

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Parts 417, 422, 423, and 483**

[CMS-4157-P]

RIN 0938-AQ86**Medicare Program; Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Proposed Changes; Considering Changes to the Conditions of Participation for Long Term Care Facilities****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Proposed rule.

SUMMARY: The proposed rule would revise the Medicare Advantage (MA) program (Part C) regulations and prescription drug benefit program (Part D) regulations to implement new statutory requirements; strengthen beneficiary protections; exclude plan participants that perform poorly; improve program efficiencies; and clarify program requirements. We are also considering changes to the long term care facility conditions of participation pertaining to pharmacy services.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 12, 2011.

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

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

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

2. *By regular mail.* You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention: CMS-4157-P*, P.O. Box 8013, Baltimore, MD 21244-8013.

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

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention: CMS-4157-P*, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments (one original and two copies) to one of 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 and D payment issues.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues

set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-4157-P.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received at: <http://www.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 at 1-800-743-3951.

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Regulations Text

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 Medical Review
CMS Centers for Medicare & Medicaid Services
CMS-HCC CMS Hierarchical 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
RPOO	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. Background

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

which it named the Medicare Advantage (MA) Program. The MMA directed that important aspects of the Part D program be similar to, and coordinated with, regulations for the MA program.

Generally, the provisions enacted in the MMA took effect January 1, 2006. The final rules implementing the MMA for the MA and Part D prescription drug programs appeared in the 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 recent legislative changes. The Patient Protection and Affordable Care Act (Pub. L. 111-148) was enacted on March 23, 2010, as passed by the Senate on December 24, 2009, and the House on March 21, 2010. The Health Care and Education Reconciliation Act (Pub. L. 111-152), which was enacted on March 30, 2010, modified a number of Medicare provisions in Pub. L. 111-148 and added several new provisions. The Patient Protection and Affordable Care Act (Pub. L. 111-148) and the Health Care and Education Reconciliation Act (Pub. L. 111-152) are collectively referred to as the Affordable Care Act. The Affordable Care Act included significant reforms to both the private health insurance industry and the Medicare and Medicaid programs. Provisions in the Affordable Care Act

concerning the Part C and D programs largely focused on beneficiary protections, MA payments, and simplification of MA and Part D program processes. These provisions affected implementation of our policies regarding beneficiary cost-sharing, assessing bids for meaningful differences, and ensuring that cost-sharing structures in a plan are transparent to beneficiaries and not excessive. In the April 2011 final rule, we revised regulations on a variety of issues based on the Affordable Care Act and our experience in administering the MA and Part D programs. The rule covered areas such as marketing, including agent/broker training; payments to MA organizations based on quality ratings; standards for determining if organizations are fiscally sound; low income subsidy policy under the Part D program; payment rules for non-contract health care providers; extending current network adequacy standards to Medicare medical savings account (MSA) plans that employ a network of providers; establishing limits on out-of-pocket expenses for MA enrollees; and several revisions to the special needs plan requirements, including changes concerning SNP approvals.

II. Provisions of the Proposed Regulations

In the sections that follow, we discuss the proposed changes to the regulations in 42 CFR parts 417, 422, and 423 governing the MA and prescription drug benefit programs. We also are considering changes to the regulations setting forth Medicare conditions of participation for long-term care facilities, which are currently codified at 42 CFR part 483. To better frame the discussion, we have structured the overall preamble narrative by topic area rather than by subpart order.

Accordingly, our proposals address the following five specific topic areas:

- 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 topic area, we provide a chart that lists the associated regulatory citations and we discuss the provisions in order of appearance in the proposed regulations. We are also considering changing the long term care facility conditions of participation

pertaining to pharmacy services and, accordingly, cover that issue under the appropriate topic in the preamble section, in order of regulation location under consideration.

We note that these regulations would be effective 60 days after the publication of the final rule that would finalize the proposed changes discussed in this proposed rule, except where otherwise noted in the preamble. Only one proposed item would have a different effective date: section 175(b) of MIPPA provides that the proposed amendments requiring that benzodiazepines and, for specified health conditions, barbiturates

be considered as Part D drugs apply to prescriptions dispensed on or after January 1, 2013.

A. Implementing Statutory Provisions

This section contains three provisions, two of which would implement sections of the Affordable Care Act and one which would implement a MIPPA mandate. We propose to consolidate and codify previous guidance regarding the Coverage Gap Discount Program mandated by the Affordable Care Act. Through this consolidation we aim to provide stakeholders a central, clear

source of direction. Regulations under a MIPPA provision would provide first line treatment for beneficiaries with certain health conditions who require benzodiazepines and, as specified, barbiturates. We believe that implementing section 6005 of the Affordable Care Act, which requires us to collect Pharmacy Benefit Manager (PBM) spread amounts, would establish necessary transparency related to 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 1.

TABLE 1—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
II.A.2.	Inclusion of Benzodiazepines and Barbiturates as Part D Covered Drugs	Subpart W (new)	§ 423.2300–§ 423.2345
II.A.3.	Pharmacy Benefit Manager's Transparency Requirements	Subpart C	§ 423.100
		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))

The Medicare Prescription Drug Benefit was enacted into law on December 8, 2003, in section 101 of the MMA and codified in sections 1860D–1 through 1860D–42 of the Act. Section 101 of the MMA amended Title XVIII of the Act by redesignating Part D as Part E and inserting new Part D, which establishes the voluntary Prescription Drug Benefit Program (Part D). The Part D program is available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B. We contract with private companies referred to as Part D sponsors to administer the Part D program via stand alone prescription drug plans (PDPs) and prescription drug plans offered by Medicare Advantage Organizations (MA–PDs). The Part D program became effective January 1, 2006.

The MMA established standard Part D prescription drug coverage that consists of coverage subject to an annual deductible, 25 percent coinsurance (or an actuarially equivalent cost-sharing design) up to the initial coverage limit (ICL), and catastrophic coverage for individuals who exceed the annual maximum true out-of-pocket (TrOOP) threshold with cost-sharing equal to the greater of a \$2/\$5 copayment or

coinsurance of 5 percent. Prior to the enactment of the Affordable Care Act, under standard coverage, individuals that did not receive additional cost-sharing subsidies from CMS or additional coverage by other secondary payers (for example, State Pharmaceutical Assistance Programs) were responsible for paying one hundred percent of the Part D negotiated price for covered Part D claims above the ICL until their TrOOP costs exceed the annual threshold amount.

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 all covered brand-name and generic drugs and biological products 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). 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, unless we use our authority under section 1860D–43(c) of the Act to make an exception that allows coverage without an agreement.

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 believe only the Part D sponsor can accurately provide the discount at point-of-sale.

We explored the viability of a model whereby a third party administrator (TPA) could directly adjudicate the discount payment to pharmacies. In this hypothetical model, the pharmacy would submit the Part D claim to the Part D sponsor and receive information on the response that would direct the pharmacy to bill the third party for applicable claims. While this model initially showed promise, our discussions with industry through National Council of Prescription Drug Program (NCPDP) workgroups revealed that neither the current Health Insurance Portability and Accountability Act (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 would 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. Consequently, we determined that this model cannot be used to implement the Discount Program in the foreseeable future.

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, 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 needed to implement the Discount Program through program instruction because of the January 1, 2011 implementation deadline. Although not required, we are now proposing to codify most 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.

b. Definitions (§ 423.2305)

Proposed § 423.2305 includes 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 proposed rule.

(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 considers the product to be 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 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 propose 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 TrOOD.

(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 propose 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 propose adding this language to the definition to be consistent with the definition of the term “manufacturer” in section 510 for the Federal Food Drug and Cosmetic Act as well as to track the defined term in the Discount Program Agreement.

Moreover, we believe this is the only practical way to define manufacturer 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 repackage or relabel drug products and market them with their own labeler codes. Registered drug establishments are required by law to provide the FDA with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. (See section 510 of the Federal Food, Drug, and Cosmetic Act 921 U.S.C. 360.) Each listed product is identified by a unique NDC, which identifies the labeler, product, and trade package size. The first segment, the labeler code, identifies the firm that manufactures (including repackers and relabelers) or distributes (under its own name) the drug. Therefore, we can accurately identify the company responsible for labeling the product and require this company to pay the discount. Alternatively, it would be very difficult, if not impossible, to track such relabeled or repackaged products back to the original maker of the drug if we limited the definition of manufacturer to the original maker. We would interpret “entities otherwise engaged in repackaging or changing the container, wrapper, or labeling * * *” to mean the companies associated with the unique labeler codes that are included in the NDCs of the applicable drugs dispensed by pharmacies, therefore these companies would be considered manufacturers under the Discount Program.

Applicable drugs are marketed with labels that include a labeler code identifying the company that labels the product. 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 propose 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, section III(f) of the Agreement generally prohibits us from disclosing any identifying beneficiary information under the Discount Program. Although the “Medicare Part D Discount Information” does not include specific beneficiary identifiers, an issue arises when the volume of claims for an applicable drug is so low that the data provided as “Medicare Part D Discount Information” could be used to identify a Medicare beneficiary.

In order to protect the identity of Medicare beneficiaries, we have a cell-size suppression policy that prohibits disclosure of data if the data cell contains 10 or fewer individuals. In applying this policy to the Discount Program, CMS would be unable to disclose all the data elements currently specified as “Medicare Part D Discount Information” when 10 or fewer beneficiaries with the same applicable drug (identified as having the same first two segments of NDC) have claims at the same pharmacy. This threshold is based on all Part D claims for an applicable drug (identified as having the

same first two segment of the NDC) at the same pharmacy, not 10 or fewer applicable beneficiaries with coverage gap claims.

When we agreed to provide the data elements specified in Exhibit A of the current Medicare Coverage Gap Discount Program Agreement, we did not take into consideration this issue that arises if claims volume is so low that this information could reasonably be used to identify a beneficiary. Consequently, we believe we would need to further limit the information that could be provided to manufacturers based upon the prohibition on releasing beneficiary identifying information. We propose withholding the Service Provider Identifier information when a claim qualifies as low volume (that is, 10 or fewer beneficiaries receiving the same drug product at the same pharmacy). This would mean that the remaining claims-level detail would be provided, but it would not specify the service provider for each claim. By doing this, we would comply with the CMS cell size suppression policy while still providing claims-level detail that would be helpful to manufacturers for evaluating the accuracy of the invoiced discount payments. We seek comments on this proposal.

(6) Negotiated Price

We propose to define negotiated price for purposes of the Discount Program consistent with section 1860D–14A(g)(6), 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 are proposing 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 propose 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 propose 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 would also propose to make a

conforming change to the definition of supplemental benefits in § 423.100 to exclude benefits offered by EGWPs. Our proposal with respect to EGWPs 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 EGWP plans.

Under current waivers authorized by section 1860D–22(b) of the Act, EGWP sponsors submit only one formulary and standard-defined benefit package for review by CMS. EGWP sponsors may then customize actual formularies and benefit packages for specific employer or union clients, for example, by adding drugs to their formularies that are not covered under the basic benefit and/or reducing enrollee cost-sharing. Until now, we have allowed EGWP sponsors to determine whether any benefits offered under the EGWPs were Medicare (Part D) or non-Medicare (non-Part D) benefits because we did not collect information about or otherwise oversee specific EGWP benefit packages. However, with the implementation of the Discount Program, determining whether such benefits are supplemental Part D benefits (which would be applied before the applicable discount) or non-Medicare benefits (which would apply after the discount) is significant. We believe that many EGWP sponsors have already restructured their benefits so that the EGWP provides only basic Part D coverage (with full coverage gap) and considers any additional benefits as non-Medicare benefits. Given that we do not receive or review the final benefit packages and formularies offered to EGWP enrollees, we propose to exercise our waiver authority under section 1860D–22(b) of the Act to exclude all benefits offered by EGWPs from the definition of supplemental benefits and, therefore, these benefits, other than basic prescription drug coverage (as defined in § 423.100), would be considered “other health or prescription drug coverage” for purposes of the Discount Program. We seek comments on this proposal.

As an alternative to this proposal, we considered requiring EGWP sponsors to submit their final benefit packages for review and approval. Under this option, we would have limited EGWPs to offering only supplemental benefits that meet the requirements of § 423.104(f)(1)(ii). However, in addition to the significant challenges associated with expanding our review process to

accommodate another 25,000 to 50,000 benefit packages, this ultimately would not prevent employers or unions from offering separate benefits that would not be overseen or regulated by us; and therefore, would not provide the clear standard for distinguishing supplemental benefits from other health or prescription drug coverage for purposes of determining the applicable discount. Moreover, this alternative approach could adversely affect EGWP enrollees to the extent it would require EGWPs to make significant changes in order to bring their supplemental benefits in line with Part D rules—because it might prompt EGWPs to drop those supplemental benefits altogether or otherwise reduce coverage. Consequently, we believe it is better to clearly remove all employer sponsored benefits, other than basic prescription drug coverage as defined in § 423.100, from our purview, which we believe would leave EGWP enrollees in the same place they are today, while, as noted above, providing all participants in the Discount Program a bright line test for determining when the applicable discount applies.

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 appears to plainly contemplate 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) 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 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 propose to codify this policy in regulations.

The rationale for our narrower interpretation of section 1860D–43(a) of the Act is based on concern about beneficiary access to generic drugs and consideration of other contemporaneous provisions governing the Discount Program. First, given that the purpose of the Discount Program is to reduce financial burdens on beneficiaries in the coverage gap, we do not think that the requirements of section 1860D–43(a) of the Act were intended to potentially limit the availability of less expensive generic Part D drugs (which would occur if the generic products of a non-participating manufacturer were excluded). Rather, they were intended to ensure that manufacturers of brand name drugs had a strong incentive to participate in the Discount Program. When we were implementing the Discount Program last year, we were particularly concerned, in light of the short timeframe provided by the Affordable Care Act for collecting signed agreements from participating manufacturers for 2011, that a strict reading of the exclusion would have had the unintended consequence of negatively affecting the availability of generic drugs under Part D beginning January 1, 2011.

As noted above, we further believe that section 1860D–43(a) of the Act must be read in its proper context—in other words, it must coexist with all of the other requirements of the Discount Program, which are set forth in section 1860D–14A of the Act. Section 1860D–14A of the Act requires manufacturers to provide discounts on applicable drugs at the point-of-sale, to provide appropriate data to CMS, and to comply with other requirements imposed by us or the TPA. Further, as described in more detail below, manufacturers with an agreement are subject to periodic audits by CMS and civil money penalties. Finally, section 1860D–14A of the Act specifies that, beginning with 2012, a manufacturer must enter into a Discount Program Agreement for a year no later than January 30 of the previous year—in other words, for a manufacturer to participate in the Discount Program for 2012, it would have had to have signed a Discount Program Agreement by January 30, 2011. In addition to these statutory requirements, there are administrative aspects of the Discount Program that include, but are not limited to, establishing connectivity with the TPA and with CMS, establishing electronic fund transfer accounts with more than 700 Part D sponsors, maintaining labeler code information with CMS, and reviewing file layouts and records for

quarterly invoicing and payment reconciliation.

None of these statutory or administrative requirements is relevant to manufacturers of non-applicable drugs. Indeed, it would be impossible for a manufacturer with no applicable drugs to “participate” in the Discount Program (as a strict reading of section 1860D–43(a)(1) would require). Further, it would be wasteful and burdensome to require manufacturers of non-applicable drugs to undertake all of the administrative requirements set forth in the Discount Program Agreement with respect to drugs that are not subject to the requirements of section 1860D–14A of the Act.

With that in mind, we next turn to the issue of manufacturers with applicable drugs that also have non-applicable drugs. In our view, the same rationale applies to these manufacturers—although they can participate in the Discount Program with respect to their applicable drugs, they cannot do so with respect to their non-applicable drugs. We believe it would be both unfair and potentially very disruptive to beneficiaries to treat manufacturers of non-applicable drugs differently based on whether they also happen to make applicable drugs. For example, suppose that a manufacturer with no applicable drugs declines to participate in the Discount Program because it is literally unable to comply with the statutory requirements of section 1860D–14A of the Act. This manufacturer then acquires or begins to manufacture an applicable drug on February 1. If this manufacturer then was subject to the broader exclusion in section 1860D–43(a) of the Act arguably all of its drugs—both generic and applicable—would be non-covered for a period of almost two years. We do not believe that Congress intended such a disruptive result. Rather, we believe it is more appropriate to consider section 1860D–43(a) of the Act as excluding the applicable drugs of a manufacturer that fails to participate in the Discount Program.

In light of all of these considerations, we believe the a reasonable interpretation of 1860D–43(a) of the Act—one that preserves Congressional intent both to ensure manufacturer participation in the Discount Program and to alleviate financial burden for beneficiaries—is that the exclusion from Part D coverage applies only to the applicable drugs of manufacturers that fail to enter into a Discount Program Agreement and participate in the Discount Program. We seek comments on this proposal.

Section 1860D–43(c)(1) of the Act authorizes CMS to allow coverage for drugs that are not covered by Discount Program Agreements if CMS has made a determination that the availability of the drug is essential to the health of beneficiaries under this part, and we propose 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.

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. We established the model agreement on August 1, 2010 and propose to codify in § 423.2315 those 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 section II.A.1. of this proposed rule), we would propose to implement this requirement as set forth in the current Discount Program Agreement; that is, we would propose 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 CMS or 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 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 three business days after having received written notification of the codes from 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 plan 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 website 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 three business days after having received written notification of the codes from the FDA.

To permit CMS and Part D sponsors to accurately identify applicable drugs, we propose to codify the requirement set forth in the Discount Program Agreement that manufacturers electronically list and maintain 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.

We also propose 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 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 NDCs for products that no longer are 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 plan sponsors promptly because it is the manufacturers that are financially responsible for payment of applicable discounts. Given this structure, we propose to codify this requirement at § 423.2315(b)(3). We further propose 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 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 proposed rule.

Section 1860D–14A(b)(2) of the Act requires each manufacturer with a 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 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, and that 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 proposed rule.

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 propose 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 claimed 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) Length of Agreement

Section 1860D–14A(b)(4)(A) of the Act 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 one year each January 1 thereafter, unless the agreement is terminated in accordance with § 423.2345.

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

(1) Interim Payments

Section 1860D–14A(c)(1)(A)(ii) of the Act requires that manufacturer discounts be provided to applicable beneficiaries at the point-of-sale. To ensure that Part D sponsors have the funds available to advance the gap discounts at the point-of-sale, we are proposing to provide monthly interim coverage gap payments to Part D sponsors under § 423.2320(a).

We propose to base these interim payments on a percentage of the coverage gap drug cost assumptions submitted with plan bids under § 423.265 and negotiated and approved under § 423.272, adjusted as necessary to account for applicable drug costs for applicable beneficiaries. Recognizing that Part D sponsors receive payments

from manufacturers for invoiced discount amounts during the quarterly invoice process, we seek to ensure that Part D sponsors do not receive duplicate Discount Program payments for the manufacturer discounts advanced to beneficiaries at the point-of-sale. Thus, we propose to offset the Part D payments made to the Part D sponsor for each Part D plan by the discount amounts invoiced to manufacturers for that Part D plan.

EGWPs are not required to submit Part D bids. Thus, we do not have the information necessary to estimate the cost of manufacturer discounts for these Part D plans. Similar to our current policy for prospective low-income cost sharing subsidy and reinsurance subsidy payments, we propose not to provide interim payments to EGWPs. However, EGWPs will receive final reconciled coverage gap payments under the reconciliation process described in § 423.2320(b).

Program of All-inclusive Care for the Elderly (PACE) plans would not receive interim coverage gap payments because their enrollees already have zero cost-sharing without any coverage gap.

(2) Coverage Gap Discount Reconciliation

Because the interim coverage gap payments are estimates, Part D sponsors may incur actual Discount Program costs that are greater or less than the interim coverage gap payments. We would perform a cost-based reconciliation to ensure that Part D sponsors are paid dollar for dollar for all manufacturer discount amounts as reported on invoiced PDE data submitted for Part D payment reconciliation. This process is termed "Coverage Gap Discount Reconciliation" under § 423.2320(b) and will occur after Part D payment reconciliation.

The purpose of the coverage gap discount reconciliation is to make Part D sponsors whole for the gap discount amounts provided to applicable beneficiaries at the point-of-sale. In general, we would calculate the Coverage Gap Discount Reconciliation amount by subtracting the interim coverage gap payments from all manufacturer discount amounts as they are reported on PDE records by Part D sponsors. If the difference is positive, we would pay the difference to Part D sponsors. If the interim coverage gap payments exceed the manufacturer discount amounts, we would recover the difference from Part D sponsors.

Manufacturer discount amounts reported on PDE records submitted by the PDE submission deadline for Part D

payment reconciliation are included in Coverage Gap Discount Reconciliation. We would continue to accept PDEs with manufacturer discount amounts for 37 months following the end of the benefit year. Any manufacturer discount amounts reported on PDE records submitted after the PDE submission deadline for Part D payment reconciliation would continue to be invoiced to manufacturers and manufacturers would remit payments for invoiced coverage gap discount amounts to Part D sponsors.

f. Provision of Applicable Discounts on Applicable Drugs for Applicable Beneficiaries (§ 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 at the point-of-sale. As extensively 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. 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. Therefore, § 423.2325(a) would require Part D sponsors to provide applicable beneficiaries with applicable discounts on applicable drugs at point-of-sale. 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 propose 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 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 later reprocessed in the catastrophic phase as a result of an automated TrOOP balance transfer, 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 1860D–14A(g)(4)(C) of the Act requires 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 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, § 423.2325(b)(3) would require 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). If the portion of the negotiated price that falls below the ICL or above the annual out-of-pocket threshold is less than the sum of the dispensing fee and vaccine administration fee, the dispensing fee must be included first in the portion that falls below the ICL or above the annual out-of-pocket threshold. The Affordable Care Act authorizes CMS to establish procedures to determine the discount at point-of-sale and is silent on the order in which negotiated price and non-negotiated price apply (as opposed to with supplemental and other health or prescription drug coverage) and thus, we propose this requirement in order to further support the statutory goal of alleviating the burden of the coverage gap on applicable beneficiaries.

Section 423.2325(b)(4) would require Part D sponsors to 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 would require the Part D sponsors to notify such beneficiaries. This situation could occur if participating manufacturers fail to notify CMS when a new labeler code becomes available or otherwise fail to provide us with all of their labeler codes as required. As required in proposed § 423.2315(b)(4), manufacturers participating in the Discount Program must submit to CMS all of their labeler codes. We make the participating labeler code information available to Part D sponsors so they can determine which drug products are covered by Discount Program Agreements. Part D sponsors cannot cover any applicable drugs marketed with labeler codes that are not specified by CMS as participating in the Discount Program. Consequently, a manufacturer's failure to provide a labeler code to CMS could result in beneficiaries being denied access to both covered Part D drugs and applicable discounts.

While we anticipate such occurrences will be very rare, we believe it is necessary that Part D sponsors determine whether affected beneficiaries need to be notified once CMS makes the labeler code and effective date information available to the Part D sponsor. For example, Part D sponsors generally would need to notify affected beneficiaries that had denied claims if their claims history reasonably indicates that the beneficiary either might still need the previously denied drug or paid for the drug out-of-pocket. If the claims history indicates that the beneficiary has not received an alternative replacement medication since the denied claim, it might reasonably be inferred that the beneficiary still needs (or should be reimbursed for) the denied drug. We recognize that this would place a burden on Part D sponsors through no fault of their own, but, in these rare instances, we believe it would help ensure the beneficiaries have appropriate access to Part D drugs and applicable discounts. It would also increase the likelihood that manufacturers would be held responsible for paying discounts that should have been paid previously.

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. However, in limited circumstances beneficiaries 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. Therefore, our guidance and the Discount Program Agreement specify that Part D sponsors provide, and manufacturers reimburse, applicable discounts 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 Part D. In these situations, beneficiaries are still entitled to the discount and therefore, we propose to codify this requirement in § 423.2325(c).

(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 propose 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.

(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 a 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 for a beneficiary is reduced until it reaches 25 percent in 2020. Section 423.2325(e)(3) would require 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 propose 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 believe 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 propose 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.

We considered using the existing prompt pay requirements in § 423.520 as the basis for implementing the discount payment prompt pay requirements because it seemed to make sense given that the discounts are included on the pharmacy claims and the timeframes are identical. However, unlike § 423.520, § 423.2325(g) does not exclude mail order or long term care pharmacies. Therefore, Part D sponsors that do not currently pay mail order or long term care pharmacies in accordance with the § 423.520 prompt pay requirements for other network pharmacies would need to establish another mechanism for reimbursing these pharmacies for discount payments in accordance with the § 423.2325(g).

Finally, we propose 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.

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 propose 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.

While we considered allowing quarterly audits, we do not believe that there will be significant quarter to quarter changes in data collection and invoice calculation procedures that would warrant such frequent audits. Given that the TPA will need to allow all participating manufacturers the opportunity to conduct audits, we believe that an annual audit strikes the right balance of providing meaningful and timely information to

manufacturers that can reasonably be accommodated by the TPA.

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 propose 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 proposes 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 propose to codify this requirement in § 423.2330(b). Similar to the limitation in § 423.2330(a)(1), we propose to define the term periodic in § 423.2330(b)(1) as no more often than annually. In § 423.2330(b)(3) we propose 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 propose in § 423.2330(c) a multi-stage 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 disagree with the outcome of the initial appeals process.

Before proposing this multistage dispute resolution process, we reviewed potentially analogous appeals mechanisms, both within the Medicare program and in other, similar government programs, such as Tricare and Medicaid. Within the Medicare Part D program we reviewed the appeals process for organizations seeking to become Part D sponsors and the appeals process for Medicare beneficiaries challenging denials of benefits. We also reviewed the appeals mechanism for the Department of Defense (DoD) Tricare program and Medicaid—two existing government programs that collect rebates from pharmaceutical

manufacturers. In each instance, we found a multistage dispute resolution program. We concluded that a multistage process results in balanced, equitable decisions because of the multiple perspectives that are available. Therefore, we are proposing a similar multistage process for the Medicare Coverage Gap dispute resolution 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 propose 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.

We believe that the deadline for filing disputes will result in more prompt remuneration to manufacturers receiving positive decisions and more predictable workloads for the dispute infrastructure.

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 propose this requirement because the manufacturer bears the burden of proof that the PDE data is incorrect. We also propose 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 proposes 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 are proposing 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 propose that this request be made within 30 days after the manufacturer receives a decision from the IRE to facilitate a timely outcome. Finally, we propose that the decision of the Administrator would be final and binding.

We propose to codify the policies as described and welcome comments on the dispute and appeals process.

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.

As previously discussed in this preamble, we have determined that the Part D sponsor is the only entity capable of accurately providing applicable discounts at the point-of-sale because of its detailed knowledge of the drug, the beneficiary, and the claim. Part D sponsors would advance applicable discounts as part of their normal process for adjudicating Part D claims. Since we consider the discounts to be a Part D benefit we propose that the existing mechanism that Part D sponsors have in place to accommodate coverage determinations and appeals related to Part D sponsor decisions on the amount of cost-sharing for a drug be used for beneficiary disputes associated with the Discount Program (see § 423.558 through § 423.638).

Although section 1860D–14A(c)(1)(A)(vii) of the Act specifies disputes that could arise between manufacturers, applicable beneficiaries and the TPA, we believe that under the Discount Program model whereby Part D sponsors provide the discounts at point-of-sale, each Part D sponsor is the appropriate party to address any beneficiary disputes that would otherwise involve manufacturers or the TPA. We believe that the beneficiary would generally contact his or her plan with any questions about any coverage gap claims, including the availability or amount of an applicable discount. Currently a beneficiary who wishes to see how his or her claim amounts were calculated, including those affected by a manufacturer discount, would consult the Explanation of Benefit (EOB) form distributed by the Part D sponsor. For 2011, we amended the model EOB to add coverage gap discounts as "other payments" that count toward a beneficiary's out-of-pocket costs.

Beneficiaries may not know at the point-of-sale whether a manufacturer discount has been applied to their claim, or if the discount has been applied correctly. Part D sponsors direct beneficiaries to their EOBs for information about claims-payment amounts. The EOB instructs beneficiaries to contact the Part D sponsor with any remaining concerns. Maintaining this consistent process for all member benefit payments would be the easiest for the beneficiaries to understand and follow, and, we believe,

impose minimal additional burden on Part D sponsors.

Although we could establish a separate mechanism for beneficiary disputes under the Discount Program, we decline to do so because we believe it would prove duplicative and inefficient for Part D sponsors, beneficiaries, and us. It also would be potentially more confusing for beneficiaries who would be unable to rely on a single process to resolve their benefit-related inquiries. For all of these reasons, we propose to designate the existing Part D coverage determination appeals process as the mechanism for beneficiary disputes about the Discount Program.

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 propose 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) would codify 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 propose 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 propose 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 propose 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 propose to codify this requirement in § 423.2340(f). We welcome comments on this proposal.

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 propose, 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 propose 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 (a)(5) of this section. Proposed sections (a)(4) and (a)(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 propose 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 thirty 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 an independent review entity. The decision of the CMS Administrator would be final and binding on either party. We request 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 propose 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 propose 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.

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, when used for the medical indications of epilepsy, cancer, or a chronic mental health disorder and to include benzodiazepines. These amendments apply to prescriptions dispensed on or after January 1, 2013. Accordingly, we propose to revise the definition of Part D drug at § 423.100, by including barbiturates (when used for the previously noted medical indications) and benzodiazepines that are dispensed on or after January 1, 2013. Like any covered prescription drugs under the Part D benefit program, benzodiazepines and barbiturates must meet all other conditions as defined in § 423.100 of a Part D covered drug such as: FDA approved for safety and effectiveness as a prescription drug under section 505 of the Federal Food, Drug, and Cosmetic Act; used and sold in the United States; not otherwise covered by Medicare Part

A or Part B; and used only for medically accepted indications.

We remind plans 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 statute. Also, given the vulnerability of these drugs to misuse and abuse, it is recommended that Part D sponsors use their Drug Utilization Report tools to identify and prevent waste and clinical abuses/misuses.

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

Under section 6005 of the Affordable Care Act, Part A of Title XI of the Act was amended by inserting after section 1150 of the Act a new section: “SEC. 1150A. Pharmacy Benefit Manager's Transparency Requirements.” Section 1150A of the Act contains several new reporting requirements for Part D sponsors under Part D of title XVIII, qualified health benefits plans (QHBP) offered through an exchange established by a State under section 1311 of the Affordable Care Act, and entities that provide pharmacy benefits management services, referred to in this section as pharmacy benefit managers (PBMs). The purpose of these new reporting requirements is to promote transparency of financial transactions involving Part D sponsors, QHBP, and PBMs. Under section 1150A, the information is required to be reported to the Secretary by the Part D sponsor or QHBP and, in the case of a PBM, to the Part D sponsor or QHBP. In accordance with this authority, we propose to codify various reporting requirements in our regulation at § 423.514. In addition, we propose to add a definition for “bona fide service fees” to our regulations at § 423.501.

Under the authority of section 1860D–15 of the Act, we collect from Part D sponsors cost data necessary to determine payments under the Part D program. Currently, we collect from Part D sponsors PDE data that provide detailed information on each drug dispensed under Part D. In addition, we collect direct and indirect remuneration (DIR) information that indicates the amount of remuneration received by the sponsor or its PBM from pharmaceutical manufacturers and other sources. Part D sponsors are required to report these cost data to CMS within 6 months of the end of the coverage year.

We propose to amend our regulations to implement the provisions of section 1150A of the Act with respect to Part D sponsors and the PBMs that manage prescription drug coverage under a contract with a Part D sponsor. The

provisions of section 1150A of the Act with respect to QHBP and their PBMs will be addressed in separate rulemaking.

The specific information that is required to be collected and reported under Section 1150A of the Act by each Part D sponsor and PBM for a contract year is the following:

- The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies.
- 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.
- The aggregate amount and the type of rebates, discounts, or price concessions (excluding bona fide service fees) that the PBM negotiates that are attributable to patient utilization under the plan, 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.
- 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, and the total number of prescriptions that were dispensed.

Under section 1150A(c) of the Act, information disclosed by a Part D sponsor or PBM is confidential and generally shall not be disclosed by the Secretary or by a plan receiving the information. Consistent with the statute as applied to Part D sponsors and PBMs that provide pharmacy benefits management services on behalf of Part D sponsors, we propose to add language listing the following exceptions, which allow the Secretary to 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:

- As the Secretary determines necessary to carry out section 1150A or Part D of Title XVIII.
- To permit the Comptroller General to review the information provided.
- To permit the Director of the Congressional Budget Office to review the information provided.

We believe the exception allowing disclosure to States to carry out section 1311 of the Act is relevant in the context

of QHBP but is not relevant to the Part D sponsors and their PBMs. Thus, this exception will be addressed in separate rulemaking regarding the provisions of 1150A of the Act with respect to QHBP and their PBMs.

As required by section 1150A(d) of the Act, the provisions of section 1927(b)(3)(C) of the Act shall apply 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 that section."

Consistent with the statute, we are implementing this new reporting requirement by updating the regulations to specify 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, the data elements required by this rulemaking.

Accordingly, in § 423.514, we propose to add language requiring that each entity that provides pharmacy benefits management services must provide to the Part D sponsor, and that each sponsor of a Part D plan provide to CMS, all of the following information in a manner specified by CMS:

- The total number of prescriptions that were dispensed.
- The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies.

• 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.

• The aggregate amount and type of rebates, discounts, or price concessions (excluding bona fide service fees) that the PBM negotiates that are attributable to patient utilization under the plan.

• The aggregate amount of the rebates, discounts or price concessions that are passed through to the plan sponsor.

• 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.

The information submitted under this regulation would be subject to the confidentiality requirements under section 1150A(c) of the Act, and the provisions of section 1927(b)(3)(C) of

the Act are applicable to any Part D sponsor or PBM that fails to provide this information on a timely basis or that knowingly provides false information in the same manner as those provisions apply to a manufacturer with an agreement under section 1927 of the Act.

We believe that we already collect much of the above listed information. For example, we can tally the total number of prescription dispensed from PDE records. Other information can be collected by modifying existing reporting mechanisms. For example, the aggregate amount of the difference between the amount the Part D sponsor pays the PBM and the amount the PBM pays pharmacies (that is, the PBM spread) is available from the DIR data reported to CMS by Part D sponsors on the 2010 DIR Report for Payment Reconciliation: Summary Report. We plan to add to the DIR reporting requirements PBM spread amounts for retail pharmacies and PBM spread amounts for mail order pharmacies in order to meet section 1150A of the Act reporting requirements.

In the interests of administrative simplicity and to minimize reporting burden on Part D sponsors, we would like to further leverage existing data sources and reporting mechanisms. Thus, we solicit comment on whether any of the following data elements can be collected using existing data sources such as PDE records and/or added to existing reporting mechanisms, and whether any may require a separate reporting mechanism:

- Number of retail prescriptions.
- Number of mail order prescriptions.
- Number of prescriptions dispensed by independent pharmacies.
- Number of prescriptions dispensed by chain pharmacies.
- Number of prescriptions dispensed by supermarket pharmacies.
- Number of prescriptions dispensed by state-licensed mass merchandisers to the general public.

We note that the provisions regarding DIR under the Part D program do not mention DIR attributable to patient utilization, whereas section 1150A of the Act references rebates, discounts, and price concessions that are attributable to patient utilization. We are soliciting comments regarding whether there are differences between DIR under the Part D program and DIR attributable to patient utilization. If there are any such differences, we also seek comments regarding whether we should establish additional reporting requirements for DIR attributable to patient utilization.

Consistent with the requirement under section 1150A of the Act that plans exclude bona fide service fees when they report the aggregate amount and type of rebates, discounts or price concessions, we also propose to amend the regulations at § 423.501 to add the following definition for bona fide service fees:

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 drugs. Bona fide service fees include, but are not limited to, distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs).

We are soliciting comment on this definition, which is taken without modification from section 1150A of the Act and is consistent with the definitions used in Medicare FFS and Medicaid. We intend to monitor the reported bona fide service fees reported by Part D sponsors to ensure compliance with program requirements.

B. Strengthening Beneficiary Protections

This section includes provisions aimed at strengthening beneficiary protections under Parts C and D. We are also considering changes under the long term care (LTC) conditions of participation. 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 this would result in uninterrupted plan coverage for eligible beneficiaries thereby improving access to healthcare for individuals such as those with chronic conditions requiring continual monitoring and medication. Similarly, we expect that requiring enrollees in MA plans to be provided with uniform ID cards that all providers can easily recognize would facilitate access to health care for those beneficiaries. We also think that calculating creditable coverage by excluding the value of additional coverage in the coverage gap and the manufacturer's discount—the standard that qualifies retiree drug coverage for the retiree drug subsidy—would mean a beneficiary receiving retiree drug coverage would be less likely to be assessed a late enrollment penalty if he or she decided 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 authorized representative forms would, in our opinion, lessen the burden faced by providers seeking to assist enrollees with appeals and would encourage more health care professionals to step forward and help beneficiaries access this level of the appeals process. Lastly, the various arrangements that exist involving LTC facilities, LTC pharmacies and the LTC consultant pharmacists these pharmacies provide to LTC facilities, and pharmaceutical manufacturers and/or distributors have raised concerns regarding the quality of the consultant pharmacist reviews and the potential impact on resident health and safety. We believe these concerns may be addressed by changes we are considering that would require LTC consultant pharmacists be independent of the LTC facility pharmacy, pharmaceutical manufacturers or distributors, or any affiliate of these entities. The foregoing proposals and the change under consideration are set forth in Table 2.

TABLE 2—PROVISIONS TO STRENGTHEN BENEFICIARY PROTECTIONS

Preamble section	Provision	Part 417		Part 422		Part 423		Part 483	
		Subpart	Subpart	Subpart	Section	Subpart	Section	Subpart	Section
II.B.1	Good Cause and Rein-statement 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.

TABLE 2—PROVISIONS TO STRENGTHEN BENEFICIARY PROTECTIONS—Continued

Preamble section	Provision	Part 417		Part 422		Part 423		Part 483	
		Subpart	Subpart	Subpart	Section	Subpart	Section	Subpart	Section
II.B.5	Independence of LTC Consultant Pharmacists.	N/A	Subpart B ..	§ 483.60.					

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 HMO or competitive medical plan for deductible and coinsurance amounts. The cost plan must demonstrate that it made reasonable efforts to collect the unpaid amount (for example, 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. Whichever policy they choose, it must be applied consistently to all members in the plan.

In the April 2011 final rule (76 FR 21511), we established rules that allowed beneficiaries disenrolled from MA and Part D plans for failure to pay premiums the ability to request reinstatement into the plan from which they were involuntarily disenrolled provided they could establish good cause and pay all arrearages. We established these rules at § 422.74 and § 423.44 not only because they were consistent with the policy for delinquent Medicare Part B premium payments, but because beneficiaries who were disenrolled from an MA or Part D plan for failure to pay premiums generally were not eligible for a special enrollment period. We believed there may be situations where individuals had extenuating circumstances that prevented them from paying their premiums timely and that reinstatement would be appropriate.

We received broad support for this regulatory change for MA and Part D plans, and stated at the time that we would consider expanding the scope of this provision to section 1876 cost enrollees in the future. Based on feedback we have received from partners, we are proposing to amend

§ 417.460(c) regarding disenrollment for non-payment of premiums to allow for the reinstatement of enrollment for good cause subsequent to an involuntary disenrollment associated with the failure to pay premiums or other cost-sharing amounts. In order to be eligible for reinstatement, the beneficiary would have to pay all outstanding arrearages, including premiums that accrued during the period of disenrollment. We believe this is an important protection to provide beneficiaries enrolled in cost plans because even though members of cost plans do not have the same election period restrictions as those in MA and Part D plans, a reinstatement of enrollment would remove the involuntary disenrollment and result in continuous coverage.

We propose that the requirements for reinstatement be similar to those established under Part C and Part D. That is, the reinstatement must be requested, good cause determined and payment made of all premium or cost sharing arrearages, including amounts that would have been due since the disenrollment, within 3 months of the disenrollment date. Examples of good cause would be similar to those established for individuals disenrolled from MA or Part D plans and may include, but are not limited to: (1) An unexpected, prolonged hospitalization; (2) an error by a Federal government employee or plan representative; or (3) loss of home or severe impact by fire, or other exceptional circumstance outside the beneficiary's control. We also propose that good cause would not exist if the only basis for requesting reinstatement was a change in the individual's circumstances subsequent to the involuntary disenrollment resulting in his or her ability to pay the premiums.

We would note that an individual who is involuntarily disenrolled within the same timeframe from both his or her cost plan and a separate prescription drug plan (not affiliated with the cost plan) would need to seek separate good cause determinations for reinstatement into both plans. This is because the two

plans may have different grace periods and arrearage amounts.

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 standards established by CMS, 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 through sub-regulatory guidance (<http://www.cms.gov/ManagedCareMarketing/>) with respect to member identification (ID) cards for Medicare Advantage (MA) Preferred Provider Organization and Private Fee-for-Service products, we have issued no related requirements. Many MA organizations issue ID cards to their enrollees, though absent regulation, there is no way to ensure consistency of information across such documents. We believe it is important to establish requirements for the MA member ID card to ensure that information such as the plan's customer service number, link to the plan's website and member ID number are disclosed to enrollees for access to care. Specifically, we propose 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 website; (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.

Implementation of these provisions will 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, as well as our authority under section 1856(b)(1) 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 propose to amend § 422.111 by adding a new paragraph (i) to expressly require MA plans issue and re-issue, as necessary, a card that contains certain information and enables enrollees to access all covered services. Additionally, in an effort to protect beneficiaries from misuse of personal information, we will explicitly prohibit plan sponsors from disclosing social security numbers or health insurance claim numbers on the member ID cards. We will provide further instructions in the Medicare Marketing Guidelines.

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 with regard to the actuarial equivalence of retiree prescription drug coverage to the defined standard coverage. The new provision requires that when attesting to the actuarial equivalence of the plan's prescription drug coverage to the defined standard coverage, qualified retiree prescription drug plans not take into account the value of any discount or coverage provided during the gap between the initial coverage limit during the year and the out-of-pocket threshold for the defined standard coverage under Part D. This change was intended to carve-out coverage provided during the gap when determining the actuarial equivalence of retiree prescription drug coverage for the purpose of qualifying for the retiree drug subsidy payment under section 1860D–22(a)(2) of the Act. In addition, section 1860D–14A(g)(1) of the Act expressly excludes enrollees in RDS plans from the definition of "applicable beneficiary." Thus, these Part D eligible individuals are not entitled to gap coverage or any applicable discount on drugs. In accordance with these legislative changes, we revised the retiree drug subsidy calculation by amending § 423.884(d) to remove the value of any discount or coverage provided during the coverage gap from the valuation of the RDS coverage. In other words, the calculation of the actuarial value of defined standard Part D coverage for the purposes of the RDS attestation excludes discounts provided

to applicable beneficiaries in the gap by the discount program under 1860D–14A of the Act and the decreases in gap coinsurance for applicable beneficiaries under 1860D–2(b) of the Act.

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. Section 1860D–13(b)(5)(A) of the Act further states that an individual's prescription drug coverage meets the actuarial equivalence requirements only if the coverage is determined (in a manner specified by the Secretary) to provide coverage of the cost of prescription drugs the actuarial value of which (as defined by the Secretary) to the individual equals to or exceeds the actuarial value of the standard prescription drug coverage (as determined under section 1860D–11(c) of the Act). The Affordable Care Act, as amended, establishes two types of standard prescription drug coverage. Specifically, the standard defined benefit now includes provisions that apply only for applicable beneficiaries (see sections 1860D–2(b)(2)(C) and (D) of the Act), while the rest of the standard defined benefit applies for other enrollees. Thus, we calculate two actuarial values for standard prescription drug coverage—one value that would apply to applicable beneficiaries, and another value for standard prescription drug coverage when establishing the low-income subsidy. As a result of these changes, we need to clarify which actuarial equivalence standard is used for the valuation of creditable prescription drug coverage when determining whether an individual is subject to the late enrollment penalty (LEP) under 1860D–13(b) of the Act.

We believe the value of the defined standard benefit, as it applies to the valuation of creditable coverage, should be consistent with the regulation change for the valuation of the retiree drug subsidy calculation. Retiree prescription drug coverage is a primary source of creditable coverage. This being the case, we are proposing 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 value for both determinations, we will be ensuring that the individuals who are enrolled in retiree drug plans that have met and attested to 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.

To this end, we are proposing to amend § 423.56(a) to exclude the value of gap discounts or coverage, so that it is consistent with the calculation of the actuarial value of qualified retiree prescription drug coverage found at § 423.884(d). We also propose to revise the reference to "CMS actuarial guidelines" in § 423.56(a) to read "CMS guidelines." We believe this revision would allow CMS additional flexibility to provide interpretive guidance on the definition of creditable coverage for reasons beyond those relating to actuarial principles.

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 these sets of regulations to strengthen enrollee access to the Part C and Part D appeals process. 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 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 in this section. Consequently, we are proposing to revise the Part D regulations at § 423.600 to allow physicians and other prescribers to request Independent Review Entity (IRE) reconsiderations on behalf of enrollees. We are also proposing to make 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 prescribers' 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 proposal would 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 would enhance beneficiary access to the appeals process and better ensure prompt IRE decisions on whether requested drugs should be covered under Part D.

Under this proposal, the regulations would continue to require a Part D enrollee, or a prescriber acting on his/her behalf, to request an IRE review; adverse redeterminations would not be automatically forwarded to the IRE. We have considered requiring auto-forwarding of adverse redetermination requests under the Part D program, but we continue to believe that the statute supports the position that in order to obtain IRE review the enrollee (or someone acting on the enrollee's behalf) must 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 proposed 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 proposal 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 proposal would 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, such as the right to bring appeals at any level, the right to obtain information on appeals, etc. 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 proposal 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 proposing 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 receive a written decision notice from the IRE, ensuring that enrollees are fully informed about the review process and able to participate if they choose to do so. We intend to issue additional manual guidance regarding the specifics of prescriber notice requirements.

As in § 422.582 and § 423.580, we are proposing that prescribers must notify enrollees whenever they request IRE review on their behalf, and we intend to issue additional operational guidance with respect to how this requirement may be satisfied. Finally, we want to make clear that this proposal 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.

5. Independence of LTC Consultant Pharmacists (§ 483.60)

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.

In the process of performing the drug regimen reviews, if the consultant pharmacist recommends a modification of a resident's drug treatment regimen, he/she notates the resident's medical record with the recommendation to the prescribing physician. The prescribing physician must respond to the recommendation and, based on our experience, the physician generally follows it because the consultant pharmacist is considered to be an unbiased expert of pharmacology in the LTC setting. As a result of their role in LTC facilities, LTC consultant pharmacists have significant influence over the drugs that LTC facility residents receive.

In accordance with section 1860D-4(b)(1) of the Act, as codified in our regulations at § 423.120(a)(5), Part D sponsors are required to provide LTC facility residents who are plan enrollees convenient access to LTC pharmacies. We expect that each LTC facility would select one, or possibly more than one, eligible network LTC pharmacy to provide Medicare drug benefits to its residents. We have specified minimum performance and service criteria in the Medicare Prescription Drug Benefit Manual, Chapter 5 ("Benefits and Beneficiary Protections"), section 50.5.2 (available on the CMS Web site at: <http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter5.pdf>).

Commonly, nursing homes 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. In verbal conversations with industry representatives, we have been informed

that LTC pharmacies typically provide the consultant pharmacists to nursing homes at rates that are well below the LTC pharmacy's cost and below fair market value.

We have been concerned with the potential effect on patient safety and quality of care of various contractual arrangements involving LTC facilities, LTC pharmacies, the LTC consultant pharmacists these pharmacies provide to LTC facilities, and pharmaceutical manufacturers and/or distributors. These arrangements may take many forms. The practice of LTC pharmacies, providing consultant pharmacists to nursing homes at below cost or fair market value is one such type of arrangement. We are concerned that these arrangements may be used to entice nursing homes to enter into contracts with the LTC pharmacy for pharmacy dispensing services and the purchase of prescription drugs. We are greatly concerned with financial arrangements that involve payments from pharmaceutical manufacturers directly or indirectly to LTC pharmacies and LTC consultant pharmacists for encouraging physicians to prescribe the manufacturer's drug(s) for residents. The impact of these financial incentives is heightened when, as permitted under State law or by the State Pharmacy Board, LTC facilities sign agreements with LTC pharmacies permitting the consultant pharmacists to make medication switches. These types of arrangements may result in incentives for the LTC consultant pharmacist to make recommendations that conflict with the best interests of nursing home residents, as well as with Part D sponsors' formularies and/or drug utilization management (DUM) programs. Any such arrangements have the potential to directly or indirectly influence consultant pharmacist drug regimen recommendations. As a result, the arrangements bring into question the ability of the LTC consultant pharmacists to provide impartial reviews of the residents' drug regimens, which in turn raises concerns regarding the quality of those reviews and potential impact on resident health and safety.

Industry estimates indicate that three LTC pharmacy organizations have 90 percent of the market. Based on these estimates, the LTC pharmacy industry is highly concentrated, and we believe, therefore, these arrangements are widespread. As a result, we are concerned 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 home residents to certain drugs. This steering could result in the overprescribing of medications, the prescribing of drugs that are inappropriate for LTC residents, or the use of unnecessary or inappropriate therapeutic substitutions. Such potential outcomes can pose serious jeopardy to nursing home residents' health and safety. Although we have no evidence directly linking these arrangements to adverse outcomes, we believe a requirement under consideration that LTC consulting pharmacists be independent would be appropriate and prudent because it would ensure that financial arrangements did not influence the consultant pharmacist's clinical decision making to the detriment of LTC residents. Our concerns are not merely theoretical. We are aware of claims brought by qui tam relators under the False Claims Act alleging that, for instance, an LTC pharmacy received quarterly payments styled as rebates from the pharmaceutical manufacturer to engage in an active intervention program to convince physicians to prescribe a manufacturer's antipsychotic agent to the physicians' nursing home patients and to authorize all competitive products only after the failure of the manufacturer's product. In 2005, the Food and Drug Administration (FDA) issued warnings of the increasing death rate associated with the use of antipsychotic agents for behavioral symptoms for older persons with dementia. In reporting the results of 17 clinical trials, FDA noted an approximately 1.6 to 1.7 fold increase in mortality, compared to placebo-treated patients, in these studies.¹ Thus, any financial arrangements that encourage consultant pharmacists to prescribe these drugs to older LTC residents with dementia contrary to FDA warnings may detrimentally affect those residents' health and safety.

Recent research suggests the use of antipsychotic drugs in nursing homes remains high—higher, in fact, than the percentage of residents diagnosed with psychoses. Despite the serious safety concerns, researchers reported nearly 1 in 3 nursing home residents in the U.S. received antipsychotic drugs in 2007.² Prior research examining potentially inappropriate prescription drugs among

nursing home residents found half of the almost 3,400 study residents were prescribed a potentially inappropriate prescription medication. Forty percent of these residents had medication that was identified as both inappropriate and generally to be avoided among older LTC residents; a third of these medications posed a potential for severe harm. The therapeutic class most prevalent was antipsychotic agents.³

More recently, a review by the HHS Office of Inspector General of Medicare Part D claims for atypical antipsychotics for elderly nursing home residents in the first half of 2007 found that 22 percent of those drugs were not administered in accordance with CMS standards for unnecessary drug use in nursing homes. The OIG also found a very high incidence of atypical antipsychotic prescribing for elderly nursing home patients with dementia despite the presence of an FDA black box warning that such prescribing is associated with increased mortality.

In addition to research findings, nursing home survey and certification data reported in the CMS online survey and certification reporting system indicate unnecessary drug use in nursing homes continues to be a problem. In 2006, we issued updated guidance for LTC survey and certification reviews of the use of potentially unnecessary medications.⁴ The guidance, providing specific information on medications that are problematic to the nursing home population, was implemented in December 2006. In the 7 years prior to the implementation, the percent of surveys with a citation for unnecessary drug use ranged from 12.6 to 14.0 percent. Since implementation, however, the percent of surveys with these citations has increased yearly from 18.2 percent in 2007 to 19.4 percent in 2009.

The research and our survey and certification data indicate that the use of unnecessary medications, particularly antipsychotics, is problematic in LTC facilities. Although our findings do not directly connect LTC pharmacy relationships with consultant pharmacists to these research findings and survey results, we believe it is reasonable to presume that the

¹ FDA, Public Health Advisory: Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances, April 2005. Accessed online at <http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/UCM053171> on May 26, 2010.

² Chen, Y, Briesacher, BA, Field, TS Tjia, J Lau, DT, Gurwitz, JH. Unexplained Variation across US Nursing Homes in Antipsychotic Prescribing Rates. *Archives of Internal Medicine*. 2010;170(11):89-95.

³ Lau, DT, Kasper, JD, Potter, DE and Lyles, A. Potentially Inappropriate Medication Prescriptions among Elderly Nursing Home Residents: Their Scope and Associated Resident and Facility Characteristics. *Health Services Research*. 2004;39(5):1257-1276.

⁴ CMS, Guidance for Unnecessary Drugs § 483.25(l), September 2006. Accessed online at http://cms.gov/manuals/Downloads/som107ap_pp_guidelines_lpcf.pdf on June 3, 2010.

incentives present in the relationships among consultant pharmacist, LTC pharmacies and drug manufacturers can influence the prescribing practices reflected in these data.

As a result, we believe requiring the independence of consultant pharmacists is necessary and appropriate and are considering making such a change. We solicit comments on our understanding in this matter, as well as on our changes under consideration discussed in this section.

We note further that, although Federal regulations at § 483.25(l) require LTC facilities to avoid unnecessary drugs, our experience indicates that this responsibility generally is delegated to the consultant pharmacist who is, for the most part, provided by the facility's contracted LTC pharmacy. According to a June 2008 report of a study by the HHS Office of Inspector General (OIG) regarding Part D drugs and LTC facility residents, about 80 percent of the 128 nursing home administrators

interviewed for the study indicated the consultant pharmacists performing their facility's drug regimen reviews were employed by the nursing home's LTC pharmacy.⁵ Further, this report states that 54 percent of the 79 pharmacy directors interviewed for the study reported that their pharmacy receives rebates from pharmaceutical manufacturers that are frequently based on market share or volume. However, only three of the pharmacy directors reported providing rebate information to the LTC facility. Thus, in delegating responsibility for avoiding use of unnecessary drugs to consultant pharmacists, nursing homes generally are unaware of any financial interests that can bias the pharmacist's drug recommendations.

Consultant pharmacists perform monthly drug regimen reviews for all LTC facility residents. During this review, the consultant pharmacist may recommend a medication change. In making a decision whether to accept the recommended change, prescribing physicians are likewise generally unaware of the LTC pharmacy rebate arrangements with pharmaceutical manufacturers that may influence the recommendation. In the previously cited report, the OIG noted that when a consultant pharmacist recommended a medication change during the drug regimen review, the recommendation was accepted by the prescribing

physician about 74 percent of the time.⁶ We believe 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 will ensure that financial arrangements do not influence the consultant pharmacist's clinical decision making to the detriment of LTC residents.

Therefore, we are 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. For the reasons described in this section, we believe such a requirement is necessary to ensure that consultant pharmacist decisions are objective and unbiased. That is, LTC facilities must use a qualified professional pharmacist to conduct drug regimen reviews and make medication recommendations based solely on what is in the best interests of the resident. We believe this can be achieved only if the consultant pharmacist is working without the influence of conflicting financial interests that might otherwise encourage overprescribing and overutilization, which creates health and safety risks for residents. We note that some arrangements we are addressing here may also implicate the fraud and abuse laws for which the HHS OIG and the Department of Justice (DOJ) have jurisdiction.

The changes we are 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 are considering requiring that long term care facilities employ or directly or indirectly contract the services of a licensed pharmacist who is independent. We also are 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. Our changes would also prohibit nursing homes from contracting

for the provision of consultant pharmacy services with entities (such as a subsidiary of an LTC pharmacy) that have been created for the purpose of providing reorganized consultant pharmacist services.

We do not believe it necessary to define the terms "affiliate" or "affiliated" as we believe the meaning should be broadly interpreted to cover all relationships that incent overprescribing and inappropriate prescribing in LTC facilities. We do not intend, however, for any of the changes under consideration to prohibit any relationships that would be inherently free of conflict of interest. Thus, we solicit comment on the specific relationships that should be permitted.

We are aware that some Indian Tribes and Tribal organizations own LTC facilities that serve their members and that the Tribe may also own the pharmacy that serves the facility. We believe that the Tribal-owned LTC facility may employ the services of a pharmacist to provide consultation and perform drug regimen reviews who is also employed by the facility's pharmacy without violating the independence requirement. In these instances, because the LTC facility and pharmacy are commonly owned by the Tribe, the consultant pharmacist's incentives for prescribing are aligned with the best interests of not only the Tribal members who are LTC residents, but also the Tribe. We believe a similar alignment of interests would exist in Indian Health Services (IHS) owned facilities and Tribal facilities that are serviced by IHS pharmacies. We expect there are other LTC providers or systems in which the incentives for prescribing are similarly aligned to sufficiently limit the risk of conflicts of interest and ensure the best interests of the LTC residents are served. Therefore, we are thinking of including an exception for Tribal owned LTC facilities and pharmacies. We also solicit comment from the public on our interpretation that in these unique situations independence is not an issue because the risk of conflicts of interest is sufficiently limited.

We anticipate that if we were to require that LTC facilities engage independent consultant pharmacists, this would cause consultant pharmacists to reorganize to achieve independence from the parties (facility pharmacies, pharmaceutical manufacturers and distributors, and affiliated entities) with which the consultant pharmacists are currently affiliated. That is, we believe the consultant pharmacists currently assigned to LTC facilities would seek to

⁵ HHS, Office of Inspector General, "Availability of Medicare Part D Drugs to Dual-Eligible Nursing Home Residents," June 2008. Available online at <http://oig.hhs.gov/oei/reports/oei-02-06-00190.pdf>. Accessed on June 28, 2010.

⁶ HHS, Office of Inspector General, "Availability of Medicare Part D Drugs to Dual-Eligible Nursing Home Residents," June 2008. Available online at <http://oig.hhs.gov/oei/reports/oei-02-06-00190.pdf>. Accessed on June 28, 2010.

retain relationships with those facilities, either through direct employment or by banding together with other consultant pharmacists, for instance, in professional corporations. We believe that if the changes under consideration were to take effect beginning January 2013, such a time frame would provide sufficient time for implementation of the requirement. However, we recognize that there may be some areas where certain conditions or extenuating circumstances might argue for a longer implementation period. Specifically, we anticipate that LTC facilities in rural areas would face the greatest challenges in recruiting qualified consultant pharmacists, particularly if the consultant pharmacists currently serving the rural facilities do not reorganize in order to continue to provide services. Therefore, the requirements under consideration may need to be modified to assist these facilities. One way to assist would be to extend the time period for implementation. Thus, we are soliciting comment on whether to provide for a later effective date for rural facilities as opposed to other LTC facilities or to make other accommodations for the unique circumstances in which rural facilities operate. While we do not believe that any consultant pharmacist should have a conflict of interest, we are also soliciting comments on whether it would make sense to waive the independence requirement to permit alternative approaches. In describing

these other approaches, comments should address the protections that would be implemented to reduce the risk of conflict of interest due to the lack of independence of the consultant pharmacists.

It is our understanding that LTC consultant pharmacists commonly perform approximately 60 drug regimen reviews in a day. 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 are not proposing in this rule to codify changes to the drug regimen review

requirements, we are soliciting public comment on best practices related to the conduct of drug regimen reviews. We will use these comments to inform possible future rulemaking regarding the drug regimen review requirements.

C. Excluding Poor Performers

This section includes three proposals designed to strengthen our ability to remove poor performers. We believe we could protect beneficiaries through the proposal that would enable us to terminate health care prepayment plans (HCPPs) whose administration does not meet specified financial, reporting, and access requirements.

A second proposal would enable us to look at 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 propose to give CMS the authority to terminate MAOs and Part D sponsors that have failed to provide, over a course of 3-years, service meriting at least 3-star ratings. A second proposal would give CMS the authority to deny applications submitted by MAOs and Part D sponsors that have performed poorly in the past. We anticipate that this proposal would directly enable us to protect beneficiaries from poor care. Both these provisions, in our opinion, would give entities that want to administer benefits to Medicare beneficiaries a strong incentive 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 3 for details of these proposals.

TABLE 3—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.

TABLE 3—PROVISIONS TO EXCLUDE POOR PERFORMERS—Continued

Preamble section	Provision	Part 417		Part 422		Part 423	
		Subpart	Section	Subpart	Section	Subpart	Section
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 payment to HCPPs, but does not specify program requirements. Consequently, we have incorporated features of both section 1876 of the Act cost contract plan, and MA program regulations to establish benefit, enrollment, appeals, and other HCPP program features. For example, 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, we propose to codify specific reasons for HCPP termination in § 417.801(d) to strengthen our oversight and enforcement capability. In addition, specifying additional elements through notice-and-comment rulemaking would ensure that all HCPPs are aware that their failure to comply with such requirements may lead to termination of their contracts with us. 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 propose to retain the bases for termination but to modify § 417.801(d)(ii) to include three specific elements of substantial non-compliance with the CMS contract, applicable CMS regulations, or applicable provision of the Act as a basis for CMS termination of an HCPP.

First, in their agreements with us, HCPPs agree to provide adequate access to providers and to document such access. Accordingly, we would specify that failure to provide adequate access to providers, or documentation of such

access, is a basis for determining that an HCPP is not in substantial compliance with applicable regulatory requirements. We propose to include this basis for termination in 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 would specify, in new paragraph (d)(1)(ii)(B), that failure to provide such data and/or to maintain records appropriately is a basis for determining 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 propose that a new paragraph at (d)(1)(ii)(C) would specify that a failure to report costs to CMS will constitute a basis for determining that an HCPP is not in substantial compliance.

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, beneficiary survey responses, 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 MAO 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 MAO or Part D sponsor, an organization remains obligated to maintain satisfactory administrative and management arrangements, a point we propose to clarify by adding paragraphs § 422.504(a)(17) and § 423.505(b)(25) to the list of required elements in CMS' contracts with MAOs 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 propose 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 propose 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 MAO 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 a good 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 MAO 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 MAO or Part D sponsor 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 propose 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 MAO 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. 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 propose to establish as a requirement that organizations must achieve a summary plan rating of at least 3 stars for each of Part C and Part D each year by adding paragraph § 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.

The star ratings may also be used as a basis for contract enforcement actions. We have the authority under section 1857(c)(2) of the Act to terminate CMS' contract with an MAO 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 good quality services to their members.

Accordingly, we propose to amend the bases upon which CMS may terminate an MAO 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 three consecutive contract years. We believe that 3 years is sufficient time for a sponsor, once it has received notice of its low star rating, 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 most recent plan ratings, issued in September 2010, 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 2010 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 MAOs 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 MAOs provided screenings to their members for conditions such as breast cancer, colorectal cancer, elevated cholesterol, glaucoma, and osteoporosis, as well as providing 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 MAOs 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 MAOs need to address for this purpose by annually publishing the methodology and results both publicly on the CMS Web site and in the form of private previews for MAOs to review their own results. As a result, an MAO'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 MAOs 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 MAOs 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 MAO'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 MAO affords its members their coverage determination appeal rights under the Part C program. The Part C regulations at Part 422, Subpart M, require MAOs 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 MAO meets the regulatory deadlines for issuing responses to member appeals while the "Reviewing Appeals Decisions" rating measures the frequency with which the MAO determinations were overturned by the Independent Review Entity (IRE). The analysis for these measures was conducted by Maximus, Inc., 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 MAO'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 MAO's operations. The CAP measure reflects the number and type of findings made by us during an audit of an MAO's performance. Thus, these two measures provide a snapshot of the MAO's compliance with 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 MAOs 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 MAO 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 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 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 their 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 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 look at a contract's performance on a measure relative to all other contracts' performance on the same measure. In either case we usually segment the range of the actual contract scores for each measure into one of the 5-star groupings. The segmentation of the scores into groups is based on statistical techniques that minimize the distance between scores within a grouping (or "cluster") and maximize the distance between scores in different groupings. There may not be clusters in each grouping, therefore there could be as many as 5 or as few as one rating in the final data. 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 MAOs 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 propose 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. We invite 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.

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 our denial of their applications if they fail during the preceding 14-months to comply with the requirements of the Part C or D programs 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.

At this time, we are proposing to further refine our intended approach to using past performance in making application determinations. Specifically, we are concerned about entities submitting applications to us 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 are proposing 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 propose 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 CMS in prohibiting and preventing each such organization from gaming the Medicare program by reapplying for a contract as a new organization during the 2-year ban, when the applying organization has common ownership and management control. 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 gaming by organizations whose contracts have been terminated or non-renewed by CMS, we propose 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.

D. Improving Program Efficiencies

By reducing regulatory burdens for MA Organizations, Part D sponsors, and cost contractors, lowering transaction costs, and reducing waste and unnecessary spending, we believe we can improve program efficiency and keep costs down and improve the quality of care received by Medicare beneficiaries. Non-renewing cost contractors would save money if we eliminated the current regulatory requirement to purchase print advertising announcing their non-renewals. Implementing the hospital-acquired conditions (HACs) and present on admission indicator policy that is currently required under the Original Medicare Inpatient Hospital Prospective Payment system (IPPS) for MA plans would continue our efforts to enhance quality and efficiency of care, and promote incentives for hospitals to eliminate medical errors and reduce Medicare expenditures for poor quality or unnecessary care. MAOs and Part D sponsors that are no longer tied to particular agent/broker compensation amounts would save transaction and other costs if rules regarding agent/broker compensation were made more flexible. Cost-sharing tailored to a trial fill of a prescription drug would not only save money for each beneficiary who found that the drug did not work for him or her, but would also lessen the problems of disposal or diversion of unused drugs.

These proposals and others are outlined in Table 4.

TABLE 4—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 Fully-Integrated Dual Eligible Special Needs Plans (FIDE SNPs).	N/A	N/A	Subpart C	§ 422.102	N/A	N/A
II.D.3	Application of the Medicare Hospital-Acquired Conditions and Present on Admission Indicator Policy to MA Organizations.	N/A	N/A	Subpart C	§ 422.504	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	§ 423.104, § 423.153

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

Section 1876 of the Act provided 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 § 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 propose 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 is 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.

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

Congress established dual eligible SNPs (D-SNPs) under the Medicare Modernization Act of 2003 (MMA) with the intention of better integrating care for individuals eligible for both Medicare and Medicaid (“dual eligible” beneficiaries). The Affordable Care Act created a subset of D-SNPs, fully-integrated dual eligible SNPs (FIDE SNPs), which CMS further defined in

our April 2011 final rule (76 FR 21443 and 76 FR 21444) at § 422.2 as D-SNPs that: (1) Provide dual eligible beneficiaries access to Medicare and Medicaid benefits under a single managed care organization; (2) coordinate delivery of covered Medicare and Medicaid health and long-term care services; (3) possess a valid capitated contract with the State for specified primary, acute, and long-term care benefits consistent with State policy; and (4) comply with CMS and State policy regarding marketing, appeals, quality assurance, and enrollment communication procedures.

Section 2602(c) of the Affordable Care Act also charged us with making Medicare and Medicaid work together more effectively to improve patient care and lower costs. Thus, we are implementing initiatives aimed at improving quality and access to care for dual eligible beneficiaries, simplifying processes, and eliminating regulatory conflicts and cost-shifting that occurs between the Medicare and Medicaid

programs, States, and the Federal government. (For more information on this initiative, see our CY 2012 Call Letter, at <http://www.cms.gov/MedicareAdvtgSpecRateStats/Downloads/Announcement2012.pdf>.) To further these goals, we propose to give certain SNPs additional flexibility with respect to plan design, as discussed in detail later in this section. Under this proposed rule, FIDE SNPs that are currently operational, that have operated in the previous contract year, and that meet certain CMS criteria including, but not limited to, being of high-quality (as defined by CMS in the calendar year 2013 draft/final call letter), would be afforded this benefit flexibility.

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 “supplemental benefit” that is included in an MA plan for every enrollee who joins the plan (other benefits may be offered at the enrollee’s option). 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. To this end, and as described in this section, we propose amending our regulations at § 422.102(e) to allow certain FIDE SNPs that CMS deems eligible the flexibility to offer supplemental benefits beyond those that we currently allow for MA plans.

We currently apply the same guidance as to what can be offered as a supplemental benefit to all MA plans, regardless of plan type. In recent years, we have used guidance (see § 30.1 of Chapter 4 of the Medicare Managed Care Manual, “Benefits and Beneficiary Protections,” <http://www.cms.gov/manuals/downloads/mc86c04.pdf>) to clarify that supplemental benefits must be items and services that are—

- Primarily health related, meaning that an item or service is directly health-related, not for comfort or cosmetic or daily maintenance purposes, and has a use that is either national typical usage or part of a community pattern of care;
- Have a cost—that is, a non-zero direct medical cost associated with their provision; and
- Not Part A- or B-covered benefits.

This guidance was based on concerns that competitive pressures were leading some MA organizations to spend Medicare rebate dollars (MA organizations with “bid” amounts for covering A and B services below the A and B “benchmark” amount for their

county may use a percentage of the difference to offer additional benefits) on items that were more focused on providing marketing and enrollment incentives than on delivering quality, cost effective health care. We also were concerned that MA organizations could attempt to offer supplemental benefits that discriminate against certain enrollees and thereby violate the anti-discrimination prohibition in section 1852(a)(3) of the Act.

While these concerns still prevail, we believe that allowing certain SNPs greater flexibility in offering supplemental benefits beginning contract year 2013 would advance our overall goal of better integrating care for dual eligible beneficiaries. In addition, by limiting benefit flexibilities to those plans that are qualified to participate in this initiative, we reduce the likelihood that States could shift costs to the Medicare program by cutting Medicaid services and benefits from their State Medicaid plans.

We propose limiting the flexibility that would be offered under this proposed rule to FIDE SNPs. Because FIDE SNPs are required to offer LTC supports and services, we believe that an approach that limits benefits flexibility to FIDE SNPs, as opposed to all D-SNP types, would be more consistent with the objective of keeping beneficiaries at risk of institutionalization in their homes, preventing health status decline that triggers additional utilization of health services, and lowering costs for the Medicaid and Medicare programs. We request 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.

We are also proposing to further limit the benefit flexibility under this proposed rule to those qualified SNPs that serve only full-benefit dual eligible beneficiaries. We believe that dual eligible beneficiaries who receive full State Medicaid benefits would have the most to gain from fully-integrated Medicare-Medicaid plan benefit offerings that include additional Medicare supplemental benefits. Furthermore, in circumstances where a State reduces coverage of a Medicaid benefit, we believe that the ability to offer additional Medicare supplemental benefits to full-benefit dual eligible enrollees is particularly critical in order to ensure continuity of care.

We are particularly interested in assessing whether certain supplemental

benefits could prevent health status decline in the dual eligible population and reduce the quantity and cost of future health care needs. Examples of benefits that could be offered under this proposed rule would include—

- Personal care services in the home;
- Non-skilled nursing activities in the home;
- Custodial care; and
- In-home food delivery for vulnerable beneficiaries. (We note that our current guidance on supplemental benefits permits in-home food delivery on a limited basis—that is, for a limited duration and only in certain circumstances.)

We would review each qualified SNP’s proposed supplemental benefit offerings for conformance to the SNP’s model of care (MOC), and we would approve additional supplemental benefit offerings for these qualified SNPs as we deem necessary.

We request comment on what specific categories and types of supplemental benefits we should consider for the purposes of extending benefits flexibility to qualified FIDE SNPs participating in this initiative, as well as on the circumstances under which plans should be permitted to offer these additional supplemental benefits. We also request 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 also recognize that the services, Medicare Part C premium coverage, and out-of-pocket (OOP) cost-sharing benefits that dual eligible beneficiaries receive vary according to their Medicaid eligibility category and the State where they reside. We request comments 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 full benefit dual eligible population.

In order to implement this proposal, we propose amending § 422.102 to add a new paragraph (e) specifying that, subject to CMS approval, and as specified annually by CMS, certain 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 for the dual eligible population. All such benefits would be consistent with the rules for supplemental benefits under Part 422, including § 422.2, § 422.100(c)(1), and

§ 422.102. Assuming that this proposal is finalized, we would issue guidance in our annual Call Letter and in Chapter 4 of the Medicare Managed Care Manual—to provide guidance on the applicability of this provision, as well as examples of the specific additional supplemental benefits flexibilities that could be afforded under this initiative. We solicit comments on this approach.

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

We propose 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 believe this proposed change is necessary to bring MA requirements in line with current HAC-POA policy in the fee-for-service Medicare program, as well as—in the near future—to the Medicaid program.

Section 5001(c) of the Deficit Reduction Act of 2005 (DRA) added section 1886(d)(4)(D) of the Act to require a quality adjustment in Medicare Severity Diagnosis Related Group (MS-DRG) payments for certain hospital-acquired conditions. We have titled the provision “Hospital-Acquired Conditions and Present on Admission Indicator Reporting” (HAC & POA). For discharges occurring on or after October 1, 2008, IPPS hospitals do not receive the higher payment for cases when one of the selected conditions is acquired during hospitalization (that is, was not present on admission). The case is paid as though the secondary diagnosis is not present. We periodically revise the list of conditions, in consultation with the Centers for Disease Control (CDC), in accordance with the Act. There are currently 10 HAC categories, including conditions such as air embolism, blood incompatibility, various types of falls and trauma, and certain types of surgical site infections. The FY 2012 IPPS final rule (76 FR 51476) contains a full discussion of the current HAC-POA policy as well as final changes for FY 2012. The final policy includes the addition of several new ICD-9-CM diagnosis codes to current HAC categories, and a revision of one subcategory title from “Electric Shock” to “Other Injuries.” In addition, section

II.F.3. of the FY 2012 IPPS final rule includes updates and findings from the Research Triangle Institute, International (RTI) evaluation on CMS’ Hospital-Acquired Conditions and Present on Admission Indicator. This is an intra-agency project with funding and technical support coming from CMS, OPHS, AHRQ, and CDC. The RTI evaluation includes the impact of the Hospital-Acquired Condition-Present on Admission (HAC-POA) provisions on the changes in the incidence of selected conditions, effects on Medicare payments, impacts on coding accuracy, unintended consequences, and infection and event rates. The evaluation will also examine the implementation of the program and evaluate additional conditions for future selection. (For a complete discussion of the current HAC-POA policy, changes to the HAC-POA policy for FY 2012, and current RTI report see the FY 2012 IPPS final rule (August 18, 2011 (76 FR 51504 through 51522).)

Additionally, section 1886(d)(4)(D)(iii) of the Act requires that hospitals, effective with discharges occurring on or after October 1, 2007, submit information on Medicare claims specifying whether diagnoses were POA. Collection of POA indicator data is necessary to identify which conditions were acquired during hospitalization for the HAC payment provision as well as for broader public health uses of Medicare data. We have implemented a payment policy for the IPPS to pay the CC/MCC MS-DRGs for those HACs with POA codes indicating that the diagnosis was either present on admission or clinically undetermined if the secondary diagnosis was present on admission. We will not pay the complication/comorbidity and major complication/comorbidity (CC/MCC) MS-DRGs for those HACs coded with POA codes indicating that the secondary diagnosis was not present on admission or that it was unknown if the secondary diagnosis was present on admission (73 FR 48486 and 48487, August 19, 2008).

The HAC and POA web page at <http://www.cms.gov/HospitalAcqCond> provides further information. In addition, specific instructions for providers on how to select the correct POA indicator for each diagnosis code were included in the ICD-9-CM Official Guidelines for Coding and Reporting, available on the CDC Web site at: <http://www.cdc.gov/nchs/data/icd9/icdguide10.pdf>. Additional information regarding POA indicator reporting and original Medicare application of the POA reporting options is available on

the CMS Web site at: <http://www.cms.gov/HospitalAcqCond/>.

Looking toward the future of Medicare and Medicaid, Congress set forth in the Affordable Care Act requirements to further Medicare’s development of value-based purchasing programs (VBP), health care provider quality reporting, and expansion of the HAC program to encourage further incentives to improve quality and affordability of care and increase public transparency. Section 3008(b) of the Affordable Care Act requires the Secretary to undertake a study and report to Congress by January 1, 2012 on extending HAC-POA payment policy for IPPS hospitals to other facilities providing medical care to Medicare beneficiaries, such as hospital outpatient departments, non-IPPS hospitals, skilled nursing facilities, and others.

In addition, section 3008(a) of the Affordable Care Act requires us to implement for the IPPS, a rate-based payment policy to reduce payments to hospitals in the lowest quartile of performance on risk-adjusted quality measures HACs, effective beginning FY 2015. The amount of payment will be 99 percent of the amount of payment that would otherwise apply to such discharges. This section also requires us to make information available to the public regarding HACs of each applicable hospital on the Hospital Compare Internet website.

Finally, section 2702 of the Affordable Care Act requires the Secretary to identify current State practices that prohibit payment for HACs and incorporate the practices identified, or elements of such practices, which the Secretary determines appropriate for application to the Medicaid program in regulations. The new regulations will prohibit payments to States under section 1903 of the Act for any amounts expended for providing medical assistance for health care-acquired conditions specified in the regulations. In addition, section 2702 of the Affordable Care Act requires the Secretary to apply to State plans (or waivers) under title XIX of the Act the regulations promulgated pursuant to section 1886(d)(4)(D) of the Act relating to the HAC-POA payment policy, as appropriate for the Medicaid program. Final regulations implementing these requirements were published in the June 6, 2011 **Federal Register** (76 FR 32816). The final rule was effective July 1, 2011 but gives States the option to implement between July 1, 2011 and July 1, 2012.

It is important to us to continue to align these incentives between the fee-

for-service and MA programs and, as noted above, with the Medicaid program. Section 1856(b)(1) of the Act authorizes the Secretary to establish MA standards by regulation. In addition, section 1857(e)(1) of the Act authorizes the Secretary to impose additional terms and conditions found necessary and appropriate. Based on this general authority in the Act, we propose to require MA organizations to implement policies and procedures to reduce reimbursements to contracted hospitals for Part A inpatient hospital services for serious events that could be prevented through evidence-based guidelines, in accordance with the HAC-POA policy that is required for hospitals paid under the IPPS. Consistent with practice under the IPPS, MAOs should not reimburse hospitals the higher payment for cases when one of the selected conditions is acquired during hospitalization (that is, was not POA). Any such case would be paid as though the secondary diagnosis is not present. We note that MA organizations are already required to pay non-contract provider hospitals the amount that they would 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, available at <https://www.cms.gov/MedicareAdvtgSpecRateStats/downloads/oon-payments.pdf>.

The HAC-POA policy promotes increased quality, efficiency of care, and incentives for hospitals to eliminate medical errors and reduce Medicare expenditures for poor quality or unnecessary care. It is one of several VBP tools the agency uses; others include measuring performance, using payment incentives, publicly reporting performance results, applying national and local coverage policy decisions, and enforcing conditions of participation.

We believe that with robust input and participation of MA organizations and other stakeholders, we can achieve these goals for efficiency and quality in the MA program while implementing the policies in a way that takes into account the varying models, access, and payment features of the MA program. We understand that MA organizations may pay hospitals on a capitated basis or through other payment systems that may not be similar to that of the IPPS and also may not currently incorporate the POA indicator policy. We want to allow flexibility for MA organizations to determine the best methodology within their contract structures with hospitals for reporting these serious conditions and events, determining whether the condition was present on admission or

caused during the inpatient hospital stay, and paying hospitals appropriately. However, we also believe that plans already have some operational systems in place to facilitate implementation of the requirement. For example, MA organizations must already pay noncontract providers the amount that they would receive under Original Medicare, which includes reducing the payment for HACs that were not present on admission. Also, beginning January 3, 2012, MA organizations 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) (Form Number: CMS-10340 (OMB#: 0938-New). We would collect the encounter data electronically from Medicare Advantage Organizations via the Health Insurance Portability and Accountability Act (HIPAA) compliant standard Health Care Claims transactions for professional data and institutional data. The HIPAA 5010 claim form used for this transaction is the same claim form that hospital providers use to submit claims under Original Medicare, including specific fields for POA information. In addition, the current MA plan rating system includes measures related to some of these serious events. Therefore, we believe that these distinct policies can be aligned to produce all of the intended results, including net savings to MA organizations and Medicare by avoiding unnecessary costs in the delivery of care.

We propose 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 solicit comments and recommendations on what other issues to consider in finalizing our proposal to apply the current fee-for-service HAC-POA policy to MA plans.

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

Medicare beneficiaries not enrolled in an MA plan may obtain their Medicare-covered durable medical equipment (DME) items and supplies from any Medicare-certified DME supplier. If a DME supplier does not stock a particular manufacturer's product or brand of DME, the beneficiary may obtain that product or brand from

another supplier or request his or her supplier of choice order the particular product or brand he or she uses or which his or her physician has ordered. While sections 1852(a)(1)(A) and (B) of the Act require MA plans to provide Parts A and B-covered items and services (with the exception of hospice care), including DME items and supplies, network-based MA plans may maintain networks of appropriate providers sufficient to provide adequate access to covered services for their members (see § 422.112(a)(1) and § 422.114(a)). In other words, network-based MA plans may limit access to Medicare-covered items and services via networks, as long as those networks provide adequate enrollee access to services consistent with standards established by CMS.

Medicare Advantage organizations and other stakeholders have asked for our guidance with respect to limitations DME coverage that result from MA organizations limiting enrollees to specified DME providers, or to specified DME manufacturers. Specifically, some MA organizations have asked us whether they could offer lower cost-sharing for "preferred" DME products or brands versus "non-preferred" DME products or brands, as well as whether they could limit coverage of certain DME items and supplies to specific manufacturers' products or brands. In guidance 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 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 specific manufacturers' DME products or brands. While we do not collect information on this type of coverage limitation in our plan benefit package (PBP) software, we are aware anecdotally that some MA organizations employ this practice to some extent. For example, one MA organization limits coverage of diabetic test strips and monitors to those manufactured by certain entities.

Although some organizations thus are already limiting DME to specific brands, we believe that our proposal would help ensure that MA organizations maximize

program efficiencies by driving enrollee utilization to specific DME products for which MA organizations may have negotiated bulk discounts. In addition, given that MA organizations are currently employing DME product or brand coverage limitations, we believe it is important to establish a regulatory framework for ensuring appropriate and adequate MA enrollee access to DME items and supplies.

Therefore, and under our authority in section 1856(b)(1) of the Act to establish MA standards by regulation and in section 1857(e)(1) of the Act to impose additional terms and conditions found necessary and appropriate, we propose to add a new paragraph (l) to § 422.100 that clarifies that MA organizations may limit coverage to specific manufacturers or brands, and imposes conditions on doing so. Specifically, in order to ensure that MA enrollees have adequate access to their DME benefits, proposed § 422.100(l) would establish requirements with respect to access and medical necessity, require transition periods, address mid-year changes to preferred DME items and supplies, appeals, and require disclosure of DME coverage limitations to enrollees.

We recognize that this is a complex issue. Therefore, we solicit comments on all aspects of these proposed changes and whether additional or strengthened beneficiary protections would be warranted under this policy. If we finalize this proposal, we intend to monitor and assess plans' compliance with the new requirements—including through review of beneficiary complaints and grievances, and appeals data—to ensure MA enrollees have appropriate and adequate access to their Part B-covered DME items and supplies.

a. Access to Preferred DME Items and Supplies

We propose requiring that MA organizations wishing to limit coverage within a specific category of DME to specific manufacturers' products or brands take necessary steps to ensure that enrollees have access to all preferred manufacturer products through their contracts with network DME suppliers. We recognize that not all DME suppliers in a network will always stock all preferred products or brands of DME items and supplies; however, we would expect contracted suppliers to make arrangements to special order products or brands of any preferred DME item or supply, as well as any non-preferred DME item or supply that is determined to be medically necessary. We would reflect this change in proposed § 422.100(l)(2)(i).

b. Medical Necessity Requirements for DME Items and Supplies

In accordance with § 422.112(a)(6)(ii), MA organizations must have established policies and procedures that allow for individual medical necessity organization determinations if there is a question about whether a service or item 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). Within Subpart M, if the MA organization's determination is contested, reconsideration by the organization, and an independent review entity of the determination are possible under § 422.578 and § 422.592, with administrative law judge and Medicare Appeal Council hearings/reviews of unfavorable reconsiderations possible under § 422.600, and § 422.608. Therefore, we propose requiring MA organizations—to the extent that they elect to limit coverage of DME items and supplies to specific manufacturers' products or brands—to provide coverage of any medically necessary DME item and supply, including DME items and supplies made by non-preferred manufacturers. We would reflect this change in proposed § 422.100(l)(2)(ii).

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 transition 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 transition period is to transition the new enrollee to a therapeutically substitutable formulary drug or, alternatively, to obtain a formulary exception whereby the 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 propose requiring MA organizations to continue to ensure access to non-preferred brands of DME supplies—such as ostomy bags and 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 non-

preferred DME items, such as wheelchairs, feeding pumps, and hospital beds. That is, an MA organization would be required to service (including providing a loaner) DME items owned or rented by an enrollee needing repairs during the 90-day transition period. If, after the transition period ends such items needed repair, the plan could choose to pay for the repairs or instead provide its preferred brand of the item. We propose to add § 422.100(l)(2)(iii)(A) and § 422.100(l)(2)(iii)(B) to reflect this proposed requirement.

We solicit comments on the features of this transition process requirement, including whether such a transition period—modeled generally on that provided under the Part D program for non-formulary Part D drugs—is appropriate for DME items and supplies and whether there are additional transition requirements we should consider.

d. Midyear Changes to Preferred DME Items and Supplies

We propose prohibiting MA organizations from making “negative changes,” that is, eliminating preferred coverage of a Medicare-covered item of DME, midyear. Plans may add to their preferred DME products list—for example, to add new manufacturers' products to their coverage lists, to provide substitute DME items and supplies for products that are no longer available, or to reflect national and local coverage determinations for new DME items and supplies. We believe this proposed policy—allowing positive changes and prohibiting negative changes—strikes 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. We propose to reflect this change in proposed § 422.100(l)(2)(iv).

e. Appeals

While we considered establishing an exceptions process for DME under this proposed policy similar to the one established for non-formulary Part D drugs under § 423.578(b), we do not believe that adding what is essentially an additional step to the appeals process under Subpart M of Part 422 is necessary for MA organization determinations concerning coverage of specific DME brands. The Part D exceptions process was conceived as an initial means of obtaining coverage of non-formulary Part D drugs for medical necessity reasons. Once that process is exhausted, the enrollee may appeal the

decision under the rules of Subpart M of Part 423.

There is evidence that beneficiary appeals of DME coverage decisions based on products or brands are not a significant problem in the MA program. For example, since the inception of the IRE appeals process in 2006, there have been 12,500 appeals related to wheelchairs. Of these appeals, only 7 have concerned brand-specific issues. Because we have no evidence of enrollee grievances or appeals of brand-specific DME coverage issues, we believe that the current organization determination and appeals process in subpart M of part 422 is sufficient to ensure that MA enrollees have access to specific brands of DME items when medically necessary. We propose to clarify at § 422.100(l)(2)(v) that plan non-coverage of a particular manufacturer's product or brand of a DME constitutes an organization determination under § 422.566. We solicit comments on whether the organization determination and appeals process currently required in subpart M of part 422 affords MA plan enrollees with sufficient protections for ensuring appropriate and adequate access to Medicare-covered DME in MA plans that choose to limit coverage, within a specified category of DME, to specific manufacturers' products or brands. We would appreciate comments with respect to any additional protections that we should consider if we finalize this 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 preferred products or brands, 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 website, and in writing upon request—disclosures about these DME coverage restrictions and their rights to the Part C appeals process for requests to obtain medically necessary, non-preferred DME products or brands.

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

Regulations setting forth 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. CMS 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 further heard that the 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. Lastly, 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 they may set compensation rates at current-day FMV rates and are not tied to 2009 compensation amounts. Therefore, we are proposing 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 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.

6. 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)

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 are proposing that Medicare Part D sponsors be required to provide their enrollees access to a daily prorated cost-sharing rate for prescriptions dispensed by a network pharmacy for less than a 30 days supply of certain covered Part D drugs that are for an initial fill of a new medication, are intended to allow the enrollee to synchronize refill dates of multiple drugs, or 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 effective January 1, 2013). If finalized as proposed, these provisions would be codified at § 423.104 and § 423.153.

Current prescribing patterns and pharmacy benefit management (PBM) payment practices result in most prescriptions for chronic medications being written by providers, and dispensed by retail pharmacies, in 30-or-more day quantities. When the full amount dispensed is not utilized by the enrollee due to adverse medication reaction or interaction, or due to failure of enrollee therapeutic adherence because of cost, inconvenience, death, or other reason for discontinuation, it comes at an unnecessary and wasteful cost to the enrollee, 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 of discontinued chronic medications could be avoided. In addition, the avoidance of unused drugs would contribute to diminishing the environmental issues⁷ caused by disposal of unused medications, and opportunities for criminal activities and substance abuse⁸ caused by diversion of unused

⁷ See <http://www.epa.gov/ppcp> for information about Pharmaceuticals and Personal Care Products as Pollutants (PPCPs) on the website of the U.S. Environmental Protection Agency.

⁸ 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.

medications, all of which are growing concerns in the United States.

Currently, Part D enrollees' cost-sharing is the same whether they receive a 7-, 14-, or 30-day supply of a first fill of a new medication. A daily cost-sharing rate requirement imposed on Part D sponsors would encourage enrollees and their prescribers to limit day's supplies when appropriate by also 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 seeking a trial fill of a prescription for a chronic medication, for example, would pay only a prorated portion of the established amount under his or her Part D benefit plan that corresponds to the actual amount of days supply that was prescribed and is dispensed, whether it be a 7- or 14-day supply, or some other quantity less than 30 days, which would be at the discretion of the prescriber. Thus, although our proposed 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 an enrollee should receive a trial fill. Rather, the decision to try a new medication through a trial fill would be made by the enrollee 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 incentivized to inquire of his or her prescriber whether a trial fill would be appropriate when first prescribed a medication. We further believe enrollees would be most likely to inquire about a trial fill when faced with higher cost sharing for a new 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 an initial fill of a drug that has significant side effects and/or is frequently poorly tolerated. In such a case, the prescriber could write either one prescription for the trial fill for a period at the prescriber's discretion, or two prescriptions (for example, one for the trial fill and a second prescription for a 30 or 90 day supply—the latter prescription would be utilized if the enrollee and the prescriber agreed the drug therapy should be continued after the trial period). If the medication were discontinued after use of a trial 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.

Because the prescriptions could be written during one office visit, or could be refilled by the prescriber directly with the enrollee's pharmacy after a medication trial period, additional visits to the prescriber would not necessarily be required and would not need to cause a burden to the enrollee. We assume the two prescriptions option would be most convenient for the enrollee and the prescriber (when appropriate), but seek specific comment on this assumption. If an enrollee 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 the medication being prescribed should or could be dispensed in a trial fill, we would not expect our proposal to have any adverse effects on enrollees' health.

Indeed, while we envision, as described above, enrollees primarily requesting less than a full month's supply when prescribed a drug for the first time that is known to have significant side effects and to be frequently poorly tolerated, we are not limiting the requirement for Part D sponsors to establish and apply a daily cost-sharing rate to such medications. Rather, we have identified an additional benefit which is the ability to allow for synchronization of prescriptions. More specifically, if an enrollee already takes a prescription medication that is due for a refill in 10 days, the prescriber could write an initial prescription for a new medication for a 10-day supply, so that the enrollee could refill both prescriptions on an ongoing basis in one trip to the pharmacy (assuming the new medication is continued) and perhaps also achieve better medication compliance. Similarly, enrollees who currently take multiple medications that refill on different dates could request their prescribers to write prescriptions for less than 30 days (each one likely for a different days supply), but with 30-day refills, for all but one of those medications that is due for a refill, so that the enrollee could refill all prescriptions in one trip to the pharmacy, and could refill all the prescriptions for 30 days or more in one trip to the pharmacy thereafter on an ongoing basis.

The ability to synchronize medications should assist enrollees in adhering to prescription treatment regimens that involve multiple medications, and we note that at least one study supports this belief, and

suggests intervention targeted at individuals who do not request refills of all medications. In addition, we believe the ability to synchronize medications will be convenient for both those enrollees who take advantage of it and their prescribers by enabling fewer trips to the pharmacy and fewer prescription requests of prescribers from enrollees through the ability to consolidate pharmacy trips and prescriber office visits and phone calls.

We do not expect long-term care (LTC) enrollees to request trial fills to synchronize medications, as this is not our understanding of the LTC environment with respect to prescribing, and our April 2011 final rule (76 FR 21432) requires 14 day or less dispensing in LTC facilities effective January 1, 2013. However, as noted in that rule, 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." The current proposed requirement on Part D sponsors to establish and apply a daily cost-sharing rate would supersede this quoted guidance in the preamble of the April 2011 final rule. In other words, Part D sponsors would be required to establish and apply a prorated, uniform cost-sharing billing methodology for all their enrollees, including those in LTC facilities and those with LIS cost-sharing subsidies.

We recognize that establishing and applying a daily cost-sharing rate to the relatively small copayments for LIS enrollees would cause such copayments to be nominal. We seek specific comments as to alternatives to incentivize LIS enrollees to take advantage of trials fills and synchronize their medications when appropriate other than through the establishment and application of a daily cost-sharing rate requirement.

Daily cost-sharing rates also may permit pharmacies, as opposed to prescribers, to facilitate synchronization

of an enrollee's medications upon his or her request, and we seek specific comment as to this possibility, as well as to any issues we may need to address to facilitate this possibility. For instance, in order for sponsors to be able to monitor the prevalence and appropriateness of the dispensing of prescriptions in shorter than 30 days supply to ensure that a pharmacy does not dispense a 30-day prescription in stages in order to increase dispensing fees, we urge the industry to develop coding to be used by network pharmacies to communicate to sponsors whether a less than 30 day 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 believe that realized savings from the daily cost-sharing rate requirement may be partly offset by additional dispensing fees, administrative and programming costs, and additional initial fills of more expensive drugs. We assume additional dispensing fees would result when a trial fill of a medication is dispensed and the enrollee returns to the pharmacy for the remainder of the month's supply (or more) if the medication were successful, or when an enrollee chooses to synchronize medications. Thus, over a year, there would be up to 13 dispensing events for a medication continued after a trial fill as opposed to up to 12. Part D sponsors may also incur some costs to program their systems to establish and apply a daily cost-sharing rate to prescriptions dispensed to enrollees with less than a 30-day supply, as well as administrative costs to administer the trial fill requirement we propose here. Finally, we expect some additional costs due to more initial fills of brand drugs that enrollees previously declined to try due to the cost of a full month's supply when the brand drugs are known for significant side effects and/or to be frequently poorly tolerated.

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 dispensed, but unused, medications. We have learned through representatives of the program that MaineCare has achieved overall savings for 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 has been very good acceptance of the program and very little confusion upon implementation. While we acknowledge the savings benefits of the mandatory 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 a better approach in light of the voluntary nature of the Medicare Part D program.

A previous review of 2009 PDE data by CMS suggested that just under 32 percent of approximately 78.6 million first fills for maintenance medications are not refilled by Medicare Part D enrollees. Maintenance medications are used for diseases when the duration of therapy can reasonably be expected to exceed one year, and we assume 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, this review did not distinguish between community and institutional settings. Thus, to estimate the costs of discontinued medications in community settings only, since the daily cost-sharing rate requirement proposed here does not further change the dispensing requirements in the long-term care setting effective January 1, 2013, 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. Consequently, the adjusted total estimated cost of 2009 community-based discontinued first fills of chronic medications was estimated at roughly \$1.4 billion.

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 must make assumptions about how many first fills will be dispensed in quantities of less than a 30-day supply, and what the average quantity of such first fills will be. It should be pointed out that these assumptions are highly uncertain, because it is very difficult to predict enrollees' behavioral response. Having noted this caveat, we assume 20 percent of first fills in 2013 will be for a supply of less than 30 days, trending to 50

percent by 2018, and that the average of such fills will be for a 15-day supply. Assuming 32 percent of these first fills are discontinued, we estimate the potential savings to the Part D program to be \$180 million in 2013 alone, and over \$2.5 billion by 2018.

We recognize that certain medications are universally accepted in the health care community as not suitable to be dispensed in amounts less than a 30-day supply (for example, lotions and other drugs not in solid form). Therefore, we propose to further limit the requirement that sponsors establish and apply a daily cost-sharing rate to drugs similar to those to which the Medicare Part D long-term care dispensing requirements apply. That is, the daily cost-sharing rate requirement would apply 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 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 also understand 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 seek specific comments as to this assumption.

In light of the foregoing, we propose to define "daily cost-sharing rate" in § 423.100. "Daily cost-sharing rate" would mean, as applicable, the established monthly—

- Copayment under the enrollee's Part D plan divided by 30 or 31 and rounded to the nearest lower dollar amount 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 the enrollee would have paid if a month's supply had been dispensed; or
- Coinsurance rate under the enrollee's Part D plan applied to the ingredient cost of the prescription for a month's supply divided by 30 or 31. We solicit comment on whether we should establish specific rounding rules so that sponsors are consistently calculating

daily cost-sharing rates with respect to enrollee and plan liabilities.

In addition, we would 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 also propose to revise § 423.153(b) by adding a new paragraph (4). Paragraph (4)(i) would require a drug utilization management program to establish and apply a daily cost-sharing rate 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, multiplied by the days supply actually dispensed, plus any

dispensing fee in the case of coinsurance. Paragraph (b)(4)(i)(A) would limit the requirement to drugs that are in the form of solid oral doses. Paragraph (b)(4)(i)(B) would further limit the requirement to a prescription that is for an initial fill of a new medication, is intended to allow the enrollee to synchronize refill dates of multiple drugs, or is 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 effective January 1, 2013). Paragraph (b)(4)(ii) 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 manual instruction to assist MA organizations and Part D sponsors in ensuring the proper and efficient administration of the Part C and D programs. We propose to 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 5.

TABLE 5—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.	N/A	N/A
II.E.6	Timeline for Resubmitting Previously Denied MA Applications.	N/A	N/A	Subpart N	§ 422.641, § 422.660.	N/A	N/A
II.E.7	Clarification of Contract Requirements for First Tier and Downstream Entities.	N/A	N/A	Subpart K	§ 422.501	Subpart K	§ 423.505

TABLE 5—PROVISIONS TO CLARIFY PROGRAM REQUIREMENTS—Continued

Preamble section	Provision	Part 417		Part 422		Part 423	
		Subpart	Section	Subpart	Section	Subpart	Section
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 April 15, 2011 final rule (76 FR 21442), we amended § 423.38(d) to codify changes to the Annual Coordinated Election Period (AEP) mandated by the Affordable Care Act. Specifically, section 3204 of the Affordable Care Act changed the AEP to October 15 through December 7 for 2011 and future years. In making this change, we inadvertently neglected to revise a reference to the former AEP timeframe noted in § 423.56 (Procedures to determine and document creditable status of prescription drug coverage). This section requires the disclosure of creditable coverage to beneficiaries prior to the start of the AEP and specifically references the old date (that is, November 15). To make this section consistent with the statute, we are proposing to amend § 423.56(f)(3) to remove the outdated AEP reference.

In the April 2011 final rule (76 FR 21525), we also amended our regulations at § 417.430 to permit CMS approval of alternative enrollment mechanisms for cost plans in addition to paper forms, such as electronic enrollment. In making this revision, we unintentionally overlooked other sections in this subpart that referenced enrollment mechanisms for cost plans. Specifically, § 417.422 (Eligibility to enroll in an HMO or CMP) and § 417.432 (Conversion of enrollment) specifically reference the requirement

for a beneficiary signature on an enrollment form. Because it was our intent to broaden enrollment mechanisms for cost plans to go beyond paper enrollment forms, we believe we should have revised the sections above to remove requirements for signatures. Therefore, we are proposing to revise § 417.422(d) and § 417.432(d) to remove references to signatures and state that individuals must complete an application form or “another CMS-approved election mechanism” in order to meet enrollment requirements.

In addition, we are proposing to correct an outdated cross-reference at § 422.60(c) (Election process). This paragraph currently references marketing rules formerly located at § 422.80. These requirements were moved to § 422.2262 (Review and distribution of marketing materials) in previous rulemaking.

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, as well as waivers requirements to review such materials. As we noted in our April 2010 final rule (75 FR 19785) extending MA marketing requirements to cost contracts, 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. 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 propose to extend the disclosure requirements in § 422.111 and § 423.128 to cost contract plans by adding a new § 417.427.

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 be differential for 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 propose 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 propose clarifying the application of the differential of the single deductible for in-network services, and modifying 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 propose 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 have taken 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 propose 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 late in this section.

As discussed previously, we propose 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 propose 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 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 whether or not 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 RPPO could also exempt application of the deductible to particular services—for example, all home health services (in- and out-of-network).

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). We are therefore proposing to eliminate references to the option in both LPPO and RPPO plans to exclude preventive services from the single deductible at § 422.101(d)(1), and are proposing adding a new paragraph § 422.101(d)(1)(iv) to explicitly require LPPO and RPPO plans to exclude certain Medicare-covered preventive services (as defined in § 410.152(l)) from the single, combined deductible for each plan.

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 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 propose 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 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 propose 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.

5. Application Requirements for Special Needs Plans (§ 422.500, § 422.501, § 422.502, § 422.641, and § 422.660)

Several of the regulations implementing section 1859(f) of the Act, including § 422.101(f), § 422.107, and § 422.152(g), establish specific requirements for Special Needs Plans (SNPs). Specifically, § 422.101(f) requires that MAOs offering a SNP implement an evidence-based model of care to be evaluated by NCQA as part of the SNP approval requirement; § 422.107 requires that Dual Eligible SNPs (D-SNPs) have a contract with the State Medicaid Agencies in the States in which they operate; and § 422.152(g) requires that SNPs conduct a quality improvement program. These SNP-specific requirements have been incorporated into the MA application for MAOs that wish to offer a SNP so

that these MAOs can demonstrate that they meet CMS' SNP specific requirements and are capable of serving the vulnerable special needs individuals who enroll in SNPs.

Current regulations on application procedures for MAOs, found at: § 422.500, § 422.501, and § 422.502, are specific only to an applicant that is seeking to contract as a MAO offering an MA plan, and do not specify the rights and responsibilities of an applicant that seeks to offer a SNP. Additionally, regulations on Medicare Contract Determinations and Appeals, found at § 422.641 and § 422.644, also pertain only to applicants that have been determined unqualified to enter into an MA contract, and do not provide for appeal rights to applicants who have been determined unqualified to offer a SNP. Given that every applicant that seeks to offer a SNP engages in an intensive application process to demonstrate that it meets the requirements unique to SNPs in the same manner, according to the same processes and on the same timeline as applicants seeking to contract as MAOs, we believe it is important to provide SNP applicants with the same rights and responsibilities as applicants applying to contract as MAOs. We further believe it important to clarify that each applicant that has been determined unqualified to offer a SNP has the same right to an administrative review process to each applicant that has been determined unqualified to enter into an MA contract.

Therefore, in accordance with section 1859(f) of the Act, we propose to broaden our regulations on Application Requirements and Evaluation and Determination Procedures to also apply to SNP applicants. Specifically, we propose 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 propose to add paragraph (iii) to § 422.501(c)(1) to specify the documentation SNP applicants must provide to complete an application. Furthermore, we propose 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 propose 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 propose 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 the proposed changes would 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.

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 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. Presently, we operate on an annual application cycle whereby the established submission date for new applications (February of each year) occurs well after the specified date by which we deny the previous contract year's applications (May of the previous year). A literal reading of § 422.501(e) means that an application that is denied in May of 1 year could be resubmitted as early as September (4 months later), and well before the release of the application for the following contract year which typically occurs in December or January, in advance of the February submission deadline. In order to bring § 422.501 up to date, we propose 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 has been denied in the current contract year's application cycle.

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 MAOs 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 propose 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 propose 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.”

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 propose 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 propose, 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 would like to underscore 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 propose 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 previously discussed, 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 proposed rule, 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 are taking 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.

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, 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 to perform at a minimum, an annual comprehensive medication review that may 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.

In the November 2010 proposed rule, we proposed to revise the regulations at § 423.153 to require plan sponsors to offer an annual comprehensive medical review (CMR) for targeted beneficiaries, which must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider. In response to the proposal, a commenter indicated that LTC residents with cognitive impairments may not have the ability to interact appropriately with providers or pharmacists during the CMR when using telehealth technologies. In the April 2011 final rule, we responded by agreeing that the use of telehealth technologies for conducting CMRs may not be appropriate for all beneficiaries. We also recognized and agreed that beneficiaries residing in LTC facilities who have cognitive impairments may be unable to participate in an interactive CMR. The current regulations at § 423.153(d)(1)(vii)(B) reflect this awareness by exempting sponsors from offering interactive CMRs to targeted beneficiaries in LTC settings; however, the Act, as amended by section 10328 of the Affordable Care Act, does not

provide a basis for distinguishing the offering of MTM services based on settings. Since the Affordable Care Act provision for MTM programs was not effective until 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.

We generally agree with the commenter that it is likely that many patients in LTC settings may not be lucid enough to participate in the CMRs, nor might they be able to comprehend the resulting medication action plan that is provided as a result. However, we believe that consistent with section 1860D–4(c)(2)(A)(i) all targeted beneficiaries in LTC settings must be offered the opportunity to participate in the annual CMR, since not all residents of LTC settings are cognitively impaired. We also believe that beneficiaries will still benefit from having a non-interactive CMR performed by a pharmacist or other qualified provider. Accordingly, we propose 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 the medication review without the beneficiary. This provision would give the pharmacist or provider the ability to perform the medication review without the encumbrance of attempting to communicate with a patient who cannot make decisions regarding their medical needs. In such cases, we recommend that the pharmacist, or qualified provider, reach out to the beneficiary's prescriber, caregiver, or other authorized individual such as the residents' health care proxy or legal guardian, to take part in the beneficiary's CMR.

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). 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 the manner 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 propose to revise § 423.458 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.

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 prescriber identifiers 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, 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), we stated that we will continue in 2012 to permit Medicare Part D sponsors to report on PDE records any one of the above four identifiers. However, sponsors were instructed to ensure these identifiers are active and valid, but not to reject a pharmacy claim solely on the basis of an invalid prescriber identifier in order to not impede Medicare beneficiary access to needed medications. Thus, if an active and valid prescriber ID is not included on the Part D claim for CY 2012, either the sponsor, or the pharmacy if in accordance with the contractual terms of the network pharmacy agreement, must follow up retrospectively to acquire a valid ID before the PDE is submitted to CMS. The only exception to this guidance is that a foreign prescriber identifier cannot be validated, and therefore sponsors are directed to use the license number assigned by the foreign jurisdiction and report it on the PDE without validation (when prescriptions written by such prescribers are valid under applicable State law).

We also signaled in the 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, which would include 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, as we explain more fully in this section of the proposed rule.

As we noted in the CY 2012 Call Letter, the consistent use of a single validated identifier would enable us to

provide better oversight over possible fraudulent activities. As a measurable indicator, we know that approximately 90 percent of Medicare Part D claims as reported in prescription drugs events (PDEs) currently submitted to CMS contain valid individual prescriber NPIs—a single identifier—even though CMS permits alternate prescriber IDs at this time. Thus, while the vast majority of Medicare Part D claims contain individual NPIs, 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.

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 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 would also introduce potential errors in correctly matching prescribers among databases.

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 (69 FR 3445, January 23, 2004). 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 discuss in greater detail later in this section of the proposed rule. 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.

In light of the foregoing, we propose 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.

In this regard, we are also proposing to codify our current guidance 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, in order to not impede Medicare beneficiary access to needed medications. In other words, Part D sponsors may not reject pharmacy claims at point of sale without prompt follow-up to ensure that the claim has been resubmitted with a corrected and valid individual prescriber NPI, or new information has been otherwise received to correct the sponsor's information. Once a prescriber's NPI is obtained and used in a Part D claim, it will be in the Part D sponsor's and/or network pharmacy's patient information database for ongoing use, so any efforts needed to obtain corrected or missing NPIs will decrease over time.

Our proposal means 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, the prescription is not 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 remind Part D sponsors that the requirements proposed here are on sponsors, whose responsibility it would be to be able to submit PDEs to CMS with individual prescriber NPIs. Therefore, we would expect that pharmacies will be permitted to correct any invalid data before payment for a claim is reversed whether or not a negotiated contract delegates any sponsor duties in this regard to the pharmacy. Additionally, we would expect that any requirement by a plan sponsor or its contracted PBM for 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.

With respect to requests for reimbursement submitted directly by Medicare beneficiaries, sponsors were instructed in the CY 2012 Call Letter that payment to a beneficiary could not be made dependent upon the sponsor's acquisition of the prescriber ID itself. We are proposing to codify this guidance, so that requests for reimbursement from Medicare beneficiaries are handled in the same manner by Part D sponsors as claims from pharmacies. Thus, if the sponsor is unable to retrospectively acquire an active and valid NPI in connection with a request for reimbursement submitted by a beneficiary, the sponsor may not seek recovery of the payment from the beneficiary solely on that basis, unless there is an indication of fraud.

We have 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 this proposal is thus responsive to those observations. In addition, some pharmacy representatives have offered that certain States require or accept other prescriber identifiers, which impede 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. For instance, it is our understanding that the Drug Enforcement Administration (DEA) has discouraged the use of DEA numbers as prescriber identifiers, and not every prescriber has one anyway. Therefore, we seek 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 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 are 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 3-page application form that primarily seeks only identifying and location information and is free of charge. While we know that prescribers will also be concerned about beneficiary access to medications, we believe 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 understand 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 believe 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 unlike our proposal here with respect to non-foreign prescribers, we are not proposing to require drugs dispensed pursuant to prescriptions of foreign prescribers to be covered by Part D sponsors when the foreign prescribers decline to obtain an individual NPI if they do not already have one. 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 are proposing an exception to our proposal that the sponsor must pay a 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, a Part D sponsor could reject a claim involving a foreign prescriber who does not have an NPI at point-of-sale.

In fact, in light of our lack of jurisdiction over foreign prescribers and our motivation to conduct better oversight over possible fraudulent activities, we are considering whether this proposal with respect to foreign prescribers is 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. In other words, while certain prescriptions of foreign prescribers may be valid under some State laws, medications dispensed pursuant to prescriptions written by foreign prescribers would not be payable under the Medicare Part D program. Such a policy would also be consistent with the direction we have taken with respect to medical directors, that is, that Part D sponsors must employ a physician with a current and unrestricted license to practice medicine in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia. We note that we are not making such a proposal at this time, but solicit specific comments on foreign prescribers and the Part D program.

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 proposing to add a new paragraph (5)(A) which would require 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)(B) would codify current guidance and require that a Part D plan sponsor not reject a claim from a network pharmacy solely on the basis that it does not contain an active and/or valid NPI unless the issue can be resolved at point-of-sale, there is an indication of fraud, or the claim involves a prescription written by a foreign prescriber (where permitted by State law). New paragraph (5)(C) would prohibit a Part D sponsor, with respect to requests for reimbursement submitted directly by Medicare beneficiaries, from making payment to the beneficiary dependent upon the sponsor's acquisition of the prescriber NPI and would further prohibit a Part D sponsor from seeking recovery of the payment from the beneficiary solely 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.

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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

The following sections of this document contain paperwork burden but not all of them are subject to the ICRs under 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–14A (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 propose 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.

Under this proposal, Part D plan sponsors would 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 would 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).

C. ICRs Regarding Pharmacy Benefit Manager's Transparency Requirements (§ 423.514)

Consistent with the statutory requirements, our proposal adds an additional data element to the DIR data reporting: 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. This data element is already available to plans as they are aware of the amounts they pay to their contracted PBMs and they currently report to CMS the amounts paid to retail and mail order pharmacies on the PDE records. We do not believe that our proposal imposes any additional substantive burden on Part D sponsors and PBMs, and, therefore, have not incorporated a burden increase.

We are soliciting comment on whether any of the following data elements can be collected using existing data sources, thereby alleviating additional reporting burden on Part D sponsors and PBMs:

- Number of retail prescriptions.
- Number of mail order prescriptions.
- Number of prescriptions dispensed by independent pharmacies.
- Number of prescriptions dispensed by chain pharmacies.
- Number of prescriptions dispensed by supermarket pharmacies.
- Number of prescriptions dispensed by state-licensed mass merchandisers to the general public.

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 proposal would not impose any new information collection requirements.

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 propose 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)

Since we are proposing to amend 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 requirements, there is no new information collection burden on organizations.

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 Fully Integrated Dual Eligible Special Needs Plans (FIDE SNPs) (§ 422.102)

Under proposed § 422.102(e) we would allow certain FIDE SNPs participating in the Medicare-Medicaid Integration Initiative, 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. While this proposed requirement is subject to the PRA, the burden associated with it is currently approved under OCN 0938-0763 with a March 31, 2012 expiration date.

L. ICRs Regarding Clarifying Payment to Providers in Instances of Hospital-Acquired Conditions (HACs) (§ 422.504)

We propose to require MAOs 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, MAOs are already required to pay non-contract provider hospitals the amount that they would receive for services under original Medicare, including any applicable reductions for HACs. Also, beginning January 3, 2012, MA plans would 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 already in use by hospital providers for FFS claims and contains fields for POA indicator reporting. While this proposed requirement is subject to the PRA, the diagnosis, POA indicator information, and other claims information are already collected as part of the encounter data collection process, and this burden is currently approved under OCN 0938-1054.

Additionally, we believe that hospitals will already be familiar with POA reporting and would 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 would be incurred by plans in the normal course of their business activities.

M. ICRs Regarding Clarifying Coverage of Durable Medical Equipment (§ 422.101(a) and § 422.112(a))

Under § 422.100(l) we propose 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 is currently approved under OCN 0938-0753.

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

At § 422.2274 and § 423.2274, we are proposing 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 are proposing 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 currently approved under OMB control number (OCN) 0938-0753.

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 (§ 423.153)

In accordance with section 1860D-4(c) of the Act, we propose 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 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 proposal, the enrollee and his or her prescriber generally would decide if a medication supply of less than 30 days would be appropriate, and if so, the cost-sharing for the medication would be prorated by the Part D sponsor based on the days supply dispensed.

The collection of information burden on Part D sponsors imposed by this proposed regulation is negligible. Any burden associated with this proposal on sponsors related to the required data entry in the PBP software would 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) 2013 (OCN 0938-0763). Since obtaining a supply of a medication for less than 30 days is optional for the enrollee and his or her prescriber, there is no collection of information burden imposed by these proposed regulations on either Part Medicare D enrollees or their prescribers.

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 proposing technical changes that correct cross-references that should have been updated in previous rulemaking. These proposals 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, this proposal does not impose any new information collection requirements.

Q. ICRs Regarding Applying MA and Part D Disclosure Requirements to Cost Contract Plans (§ 417.427)

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. 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 websites.

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 6. 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 a 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.

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 propose 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 propose 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 MAO 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 MAO 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.

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 are proposing 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 x 4 SNP application denials = 32 hours). The estimated annual cost to an MA organization that has been denied to offer a SNP associated with this provision (assuming an attorney billing \$250 per hour) is \$8,000 (32 hours x \$250 = \$8,000) as detailed in Table 6. We are revising the PRA package currently approved under OCN 0938–0935, with a January 31, 2012 expiration date, to account for this burden.

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 MAOs 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 MAOs 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 in the PRA section.

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 MAOs 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 MAOs, 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)

Our current regulation requires that the comprehensive medication review 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. The proposed change to § 423.153 permits the sponsor to allow the pharmacist or other qualified provider to perform the medication review

without the beneficiary in cases when the beneficiary is in an LTC facility and cannot accept the sponsor’s offer of a comprehensive medication review.

The burden associated with the comprehensive medication reviews was reflected in the approved 0938–0964 which is due to expire September 30, 2012. We believe this minor revision to § 423.153(d)(1)(vii)(B) has no effect on that burden estimate.

Y. ICRs Regarding Coordination of Part D Plans with Other Prescription Drug Coverage (§ 423.458)

Since we are proposing 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 proposed 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)

Currently, Part D sponsors report any one of four prescriber identifiers on PDE records. However, the inconsistent use of identifiers that have not been validated has hindered efforts to combat fraud and abuse. Therefore, we proposed to require that effective January 1, 2013, Part D sponsors must include valid, individual prescriber NPIs as identifiers in PDEs submitted to CMS. Since Part D sponsors are already required to include a prescriber identifier on Part D PDEs submitted to CMS, there is no new collection of information burden imposed by this proposed regulation. Furthermore, this proposed regulation 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.

TABLE 6—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
§ 422.500	0938–0935	4	4	8	32	250.00	8,000	N/A	8,000
Total	24	24	272	N/A	18,613

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.

Additional Information Collection Requirements

This proposed rule imposes collection of information requirements as outlined in the regulation text and specified above. However, this proposed rule also makes reference to associated information collection requirements that are not discussed in the regulation text contained in this document. The following is a discussion of these information collection requirements.

Independence of LTC Consultant Pharmacists

As discussed in Section II.B.5, we are considering changes which would require each LTC facility to employ or obtain the services of a licensed pharmacist to provide consultation on all aspects of pharmacy services in a facility. These changes would further require an LTC facility to employ or directly or indirectly contract with a licensed pharmacist who was independent of the pharmacy located in or under contract with the facility.

The changes under consideration would require an independent licensed pharmacist to review the drug regimen of each resident at least once a month and define independent 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.

LTC facilities commonly contract with an LTC pharmacy for consultant pharmacist services. Because the changes under consideration would specifically require LTC facilities to employ or directly or indirectly contract with licensed pharmacists who are independent of the pharmacy located in or under contract with the facility, any other pharmacy-related organization, or pharmaceutical manufacturer or distributor, each facility would need to engage an independent consultant pharmacist. The annual burden associated with this requirement would relate to developing and executing contracts with independent consultant pharmacists. Although all 15,713 LTC facilities would need to provide the services of an independent consultant pharmacist, factors, such as the existence of nursing home chains and group purchasing organizations (GPOs), would affect the actual number of entities that would be engaged in the process of employing or contracting the LTC consultant pharmacists. For purposes of determining the fiscal year burden, we will assume that LTC

facilities would have a contract with one consultant pharmacist.

Based on our experience with LTC facilities, we expect that complying with the requirement under consideration would primarily require the involvement of the LTC facility's administrator with the assistance of a facility physician, and the director of nursing. We expect also that the facility's attorney would assist with drafting the contract and reviewing any revisions. We estimate that complying with this requirement would require 16 annual burden hours for each facility to execute a contract with an independent consultant pharmacist at an estimated cost of \$1,466. Thus, although we expect that many contracts will be negotiated by the facilities' parent organizations or through GPOs, were each LTC facility to directly engage in the contracting process, it would require 251,408 burden hours per fiscal year (16 annual burden hours per LTC facility \times 15,713 LTC facilities) for all 15,713 LTC facilities to comply with this requirement at an estimated cost of \$23,035,258 (\$1,466 estimated cost per LTC facility \times 15,713 LTC facilities).

After the first fiscal year, we estimate that continued compliance with the requirement under consideration would require 2 annual burden hours (1 hour each for the facility administrator and attorney) for each facility to review the contract and, if necessary execute an updated contract with an independent consultant pharmacist at an estimated cost of \$192. Thus, it would require 31,426 burden hours per fiscal year (2 annual burden hours per LTC facility \times 15,713 LTC facilities) for all 15,713 LTC facilities to comply with this requirement at an estimated cost of \$3,016,896 (\$192 estimated cost per LTC facility \times 15,713 LTC facilities).

In addition to the LTC facility costs associated with the direct compensation of consultant pharmacists, facilities with existing LTC pharmacy contracts that include the pharmacy's provision of consultant pharmacist services would potentially need to amend these contracts. However, we do not know and cannot estimate the number of LTC facilities that would need to amend their LTC pharmacy contracts. We believe that our consultant pharmacist contracting cost estimates are likely to be sufficiently overstated to cover these costs as well.

Although it is currently common for LTC consultant pharmacists to perform approximately 60 drug regimen reviews in a day, 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 effectiveness. Therefore, in the preamble, we are soliciting public comment on best practices related to the conduct of drug regimen reviews.

Pending public response to our request for comment, we have estimated the following costs related to the requirement under consideration based on an average time of 20 minutes to perform a drug regimen review. Based on the total number of LTC facilities (15,713) and total beds (1.5 million), the average LTC facility would have 100 residents. Therefore, we anticipate that it would take each facility's consultant pharmacist 2,000 minutes (20 minutes per review \times 100 residents) or 33 hours each month to perform the residents' drug regimen reviews. Using an hourly rate of \$51.53 for independent consultant pharmacist that includes fringe benefits, we estimate 396 (33 hours per month \times 12) annual burden hours per facility at an annual cost of \$20,406 (396 \times \$51.53) for a total cost of \$320,637,592 (\$20,406 per facility \times 15,713 LTC facilities). (Hourly rate according to May 2010 wage data from Bureau of Labor Statistics estimates from the Occupational Employment Statistics Survey).

V. Regulatory Impact Analysis

A. Statement of Need

The purpose of this final rule 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 proposed rule would—(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 proposed rule has been designated an “economically significant” rule under section 3(f)(1) of Executive Order 12866. Accordingly, we have prepared a regulatory impact analysis that details the anticipated effects (costs, savings, and expected benefits), and alternatives considered by proposed requirement. Details regarding the burden associated with the requirements of this proposed regulation are located in the Collection of Information section of this rule.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than \$7.0 million to \$34.5 million in any 1 year). Individuals and States are not included in the definition of a small entity. This proposed rule 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. Although this proposed rule requires MA organizations to extend the IPPS policy regarding non-payment for HACs from non-contracted provider hospitals to contracted and hospitals, we do not expect this requirement to significantly impact total hospital costs or revenues. 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 would be reached by the proposed requirements in this proposed rule because this proposed rule would have minimal impact on small entities. Therefore, an analysis for the RFA will not be prepared because the Secretary

has determined that this proposed rule would not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector of \$100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately \$136 million. This proposed rule is expected to reach this spending threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Based on CMS Office of the Actuary estimates, we do not believe that this proposed rule imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

In Table 7, 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 proposed rule. The provisions with the most significant costs (costs greater than \$100 million from FY 2013 through FY 2018) in this proposed rule are the Medicare Coverage Gap Discount Program, and the Inclusion of Benzodiazepines, and Barbiturates as Covered Part D drugs.

The total costs of the Medicare Coverage Discount Program for the periods beginning FY 2013 through FY 2018 are estimated to be \$32.7 billion, and the total costs of the inclusion of benzodiazepines and barbiturates is \$1.9 billion.

Tables 8, 9, and 10 detail the costs by cost-bearing entity. Specifically, Table 8 describes costs and savings to the Federal government, Table 9 describes costs to MA organizations and/or PDP sponsors and third party entities, Table 10 describes costs to pharmaceutical manufacturers, Table 11 describes savings to States, and Table 12 describes costs to LTC facilities.

As a result, when considering both the costs and savings associated with the provisions of this proposed rule, we conclude with a net cost estimate of \$32.5 billion for FY 2013 through FY 2018.

C. Anticipated Effects

1. Medicare Coverage Gap Discount Program

a. Required Payment of Gap Discounts

We believe there is a cost to manufacturers to pay the discounts to beneficiaries who are in the coverage gap. We estimate that aggregate discounts from pharmaceutical manufacturers would be \$31.3 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 additional use of more expensive brand name drugs because of improved beneficiary adherence as a result of the lower out-of-pocket costs and increased use of brand name rather than generic drugs. We estimate that the Discount Program would increase Medicare costs by \$1.4 billion during FY 2013 through FY 2018.

Note that these estimated Medicare costs do not include costs related to the ACA provisions that revised the Part D benefit structure to close the coverage gap. These provisions revised the coinsurance amount and 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 would incur costs as a result of the Agreement's requirements for manufacturers. For example, manufacturers would 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.

However, manufacturers already have existing systems and perform these activities as a result of their experience with Medicaid and Tricare. We estimate that analyzing and paying the quarterly invoices would require 0.5 FTEs. We estimate that the cost to manufacturers would 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 would 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 would be a marginal increase in resources focused on accounting and computer system operations and maintenance. We estimate that the additional resources required would be 0.5 FTEs, on average, per Part D sponsor. We estimate that the total cost to Part D sponsors would 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 would 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 proposed rule. Further, we believe that the carrying cost of distributing the discounts to beneficiaries would be offset by prospective payments from us as previously described.

We believe that the additional workload associated with this proposed regulation would 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 would increase resources the equivalent of 0.5 additional FTEs to accomplish these tasks. We estimate the cost to Part D sponsors would be at \$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 proposed regulation would 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 would be accommodated by the additional resources that we earlier linked to the Medicare Coverage Gap Agreement. Therefore, we are not estimating an additional economic impact to manufacturers from this provision.

5. Beneficiary Dispute Resolution

The proposed rule would 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 would 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, would result in accurate discounts that would generate few beneficiary appeals and would be accommodated within existing resources.

6. Compliance Monitoring and Civil Money Penalties

The proposed regulations would allow CMS to impose penalties if a manufacturer does not pay gap discounts that are owed according to the terms of the Agreement. We believe that, in general, manufacturers would pay the quarterly invoice according to the terms within the agreement and other guidance. Therefore, we believe that there would be few instances where manufacturers are levied a civil money penalty. We assume that monetary penalties could be levied on approximately 0.03 percent of discounts with \$9.64 million of penalties over the period FY 2013 through FY 2018.

7. Termination of Discount Program Agreement for Part D Program

We believe that we would rarely find it necessary to terminate an agreement. Upon termination, covered Part D drugs of the manufacturers would be excluded from the Part D program and the manufacturer potentially would suffer a significant reduction in revenue. We have experience with similar programs and believe that the potential reduction of revenue would encourage manufacturers to resolve our concerns. This would tend to avoid terminations and the associated fiscal effects. Consequently, we estimate that there would be no material costs to manufacturers due to potential agreement terminations during the period FYs 2013 through 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 propose 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 proposal, Part D plan sponsors would be required to submit information in their formulary files indicating that they would cover these drugs. We estimate 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 would increase proportional to the current overall Part D level.

9. Good Cause and Reinstatement Into a Cost Plan

At § 417.460(c)(3) we are proposing to allow beneficiaries enrolled in cost plans the opportunity to be reinstated into their plan if they can establish good cause for nonpayment of cost-sharing. CMS (or its contractor) would 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.

10. Determination of Actuarially Equivalent Creditable Prescription Drug Coverage

We are proposing to clarify our regulations at § 423.884 to ensure that other insurers or organizations providing creditable prescription drug coverage to their members calculate the

actuarial value in accordance with the RDS actuarial value calculation. Since this requirement is a clarification to an existing calculation already being utilized by organizations providing creditable coverage, we anticipate that there would be no cost impact on these organizations.

11. Who May File Part D Appeals With the Independent Review Entity

The proposed changes to § 423.600 would allow prescribing physicians and other prescribers to request IRE reconsiderations on behalf of Part D plan enrollees and the corresponding proposed 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 would 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 from 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 plan sponsors of approximately \$75,000, or a total of \$450,000 from FYs 2013 through 2018.

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 MAOs 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 a good 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 would 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 would 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

LTC facilities commonly contract with an LTC pharmacy for consultant pharmacist services, and it is our understanding that LTC pharmacies typically have been providing consultant pharmacists to LTC facilities at rates below fair market value. Because the changes we are considering would specifically require LTC facilities to employ or directly or indirectly contract with independent licensed pharmacists, each facility would need to engage an independent consultant pharmacist at market rates. We understand that the subsidized rates are typically \$1 per resident per month for the conduct of each resident's drug regimen review. The cost for the independent consultant pharmacists, therefore, would be substantially higher than the subsidized rates LTC facilities currently pay to the LTC pharmacies. As a result, the cost associated with complying with the requirement under consideration would be the increase in cost for the LTC facility to pay the full market value for an independent consultant pharmacist.

However, the increased costs would be offset by the amount currently paid by the 15,713 facilities to the LTC pharmacies for the provision of consultant pharmacist services. Based on the rate of \$1 per resident per month and 1.5 million beds, we estimate the total annual savings to be \$18 million.

We estimate that although all 15,713 LTC facilities would need to provide the services of an independent consultant pharmacist, factors, such as the existence of nursing home chains and GPOs, would affect the actual number of entities that would be engaged in the process of employing or contracting the LTC consultant pharmacists. For purposes of determining the impact, we will assume that LTC facilities would have a contract with one consultant pharmacist.

Based on our experience with LTC facilities, we expect that complying with the requirement under consideration would primarily require the involvement of the LTC facility's

administrator with the assistance of a facility physician, and the director of nursing. We expect also that the facility's attorney would assist with drafting the contract and reviewing any revisions. We estimate that complying with this requirement would require 16 annual burden hours for each facility to execute a contract with an independent consultant pharmacist at an estimated cost of \$1,466. Thus, although we expect that many contracts would be negotiated by the facilities' parent organizations or through GPOs, were each LTC facility to directly engage in the contracting process, it would require 251,408 burden hours per fiscal year (16 annual burden hours per LTC facility \times 15,713 LTC facilities) for all 15,713 LTC facilities to comply with the requirement under consideration at an estimated cost of \$23,035,258 (\$1,466 estimated cost per LTC facility \times 15,713 LTC facilities).

After the first fiscal year, we estimate that continued compliance with this requirement would require 2 annual burden hours (1 hour each for the facility administrator and attorney) for each facility to review the contract and, if necessary execute an updated contract with an independent consultant pharmacist at an estimated cost of \$192. Thus, it would require 31,426 burden hours per fiscal year (2 annual burden hours per LTC facility \times 15,713 LTC facilities) for all 15,713 LTC facilities at an estimated cost of \$3,016,896 (\$192 estimated cost per LTC facility \times 15,713 LTC facilities).

In addition to the LTC facility costs associated with the direct compensation of consultant pharmacists, facilities with existing LTC pharmacy contracts that include the pharmacy's provision of consultant pharmacist services would potentially need to amend these contracts. However, we do not know and cannot estimate the number of LTC facilities that would need to amend their LTC pharmacy contracts. However, we believe that our consultant pharmacist contracting cost estimates are likely to be sufficiently overstated to cover these costs as well.

Further, although it is currently common for LTC consultant pharmacists to perform approximately 60 drug regimen reviews in a day, 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 effectiveness. Therefore, earlier in the preamble, we solicited public comment on best practices related to the conduct of drug regimen reviews.

Pending public response to our request for comment, we have estimated the following costs related to the requirement under consideration based on an average time of 20 minutes to perform a drug regimen review. Based on the total number of LTC facilities (15,713) and total beds (1.5 million), the average LTC facility would have 100 residents. Therefore, we anticipate that it would take each facility's consultant pharmacist 2,000 minutes (20 minutes per review \times 100 residents) or 33 hours each month to perform the residents' drug regimen reviews. Using an hourly rate of \$51.53 for independent consultant pharmacist that includes fringe benefits, we estimate 396 (33 hours per month \times 12) annual burden hours per facility at an annual cost of \$20,406 (396 \times \$51.53) for a total cost of \$320,639,478 (\$20,406 per facility \times 15,713 LTC facilities). (Hourly rate according to May 2010 wage data from Bureau of Labor Statistics estimates from the Occupational Employment Statistics Services). As noted previously, we expect that this amount would be reduced by the \$18 million that the facilities would no longer pay to the LTC pharmacies for consultant pharmacist services. We recognize the limitations associated with these estimates and solicit public comment on more detailed costs for this provision.

We expect that requiring independent consultant pharmacists would result in more appropriate prescribing, leading to reductions in all of the following: absolute number of drugs prescribed; unnecessary use of high price, brand name drugs; and use of antipsychotics and other drugs that should be generally avoided among older LTC residents. One outcome of the use of fewer drugs and fewer brand name drugs would be lower drugs costs for LTC residents. For residents whose cost of care is covered by Medicare Part A per diem payments, the lower drug costs would result in direct savings to the facility. For LTC residents whose drug costs are covered by Medicaid, the savings from lower drug costs would accrue to the Medicaid programs for drug costs reimbursed on a fee-for-service basis and/or to the facility if drug costs are included in the LTC per diem payment. For those residents enrolled in a Medicare Part D prescription drug plan, the savings would be realized by the Part D sponsors and Medicare.

To estimate the potential savings, we used a comparison of the risk-adjusted costs for community and LTC beneficiaries. We found that LTC beneficiary costs were 23 percent higher than the costs for beneficiaries in the community. We believe some of the cost

differential is related to factors, such as differences in dosage forms, which would contribute to legitimately higher LTC costs. However, we estimate that 50 percent of the difference in cost is attributable to the overprescribing and unnecessary use of higher cost, brand name drugs resulting from the contractual arrangements between the LTC pharmacies and pharmaceutical manufacturers. An analysis of 2008 Part D data shows LTC beneficiary drug costs in that year averaged \$4520.⁹ Using the 23 percent differential, this average would be \$845 higher than the average cost for a community beneficiary. We expect the regulatory change we are considering would reduce LTC costs by 50 percent of the differential or \$423 per beneficiary per year for a total reduction of \$360,396,000 (\$423 per beneficiary \times 852,000 LTC beneficiaries).

Lower LTC drug costs would result in lower LTC pharmacy revenues. We would likewise expect that the LTC pharmacies would experience a reduction in rebates from the pharmaceutical manufacturers; however, we cannot quantify this loss.

We believe it is reasonable to presume that the incentives present in non-independent relationships with pharmacies can influence prescribing practices. As a result, we expect the independent drug regimen reviews under consideration would decrease unnecessary use of antipsychotic drugs and, therefore, save lives, although we cannot quantify the number of lives that would be saved. In addition to saving lives, we expect more appropriate prescribing and improved medication oversight would lead to fewer hospitalizations and treatments for drug-related problems (such as confusion, balance disorders and complications caused by pharmacological interactions), as well as improved quality of life for LTC facility residents. We cannot quantify the number of hospitalizations or treatments that would be averted or the associated savings that would be realized. However, we believe the benefits to Medicare, Medicaid, other payers, and the LTC residents that would result from these changes are clear. Although the specific information to reliably quantify the all the costs and savings associated with this requirement is not available, we believe the benefits and costs are offsetting. Again, given the uncertainty surrounding these estimates, we are soliciting comment

⁹ CMS, March 18, 2010 Part D Data Symposium Presentations, LTC Pharmacy Price Index. Accessed online at: http://www.cms.gov/PrescriptionDrugCostGenIn/09_ProgramReports.asp#TopOfPage on June 17, 2010.

regarding more detailed information on the costs and savings associated with this provision.

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

We estimate that our proposal proposed at § 422.102(e) to allow certain FIDE 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 \$19.0 million between FY 2013 and FY 2018. These Federal and State savings estimates are based on our assumption that based on the eligibility standards CMS establishes approximately 34 FIDE SNPs will qualify to participate in this initiative, representing a total of approximately 115,000 enrollees in 2011.

While we acknowledge that § 1859(f)(1) of the Act extends the authority for all SNPs, including FIDE SNPs, to restrict enrollment to special needs individuals through the 2013 MA contract year, to be consistent with our scoring of other provisions in this rule, we report the impact of this proposed provision from FYs 2013 through 2018. We note that this impact may vary depending on Congressional action.

We are basing our analysis of the potential cost impacts of the FIDE 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 program, 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 FIDE SNPs 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 FIDE SNP enrollment, we project \$17.1 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 FIDE SNPs would be permitted to offer under our proposed changes to § 422.102(e) would 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 FIDE 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 FIDE SNP enrollment, we estimate Federal and State Medicaid savings of \$1.79 million for the 6-year period between FY 2013 and FY 2018 as a result of this proposed provision.

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

We propose to require MAOs 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 would 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. We do not believe that extending this requirement would impose any new administrative burden on MA plans because plans already have the operational systems in place that would facilitate implementation of the requirement. In the FY 2009 IPPS final rule, published August 19, 2008 (73 FR 49075), we estimated a total savings for Medicare of \$21 million for FYs 2009, 2010 and 2011, and \$22 million for FYs 2012 and 2013. These estimates already included savings that would accrue to the MA program as a result of reductions in annual MA payment rates. We do not expect a significant amount of new savings to be derived as a result of the requirements under this proposed rule. Therefore, we estimate that this provision would have negligible impact.

17. 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 just under 32 percent of

approximately 78.6 million first fills for maintenance medications are not refilled by Medicare Part D enrollees. Maintenance medications are used for diseases when the duration of therapy can reasonably be expected to exceed 1 year, and we assume 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, this analysis did not distinguish between community and institutional settings. Thus, to determine 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. Consequently, the adjusted total estimated cost of 2009 community-based discontinued first fills of chronic medications was estimated at roughly \$1.4 billion.

In light of the cost of discontinued medications, and in accordance with section 1860D-4(c) of the Act, we are proposing 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 this proposal, the enrollee and his or her prescriber generally would decide if a medication supply of less than 30 days would be appropriate, and if so, the copayment for the medication would be prorated by the Part D sponsor based on the days supply dispensed.

Specifically, we propose to define "daily cost-sharing rate" in § 423.100. "Daily cost-sharing rate" would mean, as applicable, the established monthly—

- Copayment under the enrollee's Part D plan divided by 30 or 31 and rounded to the nearest lower dollar amount 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 the enrollee would have paid if a month's supply had been dispensed; or
- Coinsurance rate under the enrollee's Part D plan applied to the ingredient cost of the prescription for a month's supply divided by 30 or 31.

In addition, we are specifically proposing to revise § 423.104 by adding a paragraph (i) to state that a Part D sponsor is required to provide its enrollees access to daily cost-sharing rate in accordance with § 423.154(b)(4). We also propose adding paragraph (4)(i)

to § 423.153(b) to require a Part D sponsor to establish and apply a daily cost-sharing rate 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, multiplied by the days supply actually dispensed, plus any dispensing fee in the case of coinsurance. We further propose adding paragraph (4)(i)(A) to limit the requirement to drugs that are in the form of solid oral doses paragraph (b)(4)(i)(B) would further limit the requirement to a prescription that is for an initial fill of a new medication, is intended to allow the enrollee to synchronize refill dates of multiple drugs, or the prescription is dispensed in accordance with § 423.154 (which sets forth the requirements placed upon Part D sponsors with respect to dispensing of prescription drugs in long-term care facilities effective January 1, 2013). Paragraph (b)(4)(ii) 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.

Potential savings of a daily cost-sharing rate requirement on Part D sponsors would come from a reduction of the estimated \$1.4 billion in costs previously noted which would be offset by some additional dispensing fees. In order to estimate the savings, we must make assumptions about how many first fills would be dispensed in quantities of less than a 30 day supply, and what the average quantity of such first fills would be. It should be pointed out that these assumptions are highly uncertain because it is very difficult to predict the beneficiaries' behavioral response. Having noted this caveat, we assume 20 percent of first fills in 2013 will be for a supply of less than 30 days, trending to 50 percent by 2018, and that the average of such fills would be for a 15 day supply. Assuming 32 percent of these first fills are discontinued, we estimate the potential savings to the Part D program to be \$140 million in 2013 alone, and over \$2.4 billion by 2018.

The additional dispensing fees previously noted are associated with medications that begin with a trial fill and are continued therapeutically. For instance, an enrollee who receives less than a month's supply, but continues taking the medication, would be expected to obtain ongoing refills of 30 to 90 days. Over the course of a year, the expectation is that there will be up to 13 dispensing events over a period of 1

year of refills related to such enrollee with respect to the medication initially begun with a trial fill. However, for those enrollees who discontinue a medication, there will be savings for the enrollee by not having paid the full monthly copayment for that particular medication, as well as for sponsors and the Federal government to the extent that a full month's supply of medication was not covered by the Part D program. With respect to more initial fills of brand drugs, we believe there may be additional but less significant costs for more initial fills of brand drugs that enrollees previously declined to try due to the cost of a full month's supply, when the brand drugs are known for significant side effects and/or to be frequently poorly tolerated.

Aside from these additional costs, 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, which equals \$465,184.

18. Technical Corrections to Enrollment Provisions

We are proposing technical changes that correct cross-references that should have been updated in previous rulemaking. These proposals are technical corrections and do not represent a burden for small businesses, rural hospitals, States, or the private sector.

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 websites.

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 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 would result in a total annual burden of \$10,613 rounded, approximately \$0.01 million per year.

20. Denials of SNP Applications and SNP Appeal Rights

We estimate that this proposed provision would 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 would 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 would 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 two years, we estimate that approximately 4 denied applicants would 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, resulting in a total burden estimate of 32 hours (8 hours \times 4 SNP application denials). The estimated annual cost to an MA organization that has been denied to

offer a SNP associated with this provision (assuming an attorney billing \$250 per hour) is \$8,000 (32 hours \times \$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 MAOs 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 would 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 would 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 would not result in any additional costs. Not only have we expected that prescriptions would 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 MAOs or Part D sponsors and pharmacies) likely also require valid prescriptions. In light of the above realities, it is not unreasonable to presume that MAOs, 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 would change current practices.

23. Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings

Current regulations require that unless a beneficiary is in an LTC setting, the comprehensive medication review 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 an interactive CMR. Accordingly, the proposed change to § 423.153 permits the sponsor to allow the pharmacist or other qualified provider to perform the medication review without the beneficiary in cases when the beneficiary is in an LTC facility and is cognitively impaired and thus, cannot accept the sponsor's offer of an interactive CMR. We anticipate that the impact of this proposed revision will 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 an interactive CMR before administering it. We do not anticipate any costs or savings associated with this change.

24. Coordination of Part D Plans With Other Prescription Drug Coverage

The proposed regulation would 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 propose to require, effective January 1, 2013, that Part D sponsors include only valid, individual prescriber NPIs as identifiers in PDEs submitted to CMS. Specifically, § 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 propose to add a new paragraph (5)(A) that would require Part D plan sponsors to submit PDE records to CMS that contain an active and valid individual prescriber NPI. Proposed new paragraph (c)(5)(B) would also codify current guidance and require that a Part D plan sponsor not reject a claim from a network pharmacy solely on the basis that it does not contain an active and/or valid NPI. With respect to requests for reimbursement submitted directly by Medicare beneficiaries, proposed paragraph (5)(C) would prohibit a Part D sponsor from making reimbursement payment to the beneficiary dependent upon the sponsor's acquisition of the prescriber NPI, and would further prohibit a Part D sponsor from seeking recovery of the payment from the beneficiary if the sponsor were unable to retrospectively acquire an active and valid individual NPI.

The impact associated with these proposed regulations is: (1) the annual cost for PBMs and plan organizations to conduct or 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 current, valid prescriber NPIs, and to recontract with network pharmacies to support retroactive review of the prescription to obtain the current, valid prescriber ID.

We estimate 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 2011 PDEs submitted to date conducted by a contractor to CMS indicate that approximately 90 percent 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 contract with network pharmacies for prescriber validation services or build their own databases of valid prescriber NPIs, 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 currently submitted to CMS already contain valid individual NPIs, and an estimated 95 percent of physicians have an NPI, we estimate negligible costs associated with any PDE that cannot be submitted to CMS for lack of an NPI.

TABLE 7—ESTIMATED AGGREGATED COSTS TO THE HEALTH CARE SECTOR BY PROVISION FOR FISCAL YEARS 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 ...	3,990.00	4,520.00	5,090.00	5,710.00	6,350.00	7,050.00	32,710.00
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
Compliance and Civil Money Penalties.	§ 423.2340 ...	1.18	1.32	1.48	1.67	1.88	2.11	9.64

TABLE 7—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	
Other Manufacturer Costs	§ 423.2315	13.03	13.03	13.03	13.03	13.03	13.03	78.18
Inclusion of Benzodiazepines and Barbiturates as Part D Covered Drugs.	§ 423.100	200.00	280.00	310.00	340.00	370.00	410.00	1,910.00
Who May File Part D Appeals with the Independent Review Entity.	§ 423.600	1.05	1.05	1.05	1.05	1.05	1.05	6.30
Benefit Flexibility for Fully Integrated Dual Eligible Special Needs Plans (FIDE SNPs).	§ 422.102	–5.97	–3.48	–2.30	–2.41	–2.32	–2.41	–18.89
Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program.	§ 423.104 § 423.153.	–139.50	–240.00	–330.00	–430.00	–550.00	–690.00	–2,379.50
Add language specific to SNP applications to give CMS the clear authority to deny SNP applications and to give SNPs appeal rights.	§ 422.500	0.01	0.01	0.01	0.01	0.01	0.01	0.06
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
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
Developing and executing contracts with independent consultant pharmacists.	§ 483.60	23.03	3.02	3.02	3.02	3.02	3.02	38.13
Total Impact (\$ in millions)		4,113.28	4,605.40	5,116.74	5,666.82	6,217.12	6,817.26	32,536.62

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.

TABLE 8—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	180.00	200.00	230.00	270.00	280.00	280.00	1,440.00
Inclusion of Benzodiazepines and Barbiturates as Part D Covered Drugs.	§ 423.100	200.00	280.00	310.00	340.00	370.00	410.00	1,910.00
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.	§ 423.104 § 423.153.	–140.00	–240.00	–330.00	–430.00	–550.00	–690.00	–2,380.00
Benefit Flexibility for Fully Integrated Dual Eligible Special Needs Plans (FIDE SNPs).	§ 422.102	–5.85	–3.36	–2.17	–2.28	–2.18	–2.28	–18.12
Total (\$ in millions)		235.12	237.61	208.8	178.69	98.79	–1.31	957.7

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 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 Who May File Part D Appeals with the Independent Review Entity.	§ 423.2325	12.66	12.66	12.66	12.66	12.66	12.66	75.96
Establishment and Application of Daily Cost-Sharing Rate as Part of Drug Utilization Management and Fraud, Abuse and Waste Control Program.	§ 423.104 § 423.153.	0.08	0.08	0.08	0.08	0.08	0.08	0.48
Apply MA and Part D Disclosure Requirements to Cost Contract Plans.	§ 417.427	0.5	0	0	0	0	0	0.5
Add language specific to SNP applications to give CMS the clear authority to deny SNP applications and to give SNPs appeal rights.	§ 422.500	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
Total (\$ in millions)	31.04	30.54	30.54	30.54	30.54	30.54	183.74

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 MANUFACTURERS BY PROVISION FOR FISCAL YEARS 2013 THROUGH 2018

Provision(s)	Regulation section(s)	Cost per fiscal year (\$ in millions)						Total (FYs 2013–2018) (\$ in millions)
		2013	2014	2015	2016	2017	2018	
Medicare Coverage Gap Agreement.	§ 423.2315	3,810.00	4,320.00	4,860.00	5,440.00	6,070.00	6,770.00	31,270.00
Other Manufacturer Costs	§ 423.2315	13.03	13.03	13.03	13.03	13.03	13.03	78.19
Compliance and Civil Money Penalties.	§ 423.2340	1.18	1.32	1.48	1.67	1.88	2.11	9.64
Total (\$ in millions)	3,824.31	4,334.35	4,874.51	5,454.70	6,084.91	6,785.14	31,357.83

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 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 Fully Integrated Dual Eligible Special Needs Plans.	§ 422.102	0.12	0.12	0.13	0.13	0.14	0.13	0.77

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 COSTS TO LTC FACILITIES BY PROVISION FOR FISCAL YEARS 2013 THROUGH 2018

Provision(s)	Regulation section(s)	Cost per fiscal year (\$ in millions)						Total (FYs 2013–2018) (\$ in millions)
		2013	2014	2015	2016	2017	2018	
Developing and executing contracts with independent consultant pharmacists.	§ 483.60	23.03	3.02	3.02	3.02	3.02	3.02	38.13

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 proposed agreement would codify many of the operational parameters of the Discount Program. The intention of the agreement and the parameters within is to guide the distribution of an approximately 50 percent discount in beneficiary OOP cost for prescriptions filled while the beneficiary is in the coverage gap. We believe that a well-implemented Discount Program would increase beneficiary adherence to medication regimens that can improve their health and lower their pharmaceutical costs.

2. Payment Processes for Part D Sponsors

The proposed rule would require CMS to facilitate distribution of the gap discount to beneficiaries by requiring that CMS provide an interim discount payment to Part D sponsors. That interim discount payment would be subsequently reconciled against manufacturer payments for discounts provided to beneficiaries. This provision would help Part D sponsors maintain operations with minimal, if any, effect on cash flow. This would help Part D sponsors distribute the gap discount to beneficiaries.

3. Provision of Applicable Discounts on Applicable Drugs for Applicable Beneficiaries

The proposed rule would require Part D sponsors to calculate the discount that should be provided to beneficiaries in the coverage gap. Beneficiaries would, 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 would 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 would 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 discount program would 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 would 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 would 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 would generally comply with the terms of the 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 would 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

By changing the actuarial value calculation for creditable coverage to not include the additional value of gap coverage consistent with the RDS actuarial value, this provision protects Medicare beneficiaries from being subject to a LEP when they leave RDS and other forms of prescription drug coverage and enroll into a Part D plan.

10. Who May File Part D Appeals With the Independent Review Entity

The proposed changes to § 423.600 would allow physicians and other prescribers to request IRE reconsiderations on behalf of Part D

plan enrollees. This provision would 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 the enrollee's behalf, it will further improve an enrollee's access to the Part D appeals process and assist enrollees in obtaining coverage of medically necessary medications.

11. Termination for Lower-Than-3-Star Performance Ratings

The benefit of this change is that we would 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 would 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. Independence of Long Term Care Consultant Pharmacists

The various contractual arrangements that are common among LTC facilities, LTC pharmacies, LTC consultant pharmacists these pharmacies provide to nursing facilities, and pharmaceutical manufacturers and/or distributors may create incentives for the LTC consultant pharmacist to recommend overprescribing, thus creating health and safety risks for residents. We expect that an LTC consultant pharmacist who is independent of any affiliations with the nursing facilities' LTC pharmacies, pharmaceutical manufacturers and distributors, or any affiliates of these entities would be better able to comply with the changes we are considering that would require objective and unbiased consultant pharmacist monitoring and evaluation. That is, nursing facilities would use a qualified professional pharmacist to conduct drug regimen reviews and make medication recommendations based solely on what

is in the best interests of the resident. We believe the change under consideration—severing the relationship between the consultant pharmacist and the LTC pharmacy, pharmaceutical manufacturers and distributors, and any affiliated entities—would protect the safety of all LTC residents and improve the quality of their care and their well being.

We expect that the Medicare program, State Medicaid programs, as well as other payers, would realize savings as a result of independent pharmacists performing drug regimen reviews that would be uncompromised by any financial incentives. By reducing overprescribing and unnecessary use of high cost brand name drugs, the requirement we are considering would result in lower drug costs to Medicare, Medicaid and other payers. We anticipate that this requirement would likewise curb the use of drugs that are inappropriate and should generally be avoided among older LTC residents, leading to further savings to all payers from fewer hospitalizations and treatments for drug-related problems, such as pharmacologic interactions.

14. Benefit Flexibility for Fully Integrated Dual Eligible Special Needs Plans (FIDE SNPs)

Part D-SNPs that fully integrate all Medicare and Medicaid covered services, including long-term care services, can enable dual eligible beneficiaries to remain in their homes and avoid Medicaid-financed stays in LTC institutions. We believe that allowing certain FIDE SNPs to offer supplemental benefits beginning contract year 2013 would 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.

15. Application of the Medicare Hospital-Acquired Conditions and Present on Admission Indicator Policy to MA Organizations

Although we do not expect a significant amount of new savings to result from this requirement under this proposed rule, the benefit for Medicare Advantage enrollees and to Medicare will come from increased quality, efficiency of care, and continued incentives for hospitals to eliminate medical errors and reduce Medicare expenditures for poor quality or unnecessary care.

16. 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 medications, particularly those with higher cost-sharing and that are known to frequently be poorly tolerated. As noted previously, we believe trial fills would result in the avoidance of unused drugs, reduce drug costs, diminish the environmental issue 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 would 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.

17. 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 would ensure that the beneficiaries have information to help

them make best choices for their health care needs.

18. 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 would ensure that the only MAOs 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.

19. Clarification of Contract Requirements for First Tier and Downstream Entities

This clarification ensures that the MAOs and Part D sponsors retain the necessary control and oversight over their delegated entities, thereby strengthening the programs and protecting Medicare beneficiaries.

20. Valid Prescriptions

By removing any doubt as to the appropriate source of law to consult when determining whether a prescription is valid, this regulation would benefit federal law enforcement agencies. We do not believe, however, that there is a quantifiable monetary value to easing prosecutions in this manner.

21. Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings

The expected benefits of the proposed revisions to § 423.153 are that Part D sponsors will continue to be required to offer all targeted beneficiaries in LTC facilities the opportunity to participate in an interactive CMR, but in the event the beneficiary is cognitively impaired and unable either to respond to the offer or to participate in an interactive 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.

22. 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 the same protections as those Medicare beneficiaries enrolled in individual market Part D plans where such protections have not been explicitly waived.

23. 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.

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 would involve a third party administrator directly adjudicating the discount payment to pharmacies. In this model, the pharmacy would submit the Part D claim to the Part D sponsor and receive information on the response that would 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 would 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

The alternative would be to continue to calculate the actuarial value of creditable prescription drug coverage including the value of additional coverage provided in the coverage gap. However, this approach would mean Medicare beneficiaries enrolled in programs receiving RDS may be subject to a late enrollment penalty because the value of their RDS coverage would be less than the actuarial value of creditable coverage that includes the value of additional coverage in the gap.

4. Who May File Part D Appeals With the Independent Review Entity

As previously mentioned, the proposed changes to § 423.600 and § 423.602 would 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 with the IRE on behalf of their enrollees. 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 physicians or prescribers and can create an unintended barrier to enrollees accessing the appeals process. Consequently, we are proposing the change previously highlighted in this proposed 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 would 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 Fully Integrated Dual Eligible Special Needs Plans (FIDE SNPs)

We considered whether limiting the application of the flexibilities afforded under our proposed § 422.102(e) to FIDE SNPs would be the most appropriate way of implementing this proposed benefits flexibility, or whether we should extend the additional

supplemental benefit flexibility to other SNP types. Because FIDE SNPs are required to offer LTC supports and services, a regulatory approach that limits benefits flexibility to FIDE SNPs, as opposed to all D-SNP types, may be more consistent with the objective of keeping beneficiaries in their homes and lowering costs for the Medicare and Medicaid programs. We also considered whether we should consider extending these flexibilities to all qualified FIDE SNPs, or whether we should limit these flexibilities to those qualified FIDE SNPs that currently enroll only full-benefit dual eligible beneficiaries. We believe that dual eligible beneficiaries who receive full State Medicaid benefits would have the most to gain from fully-integrated Medicare-Medicaid plan benefit offerings that include additional Medicare 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 seek specific comment on this belief.

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

The alternative to this revision would be to have the pharmacist or provider attempt to perform an interactive CMR with an LTC resident who is not capable of participating. However, by requiring an interactive CMR to be offered to all targeted beneficiaries residing in LTC our proposal gives 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 non-interactive CMR, the beneficiary will still benefit from having

a non-interactive CMR performed by a pharmacist or other qualified provider.

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 EGWPs 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 are 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 as not in line with Congressional intent regarding the use of NPIs as provider identifiers.

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 this proposed rule for FY 2013 through 2014.

TABLE 13—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS AND SAVINGS, FROM FY 2013 TO FY 2018
[\$ in Millions]

Category	Year dollar	Units discount rate		Period covered
		7%	3%	
TRANSFERS				
Annualized Monetized Transfers	2011	\$168.6	\$163.6	FYs 2013–2018.
From Whom To Whom?		Federal Government to MA Organizations and Part D Sponsors		
Annualized Monetized Transfers	2011	– \$0.1	– \$0.1	FYs 2013–2018.
From Whom To Whom?		States to MA Organizations		
COSTS (All other provisions)				
Annualized Costs to MA organizations and Part D Sponsors	2011	\$26.4	\$25.9	FYs 2013–2018.
Annualized Costs to Manufacturers	2011	4,162.1	4,126.6	FYs 2013–2018.
Annualized Costs to LTC Facilities	2011	6.9	6.6	FYs 2013–2018.

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget reviewed this proposed rule.

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 record keeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as 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.

Subpart K—Enrollment, Entitlement, and Disenrollment under Medicare Contract

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 a new § 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 new (c)(3) and (c)(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.

* * * * *

Subpart L—Medicare Contract Requirements

§ 417.492 [Amended]

6. Section 417.492 is amended as follows:

- A. In paragraph (a)(1)(i) the “;” is removed and a “; and” is added in its place.
- B. In paragraph (a)(1)(ii) the “;” is removed and a “.” is added in its place.
- C. Removing paragraph (a)(1)(iii).
- D. Removing paragraph (b)(1)(iii).

Subpart U—Health Care Prepayment Plans

7. Section 417.801 is amended by revising paragraph (d)(ii) to read as follows:

§ 417.801 Agreements between CMS and health care prepayment plans.

* * * * *

(d) * * *

(ii) The HCPP is not in substantial compliance with the provisions of the agreement, applicable CMS regulations, or applicable provisions of the Medicare law, including the following:

(A) Provision and documentation of adequate access to providers.

(B) Compliance with CMS requirements concerning provision of data and maintenance of records.

(C) Compliance 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).

Subpart B—Eligibility, Election, and Enrollment

§ 422.60 [Amended]

9. In § 422.60, paragraph (c)(1) is amended by removing the cross-reference “§ 422.80” and adding in its place the cross-reference “§ 422.2262”.

Subpart C—Benefits and Beneficiary Protections

10. Section 422.100 is amended by adding a new 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 preferred DME products or brands, provided the MA organization ensures all of the following:

(i) Its contracts with DME suppliers ensure that enrollees have access to all preferred DME products or brands.

(ii) Its enrollees have access to all medically necessary non-preferred DME products or brands.

(iii) 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 non-preferred DME-supplies.

(B) Provide for the repair of non-preferred DME-items.

(iv) It makes no negative changes to its preferred DME products or brands during the plan year.

(v) It treats denials of non-preferred DME products or brands 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 non-preferred DME product or brand as part of the description of benefits required under § 422.111(b)(2) and § 422.111(h).

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 from the single deductible described in paragraph (i) for other plan-covered items and services.

(iv) Must waive from the single deductible described paragraph (d)(1)(i) all Medicare-covered preventive services (as defined in § 410.152(l)).

* * * * *

12. Section 422.102 is amended by adding a new paragraph (e) to read as follows:

§ 422.102 Supplemental benefits.

(e) *Supplemental benefits for certain fully-integrated dual eligible special needs plans.* Subject to CMS approval, and as specified annually by CMS, certain fully-integrated dual eligible special needs plans may offer additional supplemental benefits, consistent with the requirements of this part, beyond those other MA plans may offer where CMS finds that the offering of such benefits could better integrate care for the dual eligible population.

13. Section 422.111 is amended by adding a new 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) a member identification card that its enrollees may use to access covered services under the plan. The card must comply with standards established by CMS, and must include, at a minimum the following:

- (1) For a MA PPO or PPFS plan, a statement that Medicare Limiting Charges apply.
- (2) Web link to plan's website.
- (3) Customer service number.
- (4) Individual identification number for each enrollee, to clearly identify that they are a member of the plan.

Subpart E—Relationships with Providers

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).

* * * * *

Subpart K—Application Procedures and Contracts for Medicare Advantage Organizations

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. Revising paragraph (a).
- B. In paragraph (c)(1)(ii) removing “; or” and adding in its place “.”.
- C. Adding new paragraph (c)(1)(iii).
- D. Revising paragraph (e).

The addition and revision 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), 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), 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. Adding paragraphs (b)(3) and (b)(4).

D. In paragraph (c) introductory text, 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. Revising paragraphs (c)(2)(i) through (iii).

F. Revising paragraph (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. Adding new paragraphs (a)(17), (a)(18), and (i)(3)(iv).

B. Revising paragraphs (i)(3) introductory text and (i)(3)(iii), (i)(4)(i) through (iv), 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) Each and every contract governing MA organizations 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 MA organization's contractual obligations.

(iv) A provision requiring that payment will not be made to hospitals for serious preventable events and hospital-acquired conditions in accordance with section 1886(d)(4)(D) of the Act and all applicable Medicare policies.

* * * * *

(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.

* * * * *

Subpart K—Application Procedures and Contracts for Medicare Advantage Organizations

18. Section 422.510 is amended by adding a new 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.

* * * * *

Subpart N—Medicare Contract Determinations and Appeals

19. Section 422.641 is amended by adding a new 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 new 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.

* * * * *

Subpart V—Medicare Advantage Marketing Requirements

21. Section 422.2274 is amended as follows:

A. Revising paragraph (a)(1)(i).

B. Removing and reserving paragraph (a)(1)(ii).

C. Revising paragraph (a)(1)(iii).

D. Adding a new 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–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

Subpart B—Eligibility and Enrollment

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.

* * * * *

(3) Prior to the commencement of the Annual Coordinated Election Period as defined in § 423.38(b); and

* * * * *

Subpart C—Benefits and Beneficiary Protections

24. Section 423.100 is amended as follows:

A. Adding the definition of “Daily cost-sharing rate.”

B. Revising paragraph (2)(iii) of the definition of “Incurred costs.”

C. In paragraph (2)(ii) of the definition of “Part D drug,” the phrase “smoking cessation agents” is removed and adding in its place the phrase “smoking cessation agents, benzodiazepines, and barbiturates when used to treat epilepsy, cancer, or chronic mental health disorder.”

D. Revising the definition of “Supplemental benefits”.

E. Adding the definition of “Valid prescription”

The additions and revision read as follows:

§ 423.100 Definitions.

* * * * *

Daily cost-sharing rate means, as applicable, the established monthly—

(1) Copayment under the enrollee’s Part D plan divided by 30 or 31 and rounded to the nearest lower dollar amount 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 the enrollee would have paid if a month’s supply had been dispensed; or

(2) Coinsurance rate under the enrollee’s Part D plan applied to the ingredient cost of the prescription for a month’s supply divided by 30 or 31.

* * * * *

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 new 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.* A Part D sponsor is required 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 a new paragraph (c)(5) to read as follows:

§ 423.120 Use of standardized technology.

* * * * *

(c) * * *

(5)(i) Part D sponsor must submit to CMS only a prescription drug event (PDE) record that contains an active and valid individual prescriber NPI.

(ii) Notwithstanding paragraph (c)(5)(i) of this section, a Part D sponsor may not reject a claim from a network pharmacy solely on the basis that it does not contain an active and/or valid NPI unless the issue can be resolved at point-of-sale, there is an indication of fraud, the prescription was written by a provider excluded from the Medicare program or the claim involves a prescription written by a foreign prescriber (where permitted by State law).

(iii) With respect to non-standard 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 the prescriber NPI. If the sponsor is unable to retrospectively acquire an active and valid individual prescriber NPI, the sponsor may not seek recovery of the payment from the beneficiary solely on the basis that the non-standard request did not include a valid individual prescriber NPI.

* * * * *

Subpart D—Cost Control and Quality Improvement Requirements

27. Section 423.153 is amended as follows:

A. In the introductory text for paragraph (b), the phrase “that -” is removed and the phrase “that address all of the following:” is added in its place.

B. In paragraph (b)(1) removing “;” and adding in its place “.”.

C. In paragraph (b)(2) removing “; and” and adding in its place “.”.

D. Adding a new paragraph (b)(4).

E. Revising paragraphs (d)(1)(vii)(B), and (d)(2).

The addition and revision read as follows:

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

* * * * *

(b) * * *

(4)(i) Establishes and applies a daily cost-sharing rate to a prescription dispensed by a network pharmacy for a covered Part D generic or brand drug that is dispensed for a supply less than 30 days, multiplied by the days supply actually dispensed, plus any dispensing fee in the case of coinsurance—

(A) If the drug is in the form of a solid oral dose, subject to paragraph (b)(4)(ii) of this section; and

(B) The prescription is—

(1) For an initial fill of a new medication;

(2) Intended to allow the enrollee to synchronize refill dates of multiple drugs; or

(3) Dispensed in accordance with § 423.154.

(ii) The requirements of paragraph (b)(4)(i) of this section do not apply to either of the following:

(A) Solid oral doses of antibiotics.

(B) Solid oral doses that are dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance.

* * * * *

(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 residing in an LTC setting is offered the annual comprehensive medication review and cannot accept the offer to participate, the pharmacist or other qualified provider must perform the medication review without the beneficiary's participation.

Subpart J—Coordination of Part D Plans with Other Prescriptions Drug Coverage

28. Section 423.458 is amended by adding a new paragraph (c)(3) to read as follows:

§ 423.458 Application of Part D rules to certain Part D plans on or after January 1, 2006.

* * * * *

(c) * * *

(3) 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)(2) of this section.

* * * * *

Subpart K—Application Procedures and Contracts with Part D Plan Sponsors

29. Section 423.501 is amended by adding the definition of "Bona fide service fees" 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 drugs. Bona fide service fees include, but are not limited to distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements

and patient care programs (such as medication compliance programs and patient education programs).

* * * * *

30. Section 423.503 is amended as follows:

A. In paragraph (b)(1), removing the phrase "If a Part D" and adding in its place " Except as provided in paragraphs (b)(2), (b)(3), and (b)(4) of this section, if a Part D".

B. Adding new paragraphs (b)(3) and (b)(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 to read as follows:

A. Adding new paragraphs (b)(24) through (b)(26).

B. Revising paragraphs (i)(3) introductory text, (i)(3)(iii), (i)(3)(v), and (i)(4)(i) through (iv).

§ 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) Maintains 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) Maintains 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 C 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 a new 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. Redesignating paragraphs (d) through (g) as paragraphs (g) through (j), respectively.

B. 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 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.

* * * * *

Subpart M—Grievances, Coverage Determinations, Redeterminations, and Reconsiderations

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.

* * * * *

Subpart T—Appeal Procedures for Civil Money Penalties

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.

Subpart V—Part D Marketing Requirements

38. Section § 423.2274 is amended to read as follows:

- A. Revising paragraph (a)(1)(i).
- B. Removing and reserving paragraph (a)(1)(ii).
- C. Revising paragraph (a)(1)(iii).
- D. Adding a new 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.

(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 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. Part 423 is amended by adding a new subpart W 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 on applicable drugs for applicable beneficiaries.

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.

Subpart W—Medicare Coverage Gap Discount Program

§ 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 use.

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.

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 having received written notification of the codes from the FDA.

(5) Collect, have available, and maintain appropriate data, including

data related to manufacturer's labeler codes, NDC 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 the timely removal of discontinued NDCs in the FDA NDC Directory.

(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) 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 one 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 on applicable drugs for applicable beneficiaries.

(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) In determining whether an enrollee is entitled to an applicable discount and the amount of the applicable discount, the Part D sponsor must apply any dispensing fee or vaccine administration fee for a claim that straddles the coverage gap and either the initial coverage limit or annual out-of-pocket threshold (or both) such that the dispensing fee or vaccine administration fee is within the initial coverage limit or the catastrophic phase of coverage to the maximum extent possible, and then determines the amount of the applicable discount based on the negotiated price (as defined in § 423.2305).

(4) 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 Part D.

(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.

(3) In determining whether an enrollee is entitled to an applicable discount and the amount of the applicable discount, the Part D sponsor applies any dispensing fee or vaccine administration fee for a claim such that the dispensing fee or vaccine administration fee is within the supplemental benefits to the maximum extent possible, and then determines the amount of the applicable discount based on the negotiated price (as defined in § 423.2305).

(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.

§ 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, expiration date of NDCs, 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.* (1) 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:

(i) A description of the basis for the determination.

(ii) The basis for the penalty.

(iii) The amount of the penalty.

(iv) The date the penalty is due.

(v) The manufacturer's right to a hearing (as specified in § 423.1006).

(vi) 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)) 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.

§ 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 (a)(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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