of the termination with sufficient time for such effective date to be repealed if CMS determines appropriate.

(5)(i) CMS or a manufacturer that has received an unfavorable determination from the hearing officer may request review by the CMS Administrator within 30 calendar days of receipt of the notification of such determination.

(ii) The decision of the CMS Administrator is final and binding.

(b)(1) The manufacturer may terminate the Discount Program Agreement for any reason.

(2) Such termination is effective as of the day after the end of the calendar year if the termination occurs before January 30 of a calendar year, or as of the day after the end of the succeeding calendar year if the termination occurs on or after January 30 of a calendar year.

(c) Any termination does not affect the manufacturer's responsibility to reimburse Part D sponsors for applicable discounts incurred before the effective date of the termination.

(d) Upon the effective date of termination of the Discount Program Agreement, CMS ceases releasing data to the manufacturer except as necessary to ensure that the manufacturer reimburses applicable discounts for previous time periods in which the Discount Program Agreement was in effect, and notifies the manufacturer to destroy data files provided by CMS under the Discount Program Agreement.

(e) Manufacturer reinstatement is available only upon payment of any and

all outstanding applicable discounts incurred during any previous period under the Discount Program Agreement. The timing of any such reinstatement is consistent with the requirements for entering into a Discount Program Agreement under § 423.2315(c) of this subpart.

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Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: March 28, 2012.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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