

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, 423, and 480

[CMS-4085-P]

RIN 0938-AP77

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

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

ACTION: Proposed rule.

SUMMARY: We are proposing revisions to the Medicare Advantage (MA) program (Part C) and prescription drug benefit program (Part D) based on our continued experience in the administration of the Part C and D programs. The proposed revisions clarify various program participation requirements; specify changes to strengthen beneficiary protections; ensure that plan offerings to beneficiaries include meaningful differences; improve plan payment rules and processes; and implement new policy such as a Part D formulary policy.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. Eastern Standard Time (EST) on December 8, 2009.

ADDRESSES: In commenting, please refer to file code CMS-4085-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

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4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses: 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.

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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, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

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Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

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

FOR FURTHER INFORMATION CONTACT:

Alissa Deboy, (410) 786-6041, General information and Part D issues.

Sabrina Ahmed, (410) 786-7499, Part C issues.

Chris Eisenberg, (410) 786-5509, Risk adjustment data validation issues.

Terry Lied, (410) 786-8973, Collection of information requirements and regulatory impact analysis issues.

Kristy Nishimoto, (410) 786-8517, Part C and D enrollment and appeals issues.

Christine Reinhard, (410) 786-2987, Part C and D compliance and sanction issues.

Frank Szefflinski, (303) 844-7119, Part C payment issues.

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

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

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- Acronyms**
- AO Accrediting Organization
- ADS Automatic Dispensing System
- AEP Annual Enrollment Period
- AHFS—DI American Hospital Formulary Service
- AHFS—DI American Hospital Formulary Service—Drug Information
- AHRQ Agency for Health Care Research and Quality
- ALJ Administrative Law Judge
- BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
- BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
- BIPA Medicare, Medicaid, and SCHIP Benefits Improvement Protection Act of 2000 (Pub. L. 106–554)
- CAHPS Consumer Assessment Health Providers Survey
- CAP Corrective Action Plan
- CCIP Chronic Care Improvement Program
- CMR Comprehensive Medical Review
- CMP Civil Money Penalties
- CMR Comprehensive Medical Review
- CMS Centers for Medicare & Medicaid Services
- CMS—HCC CMS Hierarchal Condition Category
- CTM Complaints Tracking Module
- COB Coordination of Benefits
- CORF Comprehensive Outpatient Rehabilitation Facility
- CY Calendar year
- DOL U.S. Department of Labor
- DRA Deficit Reduction Act of 2005 (Pub. L. 109–171)
- EGWP Employer Group/Union-Sponsored Waiver Plan
- EOB Explanation of Benefits
- ESRD End-stage renal disease
- FACA Federal Advisory Committee Act
- FDA Food and Drug Administration (HHS)
- FEHBP Federal Employees Health Benefits Plan
- FFS Fee-For-Service
- FY Fiscal year
- GAO Government Accountability Office
- HCPP Health Care Prepayment Plans
- HEDIS HealthCare Effectiveness Data and Information Set
- HHS [U.S. Department of] Health and Human Services
- HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)
- HMO Health Maintenance Organization
- HOS Health Outcome Survey
- HPMS Health Plan Management System
- ICD–9–CM Internal Classification of Disease, 9th, Clinical Modification Guidelines
- ICEP Initial Coverage Enrollment Period
- ICL Initial Coverage Limit
- ICR Information Collection Requirement
- LEP Late Enrollment Penalty
- LIS Low Income Subsidy
- LTC Long Term Care
- LTCF Long Term Care Facility
- MA Medicare Advantage
- MAAA American Academy of Actuaries
- MAO Medicare Advantage Operations
- MA–PD Medicare Advantage-Prescription Drug Plans
- M+C Medicare+Choice program
- MPDPF Medicare Prescription Drug Plan Finder
- MIPPA Medicare Improvements for Patients and Providers Act of 2008
- MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)
- MSA Metropolitan Statistical Area
- MSAs Medical Savings Accounts
- MSP Medicare Secondary Payer
- MTM Medication Therapy Management
- MTMP Medication Therapy Management Programs
- NAIC National Association Insurance Commissioners
- NCPDP National Council for Prescription Drug Programs
- NGC National Guideline Clearinghouse
- NIH National Institutes of Health
- NOMNC Notice of Medicare Non-coverage
- OEP Open Enrollment Period
- OIG Office of Inspector General
- OMB Office of Management and Budget
- OPM Office of Personnel Management
- OTC Over the Counter
- PART C Medicare Advantage
- PART D Medicare Prescription Drug Benefit Programs
- PBM Pharmacy Benefit Manager
- PDE Prescription Drug Event
- PDP Prescription drug plan
- PFFS Private Fee For Service Plan
- POS Point of Service
- PPO Preferred Provider Organization
- PPS Prospective Payment System
- P&T Pharmacy & Therapeutics
- QIO Quality Improvement Organization
- QRS Quality Review Study
- PACE Programs of All Inclusive Care for the Elderly
- RAPS Risk Adjustment Payment System
- RADV Risk Adjustment Data Validation
- SCHIP State Children's Health Insurance Programs

SEP Special Enrollment Periods
 SHIP State Health Insurance Assistance Programs
 SNF Skilled Nursing Facility
 SNP Special Needs Plan
 SPAP State Pharmaceutical Assistance Programs
 SSI Supplemental Security Income
 TrOOP True Out Of Pocket
 U&C Usual and Customary
 USP U.S. Pharmacopoeia

I. Background

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

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) was enacted on December 8, 2003. The MMA established the Part D program and made revisions to the provisions in Part C of the Medicare statute governing the Medicare Advantage (MA) program. The MMA directed that important aspects of the new Medicare prescription drug benefit program under Part D be similar to and coordinated with regulations for the MA program.

The MMA also directed implementation of the prescription drug benefit and revised MA program provisions effective January 1, 2006. The final rules for the MA and Part D prescription drug programs appeared in the **Federal Register** on January 28, 2005 (70 FR 4588–4741 and 70 FR 4194–4585, respectively). Many of the provisions relating to applications, marketing, contracts, and the new bidding process for the MA program became effective on March 22, 2005, 60 days after publication of the rule, so that the requirements for both programs could be implemented by January 1, 2006. All of the provisions regarding the new Part D prescription drug program became effective on March 22, 2005.

As we have gained more experience with the MA program and the prescription drug benefit program, we have revised the Part C and D regulations to continue to improve or clarify existing policies and/or codify current guidance for both programs. For example, in December 2007, we published a final rule with comment on contract determinations involving Medicare Advantage (MA) organizations and Medicare Part D prescription drug plan sponsors (72 FR 68700). In April 2008, we published a final rule to address policy and technical changes to the Part D program (73 FR 20486). In September 2008 and January 2009, we finalized revisions to both the Medicare Advantage and prescription drug benefit programs (73 FR 54226 and 74 FR 1494, respectively) to implement provisions in

the Medicare Improvement for Patients and Providers Act (MIPPA) (Pub. L. 110–275), which contained provisions impacting both the Medicare Part C and D programs, and make other policy clarifications based on experience with both programs (73 FR 54208, 73 FR 54226, and 74 FR 2881).

Under this proposed rule, we have identified additional programmatic and operational changes (outlined below) that we believe are needed in order to further improve our oversight and management of the Part C and D programs and to further improve beneficiary experience under MA or Part D plans.

B. History and Overview

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) established a new “Part C” in the Medicare statute (sections 1851 through 1859 of the Social Security Act (the Act)) which provided for what was then called the Medicare+Choice (M+C) program. Under section 1851(a)(1) of the Act, every individual entitled to Medicare Part A and enrolled under Medicare Part B, except for most individuals with end-stage renal disease (ESRD), could elect to receive benefits either through the original Medicare program or an M+C plan, if one was offered where he or she lived. The primary goal of the M+C program was to provide Medicare beneficiaries with a wider range of health plan choices. The M+C provisions in Part C were amended by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–111), and further amended by the Medicare, Medicaid, and State Children’s Health Insurance Program (SCHIP) Benefits Improvement Act of 2000 (BIPA) (Pub. L. 106–554).

As noted previously, the MMA was enacted on December 8, 2003. Title I of the MMA added a new “Part D” to the Medicare statute (sections 1860D–1 through 42 of the Act) creating the Medicare Prescription Drug Benefit Program, one of the most significant changes to the Medicare program since its inception in 1965. Sections 201 through 241 of Title II of the MMA made significant changes to the M+C program. Title II of the MMA renamed the M+C program as the MA program and included new payment and bidding provisions, new regional MA plans and special needs plans, reestablished authority for medical savings account (MSA) plans that had been provided in the BBA on a temporary basis, addressed private fee-for-service plans, and made other changes. Title I of the MMA created prescription drug benefits

under Medicare Part D, and a new retiree drug subsidy program.

Both the MA and prescription drug benefit regulations were published separately, as proposed and final rules, though their development and publication were closely coordinated. On August 3, 2004, we published in the **Federal Register** proposed rules for the MA program (69 FR 46866 through 46977) and the prescription drug benefit program (69 FR 46632 through 46863). In response to public comments on the proposed rules, we made several revisions to the proposed policies for both programs. For further discussion of these revisions, see the respective final rules (70 FR 4588 through 4741) and (70 FR 4194 through 4585).

Also as noted above, MIPPA was enacted on July 15, 2008, which addressed a number of provisions impacting the Part C and D programs, including provisions impacting marketing under both programs. In the September 18, 2008 **Federal Register** (73 FR 54208), we published a final rule that finalized certain marketing provisions, effective October 1, 2008, that paralleled provisions in MIPPA. In the same issue of the **Federal Register** (73 FR 54226), we published a separate interim final rule that addressed the other provisions of MIPPA affecting the MA and Part D programs. We also clarified the MIPPA marketing provisions in a November 2008 interim final rule (73 FR 67407 and issued a separate interim final rule in January 2009 to address MIPPA provisions related to Part D plan formularies (74 FR 2881).

Now, with almost four years’ experience behind us, we are proposing further revisions to these programs affecting both beneficiaries and sponsoring organizations.

When the MMA required that the Part D benefit afford each enrollee a minimum of two choices in each plan region, few if any envisioned the overwhelming response from the healthcare industry would result in most beneficiaries choosing among dozens of plans with various benefit packages. In the first few years of the Part D benefit, we believed this was on the whole a great success. More plans means more variation, competition and lower prices for Medicare beneficiaries choosing to enroll in a stand-alone prescription drug plan (PDP), or Medicare Advantage prescription drug plan (MA–PD). However, with so many plans to choose from many beneficiaries reportedly find the annual task of selecting one plan from so many overwhelming, and confusing. Moreover, we have found that, as

overseers of the Part C and D programs, organizations submitting bids to offer multiple plans have not consistently submitted plan benefit designs that were significantly different from each other, which can add to beneficiary confusion.

Since its inception in 2006, the Medicare Part D program has improved access to drug coverage for elderly and offered beneficiaries a wide range of plans from which to choose. At the same time, some have suggested that significant numbers of beneficiaries are confused by the array of choices and find it difficult to make enrollment decisions that are best for them. Many do not enroll in necessarily the lowest cost plan and many eligible individuals are not enrolled in the low-income subsidy program. Finally, once beneficiaries have chosen a plan and enrolled in it, they tend to remain in those plans, despite changes in medication use or premium increases.

We remain committed to considering changes in the way we administer the Part C and D programs to enable Medicare beneficiaries to choose the plan that best suits their needs. Among other proposals, we are making following three specific proposals to simplify the program for beneficiaries:

- First, we propose to require sponsors to ensure that when they provide multiple plan offerings, those offerings sufficiently differ and thereby provide beneficiaries meaningful options (*see* section II. of this proposed rule);
- Second, we propose to eliminate plans with persistently low enrollments, since these can add complexity to choices without adding value (*see* section II.D. of this proposed rule);
- Third, we propose to require sponsors to use standardized “templates” in their beneficiary communication materials (for example, the Annual Notice of Changes (ANOC) and the Evidence of Coverage (EOC) notices), so that seniors can better understand how their current benefits and cost-sharing requirements will be changing and more easily compare their current plan with other plan options (*see* section II.B.3 of this proposed rule).

We believe that more can be done to structure choices for seniors to aid them in making better plan choices.^{1 2} For example, studies have suggested that providing personalized drug utilization and cost information to beneficiaries

can encourage seniors to switch to plans that better meet their medication needs while reducing their overall costs.³ Some have urged that the agency can do more to provide improved individual drug utilization and cost information to beneficiaries to encourage seniors to switch to lower-cost plans. Other studies have found that some beneficiaries are not fully aware of the financial implications of deferring enrollment in drug plans,⁴ a finding that suggests that we could do more to make those implications more salient to beneficiaries. We invite comments on these possibilities and other improvements the agency can make, to help beneficiaries choose the plans that best suit their needs. We also invite comment on the type of research that might be undertaken to help inform future regulatory and programmatic improvements and how we can best support our partners, such as states, to assist them in helping beneficiaries enroll in the best possible plans. For example, we are interested in assessing the impacts of random auto-assignments on low-income beneficiaries. To the extent that States are interested in exploring non-random assignment methods, we invite comment on what type of information States would find most beneficial, including the types of data analyses we could potentially undertake with the data we already have from States who utilize non-random assignment methods.

We also have found that in certain cases, we have been limited by existing program rules and regulations to implement actions that would improve sponsoring organization performance. Toward this end, we propose provisions that would limit the number of plan offerings by eliminating duplicative bids, and strengthen our program participation requirements.

We are proposing a number of additional provisions aimed at strengthening existing beneficiary protections. For example, we propose to strengthen plan transition process requirements to ensure maximum transparency regarding our expectations of Part D plans with respect to enrollees transitioning to the plan from other drug

coverage and to ensure that current subregulatory practices are codified in regulation.

We are also proposing another set of provisions that are aimed at improving payment rules and processes, and improving data collection for oversight and quality assessment. For example, we are proposing to expand the collection of prescription drug event data that we currently collect for research and other non-payment related purposes. Collecting these additional data, which are currently collected for payment purposes, would provide us additional information to conduct analyses that may be used to improve policies and assist in monitoring of Part D plan sponsors.

In addition, we are proposing significant new Part D policy in this rule. For example, in the area of Part D formulary policy, we propose a regulatory interpretation of MIPPA protected drug categories and classes provision in section 176 of MIPPA (Pub. L. 110–275) that we previously addressed in a January 19, 2009 interim final rule with comment period (IFC). Based on comments received in response to that IFC, we believe that interpretation of statutory terms is needed. In addition, we believe that additional clarification is needed relative to the process that we intend to utilize to identify the protected categories and classes of drugs that must be listed on all Part D plan formularies.

Finally, we propose other provisions that are aimed at further clarifying existing policy and we make technical corrections where needed. For example, in some cases, we are addressing topic areas that were included in our 2010 call letter to Part C and D plans, the document that outlines policy clarifications and reminders for plans bidding on plan offerings in the coming contract cycle. In the spirit of transparency, we have outlined some of these clarifications within this rule so to ensure the public has a full opportunity to comment on our policies.

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, 423, and 480 governing the MA and prescription drug benefit programs. To better frame the discussion of the specific regulatory provisions we are proposing, we have structured the preamble narrative by topic area rather than by subpart order. Accordingly, our proposals address the following eight specific goals as foreshadowed in the preceding introduction:

³ See, for example, Wrobel MV, Kling J, Mullainathan S, Shafir E, Vermeulen L (2009). A Shot in the Arm for Medicare Part D: Four Ways for the Government to Boost its Customer Communications. http://www.brookings.edu/papers/2008//media/Files/rc/papers/2008/1120_medicare_kling/1120_medicare_kling.pdf.

⁴ Hargrave E, Piya B, Hoadley J, Summer L, Thompson J (2008). Experiences Obtaining Drugs under Part D: Focus Groups with Beneficiaries, Physicians, and Pharmacists. Final Report Submitted to the Medicare Payment Advisory Commission. National Opinion Research Center.

¹ McFadden D (2006). Free Markets and Fettered Consumers. *The American Economic Review* 96(1), 5–29

² Hanock Y, Rice T, Cummings J, Wood S (2009). How Much Choice is Too Much? The Case of the Medicare Prescription Drug Benefit. *Health Services Research* 44:4; 1157–1168.

- Strengthening our ability to distinguish for approval strong applicants for MMA participation and remove consistently poor performers.
- Strengthening beneficiary protections.
- Providing plan offerings with sufficient enrollment and meaningful differences.
- Improving payment rules and processes.
- Improving data collection for oversight and quality assessment.
- Implementing other new policies.
- Clarifying various sponsor program participation requirements.
- Implementing corrections and other technical changes.

Several of the proposed revisions and clarifications affect both programs. Within each section, we have provided a chart listing all subject areas that contain provisions affecting the Part C and D programs and the associated regulatory citations that would be revised. Please note that in our discussion of these provisions, we often refer to “sponsoring organizations” to refer to both Medicare Advantage organizations (MAOs) and Part D sponsors.

A. Changes To Strengthen Our Ability To Distinguish for Approval Strong Applicants for Part C and D Program Participation and To Remove Consistently Poor Performers

This section addresses a number of proposals designed to strengthen our ability to approve strong applicants and remove poor performers in the Part C and D programs. Since the implementation of revisions to the MA and initial implementation of the prescription drug programs in January 2006, we have steadily enhanced our ability to measure MAO and PDP sponsor performance through efforts such as the analysis of data provided routinely by sponsors and by our contractors, regular review of beneficiary complaints, marketing surveillance activities, and routine audits. This information, combined with feedback we have received from beneficiary satisfaction surveys, HEDIS data, and information from MAOs and PDP sponsors themselves, has enabled us to develop a clearer sense of what constitutes a successful Medicare organization capable of providing quality Part C and D services to beneficiaries. This information has also allowed us to identify and take appropriate action against organizations that are not meeting program requirements and not meeting the needs of beneficiaries.

As our understanding of Part C and D program operations has deepened over the past 4 years, our use of our authority to determine which organizations are qualified to offer MA and PDP sponsor contracts, evaluate their compliance with Part C and D requirements, and make determinations concerning intermediate sanctions, contract nonrenewals and contract terminations has evolved as well. As set forth below, we are proposing changes and clarifications to our regulations to make certain that all current and potential MAOs and PDP sponsors clearly understand and can reasonably anticipate how we measure sponsor performance, determine when there is noncompliance, and when enforcement actions are warranted. While we are pleased that so many organizations have elected to participate in the Part C and D programs, we have an obligation to ensure that only appropriate organizations are given the responsibility for providing quality medical care and drug coverage to Medicare beneficiaries.

Each year, since contract year 2006, we have solicited applications from organizations seeking to become qualified to enter into Part C or D sponsor contracts. We received hundreds of applications in each of those years. To properly manage a workload of that size, and to ensure that we conduct a fair review of every application, we have adopted an increasingly standardized, computer-based application submission process. At the same time, we have also become increasingly strict in the application of our regulatory authority to limit the number and timing of opportunities for applicants to resubmit materials to cure applications that do not initially demonstrate that the applicant meets Part C or D requirements.

Until 2 years ago, applicants may have found that we would accept as many corrected submissions as the applicants needed to make their materials (usually documents concerning provider/pharmacy networks, subcontracting arrangements, or risk-bearing licenses) consistent with Part C or D requirements. We recognized that this was an inefficient process that afforded some applicants the opportunity to make more re-submissions than others and arguably enabled less well-prepared and qualified applicants to enter the program. To improve the fairness of the application process, and to reduce the burden it imposes on applicants and CMS alike, we have, through our application instructions issued over the last 3 years, clarified to all applicants

that we will only provide three opportunities to submit an approvable contract qualification application to CMS: The initial solicitation response, one courtesy opportunity to correct any identified deficiencies, and a final opportunity during the 10-day cure period provided for specifically in the regulations.

Some organizations have expressed surprise during the last 2 years at our use of our authority to impose strict deadlines and standards of review on applications for qualification as an MAO or PDP sponsor. To reduce the opportunity for confusion about the application process, we are proposing some regulatory clarifications in furtherance of our goal of using a fair and efficient process for ensuring that only truly qualified organizations are offered Part C or D organization contracts. These provisions, described in greater detail below, include requiring applicants to demonstrate that they meet all (not a substantial number) of the Part C and D program requirements, prohibiting applicants from submitting additional curing materials after the expiration of the ten-day period following their receipt of a notice of intent to deny their application, and requiring applicants to submit a nonbinding notice of intent to apply for a Part C or D contract.

Organizations should be aware that we will continue to exercise our authority to consider an organization's past Part C or D contract performance in evaluating whether it should be afforded the opportunity to obtain additional contracts or to serve a larger portion of the Medicare beneficiary population. Additionally, sponsoring organizations should be aware that we rely on data to evaluate compliance with program requirements in a number of ways. For example, we use data to evaluate adherence to requirements in the MMA statute or the Part C and D regulations (for example, retail pharmacy access). We also use data to evaluate adherence to the requirements outlined in our manual chapters and other guidance (for example, customer and provider call center performance standards). Finally, we conduct outlier analysis by comparing the performance across all organizations on a particular Part C or D requirement to identify organizations that appear to be poor performers. The most notable example of this kind of analysis is reflected in our performance metrics (that is, the Medicare Part D Plan Ratings). These ratings represent an effort to make additional information available to the public regarding the price and quality of services for which Medicare makes payments. The Plan

Ratings are located on the Medicare Prescription Drug Plan Finder (MPDPF) Tool at (<http://www.Medicare.gov>) and are designed to provide a clear differentiation of the various Plan offerings to beneficiaries. Organizations receiving less than “good” ratings in any category should anticipate communication from us. Another example is our review of data in the Complaints Tracking Module (CTM), which can be a particularly strong indicator of a sponsor’s inability to perform a required Part C or D function. An abnormally high complaint rate for a particular sponsor will likely prompt us to investigate other sources of information to determine whether the organization is complying with specific Part C or D requirements.

Our efforts are aimed at making certain that we have well-functioning MAOs and PDP sponsors administering Part C and D benefits on our behalf. Just

as we have become more sophisticated in our analysis of sponsor applications and compliance, we also continue to review our sanction and contract termination authority to ensure that we pursue actions when there is sufficient basis to support them. For example, we have developed an annual process for analyzing sponsor performance during the preceding contract year. We review each sponsor’s compliance history, including CMS-issued compliance notices, audit results, and performance ratings (for example, star ratings) to develop a full picture of that sponsor’s ability to deliver Part C and D services to its members. If that picture indicates that a particular sponsor has a significant pattern of poor performance or even isolated incidences of noncompliance with crucial operational requirements (for example, enrollment processing), we will consider

termination or nonrenewal of the contract of that sponsor.

With the clarifications we are proposing to the Part C and D regulations through this proposed rule and the background provided in this preamble section, MAOs and PDP sponsors should now be fully aware that we will continue to apply stricter scrutiny to sponsor qualifications and contract performance as our analytical capabilities and understanding of industry best practices improves. As the Part C and D programs have now reached a certain level of maturity and organizations’ strong interest in participating in the programs has been established, it is appropriate for us to use the authority and evidence at our disposal to make certain that beneficiary plan choices are characterized more by their quality than their quantity. These provisions are described in detail in Table 1.

TABLE 1—PROVISIONS STRENGTHENING OUR ABILITY TO DISTINGUISH FOR APPROVAL STRONG APPLICANTS AND TO REMOVE CONSISTENTLY POOR PERFORMERS

Provision	Part 422		Part 423	
	Subpart	Section	Subpart	Section
Notice of Intent to Apply	Subpart K ..	§ 422.501	Subpart K ..	§ 423.502.
Application Standards	Subpart K ..	§ 422.502	Subpart K ..	§ 423.503.
Compliance Measures/Analysis	Subpart K ..	§ 422.502	Subpart K ..	§ 423.503.
Compliance Programs	Subpart K ..	§ 422.503(b)(4)(vi)	Subpart K ..	§ 423.504(b)(4)(vi).
Network Adequacy of Coordinated Care and Network-Based Private-Fee-For-Service plans under Part C.	Subpart C ..	§ 422.112	N/A	N/A.
Clarify programmatic elements that are “deemable”.	Subpart D ..	§ 422.156(b)(7), § 422.156(f)	Subpart D ..	§ 423.165(b), § 423.165(f).
Procedures for termination and Nonrenewals: Part C and D.	Subpart K ..	§ 422.510(c)(1), § 422.506(b)(3)	Subpart K ..	§ 423.509(c)(1), § 423.507(b)(3).
Intermediate Sanctions: Procedures for imposing civil and money penalties.	Subpart O ..	§ 422.756	Subpart O ..	§ 423.756.
Contract Termination	Subpart K ..	§ 422.510(a)	Subpart K ..	§ 423.509(a).
Proper request for hearings	Subpart N ..	§ 422.662	Subpart N ..	§ 423.651.
Burden of Proof, Standard of Proof, Standard of Review and Conduct of Hearing.	Subpart N ..	§ 422.660, § 422.676(d)	Subpart N ..	§ 423.650, § 423.658(d).
Postponement of effective date of determination when a request is being filed.	Subpart N ..	§ 422.664	Subpart N ..	§ 423.652.
Extending timeframe for contract determination hearings.	Subpart N ..	§ 422.670	Subpart N ..	§ 423.655.
Appeal times: Require each party provide witness list and documents 5 calendar days before hearing.	Subpart N ..	§ 422.682	Subpart N ..	§ 423.661.
Appeal times: Require request for a review by the administrator must be received with 15 days after receipt of hearing decision.	Subpart N ..	§ 422.692(a)	Subpart N ..	§ 423.666(a).
Contract redeterminations and reopening	Subpart N ..	§ 422.696	Subpart N ..	§ 423.668.
Mutual termination of contract	Subpart K ..	§ 422.503(b)(6)	Subpart K ..	§ 423.504(b)(5).

1. Require Notice of Intent To Apply Under Part C and D Within the Application Requirements (§ 422.501 and § 423.502)

Subpart K of part 422 and subpart K of part 423 set forth the requirements for contracts with MA Organizations and Part D sponsors including application

procedures. Section 1871(a)(1) of the Act authorizes us to prescribe such regulations as may be necessary to carry out the administration of the Medicare program. We propose using that authority to establish an administrative requirement for both the Part C and D programs related to the submission to us

of applications to qualify as MA and PDP sponsor contractors.

Beginning with the applications for the 2009 contract year, the Medicare Advantage, Part D Prescription Drug benefit, and Employer/Union-Only Group Waiver Plan (Direct Contract or “800 Series”) sponsor applications are

submitted via a paperless process. Each application is completed through the CMS Health Plan Management System (HPMS). As a result of the fully electronic submission process and restrictions on access to HPMS, every applicant must complete a Notice of Intent to Apply as described in the HPMS memo dated October 10, 2008. This includes current contractors seeking to expand their organization's service area, and current contractors adding a Special Needs Plan (SNP) or an Employer Group/Union-Sponsored Waiver Plan (EGWP) to their existing contract.

The Notice of Intent to Apply provides us with critical information for generating a pending contract number and providing User ID connectivity. Submitting a Notice of Intent to Apply does not bind that organization to submit an application for the following year. However, without a pending contract number and completed CMS User ID connectivity, an organization will not be able to access the appropriate modules in HPMS to complete the application materials. We propose codifying in § 422.501 and § 423.502 our existing guidance that initial applicants and existing contractors seeking to expand complete a nonbinding Notice of Intent to Apply.

2. Application Requirements (§ 422.501(c) and § 423.502(c)) and Evaluation and Determination Procedures for Determining Whether Applicants Are Qualified for a Contract Under Parts C and D (§ 422.502 and § 423.503)

Subpart K of Part 422 and subpart K of Part 423 set forth the requirements for contracts with MA organizations and Part D sponsors, respectively, including application procedures. Section 1860D-12(b)(3) of the Act states that we must apply certain specified provisions of section 1857 of the Act including the procedures for termination in section 1857(h) of the Act in the same manner as they apply to contracts under section 1857(a) of the Act. Therefore, we are making a single proposal that applies to both MA organizations and Part D sponsors related to our application evaluation procedures and appeals of our determinations regarding applications.

During the first four years of the Medicare Advantage and Part D programs, several unsuccessful applicants contested our denial of their applications for MA organization or Part D sponsor contracts. At hearings, some of those applicants were successful in arguing that the regulations were not clear in stating that an applicant needed

to demonstrate that it met all program requirements to qualify for a contract. Accordingly, we are proposing to revise § 422.502 and § 423.503 to make it explicit that we will approve only those applications that demonstrate that they meet all (not substantially all) Part C and D program requirements.

The application requirements and evaluation and determination procedures for MA organizations and Part D sponsors are set forth in subpart K of Parts 422 and 423, respectively. The application process in each instance requires an applicant to submit for CMS review a combination of attestations that it will comply with stated program requirements, as well as contracts with organizations the applicant has contracted with to perform key Part C or D functions, evidence of the applicant's risk-bearing licenses, and data documenting that the applicant can provide its members access to Part C and D services consistent with the programs' requirements. As we have proposed to clarify at § 422.501(c)(1) and (2), § 422.502(a)(2), § 423.502(c)(1) and (2), and § 423.503(a)(2), we require that applicants demonstrate that they meet all requirements outlined in the MA organization and Part D sponsor applications.

Under the current regulations at § 422.502(a)(1) and § 423.503 (a)(1), we evaluate an entity's application on the basis of information contained in the application itself and any additional information that we obtain through onsite visits, publicly available information, and any other appropriate procedures. We propose to simplify and clarify the process by modifying § 422.502(a)(1) and § 423.503(a)(1) and limiting the evaluation of an entity's application to information contained in the application and any additional information that we obtain through onsite visits. Limiting our review to this information ensures that we will afford all applicants (numbering in the hundreds each of the last four years) a fair and consistent review of their qualifications. Organizations can be assured that we will not consider additional sources of information regarding one applicant's qualifications that we do not consider for others.

We are also proposing a clarification of our authority to decline to consider application materials submitted after the expiration of the 10-day period following our issuance of a notice of intent to deny an organization's contract qualification application. Under § 422.502(c) and § 423.503(c), we notify applicants of our determination on the application and the basis for the

determination. If the applicant does not appear qualified to contract as an MA organization or Part D sponsor and has not provided enough information to permit us to evaluate the application, the applicant receives a notice of intent to deny the application and a summary for the basis for the finding. As provided in § 422.502(c)(2) and § 423.503(c)(2), within 10 days from the date of the notice, the applicant can respond in writing to the issues or other matters that were the basis for our findings and revise its application to correct any deficiencies.

The purpose of the proposed regulatory change is to clarify that information submitted after 10 days from the notice will under no circumstances be reviewed for the purpose of approving an application. Further, consistent with the proposed revisions to § 422.650(b)(2) and § 423.660(b)(2), which are discussed elsewhere in this proposed rule, the applicant would not be permitted to submit additional revised application material to the Hearing Officer for review should the applicant elect to appeal the denial of its application. To allow for the submission and review of such information as part of the hearing would, in effect, extend the deadline for submitting an approvable application. Moreover, the proposed change would further clarify the standard for the disposition of applications for which either revisions are not provided within the 10 days or are inadequate.

Specifically, we propose to clarify § 422.502(c)(2) and § 423.503(c)(2) by adding a new paragraph (iii) to establish that if we do not receive a revised application within 10 days from the date of the intent to deny notice, or if after timely submission of a revised application the applicant still appears unqualified to contract as an MA organization or Part D sponsor and/or has not provided enough information to allow us to evaluate the application, we will deny the application.

3. Deny Contract Qualification Applications Based on Past Contract Performance (§ 422.750 and § 423.750)

As described in § 422.502(b) and § 423.503(b), we may deny an application based on the applicant's failure to comply with the terms of a prior contract with CMS even if the applicant currently meets all of the application requirements. However, we propose to modify § 422.502(b) and § 423.503(b) to state that we will review past performance across all of the contracts held by the applicant. The provision as currently drafted mentions a "prior contract" with CMS. Today,

contracts are “evergreen” and some organizations hold multiple MA and/or PDP sponsor contracts; therefore the concept of “prior contract” is outdated, as the prior performance issues could have occurred in any other contract currently or formerly held by an applicant. Therefore, we propose to revise the language in § 423.503(b) and § 422.502(b) to refer to “any current or prior contract” held by the organization, instead of the current language referring to a “previous year’s contract.” We also propose to clarify that the period that will be examined for past performance problems be limited to those identified by us during the 14 months prior to the date by which organizations must submit contract qualification applications to CMS. Fourteen months covers the time period from the start of the previous contract year through the time that applications are received for the next contract year.

Indicia of performance deficiencies that might lead us to conclude that an organization has failed to comply with a current or prior contract include, but are not limited to, poor performance ratings as displayed on the Medicare Options Compare and MPDPF web sites; receipt of requests for corrective action plans (CAPs) unrelated to an audit (as these types of CAPs generally involve direct beneficiary harm); and receipt of one or more other types of noncompliance notices from CMS (for example, notices of noncompliance or warning letters).

Additionally, as indicated by the changes to § 422.503(b), § 422.508(c), § 423.504(b), and § 423.508(e), we consider withdrawal of Part C or D operations from some or all of an organization’s newly contracted service area prior to the start of a benefit year (through mutual termination or otherwise) an indication of poor performance. Such a situation can arise when, for example, an organization, after it has signed its Medicare contract for the upcoming program year, loses a contract with a significant number or type of providers, jeopardizing its ability to provide its members adequate access to services. Also, an organization may suddenly face financial difficulties that threaten its ability to offer the benefit packages approved by CMS throughout the upcoming contract year. In such instances, we could simply leave the contract in place and take enforcement actions against the organization. Under such an approach, we would knowingly be permitting beneficiaries to remain enrolled with an organization that cannot effectively deliver the benefit. Instead, we act(s) in the best interests of the beneficiaries by

agreeing with the organization to terminate its contract and work(s) with the organization to make certain that beneficiaries receive uninterrupted access to Medicare services through another MA organization, PDP sponsor, or original Medicare. But for our acting to protect beneficiaries by agreeing to the contract termination, the organization would have faced significant compliance and enforcement actions once its failure to comply with program requirements became apparent. Also, the organization’s failure to conduct the proper due diligence on its contracted provider network or its finances represents itself a significant failure to have in place the administrative capability to operate a Medicare benefit plan worthy of compliance and enforcement actions. Accordingly, we believe(s) it is appropriate to consider an organization’s withdrawal from its contract prior to the start of the benefit year to be a strong indication of poor performance worthy of our consideration under § 422.750 and § 423.750.

We will review performance in accordance with these examples and other evidence of noncompliance, and will deny applications for initial contracts and service area expansions on the basis of noncompliant past performance. By specifically providing these examples and clarifying that we intend to exercise this authority, we believe that organizations will be motivated to enhance their compliance operations in order to avoid being out of compliance with program requirements, and this will significantly deter noncompliance leading to improved overall performance of organizations in the Part C and D programs.

4. Use of Data To Evaluate Continued Ability To Act as a Qualified Sponsoring Organization Under Parts C and D (§ 422.504, and § 423.505)

Sections 1857(e)(1) and 1860D–12(b)(3)(D) of the Act provide broad authority for the Secretary to add terms to the contracts with MA and Part D sponsors including terms that require the sponsor to provide the Secretary “with such information * * * as the Secretary may find necessary and appropriate.” Under that authority, we established § 422.516 and § 423.514, Reporting Requirements. Consistent with sections 1857(a) and 1860D–12(b)(1) of the Act, we established that we will oversee an MA organization’s and Part D sponsor’s continued compliance with Part C and Part D requirements under § 422.502(d)(1) and § 423.503(d)(1).

Some of the data acquired through § 422.516 and § 423.514 are used for the purpose of monitoring an organization’s or sponsor’s continued compliance with MA and/or Part D requirements. For example, under § 423.514(a)(5), Part D sponsors must have an effective procedure to develop, compile, evaluate, and report to CMS particular matters, such as low income subsidy (LIS) contract data, that we require. At the contract level, the sponsor’s LIS data is compared to our LIS data and a match rate is calculated. Under our guidance, the match rate between our data and the sponsor’s should exceed 95 percent. Sponsors who fail to exceed the 95 percent match rate are notified of their noncompliance and are expected to come into compliance with Part D instructions. In some instances, we may use an outlier analysis to determine a MA organization’s or Part D sponsor’s performance relative to industry standards established by the performance of all the other organizations and sponsors as described earlier in the preamble in our discussion of the development of our policies concerning the awarding, monitoring, and enforcement of Medicare contracts. For example, Part D plans report grievance data to CMS. We conduct outlier analysis to identify plans with the highest numbers of reported grievances for the purpose of identifying plans needing some type of compliance action. To conduct these types of outlier analysis, we usually perform the following steps:

- Develop a data distribution—data values ordered from low to high.
- Determine the maximum and minimum data values.
- Determine the range (maximum–minimum).
- Determine the outlier threshold—

When conducting an outlier analysis, we typically identify sponsors typically in the highest (or lowest) 5 percent of comparable sponsors (for example, compare PDPs to PDPs).

We also use the Performance Metrics (Plan Star Ratings), some of which are determined by relative ranking, for oversight and monitoring purposes to ensure plan quality. As stated in the 2009 Call Letter, organizations and sponsors with less than “good” ratings should expect to be the subject of our monitoring and compliance actions. Likewise, if after an analysis of data submitted under § 422.516 or § 423.514 an organization’s or sponsor’s performance is found to be an outlier based on relative ranking, the organization or sponsor may be considered out of compliance with MA and Part D requirements.

We propose to add paragraphs § 422.504(m)(1) and (2) and § 423.505(n)(1) and (2) to make explicit our existing authority to find organizations or sponsors out of compliance with MA and/or Part D requirements when the organization's or sponsor's performance fails to meet performance standards articulated in statutes, regulations, and guidance or when an organization's or sponsor's performance represents an outlier relative to the performance of other organizations or sponsors.

5. Compliance Programs Under Parts C and D (§ 422.503(b)(4)(vi) and § 423.504(b)(4)(vi))

Section 1857(a) of the Act provides the Secretary with the authority to enter into contracts with MA organizations and section 1860D–12(b)(1) of the Act provides the Secretary with the authority to enter into contracts with PDP sponsors. The current regulatory provisions provide that any entity seeking to contract as an MA organization or PDP sponsor must have administrative and management arrangements satisfactory to us as demonstrated by (among other requirements) having a compliance plan that consists of seven basic elements. These seven elements of the compliance plan outline fundamental requirements such as written policies and procedures, a compliance officer and committee that is accountable to senior management, effective compliance training and communication, enforcement of disciplinary standards, and procedures for internal monitoring and auditing and ensuring prompt responses to detected offenses. In addition, a compliance plan must include measures to detect, correct, and prevent fraud, waste, and abuse.

Compliance programs have long been recognized as key to achieving adherence with contract requirements and to protecting against fraud, waste, and abuse. The recent focus on the importance of these programs has been heightened not only by CMS through our ongoing audit and oversight efforts but also by several of our oversight bodies. For example, over the last several years, the U.S. Department of Health and Human Services Office of Inspector General (OIG) and the Government Accountability Office (GAO) have each focused specific oversight efforts on MA organizations' and PDP sponsors' compliance programs and have requested that we take actions to evaluate and oversee these programs to ensure entities have effective programs in place. Similarly, like the Medicare Part C and D

programs, other state programs, including the State of New York Medicaid program, now require effective compliance programs as a condition of participation.

Our recent experience is that some sponsoring organizations have instituted a compliance plan that appears to meet the minimum requirements of our regulations, but may not have an effective compliance program. Other sponsoring organizations seem to legitimately grapple with how best to implement the regulatory requirements within their organization and which particular actions on their part will meet our requirements.

We propose to stress the importance of sponsoring organization's implementing and maintaining robust compliance programs by modifying the language at § 422.503(b)(4)(vi) and § 423.504(b)(4)(vi) to explicitly provide clarification as to what will constitute an "effective" compliance program prior to contracting with CMS. We are also proposing to further clarify existing policy by modifying current language and/or adding language in support of each of the elements of an effective compliance plan in order to assist sponsoring organizations with implementing more effective compliance programs.

In the first element concerning the overall requirement to have written policies and procedures, we are proposing to further clarify existing policy by adding language at § 422.503(b)(4)(vi)(A) and § 423.504(b)(4)(vi)(A) that these policies must describe compliance expectations as embodied in the standards of conduct, implement the operations of the compliance program, provide guidance to others, identify how to communicate compliance issues to compliance personnel, describe how compliance issues are investigated and resolved and include a policy of non-intimidation and non-retaliation.

In the second element concerning the requirement to have a compliance officer and committee accountable to senior management, we are proposing to further clarify existing policy by adding language at § 422.503(b)(4)(vi)(B) and § 423.504(b)(4)(vi)(B) that the compliance officer and committee must periodically report directly to the governing body (for example, Board of Directors) and that body must be knowledgeable about the compliance program and exercise reasonable oversight over the implementation and effectiveness of the program. The governing body's direct involvement with and oversight of the compliance program is instrumental in fulfilling this

requirement and achieving an effective compliance program. Our recent experience with some sponsoring organizations has indicated that Boards of Directors may not be sufficiently aware or may have limited information about their organization's compliance programs or compliance issues. In deciding how often the compliance officer and committee must directly report to the Board of Directors, sponsoring organizations must consider many factors, including but not limited to: the size of the organization, the number of compliance problems, whether there is an emergency that calls for the Board's attention, and whether the sponsoring organization is under an intermediate sanction. Our proposed language further clarifies existing policy related to this requirement for senior management to be sufficiently engaged, informed, and to exercise appropriate governance over the organization's compliance program.

In the third element concerning the requirement to have effective training and education, we are proposing to further clarify existing policy by adding language at § 422.503(b)(4)(vi)(C) and § 423.504(b)(4)(vi)(C) that includes several key groups and individuals (the chief executive or other senior administrator, managers, and governing body members) among the sponsoring organization's employees that are required to have compliance training and education. Because these employees have specific governing and oversight responsibilities, we believe it is important to clarify these requirements. We are proposing to further clarify existing policy by adding language that also clarifies that this training must occur at a minimum annually and must be made a part of the orientation for a new employee, new first tier, downstream and related entities, and new appointment to a chief executive, manager or governing body member.

In the December 5, 2007 **Federal Register**, we published the "Medicare Program; Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals and Intermediate Sanctions Process" final rule (72 FR 68700). In the December 5, 2007 final rule, we established that compliance plans for sponsoring organizations must include training and education and effective lines of communication between the compliance officer and the sponsoring organization's employees, managers, and directors as well as their first tier, downstream, and related entities.

Since publication of the December 5, 2007 final rule, it has become apparent that application of training about fraud,

waste, and abuse to the MA organizations' first tier, downstream, and related entities may be redundant of the certification made when these entities submit enrollment applications to become Medicare physician and non-physician practitioners, institutional providers, and suppliers. Medicare practitioner enrollment applications require that applicants certify to having read and understood the Penalties for Falsifying Information contained in the application and that the applicant will not present or cause to present a false claim to Medicare. Section 422.204(b)(3) requires that basic benefits offered by MA organizations be offered through providers and suppliers who meet applicable requirements of Title XVIII and Part A of Title XI of the Act. Providers of services must have a provider agreement with us that permits them to provide services under original Medicare. Requiring an additional fraud, waste, and abuse certification as was clarified in the response to comments in the December 5, 2007 final rule imposes an additional unnecessary burden on these Medicare providers. Therefore, we are proposing to modify this paragraph to state that providers who have met this requirement through enrollment into the Medicare program are deemed to have met this training and education requirement. More specifically, we are proposing to clarify existing policy by adding language at § 422.503(b)(4)(vi)(C) specifying that MA organizations whose first tier, downstream, and related entities have met the fraud, waste and abuse certification requirements are deemed to have met the training and educational requirements for fraud, waste, and abuse. We are not proposing similar deeming language at § 423.504(b)(4)(vi)(C) because these certification requirements do not currently apply to Part D first tier, downstream, or related entities.

The current requirement for training in fraud, waste, and abuse of first tier, downstream, and related entities creates another potential problem. A particular pharmacy or other provider may contract with dozens of MA or PDP plans, each of which is required by the existing language, read literally, to provide the required training to the pharmacy, or other provider, and its staff. Clearly, we do not intend to require duplicative training. We therefore seek comment on whether or how best to rephrase the existing language to clarify this point, while still ensuring that our requirement is met with respect to each first tier, downstream, and related entity. One

option might be that the plan sponsor "assures" or "obtain an assurance" that the first tier, downstream, and related entity has received such training, but this leaves open the issue of who would then actually provide the needed training. We understand that some plans are arranging fraud, waste, and abuse collaborative training efforts and we welcome this. Another option might be to leave existing language unchanged, but issue interpretive guidance on this point. We request workable suggestions to assure that our objective is met, while eliminating unnecessary duplication.

In the fourth element concerning the requirement to have effective lines of communication, we are proposing to further clarify existing policy by adding language at § 422.503(b)(4)(vi)(D) and § 423.504(b)(4)(vi)(D) that requires that these lines of communication are confidential and accessible to all and allow for compliance issues to be reported anonymously and in good faith as issues are identified.

In the fifth element concerning the requirement to have enforcement of standards through well-publicized disciplinary guidelines, we are proposing to further clarify existing policy by adding language at § 422.503(b)(4)(vi)(E) and § 423.504(b)(4)(vi)(E) that more specifically describes that these guidelines must be implemented to include policies that articulate expectations for reporting issues and their resolution, identify noncompliance or unethical behavior, and provide for timely, consistent and effective enforcement of the standards when noncompliance or unethical behavior is detected.

In the sixth element concerning the requirement to have procedures for internal monitoring and auditing, we are proposing to further clarify existing policy by modifying the current language at § 422.503(b)(4)(vi)(F) and § 423.504(b)(4)(vi)(F) to more specifically describe that an effective system for routine monitoring and identification of compliance risks includes internal monitoring and audits and, as appropriate, external audits, in order to evaluate the organization's compliance with our requirements and overall effectiveness of the compliance program. These audits should include the sponsoring organization's first tier entities.

In the seventh element concerning the requirement to have procedures for ensuring prompt response to detected offenses and development of CAPs, we are proposing to further clarify existing policy by modifying the current language at § 422.503(b)(4)(vi)(G) and

§ 423.504(b)(4)(vi)(G) to more specifically describe the implementation of a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence and ensuring ongoing compliance with our requirements.

6. Network Adequacy of Coordinated Care and Network-Based Private Fee-for-Service Plans Under Part C (§ 422.112)

Section 1852(d)(1)(A) of the Act establishes that an organization offering an MA plan may select the providers from whom the benefits under the plan are provided so long as the organization makes such benefits available and accessible to each individual electing the plan within the plan service area with reasonable promptness and in a manner which ensures continuity in the provision of benefits. The requirements of section 1852(d)(1)(A) of the Act are implemented at § 422.112(a)(1), which provides that a coordinated care plan must maintain a network of appropriate providers that is sufficient to provide adequate access to covered services to meet the needs of the population served.

To determine if a proposed health care delivery network of an MA plan adequately makes health care services available and accessible, it has been our practice when initially approving and when reviewing to compare the proposed network with the prevailing community patterns of health care delivery in the service area of the plan. We have also used as a rough benchmark a maximum access to providers of 30 minutes/30 miles. We would be interested in comments regarding our proposed criteria for developing standards for the network adequacy of MA plans. We are in the process of developing an automated system for reviewing network adequacy on a continuing basis based on the elements that we determine define community patterns of health care delivery. In this system, MAOs offering MA plans would submit data to us through the HPMS system specifying the access and availability of its proposed provider networks. This information would be analyzed and compared through electronic mapping software against our access standards for a given geographical area to confirm whether the proposed provider network meets our access and availability standards.

Given that we are developing this automated system, we believe it is

appropriate to more explicitly define how we determine network adequacy. To that end, we propose using our authority under section 1852(d)(1)(A) of the Act to include more specific criteria that we will apply in defining community patterns of care in order to determine if a network offered by an MA plan meets Medicare access and availability requirements. We also propose applying these more specific criteria to the proposed provider networks of both coordinated care and PFFS plans that are intending to meet Medicare access to services requirements, in whole or in part, through a network of direct contracting providers.

Our operational experience has demonstrated that the concept of community patterns of health care delivery provides a useful industry standard benchmark for measuring a proposed provider network because it allows for varying geographical and regional conditions to be taken into consideration. For example, plans operating in rural rather than urban counties will necessarily face different market conditions in terms of the number and specialties of providers available and their willingness to contract with the plan.

However, given the lack of specificity regarding how we determine if a given provider network meets Medicare access and availability requirements in § 422.112(a)(1) as currently drafted, we believe it is important to amend that section of our regulations to describe how we will include the elements of the prevailing community patterns of health care delivery in its evaluations of provider networks. We believe the proposed changes will make the standards of community patterns of care more transparent and consistent across the country. The proposed changes are consistent with the elements that will be used by the automated system we are developing to assess network adequacy.

Specifically, we propose to add paragraph (a)(10) to amend § 422.112 to specify the factors comprising community patterns of health care delivery that we will use as a benchmark in evaluating a proposed MA plan health care delivery network. Under proposed § 422.112(a)(10), these factors would include, but not be limited to—

- The number and geographical distribution of eligible health care providers available to potentially contract with an MAO to furnish plan covered services within the proposed service area of the MA plans;
- The prevailing market conditions in the service area of the MA plan.

Specifically, the number and distribution of health care providers contracting with other health care plans (both commercial and Medicare) operating in the service area of the plan;

- Whether the service area is comprised of rural or urban areas or some combination of the two;
- Whether the MA plan's proposed provider network meets Medicare time and distance standards for member access to health care providers including specialties; and
- Other factors that we determine to be relevant in setting a standard for an acceptable health care delivery network in a particular service area.

We plan to further define through subregulatory guidance (for example the Call Letter) how we will operationalize these provisions. For example, as previously noted, we have in the past used as a rough benchmark a maximum access to provider ratio of 30 minutes/30 miles to determine "network adequacy." We solicit comment on whether these regulatory provisions are sufficiently clear, and whether clarification should be provided through regulation or subregulatory guidance, such as the annual Call Letter.

7. Deemable Program Requirements Under Parts C and D (§ 422.156(b)(7), § 422.156(f), § 423.165(b), and § 423.165(f))

We are proposing to clarify which regulatory requirements are "deemable" for MA organizations that offer prescription drug benefit programs. Sections 1852(e)(4) and 1860D-4(j) of the Act provide that we can authorize approved accrediting organizations (AOs) to accredit MA organizations and Part D sponsors, and deem such entities to have met our program requirements, as long as the standards the AO uses to evaluate the performance of the organizations and plan sponsors meet or exceed our own performance assessment standards. The statute also dictates which performance standards we can allow an AO to evaluate in the place of CMS. Those standards that we permit AOs to survey for, rather than CMS, are referred to as "deemable" program requirements.

The current regulations state that the Part D prescription drug benefit program is a deemable requirement for MA organizations that offer prescription drug benefits. We believe that this language does not precisely reflect the requirements that are listed as deemable in the statute. Therefore, we are proposing to modify § 422.156(b)(7) to refer to the list of deemable requirements for Part D sponsors set out at § 423.165(b)(1) through (b)(3), as we

believe this cross reference is a more accurate reflection of the specific program requirements that are deemable per section 1860D-4(j) of the Act for MA organizations that offer prescription drug benefits.

In § 422.156(f) and § 423.165(f), we are proposing to clarify the extent of our authority under the deeming program. The regulation currently states that we retain our authority to initiate enforcement actions against MA organizations or Part D sponsors that we determine, on the basis of its own survey, or the survey of an accrediting organization, no longer meet the Medicare requirements for which deemed status was granted. We believe that this language is unduly limiting and does not comport with the statute. Section 1852(e)(4)(D) of the Act states nothing in section 1852(e)(4) of the Act shall be construed to limit our authority under section 1857 of the Act, which encompasses much more than enforcement actions. Therefore, we are proposing to revise the language in § 422.156(f) and § 423.165(f) to more closely match the authority granted by the statute, which is to state that we retain authority to impose intermediate sanctions and civil money penalties (CMPs), initiate contract terminations, and perform evaluations and audits of an organization's records, facilities and operations, notwithstanding the deeming provisions.

We plan to further define through subregulatory guidance how we will operationalize these provisions. We solicit comment on whether these regulatory provisions provide sufficient clarity. If not, we solicit comment on whether clarification should be provided through regulation or subregulatory guidance, such as the annual Call Letter.

In § 423.165(b), we are proposing to delete paragraph (b)(4) from the items listed as deemable program requirements. The regulation currently states that a program to protect against fraud, waste, and abuse is a deemable program requirement. We believe that including this in the list of deemable requirements was an error, as the statute does not list a program to protect against fraud, waste, and abuse as one of the programmatic areas that is deemable. Therefore, we are proposing to remove programs to protect against fraud, waste, and abuse from the list of deemable programmatic requirements.

8. Modify the Corrective Action Plan (CAP) Process as it Relates to Procedures for Termination and Nonrenewal of a Part C or D Contract by CMS (§ 422.506(b)(3), § 422.510(c)(1), § 423.507(b)(3), and § 423.509(c)(1))

Sections 1857(h) and 1860D–12(b)(3)(F) of the Act provide that the Secretary may terminate a contract with an MA organization or PDP sponsor in accordance with formal investigation and compliance procedures established by the Secretary under which the sponsoring organizations are to be provided with reasonable notice and opportunity for hearing and reasonable opportunity to develop and implement a CAP to correct the deficiencies that were the initial basis for termination prior to terminating the contract. These statutory provisions further provide, under sections 1857(h)(2) and 1860D–12(b)(3)(F) of the Act, that these procedures shall not apply if the Secretary determines that a delay in termination, resulting from compliance with these procedures prior to termination, would pose an imminent and serious risk to the health of individuals enrolled with the sponsoring organization.

Under this statutory authority, we issued the December 5, 2007 final rule that detailed timeframes for the development and implementation of CAPs prior to an issuance of a notice of intent to terminate or nonrenew a CMS contract. These regulations, codified at § 422.506(b)(3), § 422.510(c)(1), § 423.507(b)(3), and § 423.509(c)(1), currently require us to provide sponsoring organizations with 45 calendar days from the date of our request, to develop and submit a CAP prior to CMS issuing a notice of intent to terminate or nonrenew a contract to the sponsoring organization. In addition, the current regulations provide that if, after our review, this first CAP submission is determined unacceptable, the sponsoring organization will be provided an additional 30 calendar days to submit a revised CAP to CMS for review. Under these current provisions, once we determine the CAP acceptable, we are then required to notify the sponsoring organization of the deadline by which the CAP must be fully implemented. We must then assess whether successful implementation occurred. It is only after exercising these protracted procedures that we may issue a notice of intent to terminate or nonrenew a contract to the sponsoring organization in instances when we determine that successful implementation of the CAP has not

occurred and/or the deficiencies have not been fully corrected.

Since the implementation of the December 5, 2007 final rule, we have determined that some modification is required of our overall approach to our compliance procedures, particularly in situations when serious and/or repeated compliance deficiencies are identified. More specifically, we have concluded that the compliance procedures and timeframes set forth in § 422.506(b)(3), § 422.510(c)(1), § 423.507(b)(3), and § 423.509(c)(1) related to notice and opportunity to develop and implement corrective actions could be improved to more effectively assist us and sponsoring organizations in achieving timely, efficient, and effective correction of identified underlying contract compliance deficiencies. These current compliance procedures require us to focus our internal oversight resources and expertise on reviewing and approving “how” sponsoring organizations will correct their deficiencies rather than utilizing our resources and expertise more effectively and efficiently to review information submitted by sponsoring organizations to determine if the underlying deficiencies have actually been corrected. For example, if the deficiency cited was for misclassification of appeals versus grievances, current practice requires a sponsoring organization to develop a written plan on how it will fix the misclassification problem. Then the sponsoring organization must submit the plan to us for review and approval before it would be allowed to implement the plan. Rather than focusing on the plan or process that the sponsoring organization developed, we instead, should focus on reviewing data to determine if the sponsoring organization has actually fixed the problem and is classifying appeals and grievances appropriately.

Similarly, under the current compliance procedures, sponsoring organizations potentially expend significant resources and expertise responding to requests from us for plans about how they will correct deficiencies as opposed to expending efforts on correcting the deficiencies identified by us and providing sufficient evidence that the identified deficiencies have been corrected. Given that sponsoring organizations have varying business models, levels of resources, and expertise, it is particularly challenging for us to be the decision-maker as to whether one operational plan of correction under a particular operational business model versus another will most effectively correct

identified deficiencies and achieve particular compliance outcomes.

Therefore, we believe our compliance procedures need to shift from focusing on the submission of plans for our review and approval that merely outline a process for how deficiencies will be corrected to a focus on requiring plans to demonstrate that particular outcomes have been achieved, for example, that deficiencies have actually been corrected. We are proposing to eliminate the existing language contained in regulations at § 422.506(b)(3), § 422.510(c)(1), § 423.507(b)(3), and § 423.509(c)(1) that requires CAPs to be submitted for our approval prior to us issuing a notice of intent to terminate or nonrenew a contract.

We are proposing instead to add new provisions at § 422.506(b)(3), § 422.510(c)(1), § 423.507(b)(3), and § 423.509(c)(1) that captures the outcome-oriented approach which is currently incorporated in our day-to-day ongoing contract compliance and oversight activities. Under this approach, we are proposing to add new provisions which state that before providing a notice of intent to terminate or nonrenew a contract, we will provide the sponsoring organization with a notice of its deficiencies and afford it the opportunity to develop and implement a CAP to correct these deficiencies. We are also proposing that the sponsoring organization is solely responsible for the identification, development, and implementation of its CAP and for demonstrating to us that the underlying deficiencies have been corrected within the time period afforded under the notice and opportunity for corrective action.

All sponsoring organizations are assigned a CMS account manager whose primary responsibility consists of day-to-day monitoring and oversight of that organization. In addition to these account management monitoring and oversight activities, we conduct other oversight activities based on data and information collected from sponsoring organizations and from other relevant sources. As a part of these ongoing overall monitoring and oversight activities, sponsoring organizations routinely receive written notification of their compliance deficiencies, including but not limited to, notices of noncompliance, warning notices, and requests for corrective actions. These ongoing contract monitoring and oversight processes are designed to proactively prevent, detect, and respond to compliance deficiencies at the lowest level of occurrence by providing sponsoring organizations with ongoing notification and information from CMS

about the current status of any identified compliance deficiencies that come to our attention and an opportunity to correct where appropriate. As a result, in many instances sponsoring organizations will receive written notification of noncompliance and opportunities to correct any deficiencies arising from the above-described day-to-day monitoring and oversight procedures. Therefore, in most cases the sponsoring organization will have been made fully aware of its deficiencies before CMS provides it with the notice and opportunity to implement a CAP that must be afforded prior to CMS issuing a notice of intent to terminate or nonrenew a contract under sections 1857(h) and 1860D–12(b)(3)(F) of the Act.

In addition to these proposals, we are proposing to amend the existing language at § 422.506(b)(3), § 422.510(c)(1), § 423.507(b)(3), and § 423.509(c)(1) that sets forth the specific timeframes afforded sponsoring organizations for the development and implementation of a CAP prior to CMS issuing a notice of intent to terminate or nonrenew.

Based on our experience under our ongoing contract compliance and oversight processes and our new outcome-oriented approaches to contract oversight and compliance, we have concluded that affording sponsoring organizations at least 30 calendar days to develop and implement a CAP prior to issuing the notice of intent to terminate or nonrenew is a sufficiently reasonable opportunity under the statutory authority afforded. We will consider the nature and extent of the particular compliance deficiencies and other relevant factors such as whether or not the deficiencies are isolated or repeated and longstanding, and whether or not the entity has been afforded a prior notice and opportunity to correct in reaching a decision whether it may be appropriate for the MAO or Part D Sponsor to be afforded more than 30 days to correct the identified deficiencies.

Thus, we are proposing to amend § 422.506(b)(3), § 422.510(c)(1), § 423.507(b)(3), and § 423.509(c)(1) to afford sponsoring organizations at least 30 calendar days to fully implement a CAP and to demonstrate to CMS that the underlying deficiencies have been corrected.

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

Sections 1857(g) and 1860D–12(b)(3)(E) of the Act provide the Secretary the ability to impose intermediate sanctions on sponsoring organizations. Intermediate sanctions under these statutory provisions consist of suspension of enrollment, suspension of payment and CMPs. Sections 1857(g)(2)(B) and 1860D–12(b)(3)(E) of the Act that specifically govern enrollment suspensions require the intermediate sanctions to remain in place until the Secretary is satisfied that the basis for the sanction determination has been corrected and is not likely to recur. Additionally, under sections 1857(e)(1) and 1860D–12(b)(3)(D) of the Act, sponsoring organizations are required to provide the Secretary with such information as the Secretary may find necessary and appropriate. Current regulations governing intermediate sanctions are contained in Subpart O of parts 422 and 423. Sections 422.756 and 423.756 provide specific procedures for imposing intermediate sanctions and CMPs, and include provisions outlining the duration of the sanction.

Existing regulations at § 422.756(d)(3) and § 423.756(d)(3) incorporate the statutory standard by providing that the sanction remains in effect until we notify the sponsoring organization that we are satisfied that the basis for imposing the sanction has been corrected and is not likely to recur. Based on recent experience, it has been difficult at times for us to make the determination to lift a sanction. For example, when we impose an enrollment sanction on a sponsoring organization because it has failed to comply with enrollment and disenrollment requirements, it is very difficult for us to conclude that the sponsoring organization's enrollment deficiencies have been corrected and are not likely to recur when the organization is not permitted to enroll members. Difficulties also arise when the sponsoring organization attempts to fix deficiencies with highly technical internal business processes. In order to assist us in making the determination that the deficiencies have been corrected and are not likely to recur, we need to have greater flexibilities at our disposal.

We are proposing two changes to the regulation that provide additional flexibilities to assist us in making the determination to lift a sanction. First, we are proposing that we may require the sponsoring organization to hire an

independent auditor to provide us with additional information to determine if the deficiencies upon which the sanction was based have actually been corrected and are not likely to recur. The independent auditor would be hired by the sponsoring organization and work in accordance with our specifications in order to provide accurate and reliable information to CMS.

In making a determination to lift sanctions, we often must rely on either self-disclosed information from the sanctioned sponsoring organization, CMS data, some of which is also self-disclosed, or we must attempt to engage in a process to independently verify that the underlying deficiencies have been corrected and are not likely to recur. Given our experience with the nature and extent of some compliance deficiencies (for example, those caused by information technology system deficiencies or lack of adequate internal controls) and the need to obtain the level of skill and experience necessary to conduct an exhaustive audit and verification of the correction of these deficiencies, we have concluded that an independent auditor hired by the sponsoring organization would be beneficial for both the sponsoring organization and CMS. This proposal is consistent with our statutory authority which requires sponsoring organizations to provide information to us when we deem it is necessary and appropriate. An independent auditor, who is familiar with the processes of the sanctioned sponsoring organization, may be able to provide CMS with important information that we may use to help us make a more timely decision as to when to lift a sanction.

A similar approach is used by the HHS Office of Inspector General (OIG) in their Corporate Integrity Agreements and/or Self-Disclosure Protocol processes. The OIG often negotiates compliance obligations with health care providers and other entities as part of the settlement of Federal health care program investigations. A provider or entity consents to these obligations as part of the civil settlement and in exchange for the OIG's agreement not to seek an exclusion of that health care provider or entity from participation in Medicare, Medicaid, and other Federal health care programs. The typical terms of a comprehensive OIG corporate integrity agreement include the requirement for the provider to retain an independent review organization to provide independent validation and verification of adherence to Medicare requirements in relevant areas where

the provider has been found to be noncompliant.

We do not intend to require all sponsoring organizations that are under intermediate sanctions to hire an independent auditor because not all determinations will require the expertise of an independent auditor. However, there are situations when the expertise of an independent auditor will be helpful and in those cases, we are proposing we be afforded the discretion to require that an auditor be hired by the sponsoring organization. For example, an independent auditor who specializes in complex information technology systems and who has knowledge of how the systems interact with each other to be compliant with our requirements may be helpful in those instances where an organization with enrollment and disenrollment processing systems has been sanctioned. This is an example of a situation where we would require the sponsoring organization to hire an independent auditor in order to assist in making the determination that the deficiencies that formed the basis of the sanction have been corrected and are not likely to recur.

We are also considering an alternative proposal whereby instead of providing us with the authority to require sponsoring organizations to engage an independent auditor, we would grant sponsoring organizations the discretion to hire an independent auditor to evaluate the organization's compliance with our requirements. We would afford the results of the independent auditor's review some weight in our determination of whether the bases for the sanction have been corrected and are not likely to recur. We invite comments from sponsors and the industry about this alternative proposal and suggestions on other options we could implement to accomplish the desired outcome.

At this time we are proposing to add language to § 422.756 and § 423.756 that would allow us to require that a sponsoring organization hire an independent auditor to provide us with additional information to determine if the deficiencies that are the basis for a sanction have been corrected and are not likely to recur. Under either this proposal or our alternative proposal, the independent auditor would work in accordance with our specifications and must be willing to attest that a complete and full independent review has been performed.

Next, we are proposing that in instances where an enrollment and/or marketing suspension has been imposed, we may determine that it is appropriate to subject the sponsoring

organization to a "test period" whereby the organization or sponsor will, for a limited time, engage in marketing activities and/or accept enrollments in order to assist us in making a determination as to whether the bases for the sanctions have been corrected and are not likely to recur. The basis for this proposal is that we have found that there is often not a satisfactory way to determine if marketing and/or enrollment problems have been corrected while a sanction is in place and no such activities are permitted. Similarly, sponsoring organizations also have experienced challenges in demonstrating to us that these kinds of deficiencies have been corrected and are not likely to recur while they are under marketing and/or enrollment sanctions. In order to lift intermediate sanctions as expeditiously as possible when the sponsoring organization has corrected the deficiencies and to protect beneficiaries if the deficiencies have not been fully corrected, this proposed provision will permit us to assess whether the deficiencies upon which the sanction was made have been corrected and are not likely to recur by conducting a test of the organizations or sponsor's processes. The specific requirements for the marketing and/or enrollment "test period" will be determined by considering numerous factors, including but not limited to: the size of the organization, the specific deficiencies, and the timeframe in which the "test period" is conducted.

This provision will benefit sponsoring organizations, beneficiaries, and CMS. Sponsoring organizations will have an effective way to demonstrate that a sanction should be lifted. Beneficiaries will be protected because we will have sufficient evidence that deficiencies have been corrected prior to lifting sanctions and we will be assured that the bases for the sanctions have been corrected and are not likely to recur.

Therefore, we are proposing to add language to § 422.756 and § 423.756 that in instances where marketing or enrollment or both intermediate sanctions have been imposed, we may determine, in our sole discretion, that it is appropriate to require the sponsoring organization to market and/or to accept enrollments for a limited time in order to assist us in making a determination as to whether the deficiencies that are the bases for the intermediate sanctions have been corrected and are not likely to recur. Following this time period, if we determine the deficiencies have not been corrected or are likely to recur, the intermediate sanction will remain in effect until such time that we are assured the deficiencies have been

corrected and are not likely to recur. The sponsoring organization would have not had a right to a hearing to challenge our determination to keep the sanction in effect.

In addition to the above proposed changes to § 422.756 and § 423.756, we are proposing to delete the existing provisions at § 422.756(c) and § 423.756(c) which currently detail the three types of intermediate sanctions that may be imposed pursuant to our authority under sections 1857(g)(2)(B) through (C) and 1860D–12(b)(3)(E) of the Act. These provisions are duplicative of the list of sanctions at § 422.750(a) and § 423.750(a) and are unnecessary. Due to this deletion, we are proposing to redesignate paragraphs (d) through (f) in § 422.756 and § 423.756 as paragraphs (c) through (e), respectively.

10. Termination of Contracts Under Parts C and D (§ 422.510(a) and § 423.509(a))

Sections 1857(c)(2) and 1860D–12(b)(3)(B) of the Act permit CMS to terminate a sponsoring organization's contract if the sponsoring organization—

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

Existing regulations at § 422.510(a)(6) through (12) and § 423.509(a)(6) through (11) provide a number of bases (in addition to the statutory bases) upon which a contract may be terminated. This list does not include every reason for which we have the authority to terminate a contract. For example, the list does not explicitly include a provision that provides that a failure by the sponsoring organization to comply with enrollment and disenrollment regulations may be a basis for CMS termination. However, sponsoring organizations must follow enrollment and disenrollment regulations and a failure to comply with these regulations may be a basis for terminating the sponsoring organization's contract because it would have failed substantially to carry out the terms of its contract as required by the Act. We are concerned that by not specifically including each and every requirement on this enumerated list, organizations may be under the mistaken impression that we cannot take an action to terminate (or non-renew) a contract, or sanction an organization, for a failure to comply with a requirement(s) that is not

enumerated. Therefore, we are proposing to delete the enumerated bases for termination contained at § 422.510(a)(6) through (12) and § 423.509(a)(6) through (11). In addition, we are proposing to revise § 422.510(a) and § 423.509(a) to separate the language into two paragraphs. The first paragraph, (a)(1), will list the statutory bases for termination under sections 1857(c)(2) and 1860D–12(b)(3)(B) of the Act which state that we may at any time terminate a contract if we determine that the sponsoring organization has: (i) Failed substantially to carry out the contract; (ii) is carrying out the contract in a manner inconsistent with the efficient and effective administration of this part; or (iii) no longer substantially meets the applicable conditions of this part. The second paragraph, (a)(2), will clarify—(i) that a sponsoring organization's failure to comply with our regulations, (ii) failure to meet performance standards; and/or (iii) participation in false, fraudulent, or abusive activities, may constitute a basis for CMS to determine that the sponsoring organization meets the requirements for contract termination in accordance with paragraph (a)(1).

More specifically, we are proposing to add new language to § 422.510(a)(2)(i) and § 423.509(a)(2)(i) that failure to comply with any of the regulatory requirements contained in Parts 422 or 423 may constitute a basis for CMS to determine that the sponsoring organization meets the requirements for contract termination in accordance with paragraph (a)(1). This new provision is intended to clarify that compliance with all regulations is necessary to remain a contracting organization with CMS and if the sponsoring organization's failure to comply with the regulations supports one or more of the bases for termination in paragraph (a)(1), then we may terminate the contract.

We are also proposing to add new language to § 422.510(a)(2)(ii) and § 423.509(a)(2)(ii) that failure to meet our performance expectations in carrying out the Part C and Part D regulatory requirements may constitute a basis for us to determine that the sponsoring organization meets the requirements for contract termination in accordance with proposed paragraph (a)(1). This includes when we determine that a sponsoring organization is out of compliance with a Medicare requirement because our analysis of data related to that sponsoring organization's performance indicates it is an outlier relative to that of other organizations.

In some instances, we may use an outlier analysis to determine a sponsor's

performance relative to industry standards that were established by looking at the performance of all sponsors across the program, as described earlier in the preamble in our discussion of the development of our policies concerning the awarding, monitoring, and enforcement of Medicare contracts. This strategy is part of a larger strategy to oversee the program using a data driven, risk-based, transparent approach. This information is used to monitor plan sponsor compliance and make plan-specific and programmatic decisions. As reflected in the proposed regulations, in addition to using these data for program-wide evaluations and assessments, these performance standards will continue to be used to make assessments concerning compliance with our requirements and, when deemed appropriate, to take CMS contract actions, including contract termination and nonrenewal.

Finally, in our proposed language we are retaining the authority to terminate a sponsoring organization that has committed or participated in false, fraudulent, or abusive activities as currently stated in § 422.510(a)(4) and § 423.509(a)(4). However, we are proposing to redesignate current § 422.510(a)(4) and § 423.509(a)(4) as § 422.510(a)(2)(iii) and § 423.509(a)(2)(iii), respectively, as such failures may also constitute a basis for us to determine that the sponsoring organization meets the requirements for contract termination in accordance with the proposed revisions to paragraph (a)(1).

In addition, we are proposing additional amended language to this regulation. The existing regulations permit us to terminate a contract only when we determine that a sponsoring organization's fraudulent activities concern the Medicare program. We believe that we should not be contracting with MA organizations and Part D sponsors who commit or participate in fraudulent activities related to any governmental health care programs. Therefore, we are proposing to amend this regulation to include false, fraudulent, or abusive activities affecting Medicaid, or other State or Federal health care programs.

In addition, existing regulations that govern termination at § 422.510(a)(5) and § 423.509(a)(5) provide that we may terminate a contract if the sponsoring organization experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent

that such a risk to health exists. This language incorporates the Secretary's authority under sections 1857(h)(2) and 1860D–12(b)(3)(F) of the Act to take an immediate termination if it is determined that a delay in termination, in order to comply with the CAP and appeal termination procedures, would pose an imminent and serious risk to the health of the individuals enrolled. We are proposing changes elsewhere in these regulations to our provisions governing expedited terminations. Therefore, we are proposing to delete the regulatory text contained at § 422.510(a)(5) and § 423.509(a)(5). Recognizing that it is not possible to enumerate every reason for which we have the authority to terminate a contract, we believe we have reached a good balance between providing sufficient regulatory detail and preserving administrative flexibility. When regulatory provisions require further clarification, we plan to further define through subregulatory guidance how we would operationalize these provisions. We have historically used our manual chapters, reporting requirements, and marketing guidelines to indicate how we measure compliance with our performance requirements and what we consider acceptable practice. We solicit comment on whether these regulatory provisions provide sufficient clarity. If not, we solicit comment on whether clarification should be provided through regulation or subregulatory guidance, such as the annual Call Letter or our Manual.

11. Request for Hearing Under Parts C and D (§ 422.662 and § 423.651)

Sections 1857(c) and 1860D–12 of the Act permit us to terminate contracts with sponsoring organizations. Current regulations at § 422.662(a) and § 423.651(a) governing the hearing procedures require sponsoring organizations to file a request for a hearing on contract determinations with the Hearing Officer and to also file it with "any CMS office." This procedure is ineffective and inefficient because it is likely to result in a request for hearing not being received by the appropriate officials within CMS. Consequently, we are proposing a modification in the language contained at § 422.662(a) and § 423.651(a) to state that the sponsoring organization must file the request for a hearing in accordance with the requirements specified in the notice of the contract determination or intermediate sanction, thus ensuring that the proper officials within CMS receive the request and can act upon the request in a timely manner.

We are also making a conforming change at § 422.662(b) and § 423.651(b) which govern the timeframes for filing the request for hearing to provide that the request must be filed within 15 calendar days after receipt of the notice (versus the existing language which states 15 calendar days from the “date CMS notifies” the sponsoring organization of its determination). This change is to ensure consistency with the way deadlines are described in other regulatory provisions of parts 422 and 423 governing contract determinations or the imposition of intermediate sanctions (including related appeals processes).

12. Burden of Proof, Standard of Proof, Standards of Review, and Conduct of Hearing (§ 422.660, § 423.650, § 422.676 and § 423.658)

Under the existing regulations at § 422.660(b), and § 423.650(b), when appealing a contract determination or an intermediate sanction, the sponsoring organization bears the burden of proof to demonstrate that it was in “substantial compliance” with our requirements on the “earliest of” following three dates:

- The date of the notice of contract determination or intermediate sanction.
- The date of the most recent onsite audit.
- The date of the alleged breach of the current contract or past substantial noncompliance as determined by CMS.

In practice, these existing standards of review (“substantial compliance” and “earliest of test”) have led to confusion among parties to the hearing and have been difficult for the Hearing Officer to apply. We have come to realize that the existing “substantial compliance” standard of review articulated at § 422.660(b), and § 423.650(b) does not reflect the nuances of the different legal standards provided in the Act for making contract determinations and imposing intermediate sanctions. For example, sections 1857(c)(2)(B) and 1860D–12(b)(3)(F) of the Act provide that the Secretary may terminate a contract if the Secretary finds that the sponsoring organization “has failed substantially to carry out the contract, is carrying out the contract in a manner inconsistent with the efficient and effective administration of this part, or no longer substantially meets the applicable conditions of this part.” Similarly, there is no reference to a substantial compliance standard in the bases available to CMS for imposing intermediate sanctions. Based on these nuances, we have determined that the application of the substantial compliance standard of review to all

appeals is unnecessarily confusing and may have led to unintended consequences in that it may have distorted review of the applicable statutory and regulatory requirements. Accordingly, we are proposing to delete “substantial compliance” as a standard of review.

In addition to the preceding, the “earliest of” test does not accurately reflect how and when we make our determinations for different contract actions or intermediate sanctions. For example, when making a determination as to whether or not we should enter into a contract with an applicant, we review all of the information that the applicant provides and decides whether it meets our standards according to § 422.501 and § 422.502 or § 423.502 and § 423.503. If the applicant does not meet those standards, then we will deny the application. During a hearing, it would be inappropriate for the applicant to insist that its application should be approved because it corrected its deficiencies after we issued a denial of the application. The “earliest of” test may create this mistaken impression because it provides that during a hearing the applicant must demonstrate that it was in “substantial compliance” with our requirements on the “earliest of” one of three dates. This creates confusion and imposes an unworkable time period for the applicant or sponsoring organization to demonstrate that it has met CMS standards. Therefore, we are also proposing to delete the existing regulations which provide for an “earliest of” test.

Finally, though the existing regulations explicitly state that the sponsoring organization bears the burden of proof, it does not provide the standard of proof that is to be applied by the hearing officer. We believe that the sponsoring organization bearing the burden of proof is appropriate since the purpose of the hearing is to provide the sponsoring organization an opportunity to appeal and dispute our contract determination or imposition of intermediate sanction. Therefore, we believe that no change is necessary concerning the burden of proof. In order, however, to more clearly articulate the standard of proof and standards of review we are proposing the following changes to our regulations.

First, we are clarifying the standard of proof that we believe applies to these appeals proceedings. It has been our experience that the hearing officer does appropriately use the preponderance of evidence standard when weighing the evidence at a hearing for an appeal of a CMS contract determination or

imposition of intermediate sanction. We believe, however, that it is important to explicitly state the standard of proof so as to provide as much clarity and consistency as possible for the Hearing Officers and the parties to a hearing. In addition, the preponderance of the evidence standard is consistent with the standard of proof used in Subparts T to Parts 422 and 423 which governs appeal proceedings for civil money penalties.

Second, we are addressing the use of a proper standard of review. The proposed standard of review that we believe applies to these appeal procedures is dependent on the type of contract determination or intermediate sanction. Our proposed revisions make explicit which standard of review is to be applied by the Hearing Officer to the three types of contract determinations identified at § 422.641(a) and § 423.641(a) and to intermediate sanctions identified at § 422.750 and § 423.750 by noting the different requirements for each type of action. Specifically, the proposed regulation clarifies that the standards of review are different for determinations involving Part C or D contract application qualifications, those involving the termination or non-renewal of a sponsoring organization’s contract, and those involving the imposition of intermediate sanctions. These separate and distinct standards of review are intended to reflect the inherent differences in the processes and standards we use to make each type of determination.

Therefore, we are proposing to delete the existing language contained at § 422.660(b) and § 423.650(b) and replace it with language which provides that the applicant or the sponsoring organization has the burden of proving by a preponderance of the evidence that our determination was inconsistent with the requirements of the applicable part. We specify that these requirements are § 422.501 and § 422.502 that governs the processes and standards for applicants for the MA program, § 423.502 and § 423.503 for applicants for the Part D program, § 422.506 or § 422.510 for MA contract determinations, § 423.507 or § 423.509 for Part D contract determinations, and § 422.752 or § 423.752 for intermediate sanctions.

Additionally, we propose to modify § 422.660(c) and § 423.660(c), which currently specify that the notice of any decision favorable to a Part C or D applicants appealing a determination that it is not qualified to enter into a contract with us must be issued by July 15th for the contract in question to be effective on January 1st of the following year. We propose changing the July 15th

deadline to September 1st. Over the past 4 years, we have found the July 15th deadline to be an unreasonable timeframe within which to complete the hearing process afforded denied applicants pursuant to Subpart N of Parts 422 and 423. September 1st allows sufficient time for an applicant to receive a decision issued by the CMS Hearing Officer on the status of its application and for us to contract with the applicant should the applicant receive a favorable decision.

Accordingly, we are also proposing to make the following conforming changes to § 422.660 and § 423.650.

- Revise the section headings for § 422.660 and § 423.650 to read “Right to a hearing, burden of proof, standard of proof, and standards of review” in order to conform with the section headings to our proposed changes.

- Add paragraph headings. We believe that these additions would improve the structure and readability of the proposed regulatory text.

- Correct the references in § 422.660(a)(1) and § 423.650(a)(1). Sections 422.660(a)(1) and 423.650(a)(1) currently state that a contract applicant that has been determined to be unqualified to enter into a contract with CMS under § 422.501 and § 423.503 respectively, is entitled to a hearing. The correct citations for the sections that we use when making a determination as to whether to enter into a contract with an applicant are § 422.501 and § 422.502 for Part C contracts and § 423.502 and § 423.503 for Part D contracts. Therefore, we are proposing to accurately reflect these references in the regulations by making a technical change which incorporates the appropriate and necessary citations by adding the reference § 422.502 to § 422.660(a)(1), and by adding the reference § 423.502 to § 423.650(a)(1).

- Make technical changes in § 422.660(a) and § 423.650(a). In paragraphs (a)(1) through (a)(4) of these sections, we are proposing to revise the terminology preceding the cross-reference (that is, change “pursuant to” to “in accordance with” or “under”), adding a section symbol before the section number, and completing the cross-reference by adding the phrase “of this part” after the section number.

Finally, we are also proposing to modify the existing regulations at § 422.676(d) and § 423.658(d) governing the conduct of the hearing. We are proposing to revise the language contained in § 422.676(d) and § 423.658(d) to provide that, consistent with the burden of proof, during the hearing the sponsoring organization bears the burden of being the first to

present its argument to the Hearing Officer according to any briefing schedule determined by the Hearing Officer. We believe that requiring the sponsoring organization to present its argument to the Hearing Officer first is appropriate since the basis for our determination is detailed in the notice of determination that is sent to the sponsoring organization. Since the purpose of the sponsoring organization’s appeal is to dispute our determination it seems appropriate that the sponsoring organization should first be required to present its argument as to why it believes the determination is incorrect or otherwise not supported prior to CMS’ putting on its case in support of its contract or intermediate sanction determination.

13. Expedited Contract Terminations Procedures (§ 422.510, § 423.509, § 422.664, § 423.652, § 422.644, and § 423.642) Under Parts C and D

Sections 1857(h)(2) and 1860D–12(b)(3)(F) of the Act provide the procedures requiring reasonable notice and opportunity to develop and implement a CAP and for a hearing shall not apply prior to termination if the Secretary determines that a delay in termination, resulting from compliance with these procedures would pose an imminent and serious risk to the health of individuals enrolled with the sponsoring organization. These kinds of terminations are referred to as “expedited terminations” under current regulations.

Sections 422.510(a)(4) and (5), and § 423.509(a)(4) and (5) currently provide two of these bases for expedited terminations. Under § 422.510(a)(4) and § 423.509(a)(4), we may terminate a contract when there is credible evidence that the sponsoring organization committed or participated in false, fraudulent, or abusive activities affecting the Medicare program. Under § 422.510(a)(5) and § 423.509(a)(5), we may terminate a contract when the sponsoring organization experiences financial difficulties so severe that its ability to make necessary health services available is impaired “to the point of posing an imminent and serious risk to the health of its enrollees or otherwise fails to make services available to the extent that such a risk to health exists”, thereby incorporating the expedited termination statutory language.

Termination procedures at § 422.510(c)(2) and § 423.509(c)(2) provide that if a contract is terminated under § 422.510(a)(4) or (a)(5), and § 423.509(a)(4) or (a)(5), the sponsoring organization will not have the opportunity to submit a CAP prior to

termination. Our notice of termination procedures also provide at § 422.510(b)(2)(i) and § 423.509(b)(2)(i) that, if a contract is terminated under § 422.510(a)(4) or (a)(5) and § 423.509(a)(4) or (a)(5), we will notify the sponsoring organization that its contract will be terminated on a date specified by CMS. Appeal procedures at § 422.664(b)(2) and § 423.652(b)(2) currently provide that a contract terminated under either of these bases will be terminated on the date specified by CMS and will not be postponed if a hearing is requested.

These current regulations governing expedited terminations do not adequately reflect the scope of the Secretary’s authority under section 1857(h)(2) and 1860D–12(b)(3)(F) of the Act. The Act does not limit the Secretary’s authority to effectuate expedited terminations solely based on the circumstances prescribed in § 422.510(a)(4) or (a)(5), and § 423.509(a)(4) or (a)(5) and therefore, these regulations are unduly limiting. If compliance with the CAP provisions and hearing procedures prior to termination would pose an imminent and serious risk to the health of individuals enrolled with the sponsoring organization, the Act permits us to terminate a contract without providing a right to a CAP or hearing prior to termination. While the current regulations provide several instances where such a determination would be appropriate, these are not the only instances where such a determination would need to be made to protect beneficiaries from imminent and serious risk to their health.

Therefore, we are proposing to delete the references to § 422.510(a)(4) or (a)(5) and § 423.509(a)(4) or (a)(5) as contained in the termination (§ 422.510(b)(2)(i), § 423.509(b)(2)(i), § 422.510(c)(2) and § 423.509(c)(2)) and in the appeal procedures (§ 422.664(b)(2) and § 423.652(b)(2)). More specifically, we are proposing to amend the termination procedures language of § 422.510(b)(2)(i) and § 423.509(b)(2)(i) to clarify that for terminations based on violations prescribed in § 422.510(a) and § 423.509(a), if we determine that a delay in termination, resulting from compliance with CAP and hearing procedures prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the sponsoring organization, the effective date of the termination will be specified, in writing by CMS. In addition, we are proposing to amend the termination procedures language at § 422.510(c)(2) and § 423.509(c)(2) to clarify that if we determine that a delay

in termination, resulting from compliance with the CAP procedures, would pose an imminent and serious risk to the health of the individuals enrolled with the MA organization or Part D sponsor, the MA organization or Part D sponsor will not be provided with an opportunity to develop and implement a CAP prior to termination. Lastly, we are proposing to amend the appeals procedures language at § 422.664(b)(2) and § 423.652(b)(2) to state that if we determine that a delay in termination, resulting from compliance with the notice and opportunity for hearing procedures, prior to termination, would pose an imminent and serious risk to the health of individuals enrolled with the MA organization or Part D sponsor, the date of termination will not be postponed if the MA organization or Part D sponsor requests a hearing.

It is important to note that our proposal to delete the references to § 422.510(a)(4) or (a)(5), and § 423.509(a)(4) or (a)(5) contained in the existing termination and appeal procedures should not be interpreted in any way to limit our ability under our statutory authority to expedite a termination when we determine that a sponsoring organization is experiencing severe financial difficulty, otherwise fails to make services available to the extent that such a risk to the health exists or when there is credible evidence that a sponsoring organization committed or participated in false, fraudulent, or abusive activities.

We are also making conforming changes (to ensure consistency of the proposed regulations) to the termination notice procedures contained in § 422.510(b) and § 423.509(b) and notice of contract determinations contained in § 422.644(c) and § 423.642(c) which reference the expedited termination bases. In § 422.510(b) and § 423.509(b), we are deleting the references to § 422.510(a)(4) or (a)(5), and § 423.509(a)(4) or (a)(5). In § 422.644(c) and § 423.642(c), we are deleting the references to § 422.510(a)(4) or (a)(5), and § 423.509(a)(4) or (a)(5) and replacing the language with the proposed language contained in § 422.510(b)(2)(i) and § 423.509(b)(2)(i).

14. Time and Place of Hearing Under Parts C and D (§ 422.670 and § 423.655)

Sections 1857(h)(1)(b) and 1860D–12(b)(3)(F) of the Act provide the procedures requiring reasonable notice and opportunity for hearing when we terminate a sponsoring organization's contract. Current regulations at § 422.670(b) and § 423.655(b) provide the Hearing Officer may, on his or her

own motion, or at the request of party, change the time and place for the hearing and may adjourn or postpone the hearing. Based on our experience with this process, we believe that both sponsoring organizations and we may need additional time to prepare for a hearing. Therefore, we are proposing to add language to § 422.670(b) and § 423.655(b) to state the sponsoring organization or we may request that the hearing date be postponed by filing a written request no later than 5 calendar days prior to the scheduled hearing, when either the sponsoring organization or CMS requests an extension, the Hearing Officer will provide a one-time 15 calendar day postponement, and additional postponements may be granted at the discretion of the Hearing Officer.

In addition, current regulations at § 422.670(a) and § 423.655(a) require that the CMS Hearing Officer schedule a hearing to review a contract determination or the imposition of an intermediate sanction within 30 calendar days from the "receipt of request for the hearing." We are proposing to change the language at § 422.670(a) and § 423.655(a) to provide that the CMS Hearing Officer schedule a hearing to review a contract determination or the imposition of an intermediate sanction within 30 calendar days after the "receipt of the request for the hearing." This change is to ensure consistency with the way deadlines are described in other regulatory provisions of parts 422 and 423 governing contract determinations or the imposition of intermediate sanctions (including related appeals processes).

15. Discovery Under Parts C and D (§ 422.682 and § 423.661)

Sections 1857(h)(1)(b) and 1860D–12(b)(3)(F) of the Act provide the procedures requiring reasonable notice and opportunity for hearing when we terminate a sponsoring organization's contract. The statute does not require a formal discovery process for CMS appeal procedures. In the December 5, 2007 final rule, we provided in § 422.682 and § 423.661 for a formal discovery process prior to hearing. However, based on our experience since the promulgation of this rule, we do not now believe a formal discovery process is necessary or appropriate for these kinds of proceedings. In addition, the existing timeframe in which the hearing normally must take place, 30 calendar days after request for a hearing, does not easily accommodate a formal discovery process.

Therefore, we are proposing to delete the formal discovery process contained in § 422.682 and § 423.661. Simultaneously, we need to ensure that both parties receive witness lists and relevant documents with enough time prior to the hearing while at the same time ensuring the hearing is conducted in a timely and orderly fashion.

Therefore, we are proposing to amend the regulations at § 422.682 and § 423.661. First, we propose to modify the existing regulations to change the titles of § 422.682 and § 423.661 from "Discovery" to "Witnesses and Documents" to reflect the changes made. Second, under this newly titled section, we are proposing to substitute new language which requires that witness lists and documents must be identified and exchanged at least 5 calendar days prior to the scheduled hearing. We believe this change more appropriately reflects what is necessary to meet the evidentiary needs of the parties by providing the parties with the appropriate amount of information in advance of the hearing to present their evidence and counter arguments.

Additionally, existing regulations at § 422.670(a)(2) and § 423.655(a)(2) currently provide that the Hearing Officer will notify the parties of the ability to conduct formal discovery. Because we are proposing to delete the formal discovery processes in § 422.682 and § 423.661, we are proposing to make a conforming change by deleting § 422.670(a)(2) and § 423.655(a)(2).

16. Review by the Administrator Under Parts C and D (§ 422.692(a) and § 423.666(a))

Sections 1857(h)(1)(b) and 1860D–12(b)(3)(F) of the Act provide the procedures requiring reasonable notice and opportunity for hearing when we terminate a sponsoring organization's contract. Our current regulations at § 422.692 and § 423.666 provide for a sponsoring organization to request review by the CMS Administrator of a hearing decision. These existing regulations provide that a sponsoring organization may request review by the Administrator within 15 calendar days of "receiving the hearing decision."

We are proposing to revise the language at § 422.692(a) and § 423.666(a) to provide that the sponsoring organization may request review by the Administrator within 15 calendar days after "receipt of the hearing decision." In addition, we are proposing to change the language at § 422.692(c) and § 423.666(c) governing the notification of Administrator determination to state that the Administrator must notify both parties

of his or her determination regarding review of the hearing decision within 30 calendar days after “receipt of the request for review” (versus the existing language which provides within 30 calendar days of “receiving the request for review”). These changes ensure consistency with the way deadlines are described in other regulatory provisions of Parts 422 and 423 governing contract determinations or the imposition of intermediate sanctions (including related appeals processes).

17. Reopening of an Initial Contract Determination or Decision of a Hearing Officer or the Administrator Under Parts C and D (§ 422.696 and § 423.668)

Sections 1857(h)(1)(b) and 1860D–12(b)(3)(F) of the Act provide the procedures requiring reasonable notice and opportunity for hearing when we terminate a sponsoring organization’s contract. Our current regulations at § 422.696 and § 423.668 govern the reopening of an initial contract determination or decision of a Hearing Officer or the Administrator. More specifically, existing regulations at § 422.696(a) and § 423.668(a) state that we may reopen and revise an “initial determination” upon our own motion. The term “initial determination” is not used elsewhere in Subpart N (Contract determinations and Appeals). Therefore, we are proposing to revise these regulations by replacing the language “initial determination” with “contract determination” in the section headings of § 422.696 and § 423.668 and in the text of § 422.696(a) and § 423.668(a).

18. Prohibition of MA and Part D Applications for 2 Years After a Mutual Termination (§ 422.503(b)(6) and § 423.504(b)(5))

The regulations in § 422.503(b)(6) and § 423.504(b)(5) currently provide that MA organizations and Part D sponsors that nonrenew contracts with CMS are considered unqualified to recontract with us for a period of 2 years, unless we identify circumstances that warrant special consideration. This is consistent with § 422.506(a)(4) and § 423.507(a)(3), which describe contract nonrenewal requirements and procedures. We interpret these provisions to apply to MA organizations and Part D sponsors that nonrenew all of their contracts with us in a given area for a given line of business (MA or Part D), thereby severing their contractual relationship with the Agency across all of their MA, Part D, or both lines of business in the area. We have not interpreted this provision to apply to an organization that, for instance, holds many MA contracts in an area but chooses to

nonrenew fewer than all of those contracts.

In practice, a voluntary nonrenewal of a contract by a Part D sponsor or MA organization is not dissimilar from an organization requesting and being granted a mutual termination of their contract under § 422.503 and § 423.508. The primary difference between the two events is often timing, whereby a nonrenewal request to take effect at the end of the current contract year must be received by us on or before the first Monday in June (the bid deadline), as specified in § 423.507(a)(2)(i) and § 422.506(a)(2)(i). Once an organization submits a bid, it can no longer voluntarily nonrenew its contract for the following year. Rather, the Part D sponsor or MA organization must request a mutual contract termination. The later in the year the organization requests such a mutual termination for the following contract year, the more disruptive and difficult the process becomes. Particularly, once the organization completes all of its contract renewal obligations, such as signing a new bid attestation and a contract with CMS, where applicable, we begin including the new plan offerings under the contract on our Web site and in print materials to inform beneficiaries about the opportunity to enroll in those plan offerings for the upcoming contract year. To request a mutual contract termination late in the year once such information has become publicly available, marketed to beneficiaries, and beneficiaries have been given the opportunity to enroll is to create significant disruption for us and beneficiaries. Similarly, even greater disruption results from mutual terminations requested to take effect during the course of a contract year.

Circumstances are sometimes such that the requesting MA organization or Part D sponsor is requesting the mutual termination because it realizes it would be significantly out of compliance with one or more program requirements should it keep the contract in place. Therefore, it is sometimes in the organization’s and our interest to execute the mutual termination. Nevertheless, the disruption is significant and completely the responsibility of the sponsor. Yet, currently the regulations are silent on whether the MA organization or Part D sponsor would be qualified to enter into new contracts with CMS in future years. We believe that a termination by mutual consent, which involves a termination by an MA organization or a Part D sponsor as well as by CMS, should be considered a termination of a contract for purposes of the 2-year ban on

entering into new contracts under section 1857(c)(4)(A) of the Act, which is incorporated for Part D under section 1860D–12(b)(3)(B) of the Act.

For these reasons, we are proposing that as a condition of the consent to a mutual termination, we will prohibit the MA organization or Part D sponsor from applying for new contracts or service area expansions for a period of 2 years, absent circumstances that warrant special consideration as provided under section 1857(c)(4)(A) of the Act. Such language would be incorporated into the mutual termination consent agreement to be signed by both parties.

Therefore, we are proposing to modify § 423.508 by adding paragraph (e), which states that as a condition of the consent to a mutual termination, we will require as a provision of the termination agreement language prohibiting the Part D sponsor from applying for new contracts or service area expansions for a period of 2 years, absent circumstances warranting special consideration. Similarly, in § 423.504(b), we propose to add a new paragraph (b)(6) stating that organizations may be qualified to apply for new contracts to the extent that they have not terminated a contract by mutual consent under which, as a condition of the consent, the Part D sponsor agreed that it was not eligible to apply for new contracts or service area expansions for a period of 2 years per § 423.508(e). To accomplish these changes, we propose to redesignate the current § 423.504(b)(6) to § 423.504(b)(7).

We propose to make the same modification to the MA regulations. Specifically, we are proposing to modify § 422.508 by adding paragraph (c), which states that as a condition of the consent to a mutual termination, we will require as a provision of the termination agreement language prohibiting the MA organization from applying for new contracts or service area expansions for a period of 2 years, absent circumstances warranting special consideration. Similarly, in section § 422.503(b), we propose to add a new paragraph (b)(7), stating that organizations may be qualified to apply for new contracts to the extent that they have not terminated a contract by mutual consent under which, as a condition of the consent, the MA organization agreed that it was not eligible to apply for new contracts or service area expansions for a period of 2 years per § 422.508(c).

B. Changes To Strengthen Beneficiary Protections

This section includes provisions aimed at strengthening beneficiary protections under Parts C and D. Under Part D, we address proposals in the area of eligibility and enrollment policy, transition period requirements, coordination of benefits policy, retroactive claims adjustment reimbursements and recoveries, and use of standardized technology. We also propose to revise Part D rules regarding timeframes and responsibility for making redeterminations.

Under Part C, we propose to revise our rules to—

- Authorize us to annually establish an overall annual cap on member cost sharing;
- Prohibit PPO, PFFS, and MSA plans from using compliance with voluntary prior notification procedures in determining cost-sharing amounts;
- Establish new requirements for organization determinations; and
- Offer two definitional revisions.

In the area of Parts C and D marketing, we continue to monitor plans that use independent agents and brokers to ensure sponsoring organizations adhere to CMS requirements. In this rule, we

solicit comments on options aimed at further protecting beneficiaries in this area. We also propose to strengthen our marketing requirements, distinguishing marketing materials from enrollee communications materials and mandating the use of standardized marketing material language and format to ensure clarity and accuracy among plan documents. We also clarify notice requirements, and propose that sponsoring organizations disclose information concerning the organization’s performance and compliance deficiencies to enable beneficiaries to make informed choices. This information is detailed in Table 2.

TABLE 2—PROVISIONS TO STRENGTHEN BENEFICIARY PROTECTIONS

Provision	Part 422		Part 423	
	Subpart	Section	Subpart	Section
Broker & Agent Requirements under Parts C and D	N/A	N/A	N/A	N/A.
Beneficiary Communications Materials under Parts C and D.	Subpart V	§ 422.2260, § 422.2262	Subpart V	§ 423.2260, § 423.2262.
Required Use of Standardized Model Materials under Parts C and D.	Subpart V	§ 422.2262	Subpart V	§ 423.2262.
Extend the mandatory minimum grace-period for failure to pay premiums.	Subpart B	§ 422.74	Subpart B	§ 423.44.
Maximum allowable out-of-pocket cost amount for Medicare Parts A and B services.	Subpart C	§ 422.100	N/A	N/A.
Maximum allowable cost sharing amount for Medicare Parts A and B services and prescription drugs.	Subpart C	§ 422.100	Subpart C	§ 423.104
Prohibition on prior notification by PPO, PFFS, and MSA plans.	Subpart A	§ 422.2, § 422.4, § 422.105(b).	N/A	N/A
Requirements for LIS eligibility: Expand the deeming period for LIS-eligible beneficiaries to cover at least 13 months.	N/A	N/A	Subpart P	§ 422.773(c)(2).
Expand auto-enrollment rules to entire LIS-eligible population.	N/A	N/A	Subpart B	§ 423.34
Special Enrollment Period (SEP) Policies	N/A	N/A	Subpart B	§ 423.38.
Transition Process	N/A	N/A	Subpart C	§ 423.120(b)(3).
Sponsor responsibility for retroactive claims adjustment reimbursements and recoveries.	N/A	N/A	Subpart J	§ 423.464.
Time Limits for Coordination of Benefits	N/A	N/A	Subpart J	§ 423.466.
Pharmacy use of Standard Technology (ID cards) under Part D.	N/A	N/A	Subpart C	§ 423.120.
Allow members in stand-alone Part D plans to be temporarily out of area for up to 12 months.	N/A	N/A	Subpart B	§ 423.44.
Prohibit mass SPAP reenrollments during plan year	N/A	N/A	Subpart J	§ 423.464(e).
Non-Renewal Public Notice 60-day non-renewal beneficiary notification requirement.	Subpart K	§ 422.506	Subpart K	§ 423.507.
Notice of Alternative Medicare Plans	Subpart K	§ 422.5(a)(2)(ii)	Subpart K	§ 423.507(2)(ii).
Timeframes and Responsibility for making Redeterminations under Part D.	N/A	N/A	Subpart M	§ 423.590.
Requirements for Requesting Organization Determinations.	Subpart M	§ 422.568	N/A	N/A.
Organization Determinations under Parts C	Subpart M	§ 422.566 & § 422.568	N/A	N/A.
Refine/clarify definitions related to authorized representatives.	Subpart M	§ 422.561, § 422.574 & § 422.624.	N/A	N/A.
Sponsors may be required to disclose to enrollees compliance and performance deficiencies.	Subpart C	§ 422.111(g)	Subpart C	§ 423.128(f).
Revise definition of “service area” to exclude facilities in which individuals are incarcerated.	Subpart A	§ 422.2	N/A	N/A.

1. Broker and Agent Requirements Under Parts C and D

Prior to January 1, 2006, beneficiaries could enroll in MA plans (then called

Medicare+Choice plans) at any time throughout the year, effective the first day of the next month. Under those circumstances, most MA plans were able to employ a full-time sales force.

Effective January 1, 2006, enrollment in MA plans and Part D prescription drug plans (PDPs) was limited to an annual coordinated election period in the fall, and in the case of MA plans only, the

open enrollment period during the first 3 months of the year. As a result, maintaining a full-time, year-round sales force became untenable for many organizations, leading to increasing reliance on independent agents and brokers to educate beneficiaries about their Medicare health care options and enroll them in their products.

In 2008, the Congress enacted the Medicare Improvements for Patients and Providers Act (Pub. L. 110–275) (MIPPA). In order to address concerns raised by reports of significant agent and broker misconduct in the market place, section 103 of MIPPA placed certain restrictions and limits on the marketing of MA plans and PDPs. Our objective in implementing the marketing requirements included in the MIPPA was to ensure that agent and broker compensation would not create financial incentives for agents and brokers to enroll Medicare beneficiaries in particular MA plans or PDPs based on considerations other than the best interests of the beneficiary.

In the September 18, 2008 **Federal Register**, we published an interim final rule with comment period (73 FR 54226) implementing the MIPPA compensation provisions. In the November 14, 2008 **Federal Register**, we published the Medicare Advantage & Prescription Drug Programs: Clarification of Compensation Plans interim final rule with comment period (73 FR 67406), which clarified and modified the September 18, 2008 rule in part because we believed that plans were misinterpreting certain provisions of the September 18, 2008 interim final rule. Because so little time has passed since the publication of these rules, we believe it is too soon to fully evaluate whether these changes involving agent compensation have achieved the MIPPA's goal of creating incentives for agents and brokers to assist beneficiaries with selecting plans based on their health care needs rather than on agent or broker financial interests.

We recognize the important role that agents and brokers play in assisting beneficiaries with accessing and understanding plan information, making informed choices, and enrolling them in Medicare health plans. However, we remain concerned about the inherent financial incentives independent agents and brokers have when selling Medicare products. For this reason, we are continuing to explore the most effective means of providing Medicare health plan and drug plan information and enrollment assistance in order to ensure that beneficiaries select the plan that best meets their needs, including whether additional changes are needed

in the requirements related to plan sponsors' use of agents and brokers.

Our overarching objective is that with any potential further limitations on independent agent and broker activity beneficiaries will continue to have the assistance they need to make health care choices best suited to their needs. We provide a number of tools, both through our print publications and our online resources (Medicare Options Compare, MPDPF, and Online Enrollment Center) to assist beneficiaries with their health care decisions, and we continuously seek to improve these tools. We are exploring whether State Health Insurance Assistance Programs (SHIPs) have the capacity to serve significantly more Medicare beneficiaries. We also are considering limiting the use of independent agents and brokers by MA organizations to certain times of the year, specifically, the open enrollment period (OEP) and annual enrollment period (AEP), or to selected groups of beneficiaries. Limiting the use of independent agents and brokers to the OEP and AEP or to a subset of beneficiaries would allow us to better focus our monitoring efforts throughout the year, while still recognizing the role independent agents and brokers play in assisting beneficiaries with obtaining and evaluating plan information (including year to year plan benefit changes), making informed choices, and enrolling in Medicare health plans.

While we are not proposing any changes at this time, we are seeking comments on the approaches discussed in this section, as well as other potential solutions to ensure that beneficiaries receive adequate assistance in understanding their choices and with enrollment, including potential alternative roles for agents and brokers. Any changes resulting from comments to this section will be implemented through future notice and comment rulemaking.

2. Beneficiary Communications Materials Under Parts C and D (§ 422.2260, § 422.2262, § 423.2260, and § 423.2262)

Section 1851(h) of the Act, which is made applicable to Part D in section 1860D–1(b)(1)(vi) of the Act, established requirements regarding the review and approval of marketing materials by MA organizations and PDP sponsors. Sections 422.2260 and 423.2260 of the regulations define marketing materials as informational materials targeted to Medicare beneficiaries which may include the following:

- General audience materials such as—
 - ++ General circulation brochures;

- ++ Newspapers;
- ++ Magazines;
- ++ Television;
- ++ Radio;
- ++ Billboards;
- ++ Yellow pages; or
- ++ The Internet.

- Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

- Presentation materials such as slides and charts.

- Promotional materials such as brochures or leaflets, including materials for circulation by third parties (for example, physicians or other providers);

- Membership communication materials such as—

- ++ Membership rules;
- ++ Subscriber agreements;
- ++ Member handbooks; and
- ++ Wallet card instructions to enrollees.

- Letters to members about—

- ++ Contractual changes;
- ++ Changes in providers;
- ++ Premiums;
- ++ Benefits, plan procedures, and membership; or
- ++ Claims processing activities.

Sections 422.2260, 422.2262, 423.2260, and 423.2262 codify requirements regarding CMS review and approval of marketing materials. Given a number of years of experience in implementing these processes under both the Part C and Part D programs, we have found that our definition of the term “marketing materials” is so broad as to encompass plan notification materials that are often either situational materials or beneficiary specific customized communications. As these materials are considered marketing materials, they are subject to our rules regarding review, distribution, and approval in § 422.2262 and § 423.2262. However, we have found that CMS Regional Office review and approval procedures for situational marketing materials should follow a separate review process determined by CMS. Materials that are beneficiary specific letters are not considered to be marketing materials such as—

- Part D explanations of benefits (EOBs);
- Notifications about claims processing changes or errors; and
- Other one-time or situational, beneficiary specific letters to current enrollees.

Therefore, we propose to revise § 422.2260 and § 423.2260 to exclude materials about claims processing activities from the definition of marketing materials. We also propose to add a definition of current enrollee

communications materials not to be considered marketing materials encompassing information targeted to situational or beneficiary-specific circumstances, including claims processing issues and other one-time communications about operations. In addition, we propose to revise § 422.2262 and § 423.2262 to specify that, while current enrollee communications are not subject to the statutory requirement that applies to marketing materials (that is, that they be submitted to CMS for review prior to use), we retain the right to review them, and their use could be disapproved by CMS, or disapproved unless modifications are made. We believe these changes will streamline the review and approval of beneficiary communication notices to current members.

3. Required Use of Standardized Model Materials Under Parts C and D (§ 422.2262 and § 423.2262)

Section 1851(h) of the Act establishes standards for review and approval of marketing materials. Section 1860D–1(B)(1)(vi) of the Act requires CMS to use rules “similar to (and coordinated with)” the foregoing marketing rules set forth in section 1851(h) with respect to Part D marketing. Specifically, organizations may not distribute marketing materials unless they have been submitted to CMS for review. Materials submitted for such review are deemed to be approved unless disapproved within 45 days, or 10 days when using model language specified by CMS. In reviewing marketing materials or election forms under § 422.2264 and § 423.2264, we ensure that marketing materials are provided in a format (with appropriate print size, as applicable) specified by CMS and will use standard terminology specified by CMS.

Our current marketing materials submission and review process encourages MAOs and PDP sponsors to use model materials to expedite the review and approval process. The model documents contain language provided by CMS, including language that is optional (or that can be modified), for plan use. Under this arrangement, MAOs and Part D sponsors may submit customized materials that reflect preferred word choices or phrasing tied to corporate messaging.

As marketing materials that describe plan benefits are critical to ensuring that beneficiaries make the best health care decisions for their particular needs, it is imperative that plan materials are accurate, free of errors, and comparable across MAOs and PDPs. Accordingly, in order to reduce variability of marketing

materials and to ensure documents are more accurate and understandable to beneficiaries, we propose to move toward greater standardization of the information provided in plan marketing materials. Specifically, we are proposing to revise § 422.2262 and § 423.2262 to require that MAOs and PDP sponsors use standardized marketing material language and format, without modification, in every instance in which we provide standardized language and formatting. We provide MAOs and PDP sponsors with standardized marketing materials through the annual Call Letter or Health Plan Management System (HPMS) memoranda. We believe this change would ensure beneficiaries receive more accurate and comparable information to make informed decisions about their health care options. This proposed change will also ensure increased efficiencies and greater consistency in our marketing material review protocols and processes.

4. Involuntary Disenrollment for Failure To Pay Plan Premiums Under Parts C and D (§ 422.74 and § 423.44)

Section 1851(g)(3)(B)(i) of the Act provides that MA organizations may terminate those MA plan enrollees who fail to pay basic and supplemental premiums within the grace period established by the MA organization. Section 1860D–1(b)(1)(B) of the Act generally directs us to use disenrollment rules for Part D sponsors that are similar to those established for MA organizations under section 1851 of the Act. Consistent with these sections of the Act, the Parts C and D regulations set forth our requirements with respect to involuntary disenrollment procedures under § 422.74 and § 423.44, respectively.

Currently, § 422.74(d)(1)(i)(B) specifies that an MA organization must provide, at minimum, a 1-month grace period before disenrolling individuals for failure to pay the premium. Similarly, under current regulations at § 423.44(b)(1)(i) and § 423.44(d)(1), Part D sponsors may disenroll an individual from a PDP for failing to pay PDP premiums on a timely basis, using the process set forth in the regulations. Unlike the statute, the Part D regulations do not specifically use the term “grace period,” but we have interpreted the regulations in the Medicare Managed Care Manual provisions (Section 40.3.1 of the Enrollment Chapter) to require that organizations provide beneficiaries a grace period of not less than 1 month, beginning on the first day of the month for which the premium is unpaid, before disenrollment for failure to pay premiums timely. For both Parts C and

D, these involuntary disenrollments are not mandatory; thus, organizations may choose to implement longer grace periods or forego involuntary disenrollments entirely.

However, MA organizations and Part D sponsors that choose to disenroll enrollees for failure to pay premiums must notify the enrollee of the delinquency and allow the enrollee an opportunity to resolve the delinquency within 30 days. Further, the organization or sponsor must also be able to demonstrate to us that it has made reasonable efforts to collect the unpaid premium amounts. Given the time required to notify the enrollee of the delinquency, for the enrollee to make payment, and for the payment to be received by the organization in cases where the organization has established the minimum grace period, the actual amount of time the enrollee has to resolve the delinquency may be less than one month.

A beneficiary who is disenrolled from his or her MA or Part D plan for failure to pay premiums is not eligible for a special enrollment period based on that disenrollment. This beneficiary may be unable to enroll in another plan until the next annual election period in the fall. This may leave a significant gap in coverage for MA–PD and PDP enrollees, since their disenrollment will likely leave them without prescription drug coverage for the remainder of the year, and in addition they potentially face a late enrollment penalty (LEP) should they subsequently choose to re-enroll in some type of Medicare prescription drug coverage. Given the possible risk to the health status of individuals that lose prescription drug coverage, as well as the LEP consequences, we propose to codify in regulations a stronger version of our existing policy.

Therefore, we are proposing to amend the regulations at § 422.74(d)(1) and § 423.44(d)(1) regarding disenrollment for nonpayment of premium to require a minimum grace period of 2 months before any involuntary disenrollment associated with failure to pay a premium. We further propose to codify the aforementioned manual provision regarding the beginning of the grace period for Part D. We believe that a 2-month period will provide adequate time for organizations to respond to instances in which individuals fail to pay their premiums, and for affected enrollees to take steps to remedy the situation and avoid disenrollment. We note that organizations would still be able to offer a more generous grace period than provided in the regulation, if they so choose.

5. Maximum Allowable Out-of-Pocket Cost Amount for Medicare Parts A and B Services (§ 422.100)

Under section 1852(b)(1) of the Act, we may not approve MA plans if we determine that the design of the plan and its benefits would substantially discourage enrollment by certain MA eligible individuals. Based on program experience and efforts to curb discriminatory benefit packages, we are proposing that all local MA plans include an annual out-of-pocket cap on members' total cost-sharing liability for Part A and Part B services, the amount of which will be set annually by CMS. Given that regional PPO plans already are required to have an annual cap on member out-of-pocket costs and that many local MA plans already have such limits, we believe that requiring the inclusion of such a limit in plan design is necessary in order to avoid discouraging enrollment by individuals who utilize higher than average levels of health care services (that is, in order for a plan not do be discriminatory in violation of section 1852(b)(1) of the Act).

While our concern about discriminatory or confusing benefit packages is longstanding, it has been particularly acute since the implementation of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Since that time, plan offerings have become increasingly complex in terms both of cost sharing design and rules governing the application of cost sharing. For example, Health Maintenance Organization (HMO) plans may have a point of service benefit that allows the enrollee to obtain services out of network, but for higher cost-sharing levels. Preferred provider organization (PPO) plans are required to cover all plan services both in and out of network with typically higher out-of-network cost sharing. Members in private fee-for-service (PFFS) plans with a network may have differential cost sharing depending on whether they obtain services from a contracting or a deemed provider. Also, some coordinated care plans have introduced cost sharing “tiers” by which enrollees may be assessed different cost-sharing amounts depending on, for example, the plan contracted hospital from which they seek care. Because MA plans can vary in numerous ways, we are increasingly concerned that, faced with too many complex choices, beneficiaries are unable to confidently compare health plans and make meaningful choices. Because of these concerns, in the last

few years, we have used our authority under section 1852(b)(1) of the Act to scrutinize cost sharing and benefit designs offered by MA plans, and to require changes on a case by case basis where we found discriminatory cost-sharing. We also established out-of-pocket limits that, if adopted under an MA plan, would exempt the plan cost sharing from the same level of scrutiny it would otherwise receive.

For example, during the period since 2003, we have issued guidance: (1) Establishing an optional out-of-pocket maximum that plans could adopt which would result in less scrutiny of cost-sharing amounts for individual benefits under the plan; and (2) identifying certain health care services for special review that beneficiaries with higher than average health care needs are likely to need (for example, in-patient hospital, dialysis, skilled nursing facility (SNF), mental health services, Part B drugs and home health care).

To implement this guidance, we established a comprehensive process to review the proposed cost sharing of each plan benefit package and determine if the cost sharing design discriminates against those beneficiaries with higher than average health care needs. Specifically, we have conducted outlier analyses for the purpose of reviewing whether cost sharing levels on submitted benefit designs are discriminatory. We review, for example, the distribution of cost sharing levels submitted by MA organizations to identify the levels in the upper tail end of the range. This analysis assists us in determining the cost sharing threshold above which we consider the level to be discriminatory. We believe these efforts have resulted in some improvements in reducing discriminatory cost sharing and transparency of plan design. For example, including regional PPO plans, nearly 60 percent of all current MA plans have an out-of-pocket cap on beneficiary cost sharing with some local plans excluding certain services. Based on this experience, we believe that both a standard and mandatory cap on member cost sharing for all local MA plan types is an important and necessary step to ensure that plans are not discriminatory and beneficiaries are protected from unreasonable financial costs regardless of which MA plan they enroll.

Under our authority in section 1852(b)(1)(A) of the Act to ensure against MA plans that discriminate, our authority under section 1856(b)(1) of the Act to establish MA standards by regulation, and our authority under section 1857(e)(1) of the Act to add necessary and appropriate contract

terms, we propose to amend § 422.100(f)(3) by adding a new paragraph (f)(4) to specify that all local MA plans must establish an out-of-pocket maximum inclusive of all Medicare Parts A and B services that is no greater than the annual limit set by CMS. The cap for local PPO plans will be inclusive of all in-network and out-of-network beneficiary cost sharing. The methodology for determining the out-of-pocket maximum for local MA plans will be similar to the methodology we used to establish the voluntary out-of-pocket maximum amount for MA plans for contract year 2010. The out-of-pocket maximum will be set at a certain percentile of expected FFS spending, and this amount will be estimated by the Office of the Actuary (OACT). We summarized the methodology used to determine the voluntary out-of-pocket maximum for MA plans for contract year 2010 on page 13 of the 2010 Call Letter. As summarized in the 2010 Call Letter, MA out-of-pocket threshold is based on a beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Original Medicare. The CY 2010 out-of-pocket threshold of \$3,400 represents the 85th percentile of projected beneficiary spending in 2010. We do not expect an impact on cost-sharing and premiums, all other things being equal, for plans that already provide for an out-of-pocket maximum. However, requiring all plans to have an out-of-pocket maximum will likely result in increases to premiums and/or cost-sharing, although we are not able to quantify the extent of this increase. We propose to continue to furnish information to MA organizations on our methodology and the amounts for acceptable out-of-pocket caps on a timely basis through the annual Call Letter or Health Plan Management System (HPMS) memoranda. We solicit comments on this approach.

6. Maximum Allowable Cost Sharing Amount for Medicare Parts A and B Services and Prescription Drugs (§ 422.100, § 423.104)

We have always reviewed cost sharing levels for individual services for the purpose of determining whether or not such levels are discriminatory. Based on our experience, in which we annually review the levels of cost sharing across all bids, we propose to amend our regulations on the general requirements related to MA benefits and qualified prescription drug coverage to expressly authorize us to establish cost sharing thresholds for individual services below which cost sharing will be considered non-discriminatory. We believe that requiring the inclusion of such cost

sharing thresholds in plans' benefit designs affords greater predictability and protection against high out-of-pocket costs for beneficiaries with medical conditions that could result in exceptionally high out-of-pocket costs obligations, and further ensures that those beneficiaries are not discouraged from enrolling in an MA plan.

Under Part C, we propose annually to review bid data to determine specific cost sharing levels for Medicare A and B services below which would not have a discriminatory effect, and therefore may be approved in an MA benefit package. Similarly, under Part D, we would annually review bid data to determine acceptable cost sharing tiers for non-defined standard benefit designs. We will furnish information to MA organizations and Part D sponsors on its methodology and the acceptable cost sharing amounts based on the prior year's bids on a timely basis either through the annual Call Letter or Health Plan Management System (HPMS) memoranda. The methodology for determining the cost-sharing thresholds for Part A and B services will involve reviewing the prior year's bid data, as well as actuarial equivalencies from original Medicare, to determine outliers. These amounts could be adjusted based on new bid submissions for the current year.

We propose to determine these acceptable cost sharing levels based on factors such as distribution of cost sharing among submitted bids, comparison to Original Medicare cost sharing (in the case of Part C), and other factors that we find to assist in identifying discriminatory levels of cost sharing (for example, the number of tiers in the case of a Part D plan). A sponsoring organization's cost sharing will be considered discriminatory if it is higher than the maximum level that we determine to be non-discriminatory for a particular service in the case of an MA plan or a drug cost tier in the case of a Part D plan. We will communicate expected discriminatory cost sharing thresholds to sponsoring organizations through the annual Call Letter or HPMS memoranda during the annual bid and benefit package review process. These thresholds will be based on the prior year's experience and may be adjusted based on bid submissions for the current year. We solicit comment on this approach, including the extent to which we have provided sufficient clarity on how we determine whether cost-sharing levels are discriminatory.

Organizations submitting MA plan or prescription drug plan bids found to have discriminatory cost sharing will have an opportunity to resubmit their

bid and benefit package to comply with our non-discrimination requirements. We will annually evaluate our review process and the criteria we use to determine cost sharing discrimination and may make changes to ensure that beneficiaries are protected from discriminatory cost sharing.

We propose to amend § 422.100 by adding a new paragraph (f)(5) to specify that cost sharing for Medicare A and B services may not exceed levels annually determined by CMS to be discriminatory. Additionally, we propose to revise § 423.104(d)(2) by adding a new paragraph (iii) to specify that tiered cost sharing for non-defined standard benefit designs may not exceed levels annually determined by CMS to be discriminatory.

7. Prohibition on Prior Notification by PPO, PFFS and MSA Plans Under Part C (§ 422.2, § 422.4, and § 422.105(b))

In the preamble of the Medicare Program; Establishment of the Medicare Advantage Program final rule published in the January 28, 2005 **Federal Register** (70 FR 4598 through 4599), as well as in the 2009 and 2010 Call Letter, <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CallLetter.pdf> and <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/2010CallLetter.pdf>, respectively, we provided guidance permitting local and regional PPO plans (for out-of-network services) and PFFS plans to provide for lower cost sharing amounts in cases in which an enrollee or provider voluntarily gives the MA organization with prior notification that the service will be received. We also made clear that PPO plans (for out-of-network services) and PFFS plans may not require such notice, or prior authorization or referrals from gatekeepers, as a condition of coverage in order to restrict an enrollee's access to services. As stated below, Medical Savings Account (MSA) plans similarly may not impose prior authorization requirements as a condition of coverage. Under prior authorization, a plan requires an enrollee to seek its approval before obtaining services from a provider; if the enrollee does not obtain prior approval, then the plan can deny coverage for the service. We provided additional guidance to PPO and PFFS plans on how they must explain to current and prospective enrollees the plan's standard cost sharing and the reduced cost sharing related to prior notification.

However, since that time, we have become increasingly concerned about the use of prior notification by PPO and

PFFS plans. Program experience has demonstrated that prior notification is confusing to beneficiaries, misleading in terms of disclosure of cost-sharing, and, in some instances, used inappropriately as a form of prior authorization. In the GAO report titled "Medicare Advantage: Characteristics, Financial Risks, and Disenrollment Rates of Beneficiaries in Private Fee-for-Service Plans (GAO-09-25)," the GAO noted that some PFFS plans it reviewed "inappropriately used the term prior authorization rather than pre-notification in the informational materials they distributed to beneficiaries, which may have caused confusion about beneficiaries' financial risks." We have concluded that the complexity of cost sharing designs using prior notification has made it more difficult for both enrollees and providers to understand the enrollee's cost sharing obligation in advance of receiving services. Therefore, in order to reduce the complexity of MA plans' cost sharing designs and improve transparency for both enrollees and providers, we are proposing to prohibit PPO plans (for out-of-network services) and PFFS plans from providing for lower cost-sharing where prior notification rules have been satisfied. We propose to revise § 422.4(a)(1)(v) and (a)(3) to provide that PPO and PFFS plans will be prohibited from establishing prior notification rules under which an enrollee is charged lower cost sharing when either the enrollee or the provider notifies the plan before a service is furnished.

We also propose to prohibit MSA plans from establishing prior notification rules. The definition of a MSA plan in section 1859(b)(3)(A)(iii) of the Act ensures open access to services for MSA enrollees without restriction to a provider network and without prior authorization reviews for health care services. MSA plans may have networks of providers, but may not restrict an enrollee's access to those network providers. We believe that prior notification rules established by MSA plans would also be confusing to enrollees of those plans and have similar negative effects as those described above for PPO and PFFS plans. We propose to modify § 422.4(a)(2) such that MSA plans will also be prohibited from establishing prior notification rules under which an enrollee is charged lower cost sharing when either the enrollee or the provider notifies the plan before a service is furnished.

In the preamble of the Medicare Program; Establishment of the Medicare Advantage Program final rule published in the January 28, 2005 **Federal Register**

(70 FR 4617 through 4619), we discussed rules related to point of service (POS) options that are offered by some MA organizations. We stated that PPOs may offer a POS-like benefit under which beneficiary cost sharing would be less than it would otherwise be for non-network provider services, but still might be greater than it would be for in-network provider services, provided an enrollee follows preauthorization, pre-certification, or prenotification rules before receiving out-of-network services. We also noted that such preauthorization, pre-certification, or prenotification cannot be a necessary condition for receipt of, or required MA plan reimbursement for, out-of-network covered services by a PPO enrollee, but that it could act as a financial incentive (by lowering the normal out-of-network cost sharing that would otherwise apply) to an enrollee to voluntarily participate. Similar to our concerns about the use of prior notification rules by PPO and PFFS plans, as discussed above, we believe that the complexity of cost sharing designs for PPO plans with a POS-like benefit make it more difficult for both enrollees and providers to understand the enrollee's cost sharing obligation in advance of receiving services. In order to reduce the complexity of PPO plans' cost sharing designs and improve transparency for both enrollees and providers, we are proposing to prohibit PPO plans from offering a POS-like benefit. We propose to revise the definition of POS in § 422.2 and § 422.105(b) to indicate the only HMOs may offer a POS benefit. The proposed change is consistent with section 1851(a)(2)(A)(i) of the Act, which states that an HMO may include a POS option.

Although PPO (for out-of-network services), PFFS, and MSA plans may not impose prior authorization and referral requirements as conditions for covering services, enrollees and providers have the right to request a written advance coverage determination from the plan, in accordance with Subpart M of Part 422, before an enrollee receives a service in order to confirm that the service is medically necessary and will be covered by the plan.

8. Requirements for LIS Eligibility Under Part D (§ 423.773)

Section 423.773(c) specifies that the individuals treated as full subsidy eligible individuals include the following:

- Full-benefit dual eligible individuals;
- Supplemental Security Income (SSI) recipients under Title XVI of the Act; and

- Individuals eligible for Medicaid as a Qualified Medicare Beneficiary, Specified Low-Income Medicare Beneficiary, or a Qualifying Individual under a State's Medicaid plan.

In § 423.773(c)(2), we are proposing to amend the length of the period for which individuals are re-deemed eligible for the full low income subsidy to conform with guidance we issued in section 40.2.2 of Chapter 13 of the Medicare Prescription Drug Benefit Manual. Section 423.773(c)(2) currently specifies that a full subsidy eligible individual is deemed eligible for the full subsidy for a period up to 1 year. However, in practice, the period of deemed eligibility varies from as little as 7 months to as long as eighteen months, depending on when the individual attained deemed status (that is, became eligible for Medicaid, a Medicare Savings Program, or for SSI).

Every year, we review data from State Medicaid Agencies and the Social Security Administration (SSA) sent to us in July and August, respectively, to determine whether individuals currently deemed eligible for the subsidy should continue to be deemed (that is, "re-deemed") eligible for the subsidy. This allows us sufficient time to update individuals' records in our systems, if necessary, and to notify them if they are losing deemed status, so that they can take the appropriate steps to apply for the subsidy, in time for coverage to be effective at the start of the new calendar year.

When we are reviewing data in July and August, we also identify individuals who are newly eligible for Medicaid, a Medicare Savings Program, or SSI, and deem these individuals eligible for the subsidy for the remainder of the current calendar year. We also redeem these individuals for the subsidy for the next calendar year, because we do not have sufficient time in the final months of the year to conduct a separate redeeming process for these individuals. If we waited to redeem these beneficiaries after the start of the calendar year, they could incur greatly increased premium liability and cost sharing amounts at the start of the new calendar year than they would have otherwise.

For example, if a State Medicaid Agency submits data to CMS indicating an individual is eligible for Medicaid in March of a given year, and that individual is Part D eligible, we deem that individual eligible for the Part D low income subsidy from March 1st through December 31st of that year. We redeem that individual for the following calendar year only if we receive subsequent information from the State

or SSA indicating that the individual remains eligible for Medicaid, a Medicare Savings Program, or SSI.

On the other hand, if a State submits data to CMS indicating that an individual is eligible for Medicaid in July or a later month of a given year, and the individual is Part D eligible, we deem the individual eligible for the Part D subsidy for the remainder of that calendar year and all of the following calendar year. (See section 40.2.2 of Chapter 13 of the Medicare Prescription Drug Benefit Manual.) Therefore, we propose to amend § 423.773(c)(2) to indicate that the deeming will be, at a minimum, for the following periods: If deemed status is determined between January 1st and June 30th of a calendar year, the individual is deemed subsidy eligible for the remainder of the calendar year. If deemed status is determined between July 1st and December 31st of a calendar year, the individual is deemed subsidy eligible for the remainder of the calendar year and the next calendar year. We believe this change will streamline the deeming/redeeming process and decrease the administrative burden on agencies and subsidy eligible individuals.

9. Enrollment of Full Subsidy Eligible Individuals and Other Subsidy Eligible Individuals Under Part D (§ 423.34)

In the January 28, 2005 **Federal Register**, when we issued the Medicare Prescription Drug Benefit final rule (70 FR 4193), we added § 423.34 to describe our procedures for enrollment of full-benefit dual eligible individuals. We discussed how full-benefit dual eligible individuals are enrolled, which PDPs they are assigned to, and the effective date of their enrollment. As noted in the preamble to the final regulation, enrollment of other low-income subsidy (LIS) eligible individuals would also be conducted, and details would be issued in operational guidance. However, we did not incorporate into the initial Part D regulations further detail about the enrollment procedures that would apply to this remaining population of LIS-eligible individuals.

Section 1860D-1(b)(1)(A) of the Act directs the Secretary to establish a process for the enrollment of Part D eligible individuals. As we indicated in the preamble to the January 28, 2005 final rule (70 FR 4209), while the statute does not explicitly provide for the auto-enrollment of other LIS-eligible individuals into the Medicare Part D program, we believe that enrolling these individuals clearly is consistent not only with statutory intent but also with the intent of the individuals themselves.

The express purpose of applying for the Part D low-income subsidy is to obtain prescription drugs on a subsidized basis, which can only be accomplished through enrollment in a Part D plan. Therefore, we established a separate enrollment process for these individuals known as “facilitated enrollment.” We randomly assign these individuals to a PDP in their area with a premium below the low-income benchmark and notify these individuals that they may choose a Part D plan on their own and that if they do not choose a plan, we will enroll them in a plan in their area. We have been carrying out the “facilitated” enrollment process for more than 3 years without objections from beneficiaries or from the advocacy community; in fact, we believe that many individuals are under the mistaken impression that being approved for the subsidy actually equates with enrolling in a plan, so we believe our proposal will help rectify that problem. (See section 30.1.4 of Chapter 3 of the Medicare Prescription Drug Benefit Manual for more information about facilitated enrollment).

Based on this experience, we believe it would be appropriate to codify in regulation the enrollment procedures that we use for these individuals, which are similar to those specified in the regulation for the dual eligible population. We believe that our regulations would be more accurate and complete if they specifically addressed this population. Thus, we are proposing to amend § 423.34 to reflect the guidance we have issued in Chapter 3 of the Prescription Drug Program Manual. Specifically, we are proposing to include information on how we enroll all LIS-eligible individuals, including full-benefit dual eligible individuals.

We are proposing the following revisions to § 423.34:

- In § 423.34(a), we propose to expand the general rule to refer to all LIS-eligible individuals, so that the rest of that section applies not only to full-benefit dual eligible individuals, but also to all LIS-eligible individuals.
- In § 423.34(b), we would retain the definition of full-benefit dual eligible individual, and add a definition for “low-income subsidy eligible individual.”
- We propose to amend the paragraph heading of § 423.34(c) to indicate that this paragraph describes the process we use to reassign LIS individuals during the annual coordinated election period. We would indicate that the reassignment process applies to certain low-income subsidy eligible individuals

(that is, not just full benefit dual eligible individuals).

- We are proposing to revise the paragraph heading of § 423.34(d) from “Automatic Enrollment Rules” to “Enrollment Rules.” We are proposing this change to reflect the inclusion of full subsidy and other subsidy eligible groups in this enrollment process, in addition to full-benefit dual eligible individuals. In our guidance, we refer to the process of enrolling full-benefit dual eligible individuals as “automatic enrollment,” and the process for other LIS eligibles as “facilitated enrollment.” (See section 30.1.4 of Chapter 3 of the Medicare Prescription Drug Benefit Manual.)

- We propose to amend § 423.34(e) to indicate that the rules regarding declining enrollment and disenrollment also apply to all LIS-eligible individuals.

- In § 423.34(f), we would clarify that the paragraph heading and contents of this paragraph are limited to the effective date of enrollment for full-benefit eligible individuals. We propose to amend § 423.34(f)(3) to specify that, for individuals who are eligible for Part D and subsequently become eligible for Medicaid on or after January 1, 2006, the effective date of enrollment would be the first day of the month the individual becomes eligible for both Medicaid and Medicare Part D.

- In § 423.34(g), we propose adding a new paragraph to specify that the effective date for low income subsidy eligibles who are not full benefit dual eligibles would be no later than the first day of the second month after we determine that the individual meets the criteria for enrollment into a PDP under this section. This change conforms to section 30.1.4 of Chapter 3 of the Medicare Prescription Drug Benefit Manual. Unlike full benefit dual eligible individuals who may have retroactive Part D coverage, these individuals have only prospective Part D coverage.

Although we believe that all these provisions will benefit the LIS-eligible population, we recognize that concerns have been raised about the impact of the current random auto-enrollment process on affected beneficiaries. For example, focus groups of seniors suggest the possibility that some auto-enrolled beneficiaries may not realize they have been enrolled in a drug plan or that they have been reassigned to a different drug plan. We are committed to taking appropriate steps to improve this process. Thus, we welcome comments related to all aspects of these procedures, including comments on issues such as the following:

- The efficacy of the existing auto-enrollment and facilitated enrollment procedures, and suggestion for improving these procedures;
- Ways to assess the impact of these procedures on the dual eligible and LIS population, including the costs, benefits, and potential unintended consequences. For example, is it possible that seniors who are LIS-eligible but not eligible for Medicaid will not realize that they have been auto-enrolled into a drug plan? Is there any possibility that auto-enrolling these individuals could ever lead to delinquencies in payments? Given that LIS-eligible individuals are auto-enrolled into plans with premiums below the benchmark, we do not believe these individuals would ever become subject to premium issues or liable for other such costs that they are not aware of in advance. However, we welcome comment on whether the possibility exists and, if so, how payment delinquencies should be handled in this vulnerable population.
- How we can better assist beneficiaries in identifying plan choices that best suit their individual drug needs, and encourage them to make an active election.

10. Special Enrollment Periods Under Part D (§ 423.380)

Consistent with the changes in § 423.34, we are proposing to expand the special enrollment period described in § 423.38(c)(4), which currently applies to full-benefit dual eligible individuals, to all LIS-eligible individuals. This change is consistent with our authority in section 1860D–1(b)(3)(C) of the Act and would conform our regulations to current practice as reflected in CMS guidance in section 20.3.8, item 7, of chapter 3 of the Medicare Prescription Drug Benefit Manual.

11. Transition Process Under Part D (§ 423.120(b)(3))

Section 1860D–11(d)(2)(B) of the Act gives the Secretary authority similar to that of the Director of the Office of Personnel Management with respect to health benefits plans under chapter 89 of title 5, United States Code. This includes the authority to “prescribe reasonable minimum standards for health benefits plans.” In addition, section 1860D–11(e)(2)(D) of the Act prohibits us from approving a plan if “the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals.”

Under the authority of section 1860D-11 of the Act, we established a requirement in the January 28, 2005 final rule implementing the Part D program that requires sponsors of Part D plans to provide for an appropriate transition process for new enrollees prescribed Part D drugs that are not on its plan's formulary (70 FR 4264). We further specified in regulation that the transition policy must be consistent with written policy guidelines and other CMS instructions. The transition requirement is codified in at § 423.120(b)(3).

Following publication of the regulation, we issued guidance in 2005 on what constituted an appropriate transition process for new Part D enrollees. We noted in our guidance that an appropriate transition process was one that balances the protection of certain vulnerable populations with the flexibility necessary for Part D plans to develop a benefit design that promotes beneficiary choice and affordable access to medically necessary drugs. We updated the transition guidance for contract year 2007 as part of the 2007 Call letter, noting that the transition guidance represented a minimum set of standards for a Part D sponsor transition process. This guidance was incorporated into Chapter 6 of the Medicare Prescription Drug Benefit Manual located at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/R2PDBv2.pdf>.

Our experience has shown that transition processes represent an important enrollee protection to ensure access to needed Part D drugs. Given the movement from year to year of some dual eligible beneficiaries due to reassignment, and the annual bidding cycle related to Part D plan offerings in which benefits and formularies may be modified, we believe that some protections are necessary for plan enrollees with immediate prescription needs who experience a change in enrollment or who experience formulary changes under their existing plan at the beginning of a contract year. These protections are particularly important when an individual first presents at a participating pharmacy with a prescription for a drug that is not on the formulary, unaware of what is covered by the plan or of the sponsor's exceptions process for providing access to Part D drugs that are not on the plan's formulary. For example, a full-benefit dual eligible enrollee who is auto-enrolled into a plan may not make an affirmative choice based on review of a plan's benefit relative to his existing medications needs. For these types of

situations, we directed Part D sponsors to have systems capabilities to allow them to provide a one time, temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) in order to accommodate the immediate needs of an enrollee, as well as to allow the sponsor and/or the enrollee sufficient time to work out with the prescriber an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons. Our guidance has developed over time in response to these concerns, and we believe it strikes the right balance between enrollee protection and plan flexibility.

Given the importance of our transition policy as an enrollee protection—particularly for auto-assigned and reassigned beneficiaries who did not affirmatively choose a Part D plan—we propose to codify in regulation certain policies from our guidance on the necessary elements of a plan transition process. We also believe that any plan that fails to meet its transition policy requirements discourages enrollment (or re-enrollment) by Part D eligible individuals that may currently be taking prescription drugs that are not on the plan's formulary. Accordingly, we propose that a Part D sponsor must provide for a transition for the following:

- New enrollees into PDPs following the annual coordinated election period;
- Newly eligible Medicare enrollees from other coverage;
- Individuals who switch from one plan to another after the start of the contract year; and
- Current enrollees remaining in the plan who are affected by formulary changes from one contract year to the next.

Our experience thus far has shown that these groups represent the minimum target populations that are most likely to require protections to ensure immediate access to their prescription drug benefit.

We also propose, consistent with our current guidance, that a Part D sponsor's transition process requirements be applicable to non-formulary drugs, meaning both: (1) Part D drugs that are not on a sponsor's formulary; and (2) Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a plan's utilization management rules. The latter is included because a formulary drug to which access is

restricted via utilization management requirements is essentially equivalent to a non-formulary Part D drug to the extent that the relevant utilization management requirements are not met for a particular enrollee.

Additionally, we propose, consistent with our current guidance, to codify the timeframes for the transition process and the days' supply limit for a transition fill of an enrollee's medication. Our guidance was premised on the position that it made sense to limit the amount of time during which a transition process is applicable to new enrollees to the first 3 months under the plan as we believed an enrollee unfamiliar with his or her plan's formulary requirements would likely to present with a prescription during the first few months enrolled. We also propose to codify the transition process timeframe to apply during the first 90 days of coverage under a new plan. This 90-day timeframe would apply to retail, home infusion, long-term care, and mail-order pharmacies.

We also propose to require plans to provide a temporary supply of drugs under their transition process. As we noted in our original transition guidance to Part D plan sponsors in Chapter 6 of the Medicare Prescription Drug Benefit Manual, providing a temporary supply represented the most efficient method of triaging requests for filling initial prescriptions of non-formulary drugs for large numbers of new enrollees who, despite education efforts to make them aware of the plan's benefit, may not be aware of which drugs are listed on the plan's formulary. Consistent with Chapter 6, we propose that Part D plan sponsors must ensure that the one-time, temporary supply of non-formulary Part D drugs requested during the first 90 days of coverage in an outpatient setting must be for at least 30 days of medication, unless the prescription is written by a prescriber for less than 30 days, in which case the Part D sponsor must allow multiple fills to provide up to a total of 30 days of medication. For a new enrollee in a Long term Care (LTC) facility, the temporary supply may be for up to 31 days (unless the prescription is written for less than 31 days), consistent with the dispensing practices in the LTC industry. In addition, due to the often complex needs of LTC residents that often involve multiple drugs and necessitate longer periods in order to successfully transition to new drug regimens, sponsors must honor multiple fills of non-formulary Part D drugs, as necessary during the entire length of the 90-day transition period. This is particularly important if transitions to

formulary drugs have not been effectuated prior to the refills. We propose to require up to a 31-day transition supply for enrollees in an LTC facility given that many LTC pharmacies and facilities dispense medication in 31-day increments. Thus, a Part D sponsor would be required to provide a LTC resident enrolled in its Part D plan at least a 31 day supply of a prescription when presenting in the first 90 days of enrollment (unless the prescription is written for less) with refills provided, if needed, up to a 93 day supply.

In addition to codifying the preceding requirements, we also propose to take the opportunity in this rulemaking to clarify our expectations of sponsors with respect to providing transition notices. Based on our experience overseeing the Part D program, we have learned that a successful transition process is contingent upon informing enrollees and their caretakers about their options for ensuring that enrollees' medical needs are safely accommodated within a Part D sponsor's formulary. An enrollee who receives a temporary supply of a non-formulary Part D drug at a network pharmacy might simply assume that, by virtue of filling his or her prescription, the plan will cover that drug for the remainder of the contract year. For this reason, we are proposing to require sponsors to provide enrollees with appropriate notice regarding their transition process within a reasonable amount of time after providing a temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules).

Our guidance specifies that Part D sponsors send a written notice, via U.S. First Class mail, to each enrollee who receives a transition fill. This standard is consistent with our requirement that other enrollee communications, including formulary change notices and explanations of benefits, be sent via U.S. First Class mail. In addition, our guidance directs sponsors to send this notice to each affected enrollee within 3 business days of the temporary fill. Our rationale for this turnaround time is that it is necessary in order to provide an affected enrollee with sufficient time—especially in light of our 30-day transition fill policy in the outpatient setting to work with his or her prescriber to switch to a therapeutically equivalent drug that is on the plan's formulary or to process an exceptions request.

Given the importance of enrollee access to medications, especially during

a transition in coverage, or a transition in a level of care, we propose to codify this portion of our guidance and require provision of transition notices.

However, in addition to this codification, we also propose to require plan sponsors to make reasonable efforts to notify prescribers, via mail, electronic or verbal communication, that the affected enrollees' prescription cannot be refilled, either because of utilization management requirements such as prior authorization or step therapy, or because the prescribed medication is not on the plan sponsor's formulary. We believe that this communication is necessary in order to expedite the prescriber's plan to seek therapeutic alternatives for the enrollee or to fill out the requisite paper work to submit to the Part D sponsor to initiate the exceptions process. We invite comments on this proposal.

Accordingly, we propose the following revisions to § 423.120(b)(3):

- Add paragraph (3)(i) to clarify which enrollees the transition process should apply;
- Add paragraph (3)(ii) to ensure access to a temporary supply of drugs within the first 90 days of coverage under a new plan;
- Add paragraph (3)(iii) to provide a temporary fill when an enrollee requests a fill of a non-formulary drug during the time period specified in paragraph (ii) (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules) and the days supply in the outpatient setting must be for at least 30 days of medication. In the long-term care setting, the temporary supply must be for up to 90 days in 31 day supply increments;
- Add paragraph (3)(iv) to ensure written notice is provided to each affected enrollee within 3 business days of the temporary fill;
- Add paragraph (3)(v) to ensure that reasonable efforts are made to notify prescribers of affected enrollees who receive a transition notice under paragraph (iv).

12. Part D Sponsor Responsibility for Retroactive Claims Adjustment Reimbursements and Recoveries Under Part D (§ 423.464)

Sections 1860D–23 and 1860D–24 of the Act require PDP sponsors to coordinate with state pharmaceutical assistance programs (SPAPs) as well as other drug plans, including Medicaid programs, group health plans, Federal Employee Health Benefit Plans (FEHBP), military coverage and other plans or programs providing

prescription drug coverage. These requirements are codified at § 423.464 and set forth in the Medicare Prescription Drug Benefit Manual. As we have gained more experience with the prescription drug program, we have found that some beneficiary changes (for example, those resulting from retroactive low income subsidy LIS eligibility determinations, LIS status changes, or midyear Part D enrollment changes) that necessitate retroactive claims adjustments are a significant issue under Part D. These changes, as well as long-term care pharmacy billing practices for dual-eligible beneficiaries and the presence of secondary, tertiary and even quaternary payers have all contributed to a higher than expected volume of retroactive claims adjustments requiring Part D sponsor reimbursements and recoveries, as well as a greater than anticipated complexity of calculating these amounts. While we previously anticipated that beneficiaries would be owed reimbursements due to changes in LIS status, and required plan sponsors to make such reimbursements in § 423.800(c), we have since learned that our current regulations do not reflect the other entities that may sometimes need to be taken into account in reimbursement or recovery transactions. Moreover, we have also learned that no industry standard electronic process exists to explicitly handle underpayment recoveries or overpayment reimbursements created by these adjustments, and that the current Health Insurance Portability and Accountability Act (HIPAA) standard for coordination of benefits for pharmacy claims only partly supports these activities when the pharmacy initiates “reverse and rebill” transactions. As a result, we are aware that Part D sponsors are sometimes struggling with how to manage these retroactive adjustments and that those sponsors that are refunding overpayments or seeking underpayment recovery are each doing it differently.

Since current regulations do not address retroactive adjustments and the complexities associated with coordination of benefit activities that cannot be accomplished between the Part D sponsor and the pharmacy through reversal and re-billing, we have issued general guidance to direct sponsor coordination of benefit activities. Sections of the COB and LIS chapters of the Medicare Prescription Drug Benefit Manual specify standards for a PDP sponsor to: work with other providers of prescription drug coverage to resolve payment issues; have a process in place to handle the payment

resolution that is not restricted by implementation of timely filing requirements; make retroactive adjustments and promptly refund monies owed to the correct party (including, but not limited to the beneficiary); and generally limit requests for pharmacy reprocessing to those situations involving a pricing error. Additionally, CMS guidance includes as part of the coordination of benefits the transfer of true out-of-pocket (TrOOP) costs and gross covered drug cost data to a new Part D plan when a beneficiary changes enrollment during the coverage year. In our October 20, 2008 Part D sponsor implementation guidance on the automated process for the transfer of these TrOOP-related data, we established a 45-day maximum time limit from receipt of a post-adjudicative change in the reported data for the sponsor to take adjustment action, make a refund, and/or initiate recovery. We established this time limit after an informal survey and discussions with Part D sponsors and their processors. While some entities indicated they were making adjustments more frequently, the industry generally supported a 90-day limit, which is consistent with the time limit on pharmacy claim reversals. However, we believe this longer timeframe is not in the best interests of the beneficiary because it would delay the payment of refunds and notification of the need for payment recovery. On the other hand, because many of the claims reversals occur early in the 90-day period, a very short adjustment timeframe could lead to a series of consecutive refunds and recoveries that would be confusing and, therefore, also not in the best interests of the beneficiary. Accordingly, we believe that a 45-day time limit represents a reasonable compromise.

Many of the post-adjudicative adjustments, such as those that are due to enrollment changes, are changes that affect beneficiary cost-sharing, premiums and/or plan benefit phase. Establishing a reasonable time limit for all Part D adjustment, refund, and recovery activity is in the beneficiaries' best interests because it ensures that required changes are effectuated on timely basis, thus correcting retroactive and prospective beneficiary premium and cost-sharing amounts. Moreover, it is in the best interest of others who have paid a claim, or are holding a balance due, on the beneficiary's behalf because it ensures that these amounts are resolved timely.

At § 423.464 and § 423.466, we are proposing to codify our previous policy guidance (for instance, our memorandum on plan LIS changes

dated October, 30, 2006) by proposing that sponsors must both make retroactive claim adjustments and take other payer contributions into account as part of the coordination of benefits. Further, we are also proposing to add a new timeliness standard at § 423.466 to require adjustment and issuance of refunds or recovery notices within 45 days of the sponsor's receipt of the information necessitating the adjustment. While claims adjustments must be made and notices issued within the established timeframes, we continue to recognize that calculating the precise amount of the adjustment and any resulting reimbursements or recoveries may not always be practicable due to limitations in the electronic transaction set and contractual terms and conditions for payment in use in the pharmacy industry. However, sponsors must exercise due diligence in fulfilling these requirements.

To date, most Part D coordination of benefits activity has been performed at point-of-sale or soon after, so pharmacy reversal and rebilling of claims can be accomplished within the payers' timely filing windows. For Part D, this window must be a minimum of 90 days, but for other (non-Part D) providers of prescription drug coverage the filing window could be as short as 30 days. With the instability of LIS data and Part D enrollments creating a significant volume of retroactive adjustments, it has become evident that sponsors are facing more claims adjustments than current pharmacy claim reversal and rebilling approaches can adequately address.

Online real-time coordination of benefits, in which the order of payment among multiple payers is established and programmed into payer systems, generally did not take place in pharmacy benefit management prior to Part D implementation. Therefore, following the issuance of the Medicare Prescription Drug Benefit final rule on January 28, 2005, CMS and the industry, in collaboration with the National Council for Prescription Drug Programs (NCPDP), collaborated to develop an electronic process consistent with HIPAA-authorized transaction standards to allow supplemental payer information to be available at point-of-sale and patient-pay amounts remaining after supplemental payer payments to be reported back to the primary Part D sponsor for purposes of tracking TrOOP. However, by design, all billing transactions still require the pharmacy to initiate the activity. What this means in the case of a claims adjustment is that if the beneficiary is no longer at the counter and a supplemental payer's claim filing window is closed, the

pharmacy can no longer effectively coordinate benefits between payers. And payers cannot effectively coordinate among themselves, both because of the absence of electronic standards for post-adjudication claim adjustments among payers (as opposed to between pharmacies and payers), and the presence of contractual prohibitions between payers and pharmacies on the disclosure of proprietary pricing information. Therefore, at the present time, CMS and the industry are struggling to determine how best to handle retroactive claims adjustments whenever the adjustment cannot be resolved simply between the sponsor and the pharmacy.

Pharmacies regard their pricing information as proprietary and are concerned about the potential chilling effect any disclosure of this information might have on their ability to negotiate with payers. Therefore, to ensure the confidentiality of pricing information, coordination of benefits on the initial claim is accomplished without reporting complete information on negotiated pricing. The amount reported in the transaction to the Part D plan is the amount of the beneficiary payment after the supplemental payment. As a result, a Part D sponsor attempting to determine refund or recovery amounts without having the pharmacy reverse and rebill the original claim can generally only impute the amount of any supplemental payment made by another payer by determining the difference between the Part D cost-sharing and the beneficiary amount paid after the supplemental payment. The only alternative is to ask the pharmacy to reverse and rebill the claim to all payers. However, this procedure is generally unreasonable after the industry standard 30-day window because many supplemental payers will not accept the late claim and, as a consequence, the pharmacy would be left short the supplemental payer payment amount, as well as any difference in beneficiary cost sharing that might be due.

In the absence of legal authority to compel supplemental payer cooperation and to avoid pharmacy underpayment, imposing a requirement on sponsors to nonetheless calculate a precise reimbursement or recovery liability would require the creation of a new payer-to-payer transaction that both enables reprocessing and addresses pharmacies' concerns about revealing their proprietary pricing. It is not clear that both goals can be achieved. Nor is it clear that even if this conflict could be resolved, that the cost of doing so would be justified by the benefits. That

is, it is not clear to us that the benefits of more precisely calculating the differential amounts owed or due (the incremental amounts more or less that supplemental payers and beneficiaries would have paid if the correct LIS subsidy had been applied to the original claim) outweigh the costs of developing customized electronic transactions for such calculations. This is because while some adjustments are from non-subsidized to subsidized cost sharing, many others only change patient pay amounts after the Part D plan payment by a dollar or two, and many would not change the beneficiary cost sharing at all because the difference would be picked up by or owed to a supplemental payer. Thus, despite the importance of accurate reimbursement to all parties, the cost of developing specialized transactions may outweigh the benefits that would accrue.

Some supplemental payers are cooperating in the exploration of a solution through NCPDP, for example, certain SPAPs, but others continue to close their claims filing window at 30 days and permit no further coordination. Part D sponsors and/or their claim processors are likewise currently engaged with CMS through NCPDP in examining the scope of the problem and exploring alternative approaches to retroactively and electronically adjust claims. However, at this time, while simple adjustments involving just the Part D sponsor and the pharmacy are relatively straightforward (and can and should be promptly transacted), those involving other payers are not. Thus, we continue to hold the plans accountable for making best efforts to coordinate benefits occasioned by claim adjustments, but we acknowledge that electronic transaction standards have not yet been developed to support timely, reliable, and precise coordination on adjusted claims when multiple payers are involved. Therefore, we will continue to work with the industry on methods to make best efforts in this area, including limiting other payer recoveries and reimbursements to imputed amounts due to and from supplemental payers that choose to fully cooperate with industry consensus-driven processes developed through NCPDP. We note that amounts due to or from beneficiaries must also be imputed in some of these situations. We are soliciting comments on alternative approaches to improving post-adjudication coordination of benefits necessitated by retroactive Medicare enrollment and low-income subsidy

changes when multiple payers are involved, as well as our assessment that the costs of achieving precision in such transactions may far outweigh the benefits.

In the short-term, there are some adjustment-related activities that plans can control and, consistent with our authority in section 1860D–24(a)(1) of the Act, we can require that sponsors do these better. Therefore, we are proposing the following revisions to § 423.464:

- Revising paragraph (a) to clarify that all Part D sponsors must comply with administrative processes and requirements established by CMS to ensure effective coordination between Part D plans and other providers of prescription drug coverage for retroactive claims adjustments, underpayment reimbursements and overpayment recoveries; and
- Adding a paragraph (g)(7) to address the sponsors' responsibility to account for payments by SPAPs and other providers of prescription drug coverage in reconciling retroactive claims adjustments that create overpayments and/or underpayments, as well as to account for payments made, and for amounts being held for payment, by other individuals or entities. The new paragraph also specifies that Part D sponsors must have systems to track and report adjustment transactions and to demonstrate that—
 - ++ Adjustments involving payments by other plans and programs providing prescription drug coverage have been made;
 - ++ Reimbursements for excess cost-sharing and premiums for low-income subsidy eligible individuals have been processed in accordance with the requirements in § 423.800(c); and
 - ++ Recoveries of erroneous payments for enrollees have been sought as specified in § 423.464(f)(4).

13. Time Limits for Coordination of Benefits (§ 423.466)

Currently, there is no statutory or regulatory time limit for Part D sponsor coordination of benefits with SPAPs, other providers of prescription drug coverage, or other payers. Current CMS guidance as set forth in the Coordination of Benefits (COB) chapter of the Medicare Prescription Drug Benefit Manual requires Part D sponsors to establish at least a 90-day timely claims filing window and to make appropriate allowances for COB claims on a case-by-case basis. Section 50 of the COB chapter also requires sponsors, in retroactive enrollment situations, to coordinate benefits with other payers as required by the regulations at

§ 423.464(f), as well as accept claims from the beneficiary without imposing time limits. This section states further that sponsors, even in those situations when retroactive enrollment is not an issue, continue to be liable for claims received after the end of the coverage year as defined in § 423.308 and note that while contract provisions regarding timely claims filing may limit claims from network pharmacies, nonnetwork pharmacies and beneficiaries must still have the opportunity to submit claims for reimbursement without the imposition of time limits by the Part D sponsor.

Experience with Part D has shown there is benefit to be derived from placing a time limit on claims submission for Part D sponsor coordination of benefits. In addition to limiting sponsors' financial liability, a time limit would strengthen the ability of SPAPs, other providers of prescription drug coverage and other payers, including beneficiaries to obtain payment for covered Part D drugs. We would likewise benefit from a COB time limit by enabling us to close our Part D prescription drug databases.

In considering now establishing time limits on the submission of claims to Part D sponsors by beneficiaries and other payers of prescription drug coverage for proper coordination of benefits, we note that the Medicare FFS time limit for filing claims, as specified in § 424.44, is December 31st of the following year for services furnished during the first 9 months of a calendar year and December 31st of the second following year for services furnished during the last 3 months of the calendar year. The time for filing will be extended 6 months if the failure to file timely is due to an error or misrepresentation by an employee, intermediary, carrier, or agent of the Department. We also noted that States have a 3-year time limit for seeking recovery of Medicaid claims payments when the State is not the primary payer. Specifically, the Deficit Reduction Act of 2005 (Pub. L. 109–171) (DRA) strengthened the State Medicaid programs' ability to obtain payment from health insurers with which they need to coordinate benefits by adding section 1902(a)(25)(I) of the Act. The new section requires States to have laws in effect that require health insurers to make payment as long as the claim is submitted by the State within 3 years from the date on which the item or service was furnished. This DRA provision does not include SPAPs and, therefore, does not impose a time limit on the requirement for Part D sponsors to coordinate benefits with SPAPs.

Having considered these filing limit precedents, we now propose to establish a 3-year filing limit for Part D coordination of benefits with SPAPs, other entities providing prescription drug coverage, and all other payers, including beneficiaries or other individuals or entities paying, or holding amounts for payment, on the beneficiaries' behalf. Specifically, we propose to revise new § 423.466 by adding a new paragraph (b) that would establish a 3-year time limit on Part D coordination of benefits. That is, we propose to require Part D sponsors to coordinate benefits with SPAPs, other entities providing prescription drug coverage, and other payers for a period not to exceed 3 years from the date on which the prescription for the covered Part D drug was filled. By adding this provision to the regulation, we clarify timely filing responsibilities and deadlines for all beneficiaries and payers, as well as place a limit on Part D sponsors' claims payment liabilities and coordination of benefits responsibilities.

We are proposing this requirement consistent with our authority under sections 1860D-23(a)(2) and 1860D-24(a)(1) of the Act to establish requirements to ensure effective coordination among Part D plans, SPAPs, and other providers of prescription drug coverage, and consistent with our general rulemaking authority under section 1871(a) of the Act. Experience since the implementation of Part D has demonstrated that the ability of both CMS and the sponsors to manage our respective responsibilities in administering the program is complicated by the absence of any time limit for coordination of benefits. Part D sponsors face open-ended financial liability for continued benefit coordination and must project and include the costs of future liabilities in their bids. We also incur the expense of keeping our databases open to continue to accept prescription drug event data for the purpose of reopening Part D payment determinations to account for claims received by Part D sponsors from SPAPs, other entities providing prescription drug coverage, and other payers after the end of the coverage year. We believe that a 3-year limit provides more than ample time for beneficiaries to seek reimbursement of out-of-network and other paper claims, as well as sufficient time for coordination of benefits activities to take place among payers.

14. Use of Standardized Technology Under Part D (§ 423.120)

Section 1860D-4(b)(2)(A) of the Act, as codified in § 423.120(c), requires Part D sponsors to issue (and reissue, as appropriate) a card or other technology that may be used by an enrollee to assure access to negotiated prices under section 1860D-2(d) of the Act. Section 1860D-4(b)(2)(B) of the Act requires us to provide for the development, adoption, or recognition of standards relating to a standardized format for the card or other technology that are compatible with the administrative simplification requirements of Title XI of the Act and to consult with the NCPDP and other standard setting organizations, as appropriate. In accordance with section 1860D-4(b)(2)(B) of the Act, we consulted with NCPDP and subsequently issued guidance adopting NCPDP's "Pharmacy ID Card Standard", which is based on the American National Standards Institute (ANSI) INCITS 284-1997 standard entitled "Identification Card-Health Care Identification Cards", as the standard for identification cards for the Part D program. Information required in the Pharmacy ID Card Standard includes billing identifiers necessary to direct online real-time transactions to the appropriate online processor to enable real-time adjudication of the prescription drug claim at point of sale.

Our current regulations and guidance specifically address the requirement for Part D sponsors to issue (and reissue, as appropriate) standardized cards that may be used by an enrollee to ensure access to negotiated prices under section 1860D-2(d) of the Act. The only way that an enrollee can be assured access to the negotiated price at the point of sale is through online adjudication of the prescription drug claim. Any other price available to the beneficiary at the point of sale, as for instance, the pharmacy's "cash price", cannot be deemed to be the negotiated price mandated under section 1860D-2(d) of the Act. Therefore, to ensure access to these negotiated prices, the billing information on the cards must be used by the pharmacies at which beneficiaries fill their prescriptions to submit claims to an enrollee's Part D sponsor (or its intermediary). Beginning with the COB requirements originally issued on July 1, 2005, as required by section 1863D-23(a)(1) of the Act, and subsequently maintained as Chapter 14 of the Prescription Drug Plan Manual, we have instructed plan sponsors to process all claims online real-time (see section 50.4 entitled, "Processing Claims and Tracking TrOOP". The

requirements of accurate TrOOP accumulations, Part D benefit administration of multiple coverage intervals, and coordination of benefits with other payers all necessitate online real-time adjudication of individual pharmacy claims. Furthermore, since July 1, 2005, we have stated that we expect that Part D plan sponsors will establish policies and procedures appropriately restricting the use of paper claims to those situations in which on-line claims processing is not available to the beneficiary at the point of sale in order to promote accurate TrOOP accounting, as well as to minimize administrative costs to the Part D plans and the Medicare program and reduce opportunities for fraudulent duplicative claim reimbursements. We are now proposing at section 423.120(c)(3) to require Part D sponsors to contractually mandate that their network pharmacies submit claims electronically to the Part D sponsor or its intermediary on behalf of the beneficiary whenever feasible unless the enrollee expressly requests that a particular claim not be submitted to the Part D sponsor or its intermediary.

We are proposing to codify this guidance in regulation at this time because we have been made aware of an increasing number of instances in which network pharmacies are not submitting pharmacy claims to Part D Sponsors on behalf of Part D enrollees. Generally, we believe it is in the best interest of Part D enrollees to have their claims consistently processed through the Part D sponsor (or its intermediary). Not only does processing claims through the Part D sponsor ensure access to Part D negotiated prices, but it also ensures that proper concurrent drug utilization review (including safety checks) is performed (as required under 1860D-4(c) of the Act). Only the plan can conduct accurate concurrent drug utilization review when multiple pharmacies are utilized by the beneficiary or prevent payment to excluded providers. Online, real-time processing also facilitates accurate accounting for enrollees' true out-of-pocket (TrOOP) and total drug costs by the Part D sponsor so that each claim is processed in the appropriate phase of the benefit and accurate cost sharing assessed. In addition, a Part D sponsor cannot coordinate benefits with other payers as required under sections 1860D-23 and 1860D-24 of the Act if it never receives the claim.

We also propose to add a new paragraph (2) to § 423.120(c) to codify our existing guidance that Part D sponsors utilize standard electronic transactions established by 45 CFR

162.1102 for processing Part D claims. We will issue guidance on the use of optional or conditional fields in the HIPAA standard transactions through the Call Letter and Prescription Drug Benefit Manual instructions. We routinely work with NCPDP and industry representatives in arriving at recommendations for standardized use of such fields when necessary to improve administration of the Part D benefit. Previous examples of such guidance include those described in sections 50.4 and 50.5 of Chapter 14 of the Prescription Drug Benefit Manual on "Processing Claims and Tracking TrOOP" and "Standardized Claims Messaging", respectively. Such instructions are consistent with the rules governing use of HIPAA transactions whereby use of optional and conditional fields is governed by contractual terms between trading partners.

In a related matter, we are interested in better understanding the impact of a requirement for Part D sponsors to establish uniquely identifiable Part D payer/processor and enrollee identification numbers in billing and other coordination of benefits-related transactions. We have learned that not all processors organize their enrollment data this way, and some may rely upon other data such as person codes or dates of birth to distinguish between two enrollees (such as spouses) with a single identification number ("RxID"). This practice complicates coordination of benefits activities with other parties when unique identifiers are necessary. We have also learned that pharmacies cannot routinely distinguish Medicare Part D claims from other types of prescription drug coverage when the same routing information ("RxBIN and RxPCN") is used for all lines of business managed by a single processor. If pharmacies cannot consistently distinguish Part D claims, they cannot ensure that Part D claims and beneficiaries are handled in accordance with Part D-specific policies and procedures. Consequently we are proposing to add a new paragraph (c)(4) in § 423.120 to require that sponsors and their intermediary processors establish and exclusively utilize unique RxBIN or "RxBIN/RxPCN combinations" to identify all Medicare part D member claims, as well as to assign unique "RxID" identifiers to individual Part D beneficiaries. We solicit comments on the operational issues and timelines that would be involved in making these proposed technical changes to claims processing systems.

As stated previously, we generally believe it is in the best interest of Part

D enrollees to have their claims electronically submitted at the point of sale by pharmacies to the Part D sponsor (or its intermediary), but recognize there are situations when this will not be feasible or warranted. The most obvious example involves prescriptions filled at out-of-network pharmacies when Part D enrollees generally must pay out of pocket and submit paper claims for reimbursement from the Part D sponsor. Another example involves situations when network pharmacies offer special discount prices that are lower than plan negotiated prices. If this discounted price is not a pharmacy's usual and customary (U&C) price, we understand that the pharmacy may not offer it to the Part D sponsor (or its intermediary) for claims processing. In these situations, we have articulated a "lower cash price" policy whereby the enrollee may pay the pharmacy in full and submit a paper claim for reimbursement so that the costs will be counted towards his or her total drug spend and TrOOP balances. Finally, we also recognize that enrollees may have personal reasons for not wanting specific prescription claims processed through their Part D sponsor (or intermediary) and we uphold the enrollees' right to make such decisions. In situations such as the last two examples, our proposed requirement now clarifies that the enrollee must expressly request that a particular claim not be submitted to the Part D sponsor or its intermediary for processing. That is, the beneficiary should of his or her own initiative request that the claim not be submitted to the Part D plan, and this decision must neither be solicited nor assumed by the pharmacy.

While the previous examples explain why some pharmacy claims for Part D enrollees legitimately will not be processed through the Part D sponsor (or its intermediary), we are concerned about other reasons why network pharmacies may be failing to submit claims to Part D sponsors (or their intermediaries). Most notably, we are concerned that enrollees, their pharmacists or both incorrectly believe that the enrollee will always pay their Part D sponsor's higher negotiated price in situations when the pharmacy has a lower price. In many cases, this is illustrated by the enrollee submitting a paper claim after having paid cash at a network pharmacy even though the enrollee would have received the same price if the claim was processed through the Part D sponsor (or its intermediary) by the network pharmacy. We believe there may be confusion resulting from the increasing availability of very low

cost generic drugs at many Part D network pharmacies.

It is important to distinguish between a lower pharmacy price that is the pharmacy's U&C price versus a lower pharmacy price that is a non-U&C special discounted price. As our "lower cash price" policy describes, an enrollee would need to pay out of pocket and submit for reimbursement if the pharmacy's lower price is not its U&C price because the pharmacy will not submit that price to the Part D sponsor (or its intermediary). However, if the pharmacy submits a U&C price that is lower than a Part D sponsor's negotiated price, the enrollee will pay the lesser of the Part D sponsor's negotiated price or the pharmacy's U&C price. Therefore, the enrollee is better off when the pharmacy submits the claim to the Part D sponsor (or its intermediary) because the enrollee will pay the lower pharmacy price and have the dollar amounts reflected in their TrOOP and total drug spend balances.

Finally, we are concerned that sometimes enrollees are not aware that claims are not being processed through their Part D sponsor. We believe this can occur when pharmacies mistakenly believe that processing the claim through the Part D sponsor will result in the enrollee paying a higher Part D sponsor negotiated price or because the pharmacy deliberately does not want to incur transaction costs when the enrollee will be paying the pharmacy U&C price regardless. Our new requirement makes it clear that Part D sponsors must contractually require their network pharmacies to submit claims to the Part D sponsor (or its intermediary) whenever feasible unless the enrollee expressly requests that such claims not be submitted. We believe this requirement will help to ensure that Part D enrollees always have access to critical safety checks, as well as Part D negotiated prices and that their TrOOP and total drug spend balances accurately reflect their Part D expenditures.

15. Absence From Service Area for More Than 12 Months Under Part D (§ 423.44)

Section 1860D-1 of the Act establishes eligibility criteria for enrolling in a PDP plan or an MA-PD plan. In accordance with section 1860D-1(a)(3) of the Act, a "Part D eligible individual" is defined as an individual who is entitled to or enrolled in Medicare benefits under Part A or enrolled in Part B. In order to enroll in a PDP, the individual must reside in the plan's service area, and cannot be enrolled in an MA plan, other than an MSA plan or PFFS plan that does not

provide qualified prescription drug coverage.

Section 1860D–1(b)(1)(B) of the Act generally directs us to use disenrollment rules similar to those established under section 1851 of the Act. We applied the provisions of section 1851(g)(3) of the Act that provide authority for the basis of terminations for MA plans, which are codified in § 422.74. The disenrollment provisions for PDPs are outlined in § 423.44.

Under the current MA and PDP rules at § 422.74 and § 423.44, respectively, individuals who are out of the service area for more than 6 months will be disenrolled. There is an exception for MA plans that offer visitor or traveler benefits which allows a temporary absence from the service area for up to 12 months. However, given the inherent difference between PDPs and MA plans (in particular, the range of services each provides) we believe that it may not be appropriate or necessary to apply the disenrollment requirements established under MA in the same way for PDPs. The 6-month limit on the length of time an MA enrollee may be out of the service area before being disenrolled is based in large part on the inability of the enrollee to access the full range of medical services while out of the plan service area. However, Part D benefits generally can be accessed through a national pharmacy network, which can serve individuals effectively regardless of whether they are in their PDP region of residence. Thus, the same out-of-area time limit for PDPs may not be necessary, as long as there are specific assurances from the PDP that individuals will have access to PDP benefits while out of the area (provided the individual remains in the United States). For example, a PDP may have shared computer systems with PDPs in other regions or have a network of pharmacies in other regions (or nationwide) that would provide immediate access to prescription drugs outside of the region on the same basis as pharmacies within the enrollee's region of residence.

Therefore, given the nature of the Part D benefit and the strong likelihood that a PDP enrollee can access the full range of PDP benefits while out of the service area, we are proposing to amend § 423.44 to allow a temporary absence from the PDP plan service area for up to 12 months before disenrollment would be mandatory. We believe 12 months is an appropriate time frame because it is consistent with the time frame for MA plans' visitor or traveler benefits.

16. Prohibition of Mid-Year Mass Enrollment Changes by SPAPs Under Part D (§ 423.464(e))

Section 1860D–23(b) of the Act defines a SPAP as a State program that (1) provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of part D eligible individuals; (2) when determining eligibility and the amount of assistance to Part D eligible individuals under the Part D program, provides assistance to such individuals in all Part D plans and does not discriminate based upon the Part D plan in which the individual is enrolled; and (3) satisfies the requirements of other provisions in section 1860D–23 of the Act, like Medicare as primary payer. Section 1860D–23(a)(1) of the Act provides that the Secretary has the authority to establish requirements for Part D sponsors to ensure the effective coordination between a Part D plan and an SPAP. Included among those requirements are enrollment file sharing, claims processing and payment, claims reconciliation, application of the out-of-pocket expenditures, and other administrative processes set by the Secretary. In order to coordinate effectively with Part D sponsors, we permit SPAPs to conduct large volumes of enrollments (sometimes referred to as “mass enrollments”) consistent with our nondiscrimination guidance (see Chapter 14 of the Medicare Prescription Drug Benefit Program Manual). Most SPAPs perform these mass enrollments on a calendar year basis for all its members who have not chosen a Part D plan; however, some SPAPs have chosen to perform these enrollments on a noncalendar year basis. In these situations, Part D sponsors have found that substantial disenrollment of large numbers of SPAP members from one plan, followed by mass enrollment into another during the calendar year significantly affects their financial operations.

We believe that mass re-enrollment into a new plan mid-year disrupts any continuity of care the beneficiary has established with his other current Part D plan, and introduces transition risks such as drugs not being covered by the member's new plan, or requiring the member to change his or her pharmacy that are not outweighed by any administrative convenience to the SPAP. Therefore, given these concerns, we are proposing, under our authority described above, to add a requirement to § 423.464(e) to prohibit mid-year mass enrollment changes by SPAPs. We believe this revision would deter any SPAPs from engaging in what has been

a rare but exceedingly disruptive practice, and require large enrollment changes to be made on a calendar year basis only. We note that individual members of qualified SPAPs (or the State acting as the authorized representative of individual members) will continue to have Special Enrollment Periods (SEP), as provided in the current CMS guidance, for case-by-case enrollment actions.

In addition to beneficiary disruptions, our actuaries have determined that there are significant financial disparities among the Part D plans related to mass mid-year plan enrollment changes. The source of the disparity is the front-loading of plan liabilities in the annual bid due to the unique benefit structure of Part D program, including the coverage gap. Specifically, plans that have beneficiaries early in the year are likely to incur expenses attributable to the initial coverage period, the portion of the benefit that includes 75 percent coverage. Plans that have beneficiaries later in the year are more likely to have beneficiaries during the coverage gap portion of the benefit, which requires 100 percent beneficiary cost-sharing and no plan payment obligation in most cases. Because the funding of the benefit is uniform over the entire plan year, plans that lose beneficiaries mid-year are more likely to incur losses (the premiums associated with these beneficiaries after the initial coverage period), and plans that acquire beneficiaries mid-year from other Part D plans are more likely to experience gains (due to the beneficiaries enrolling during the gap in coverage) that in neither case have been anticipated in the plan's bids. This inequitable result demonstrates the importance of having a policy in place that minimizes mass mid-year plan changes.

17. Nonrenewal Beneficiary Notification Requirement Under Parts C and D (§ 422.506, and § 423.507)

Section 1857(a) of the Act provides the Secretary with the authority to enter into contracts with MA organizations, and section 1860D–12(b)(1) of the Act provides the Secretary with the authority to enter into contracts with PDP sponsors. Additionally, sections 1857(c)(1) and 1860D–12(b)(3)(B) of the Act grant the Secretary the authority to renew contracts. In accordance with the above-referenced authority, we have issued contracting regulations including § 422.506 of the MA regulations, and § 423.507 of the Part D regulations which provide for the nonrenewal of a contract.

Nonrenewals of MA or PDP contracts require the MA organization, the Part D

sponsor, or CMS to notify both the enrollees of the organization or sponsor and the general public of the nonrenewal. Existing regulations require notification 60 days prior to the effective date of the nonrenewal for notification both to enrollees and to the general public. The effective date of contract nonrenewals in the MA and PDP programs is January 1st of each calendar year. We propose to change the requirement for notification to enrollees from an "at least 60 day requirement" to an "at least 90 day requirement", as it was prior to January 1, 2009.

Changing the requirement for the personalized beneficiary specific CMS-approved notice to at least 90 days provides beneficiaries with an increased notice period giving beneficiaries more time to choose a new Medicare plan prior to the start of the new benefit year. When we changed the required notice period to 60 days, we did so primarily to provide adequate time for the appeals process to conclude prior to the start of the next calendar year; however, our recent experience has indicated that the vast number of nonrenewals are voluntarily elected by the PDP sponsor or MA organization, so there is rarely a need to accommodate the appeals process. For this reason, we propose revising § 422.506(a)(2)(ii) and (b)(2)(ii) of the MA regulations and § 423.507(a)(2)(ii) and (b)(2)(ii) of the Part D regulations to change the beneficiary notice requirement from at least 60 days to at least 90 days.

We also propose removing the current requirement for nonrenewing plans (in voluntary nonrenewal situations) and for us (in CMS-initiated nonrenewal situations) to provide notice to the general public by publishing a notice in one or more newspapers of general circulation concerning the impending nonrenewal. This change is motivated by the cost of newspaper advertisements and the declining rate of newspaper circulation, weighed against the very limited benefit gained from notice to the general public who is minimally, if at all, affected by the nonrenewal. Also, non-renewal information is now easily available to the general public through Internet web sites maintained by us (for example, <http://www.Medicare.gov>), a resource not available to the public when the newspaper notice requirement was first adopted. We believe that the requirement to provide personalized nonrenewal information to plan enrollees is sufficient to ensure adequate nonrenewal notice to the beneficiaries that are being nonrenewed, the population that is most directly affected by the nonrenewal. For this

reason, we propose deleting § 422.506(a)(2)(iii) and (b)(2)(iii) of the MA regulations and § 423.507(a)(2)(iii) and (b)(2)(iii) of the Part D regulations to remove the requirement that the general public be informed of the impending nonrenewal through the publication of newspaper notices.

18. Notice of Alternative Medicare Plans Available To Replace Nonrenewing Plans Under Parts C and D (§ 422.506(a)(2)(ii) and § 423.507(a)(2)(ii))

To allow additional operational flexibility, we also propose to change the requirement for PDP sponsors and MA organizations to provide written notification of the alternative Medicare plans available to replace the nonrenewing plan. We propose changing the requirement to include the option of either providing a written list of alternatives available, or placing outbound calls to all affected enrollees to ensure beneficiaries know whom to contact to learn about their enrollment options. We believe this change will be advantageous for beneficiaries because, depending on where the beneficiary resides, a listing of available plan options is often very long and may be too overwhelming for the beneficiary to use appropriately. A much more useful approach would be to provide beneficiaries with contact information and resources for identifying the most appropriate option given their unique, individual circumstances. For this reason, we propose revising § 422.506(a)(2)(ii) of the MA regulations and § 423.507(a)(2)(ii) of the Part D regulations, to provide the option of sending written notices of all available alternatives or placing outbound beneficiary calls to ensure beneficiaries know whom to contact to learn about their enrollment options. In either case, as discussed earlier in this section, a personalized CMS-approved beneficiary notice regarding the nonrenewal still must be sent to each beneficiary.

19. Timeframes and Responsibility for Making Redeterminations Under Part D (§ 423.590)

In accordance with section 1860D-4(g) of the Act, the Part D redetermination notice provisions in § 423.590 largely mirror the MA reconsideration notice provisions in § 422.590. There is one notable exception—§ 422.590(d)(3) allows MA plans to make the initial notice of a completely favorable expedited reconsideration orally, so long as a written confirmation is mailed to the enrollee within 3 calendar days of the oral notice. We did not carry over this

requirement to § 423.590, although a parallel instruction is contained in our subregulatory guidance in Chapter 18 of the PDP manual. Therefore, we propose to reconcile this discrepancy by adding new § 423.590(d)(2). Consistent with the requirements in § 422.590(d)(3), new § 423.590(d)(2) will allow Part D plan sponsors to make the initial notice of a completely favorable expedited redetermination orally, so long as a written confirmation of the fully favorable decision is mailed to the enrollee within three calendar days of the oral notice.

We also propose in § 423.590(d)(2) to allow Part D plan sponsors to make the initial notice of an adverse expedited reconsideration orally, so long as a written confirmation of the decision is mailed to the enrollee within three calendar days of the oral notice. We also propose to add a cross reference to paragraphs § 422.590(d)(1) and (d)(2) in paragraph (g) in order to apply the written notice requirements in paragraph (g) to adverse expedited redetermination decisions. We recognize that the MA reconsideration notice provisions at § 422.590(d)(5) and (e) do not provide explicit instructions regarding how MA organizations are to notify MA enrollees of adverse expedited reconsideration decisions. However, given the expedited status of these requests, we believe adding these two proposed notice requirements to the Part D expedited redetermination process is in the enrollee's best interests. Additionally, because adverse redetermination decisions are not automatically forwarded to the Part D Independent Review Entity, Part D enrollees need to receive clear information about the right to appeal and the procedures for appealing. We note that these two proposals are consistent with our subregulatory guidance and the process for notifying enrollees of expedited adverse coverage determination decisions in § 423.572(b).

Similarly, § 423.590(a)(1) requires a plan sponsor to send an enrollee written notice of a completely favorable decision for benefits; however, the regulations do not specify the content of that notice. Consistent with the statute, § 423.590(a)(1) mirrors the parallel provision at § 422.590(a)(1). However, for the same reasons outlined in the discussion above in this section, we believe incorporating notice requirements for the Part D standard reconsideration notice provisions does not conflict with the related MA provisions, and will provide an important beneficiary protection that will ensure continuity of care for Medicare beneficiaries who are

obtaining refills of prescription drugs under Part D. Therefore, we propose to add § 423.590(h) to establish the form and content requirements for completely favorable redetermination decisions, and propose making those notice requirements applicable to redeterminations issued under paragraph (a)(1). We also propose to reference paragraphs (d)(1) and (d)(2) in paragraph (h), so the proposed form and notice requirements in paragraph (h) will apply to completely favorable expedited redetermination decisions.

20. Requirements for Requesting Organization Determinations Under Part C (§ 422.568)

Section 1852(g)(3) of the Act allows an enrollee to request an expedited organization determination either orally or in writing. However, the method for requesting a standard determination is not addressed in either the Act or the implementing regulations at § 422.568. Both beneficiary advocates and MA plans have voiced concern about the absence of express regulatory authority allowing enrollees to request standard organization determinations both orally and in writing. Therefore, we propose adding specific language in § 422.568 allowing oral requests for organization determinations, except where the request is for payment.

21. Organization Determinations Under Part C (§ 422.566 and § 422.568)

Section 1852(g)(1)(A) of the Act requires MA organizations to have a procedure for making determinations regarding whether an enrollee is entitled to receive health services or payment under the program. In accordance with section 1852(g)(1)(A) of the Act, § 422.566 and § 422.568 establish the requirements related to organization determinations and notices. Existing § 422.566(b)(4) specifies that an organization determination includes a determination resulting in “[d]iscontinuation or reduction of a service *if* the enrollee believes that continuation of the services is medically necessary.” (emphasis added). Similarly, under § 422.568(c), the plan must give the enrollee a written notice of the determination “*if* an enrollee disagrees with the MA organization’s decision to discontinue or reduce an ongoing course of treatment.” (emphasis added).

Both of these provisions have at times been read to imply that the existence of an organization determination, and the associated notice requirements, were tied to the enrollee’s “belief” or “disagreement.” Therefore, we propose changing this language to better reflect

its meaning and purpose by removing the phrases “if the enrollee believes that continuation of the services is medically necessary” and “if an enrollee disagrees with an MA organization’s decision to”. Regardless of an enrollee’s decision whether to appeal as a result of this discontinuation or reduction, the key purpose of these provisions was to ensure that enrollees received an explanation of the plan’s decision and their rights if they choose to appeal the determination. Therefore, we propose removing the language noted above from § 422.566(b)(4) and § 422.568(c).

22. Representatives (§ 422.561, § 422.574, and § 422.624)

For various reasons, enrollees may choose or need to have someone represent them in the appeals process in order to protect their interests. Presently, under sections 1852(f) and (g) of the Act, a representative may act on behalf of an enrollee or other party when filing a grievance. However, existing § 422.561 does not explicitly permit the filing of grievances by representatives unlike the corresponding Part D regulation. In order to rectify this and be consistent with the Part D definition of representative at § 423.560, we propose to amend § 422.561 to clarify that a representative may act on an enrollee’s behalf with respect to the grievance process.

23. Disclosure Requirements Under Parts C and D (§ 422.111(g) and § 423.128(f))

Section 1857(a) of the Act provides the Secretary with the authority to enter into contracts with MA organizations, and section 1860D–12(b)(1) of the Act provides the Secretary with the authority to enter into contracts with PDP sponsors. Currently, § 422.111 and § 423.128 provide specific requirements on information that must be disclosed to enrollees, either at specific designated times, or upon request. We are proposing at § 422.111(g) and § 423.128(f) to state that we may require a sponsoring organization to disclose to its enrollees and potential enrollees information concerning the sponsoring organization’s performance and contract compliance deficiencies in a manner specified by CMS. This disclosure may be required when a sponsoring organization is sanctioned, or when a sponsoring organization’s compliance and/or performance deficiencies rise to a certain level, such that we determine it is necessary for the sponsoring organization to notify its existing and potential enrollees of these deficiencies. The vehicle by which the information is

disclosed by the plan, such as through the organization’s Web site, pre-enrollment materials, or separate letter to enrollees, and the timing and content of that disclosure, are subject to CMS review and approval. The language we are proposing is not intended to limit these required disclosures to particular times of the year when beneficiaries would ordinarily be able to make changes or elections (for example, AEP or OEP). We believe that this kind of transparency will provide additional incentives for sponsoring organizations to make improvements to their operations and also provide relevant information to beneficiaries and the public concerning plan choices. We solicit comment on these regulatory provisions. In particular, we solicit comment on whether these disclosure requirements should be imposed only in those circumstances where a beneficiary would be afforded the opportunity to act on them (for example, requiring disclosure during the particular times of year when beneficiaries would ordinarily be able to make change or elections, except in those situations where the compliance deficiency is so significant that a beneficiary may be afforded a special enrollment opportunity).

24. Definition of MA Plan Service Area (§ 422.2)

Section 1851(b)(1)(A) of the Act provides that Medicare beneficiaries are eligible to enroll in an MA plan only if they reside in the geographic area served by the MA plan, that is, the “service area.” An MA plan’s “service area” is currently defined in § 422.2 and the definition expressly requires organizations to meet access standards, in accordance with access standards in § 422.112.

One question that has been posed to us is whether incarcerated individuals are eligible to join an MA plan, especially an MA plan that does not offer Medicare prescription drug coverage. Note that the definition of service area for a Part D plan (§ 423.4) already excludes a jail or prison within the boundaries of the Part D plan service area, given that beneficiaries in jail or prison do not have access to pharmacies as required under § 423.120. It is a logical conclusion that incarcerated beneficiaries similarly would not have access to MA plan services, as required under § 422.112. Therefore, such an area could not meet the MA service area definition, which requires that such access standards be satisfied. Additionally, there is no reason for an individual to enroll in an MA plan while incarcerated, since basic health

care services typically are furnished by the jail or prison. Similarly, it would not be appropriate for an MA organization to receive monthly payments for such an individual, since medical services typically would be covered for the individual by the facility in which the individual is incarcerated. Such payments would represent an unwarranted windfall for services the MA organization would not have to, and could not, deliver. Therefore, we are proposing to amend the definition of an MA plan "service area" at § 422.2 to exclude facilities in which individuals are incarcerated.

C. Changes To Provide Plan Offerings With Meaningful Differences

This section addresses proposed changes to our regulations designed to foster plan offerings with meaningful differences. One of the underlying principles in the establishment of the Medicare Part D prescription drug benefit and the revisions to the Medicare managed care program resulting from the MMA was that both market competition and the flexibility provided to MA organizations and Part D sponsors in the statute would result in the offering of a broad array of cost-effective health and prescription drug coverage options for Medicare beneficiaries. Indeed, in the several years since implementation of the MMA, private health plans have taken full advantage of the opportunity to offer a wide array of health care plans and prescription drug benefit packages to Medicare beneficiaries. As a result, since 2006, Medicare beneficiaries throughout the United States have had available to them a multiplicity of health care and prescription drug options offered by a substantial number of private sector entities. We continue to support the concept of offering a wide variety of health plan and prescription drug coverage choices for Medicare beneficiaries consistent with our commitment to afford beneficiaries access to high value health care. However, based on several years of experience with the MA and Part D programs, we have learned that although beneficiaries need access to a variety of alternative plan options, benefit packages must represent significant differences to ensure meaningful choices. As noted previously, we have attempted to work with Part D sponsors since 2006 to

reduce the number of offerings from PDP sponsors as well as to convey information about Part D plan benefit designs in ways that are meaningful and understandable to beneficiaries. For example, we provide information about the various local MA plan and PDP options available to beneficiaries in the health plan charts included in the annual Medicare & You publication. Because there are practical limitations to the display of detailed comparative information in a print format, we also provide comparative plan information through other vehicles. We post landscape files to our Web site (see <http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/>) that provide more detailed comparative information, such as information about benefit type and, for Part D, whether the plan has a \$0 premium with full LIS subsidy, and a description of any gap coverage provided. This information is geared more toward beneficiary advocates and researchers than beneficiaries.

In addition, because a static description of plan benefits design features does not suffice to allow meaningful comparisons between drug plans, we also design and maintain the Medicare Options Compare (MOC) and the Medicare Prescription Drug Plan Finder (MPDPF) Web tool. These Web tools allow beneficiaries to customize their comparisons based on their particular needs and thus compare plan benefit packages in a meaningful way. For example, the MPDPF allows beneficiaries or their representatives to develop customized comparisons that are sensitive to a beneficiary's drug regimen, as well as tolerance for generic and therapeutic substitutes. Our goal in maintaining this tool is to strike a balance between the desire to provide as much information as possible to beneficiaries yet only provide information that is useful in making appropriate drug plan choices. We continue to look for ways to improve this tool and make information more understandable to beneficiaries and welcome comments in this area. Ensuring that Part C and D sponsors offer substantially different plan options, as the proposed regulatory changes discussed below are intended to do, will further maximize opportunities for beneficiaries to select benefit packages that meet their particular needs, while also

streamlining and simplifying the plan selection process.

Half of all Medicare beneficiaries have over 40 MA plan choices (this figure does not include special needs plans or employer group health plans which have additional criteria for enrollment), and many states offer 50 or more stand alone Part D plans, a number that can double when one includes Medicare Advantage plans with a Part D benefit. Several studies suggest that the MA and Part D program offerings are so numerous that they can be confusing. In a report by Marsha Gold of Mathematica Policy Research, Inc., for example, Gold writes of the MA program that "Existing research suggests that simplification may have advantages for beneficiaries," and that one such advantage is preventing competitors to take advantage of the system "through product design."⁵ In his study, "How Much Choice is Too Much? The Case of the Medicare Prescription Drug Benefit," T. Rice argues, based on Part D beneficiary studies that he and others in the field have conducted, that "The results show that decision quality [of seniors' ability to choose plans with the lowest annual total cost] deteriorated as the number of plans increases."⁶

As part of our goal of streamlining and simplifying the plan selection process for beneficiaries, we are also proposing to revise the nonrenewal regulations to expressly provide as a ground for nonrenewal the fact that an MA or Part D plan has failed to attract more than a small number of enrollees over a sustained period of time. In deciding whether to nonrenew a plan on this basis, we would expect to consider arguments as to why such low enrollment would be defensible in a particular situation (for example, the plan provides a benefit structure that is extremely important to its enrollees, despite the fact that they are small in number).

In this section, we discuss our proposed revisions to both the bid submission and review processes and the nonrenewal regulations. We believe these proposed revisions will help us accomplish the balance we wish to strike with respect to encouraging competition and providing health plan and PDP choices to beneficiaries that represent meaningful choices in benefit packages. Table 3 outlines these proposed revisions.

⁵ Gold, Marsha. Strategies for Simplifying the Medicare Advantage Market. Publication prepared for the Kaiser Family Foundation. July, 2009.

⁶ Rice, T. Reducing the Number of Drug Plans for Seniors: A Proposal and Analysis of three Case

Studies. Presentation at Academy of Health Annual Research Meeting: Washington, DC. June 9, 2008.

TABLE 3—PROVISIONS TO ENSURE MEANINGFUL DIFFERENCES IN PLAN OFFERINGS

Provision	Part 422		Part 423	
	Subpart	Section	Subpart	Section
Bid Submissions: Ensuring Significant Differences	Subpart F ...	§ 422.254	Subpart F ...	§ 423.265.
Bid Review Process	Subpart F ...	§ 422.256	Subpart F ...	§ 423.272.
Transition Process in Cases of Acquisitions and Mergers).	Subpart F ...	§ 422.256	Subpart F ...	§ 423.272.
Non-renewing Low-enrollment Plans	Subpart K ..	§ 422.506(b)(1)(iv)	Subpart K ..	§ 423.507(b)(1)(iii).

1. Bid Submissions—Ensuring Significant Differences (§ 422.254 and § 423.265)

Consistent with our authority under section 1857(e)(1) of the Act, incorporated for Part D by section 1860D–12(b)(3)(D) of the Act, to establish additional contract terms and our authority under section 1860D–11(d)(2)(B) of the Act to propose regulations imposing “reasonable minimum standards” on Part D sponsors, we propose to amend § 422.254(a)(4) and § 423.265(b) to specify that, when submitting bids to contract as an MA organization or Part D plan sponsor for the following contract year, MAOs and Part D sponsors must ensure that they submit bids for multiple plans in the same area only if those plans have significant differences from each other in terms of key benefit or plan characteristics such as premiums, cost-sharing, formulary structure, or benefits offered.

By proposing this change to our existing regulatory requirements regarding submission, review, and negotiation of bids, as well as CMS approval of plans, we aim to strengthen and build on our efforts to date to ensure a proper balance between affording beneficiaries a wide range of plan choices and avoiding undue beneficiary confusion in making coverage selections. Since 2005, we have reviewed Part D plan bids and negotiated with sponsors based on key benefit package characteristics, such as deductibles, substantial formulary differences, coverage in the coverage gap, and previous enrollment numbers. We also have reviewed plan offerings and negotiated with Part C contractors as part of our annual bid review and approval process, in an effort to identify and eliminate MA plans that appear to be duplicative. In connection with 2010 plan offerings, for example, we contacted MAOs whose plans in a service area represented insignificant cost differences, as well as MAOs having MA plans with 100 or fewer enrollees, and conveyed our expectation that they consolidate or terminate such plans, when appropriate.

We do not propose to specify in regulations text specific benefit package requirements or enrollment thresholds. Rather, it is our goal to permit MA organizations and PDP sponsors maximum flexibility to create plans with meaningful differences and, where warranted, to permit low enrollment plans to continue to operate when it is in the best interest of the program and of Medicare beneficiaries. We would issue guidance about the overall process, including the criteria for meaningful plan offerings and assessment of such offerings, in the annual Part C and D Call Letter. With this in mind, with respect to Part C, we would consider meaningful differences among plans offered by an MAO in a service area, as determined by CMS, to include a mix of plan types (for example, HMO, PPO, private FFS, or MSA plan), significant differences in plan benefit packages (the offering of a Part D benefit or a significant Part B buy-down, for example), or significant differences in premiums or cost-sharing (for example, a low premium-high cost-sharing plan versus a high premium-low cost-sharing plan) or aggregate costs to beneficiaries. In one possible scenario, under these general guidelines, we would particularly scrutinize whether there were sufficient differences among MA plan options if an MAO proposes to offer more than two plans of the same plan type in a service area. Even if only two plans of a given type are offered, they would, under our proposal, have to have meaningful differences relative to one another. For example, if two MA plans included a Part D benefit, we would require that there also be significant differences between these plans’ Part D benefits in terms of premiums, cost-sharing or other benefits.

If the proposed new requirement is implemented, we would require that plans be dropped that do not offer meaningful choices for beneficiaries. In making determinations about what is a meaningful choice of plan type, we could view a PPO and an HMO with a POS benefit as being similar plan offering if the POS benefit covered all A

and B services out of network. Similarly, a network private FFS plan and a PPO plan could also be viewed as similar plan offerings given the similarity in the access to services rules between these two MA plan types.

With respect to Part D plans, we would continue to focus our analysis on whether there are significant differences in proposed beneficiary out-of-pocket costs as a result of the deductible amounts (for example, \$0 deductible versus a \$310 deductible) and cost share or coinsurance (for example, a \$20 cost share versus a \$45 cost share for preferred brand drugs). We also would evaluate plan formularies (for example, a 25 percent difference in the number of unique generic entities offered on the plans’ formularies). These factors are the most significant considerations that are applicable to all benefit types. We solicit comment on how big the differences between plan offerings need to be in order to be “meaningful” to beneficiaries. For example, is there a meaningful difference between an enhanced plan with a \$0 deductible and no coverage in the gap versus an enhanced plan with a \$0 deductible and coverage of 50 generic drugs in the gap?

Additional benefit offerings such as free first fill programs and brand-name only deductibles may also be considered for the appropriate benefit types. In addition to the current considerations of formulary depth and breadth we may also consider the overall percent of utilization management applied to drugs and the specific types of utilization management (for example, prior authorization and step therapy). It is important to note that, even though a sponsor may submit different formularies for different plan offerings, all submitted formularies must be sufficiently robust to pass our rigorous formulary reviews and be determined not to discourage enrollment by certain types of beneficiaries. Based on our experience and given statutory actuarial equivalency requirements, we do not expect that, absent substantial differences in approved formularies, sponsors can demonstrate substantial differences between plans offering basic

prescription drug coverage. It is also our experience that sponsors typically must offer substantial coverage in the coverage gap as a supplemental benefit in order to demonstrate that one enhanced alternative plan design is substantially different from another.

We are proposing that, in our review process, we would provide particular scrutiny in those market areas where multiple MAOs or Part D sponsors offer multiple plans. Specifically, we would particularly target our resources to our review for “meaningful differences” in areas where the elimination of duplicative plans would still leave a large number of plan options. For example, in the highly competitive Miami-Dade county market area, we might particularly focus our review on multiple HMO offerings from the same MAO in areas where additional HMO plans are not adding meaningful new choices for prospective enrollees. Similarly, we would particularly scrutinize Part D plan offerings from the same Part D sponsors for meaningful differences in regions where multiple plans with multiple benefit types (for example, enhanced alternative coverage, coverage in the gap) already exist.

As we continue to accumulate program experience negotiating with MA organizations and Part D plan sponsors regarding bid submissions, it is our intent to apply these “lessons learned” both to our bid submission requirements and to our bid negotiation protocols. We expect to continue to determine whether there are substantial differences in plan types and benefit packages by looking at factors such as health plan benefit packages, cost-sharing, and deductibles, substantial formulary differences, and coverage in the coverage gap. We are soliciting comments on our proposed changes to the bid submission process.

As discussed more fully in section II.B.5. of this proposed rule, we are also interested in building additional checks into our process to ensure that, in structuring bids that are sufficiently different from any other bid they may propose, MAOs and Part D sponsors do not design benefit packages that have the effect of discriminating against certain types of Medicare beneficiaries. This is consistent with our statutory authority in sections 1852(d)(1)(A) and 1860D–11(e)(2)(D)(i) of the Act, which provide that we may disapprove a bid if we find that a plan’s proposed benefit design substantially discourages enrollment in that plan by certain Medicare-eligible individuals.

In the context of the MA program, we are especially concerned about cost-sharing for certain high-cost services

and would caution plans to ensure that when crafting plan packages with meaningful differences, they do not create discriminatory cost-sharing structures. We have the authority, under section 1852(b)(1) of the Act (implemented at § 422.110), to reject bids that we determine to be discriminatory. With respect to Part D sponsors, a plan that is considering an additional benefit package that is both nondiscriminatory and substantially different from its basic or enhanced alternative PDP offering(s) might choose to bid on enhanced alternative coverage that includes coverage of both some brand and generic drugs in the coverage gap. Depending on how this enhanced alternative coverage were structured, such a design could meet the threshold of being substantially different from a benefit package offering basic prescription drug coverage and/or an enhanced alternative benefit package that only offers coverage of certain excluded drugs, as provided in § 423.104(f)(1)(ii)(A).

2. Bid Review Process (§ 422.256 and § 423.272)

In order to further ensure that the benefit packages and plan cost structures offered by an MAO or Part D sponsor are meaningfully different, consistent with the preceding discussion, we propose to add § 422.256(b)(4)(i) and § 423.272(b)(3)(i) to provide that we will only approve a bid submitted by an MAO or Part D sponsor if we find its plan benefit package to be substantially different from the plan benefit packages reflected in that sponsor’s other submitted bids in terms of key plan characteristics such as premiums, cost-sharing, formulary structure, or benefits offered.

3. Transition Process in Cases of Acquisitions and Mergers (§ 422.256 and § 423.272)

Based on several years of program operational experience, we have also learned that when an MAO or Part D sponsor (or a parent organization to the sponsor) purchases another MAO or PDP sponsor, the result can be that the single parent organization offers plans through multiple subsidiaries of that same parent that are not substantially different from one another. In this specific situation, plan options may be designed by a subsidiary that has no incentive to compete against plans offered by other subsidiaries, which may result in multiple plan offerings by one sponsor or parent organization that do not represent substantial or truly meaningful choices to beneficiaries.

In the 2008 Call Letter for Medicare health plans and PDPs, we announced a policy under which PDP sponsors or parent organizations with new acquisitions would be afforded a period of 3 years to transition their plan offerings to meet the goal of ensuring that the sponsor’s offerings were substantially different from one another. For example, a PDP sponsor (or its parent organization) completing an acquisition of another sponsor in November 2009 would not be subject to requirements for offering substantially different bids until the 2013 contract year (that is, bids would be due in June 2010 for the 2011 program year; transition would occur during 2011 and 2012; and the plan sponsor or parent would need to ensure that in June 2012, when it submits its bids for program year 2013, all of its 2013 bids are for substantially different plans).

Consistent with existing policy, we propose adding a new paragraph § 423.272(b)(3)(ii) providing for a 2-year transition period in the case of a merger of Part D plan sponsors or the acquisition of a Part D plan by another Part D plan sponsor or parent organization. We believe a 2-year transition period strikes a balance between allowing sponsors (or their parent organizations) with recent acquisitions sufficient time to streamline their operations after completion of an acquisition with the need to streamline and simplify beneficiary plan selection. We are proposing the 2-year transition instead of our current policy of 3 years based on our experience with Part D sponsors that have merged with or acquired other sponsors. Based on our experience, we believe that a 2-year period permits sponsors ample time to ensure that all plans offered represent significant differences, especially because, as indicated in the sample bidding cycle outlined above, we do not count the year of the merger or acquisition as part of the 2-year period.

After a transition period of 2 years, we would only approve a bid submitted by a PDP sponsor, or a parent organization to that PDP sponsor, if the benefits or plan cost structure represented by that bid was substantially different from any other bid submitted by the same Part D sponsor (or parent organization to that Part D sponsor) in terms of key plan characteristics, such as premiums, cost-sharing, or formulary structure.

We are also proposing to make a similar change so that MA plans acquired through purchase or merger offered by same MAO or parent organization reflect meaningful differences after a 2-year transition

period. We propose to codify this policy at § 422.256(b)(4)(ii).

We request comments regarding the adequacy of our proposed transition period length of 2 years in both the MA and Part D contexts.

4. Non-Renewing Low-Enrollment Plans (§ 422.506(b)(1)(iv) and § 423.507(b)(1)(iii))

We are proposing to revise the Part C and Part D nonrenewal regulations to include, as a specific ground for nonrenewal, a finding that a plan has failed to attract a significant number of enrollees over a sustained period of time. We believe that, absent special circumstances, which we discuss below, a plan that has failed, over a sustained period, to attract enrollees is being operated in a manner “inconsistent with the efficient and effective administration” of the Part C or Part D programs, within the meaning of section 1857(c)(2)(B) of the Act, which is incorporated into Part D by section 1860D–12(b)(3)(B) of the Act, and thus would be subject to termination.

In the 2010 Call Letter, we announced that MA organizations and PDP sponsors should terminate or consolidate low-enrollment Part C and D plans. In advance of the 2010 contract year, we have contacted MAO sponsors with enrollments of 100 beneficiaries or fewer for 2 or more years, conveying our expectation that the organization consolidate or terminate such plans. We

now propose to add continuously low enrollment to the specific regulatory grounds for nonrenewal by CMS of an MA plan or PDP. We note that this requirement would be independent of the current requirement in § 422.514(a) and § 423.512(a) that MAOs and Part D sponsors meet minimum enrollment requirements at the organization level for purposes of entering into a contract with us. Those requirements apply to all enrollees of the organization, not enrollees in a particular plan.

Although low enrollments often reflect lack of beneficiary interest in a plan, there are instances when low enrollment is a function of the type of beneficiaries served, geographic location, or other circumstance. Instances in which we would consider a waiver of the proposed requirements include but are not limited to a chronic care SNP offering health care services especially tailored to this category of beneficiaries not available elsewhere, or an employer group health plan offering benefits augmenting those of an MA plan to employees of a small business. If a case can be made that low enrollment is justified and the absence of such a plan would significantly limit beneficiary health care options in a service area, consistent with effective and efficient administration of the Part C or Part D benefit, we would not nonrenew that plan. Similarly, although we believe an enrollment of 100 or fewer beneficiaries for 2 or more years

was a reasonable threshold for scrutiny under our 2010 assessment of MA plan enrollments, this number could fluctuate. As a result we are not proposing to revise our regulations to specify a specific threshold. If, using the principles described above, we identify an alternative threshold for scrutiny, we will include this information in our annual Call Letter. We solicit comment on this approach and whether we have provided sufficient clarity on how we will determine whether a low-enrollment plan will not be renewed.

D. Changes To Improve Payment Rules and Processes

This section addresses four payment issues under Part C. The first proposal outlines a new proposed dispute and appeal rights process for risk adjustment data validation audit findings that result in payment errors. The second proposal would require an actuarial certification for Part C bids. The third proposal under this section would clarify how health care prepayment plans (HCPP) and cost plans authorized under section 1876 of the Act must determine acceptable administrative costs. Finally, the last proposal would update our regulations to eliminate a 2 percent minimum update for all rate calculations, other than end-stage renal disease (ESRD), for reasons we set forth below. These provisions are outlined in Table 4.

TABLE 4—IMPROVING PAYMENT RULES AND PROCESSES

Provision	Part 417/422	Part 417/422	Part 423	Part 423
	Subpart	Section	Subpart	Section
Risk Adjustment Data Validation Appeals	Subpart G	Various sections of Part 422.	N/A	N/A.
Payments to Medicare Advantage Organizations—Actuarial Valuation.	Subpart F	§ 422.254	N/A	N/A.
Determination of Acceptable Administrative Costs by Cost Contract and Health Care Prepayment Plans (HCPPs).	Subpart O	§ 417.564	N/A	N/A.
Calculation of the Minimum Percentage Increase under Part C.	Subpart G	§ 422.306	N/A	N/A.

1. Risk Adjustment Data Validation Appeals (§ 422.310)

a. Background

Subpart G of the MA regulations at part 422 describes how payment is made to MA organizations. These payment principles are based on sections 1853, 1854, and 1858 of the Act. Subpart G also sets forth the requirements for making payments to MA organizations offering local and regional MA plans, including calculation of MA capitation rates.

Section 1853(a)(3) of the Act requires that we risk adjust our payments to MA organizations. Risk adjustment strengthens the Medicare program by ensuring that accurate payments are made to MA organizations based on the health status plus demographic characteristics of their enrolled beneficiaries and ensures that MA organizations are paid appropriately for their plan enrollees (that is, less for healthier enrollees expected to incur lower health care costs and more for less healthy enrollees expected to incur

higher health care costs). Accurate payments to MA organizations also help ensure that providers are paid appropriately for the services they provide to MA beneficiaries. In general, the current risk adjustment methodology relies on enrollee diagnoses, as specified by the International Classification of Disease, currently the Ninth Revision Clinical Modification guidelines (ICD–9–CM) to prospectively adjust capitation payments for a given enrollee based on the health status of the enrollee.

Diagnosis codes determine the risk scores, which in turn determine the risk adjusted reimbursement. As a result, physicians and providers must focus attention on complete and accurate diagnosis reporting according to the official ICD-9-CM coding guidelines (that is, coding diagnoses accurately and to the highest level of specificity).

The current risk adjustment model employed in adjusting MA plan payments is known as the CMS Hierarchical Condition Category (CMS-HCC) model. It functions by categorizing ICD-9-CM codes into disease groups called Hierarchical Condition Categories, or HCCs. Each HCC includes diagnosis codes that are related clinically and have similar cost implications. The CMS-HCC model is recalibrated approximately every 2 years to reflect newer treatment and coding patterns in Medicare FFS. In 2007, a demographic data-only payment method was completely phased-out for MA plans, and 100 percent of payment was risk-adjusted. The statute continues to provide us the authority to add to, modify, or substitute for risk adjustment factors if the changes will improve the determination of actuarial equivalence.

b. Risk Adjustment Data Validation Initiatives

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

Verifiable medical record documentation is the key to accurate payment and successful data validation. We annually select MA organizations for risk adjustment data validation (RADV) audits. RADV audits are intended to confirm the presence of risk adjustment conditions (that is, diagnoses that map to HCCs) as reported by MA organizations for their enrollees and confirmed via medical record

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

From 1999 until 2003, our payment validation activity for the M+C program had both an educational and audit focus and was intended to improve the accuracy of the risk adjustment data that was being submitted to CMS for payment. Payment adjustments were limited to enrollee-level adjustments for those enrollees sampled in the payment validation audit. At the time, only 10 percent of the MA payment amount was risk adjusted. As a result, payment recovery amounts for the small number of plans audited was very small. Since payment year 2004 was the first year for which MA payments were based on the current HCC risk adjustment model, we considered payment years 2004 through 2006 as pilot years for the purpose of RADV and no payment recovery activity occurred. For payment year 2007, we began conducting payment adjustments based on statistical RADV MA contract-level payment error audit findings. The existence of contract-level RADV audits is intended to enable us to make contract-level payment adjustments rather than simply adjusting payments for specific enrollees from an audit sample as we have done previously.

On July 17, 2008, we announced a pilot program to more extensively audit MA organizations for payment year 2007 based on calendar year 2006 payment data. In this notice, we announced its plans to make contract-level payment adjustments using payment error findings from a sample of enrollees from each of the selected contracts. This was a major change to our RADV audit approach in that it signaled for the first time the Agency's intent to recover MA organization contract-level payments. As a consequence, this would result in substantially larger payment error than

the previous enrollee-level audits. In 2009, we expanded its RADV audits to randomly selected MA organizations and MA organizations targeted because of the results of an earlier coding intensity study. Both the random and targeted RADV audits were intended to generate statistically valid contract-level payment error estimates based on 2007 payments.

c. RADV Error-Rate Calculation Disputes and Reconsiderations

Neither the MMA nor existing Medicare Advantage regulations expressly provide for an administrative appeals process that would apply to RADV-related disputes involving MA organizations undergoing RADV audits. Until 2008, because RADV audit payment adjustments were limited to sampled beneficiary-level findings only, the overall impact of these payment adjustments on MA organizations was relatively small. Nevertheless, affected MA organizations requested that we provide some type of appeal remedy for disputing RADV audit results. In response to this request, for the RADV audit activity that occurred for payment year 2005, MA organizations that disputed our RADV audit findings were permitted to do so via an administrative process known as documentation dispute. Under documentation dispute, MA organizations selected for RADV audit could dispute enrollee-level HCC findings based on the application of the ICD-9-CM guidelines. This documentation dispute process allowed MA organizations to submit new medical record documentation and clarifying documentation. Our medical record review contractors reviewed this clarifying documentation via the documentation dispute process and if this documentation overturned the initial discrepancy determination, the contractor would recalculate the MA organization's payment error estimate and make payment adjustments based upon the revised payment error estimate.

d. Proposed Addition of Medicare Advantage Organization Risk Adjustment Data Validation—Dispute and Appeal Procedures

Our experience to date in conducting RADV audits has led us to propose affording MA organizations undergoing RADV audits the formal dispute and appeal rights as possible remedies for RADV audit findings that result in payment errors. Since neither the statute nor existing MA program regulations specify RADV dispute or appeal requirements, we are, under our authority to establish MA program

standards by regulation at section 1856(b)(1) of the Act, proposing additions to part 422, subpart G at new § 422.311, to specify RADV dispute and appeal rights for MA organizations. Specifically, we propose allowing MA organizations that have undergone RADV audit(s) to—(1) submit physician and other practitioner signed attestations for physician and other outpatient medical records with missing or illegible signature and/or credentials that could result in a payment error; (2) dispute certain other types of medical record review-related errors through the use of a documentation dispute process; and (3) appeal our RADV payment error calculation. By availing themselves of these RADV dispute and appeal processes, MA organizations may be able to reduce their RADV payment error and thereby, reduce their overall estimated MA payment error. Therefore, we are proposing the following provisions under part 422:

- At § 422.2, we provide definitions of six terms that pertain to Risk Adjustment Data Validation (RADV) activities and thereby, relate to our proposals for implementing RADV dispute and appeal processes.

- At § 422.311, we propose adding a new section to Subpart G—RADV audit dispute and appeal processes—describing procedures that we would implement to afford MA organizations undergoing RADV audits the opportunity to have certain potential RADV payment errors addressed in advance of RADV-audit-related payment error determinations being made, and other types of confirmed payment errors overturned. At § 422.311(a) and (b), we summarize the procedures that we undertake to conduct RADV audits of MA organizations. Beginning with § 422.311(c), we propose implementing three RADV-related dispute and appeal procedures that MA organizations could undertake to reduce their RADV payment error to include—

- Physician/practitioner attestation(s);
- Documentation dispute; and
- RADV payment error calculation appeal.

Analysis of data originating from medical records submitted by MA organizations that have undergone RADV audit indicates that a substantial percentage of medical record-related payment error determinations are due to missing or illegible signature or credentials on medical records. Medicare program rules dictate the necessity of physician signatures on medical records, and MA risk adjustment requirements dictate that risk adjustment diagnosis data be

accepted from health services that were conducted by certain physician specialties. Therefore, RADV requirements dictate that in addition to the presence of diagnosis information that would support HCCs submitted by MA organizations, physician signatures and credentials must be present on medical records. Medical records with missing or illegible signatures and/or credentials are scored as errors under RADV audit procedures. We estimate that if given the opportunity to do so, many physicians and other practitioners that provided the diagnosis information on RADV-reviewed medical records would in fact attest that they documented the information in these medical records, even though signatures and credentials were missing. The presence of a signature or credential attestation to accompany these medical records would in our opinion, provide justification for preventing both contract-level and national-level RADV payment errors that may otherwise originate from medical record signature and/or credential discrepancies only. They would not, however, be acceptable to address any issues outside the RADV audit process.

Therefore, under our authority to establish MA program standards by regulation at section 1856(b)(1) of the Act and the authority at section 1853(a)(3) of the Act to risk adjust payments for MA organizations, at newly established § 422.311(c)(1), we are proposing to implement a process that would allow MA organizations to voluntarily submit CMS attestations (that is, only attestations developed and pre-populated by CMS). These attestations would be signed by physicians/practitioners who would attest responsibility for conducting and documenting the health services in the physician and outpatient medical record(s) being submitted for RADV audit. We specify at § 422.311(c)(1)(ii) and (iii) that MA organizations would be eligible to use attestations to address signature and/or credential-related discrepancies only from physician or outpatient medical records; attestations would not be allowed to address signature and/or credential-related discrepancies found on inpatient medical records. We do not believe it is necessary to permit attestations for inpatient medical records. The proposed use of an attestation would not in any way supplant the medical record, nor would it permit attesting physicians/practitioners to alter the existing medical record.

Based on our recent RADV experience, the percentage of payment error associated with signature and

credentials for inpatient medical records is relatively small. Furthermore, MA organizations would not be permitted to use attestations as a vehicle for introducing new HCCs for payment consideration.

At § 422.311(c)(1)(C)(iv), we indicate that we would prospectively notify MA organizations that if their one best medical record necessary to validate an audited HCC was missing a physician/practitioner signature or credential, the MA organization would be permitted to submit a CMS RADV attestation along with the medical record, to fulfill the requirement that medical records contain physician/practitioner signatures and credentials.

We describe the process that we would jointly undertake to review attestations submitted for our review at § 422.311(c)(1)(iv) and (v). Only CMS-generated attestations that meet certain requirements described at § 422.311(c)(1) and (d) are eligible for consideration. Failure to meet these requirements would result in us not reviewing submitted attestations. CMS attestations that have been altered or amended (for example, striking out pre-populated words and replacing them with hand-written replacement words) without instruction or written confirmation by CMS will not be accepted. Attestations must accompany the medical record at the same time that the medical record is submitted to CMS for RADV audit. MA organizations may not submit attestations before or after submission of their RADV medical records. Attestations must originate from the physician/practitioner whose medical record accompanies and corresponds to the attestation. We will not accept attestations or medical records from any party other than the MA organization. Organizations may not submit attestations during the documentation dispute or RADV reconsideration processes described at § 422.311(c)(2 and 3). At § 422.311(c)(1)(iv), we describe the process that we would undertake to review attestations and notify appellant MA organizations of the results of these attestation reviews. Our attestation review determinations would be final and binding upon both parties and would otherwise not be eligible for further appeal.

We believe this proposal benefits both MA organizations and the Government. First, MA organizations will be provided an opportunity to prevent substantially high RADV payment errors that would otherwise be associated with signature and/or credential errors. Second, we benefit by being able to report RADV payment errors that

originate primarily from the lack of diagnosis data necessary to justify submitted HCCs rather than missing signatures and/or credentials or the lack of legible signature and/or credentials. We believe that this is an important distinction given the underlying principles of the risk adjustment payment model—a model that pays MA organizations less for healthy enrollees and more for less-healthy enrollees based upon the existence of diagnostic data in enrollee medical records.

We further propose affording MA organizations the option of disputing other non-signature or credential-types of RADV-related medical record diagnosis coding discrepancies via a proposed documentation dispute process that we describe in new paragraph § 422.311(c)(2) et seq. This proposal is based upon our authority to establish MA program standards by regulation at section 1856(b)(1) of the Act and the authority at section 1853(a)(1)(G) of the Act to risk adjust payments for MA organizations. In order to be eligible for documentation dispute, MA organizations must submit their one best medical record to us in accordance with RADV medical record submission deadlines established by CMS during the RADV medical record request process.

At § 422.311(c)(2)(a), we specify the types of RADV-related errors that would be eligible for the documentation dispute process. The documentation dispute process will apply only to the errors that arise out of operational processing of medical records selected for RADV audit and submitted to CMS by established deadlines. In this context, errors that arise from operational processing mean errors that arise from the collection and processing of medical records for RADV audit. For example, if an MA organization submits a two-page medical record that inadvertently becomes separated into “two” medical records upon receipt by the CMS Medical Record Review Contractor—we would permit the MA organization to resubmit the two-page medical record so that the record can be reviewed in its intended two-page format. At § 422.311(c)(2)(ii), we specify the limitations that we would impose upon the documentation dispute process, namely that MA organizations would not be permitted to dispute any medical record coding discrepancies, nor would MA organizations be permitted to submit altogether new medical records in place of previously submitted medical records. Payment errors that resulted from missing medical records will not be eligible for documentation dispute. A missing

medical record means that no medical record documentation was submitted by the formal CMS-established deadline. MA organizations would not be permitted to use the documentation dispute process as a mechanism for establishing new HCCs for payment consideration. In this context, the term “new HCC” means an HCC that was not previously assigned to an enrollee, because no associated risk adjustment diagnosis data was submitted to CMS for payment.

At § 422.311(c)(2)(iii) and (iv), we indicate that we would prospectively notify MA organizations of RADV payment errors that would be eligible for documentation dispute, describe the documentation dispute process that we would undertake, along with the process that we will undertake to notify MA organizations of the results of documentation dispute reviews. As described at § 422.311(c)(2)(v), our documentation dispute review determination would be final and binding upon both parties and would not otherwise be eligible for further administrative appeal.

We believe affording MA organizations the ability to dispute the operational processing of those medical records that are submitted timely offers MA organizations and CMS a balanced approach for disputing a significant portion of RADV errors. It also does so in a manner that benefits both MA organizations and the Government. Allowing MA organizations to dispute CMS’ operational processing errors provides MA organizations an opportunity to overturn certain types of RADV payment errors and thereby reduce their overall RADV payment error. However, the approach we recommend here that limits MA organizations to disputing only certain types of errors ensures that the integrity of the CMS’ RADV audit process remains intact. We believe this is an important consideration in developing an RADV dispute process that balances the desires of the MA industry and the program integrity interests of the Federal Government. To date, some MA organizations that have undergone RADV audit have been dissatisfied with our medical record review processes and have petitioned CMS to allow additional opportunities to validate HCCs selected for audit. Given the rigor of our existing RADV audit procedures generally and multi-faceted medical record review procedures specifically, we believe this is unnecessary. Indeed, we believe that it is important to understand that while the RADV medical record review process is intentionally a rigorous procedure that

is carried out by several independent CMS contractors, we have structured the overall medical record review process so that MA organizations can successfully submit requested medical records necessary to validate diagnoses that were sent to us for determining payments under risk adjustment.

The rigor surrounding the RADV medical record review process is well established and has been known to the MA industry for several years. For purposes of clarity and context, we summarize that process here. To validate the CMS–HCCs selected for audit, MA organizations need only submit medical record documentation for each enrollee CMS–HCC requested by CMS for the specified audit time frame. The medical record must reflect a date of service that occurred during the respective audit period. We instruct each MA organization to select and submit the one best medical record necessary to support each enrollee CMS–HCC being validated. Furthermore, we provide each MA organization undergoing RADV audit 12 weeks to submit the one best medical record for validation. Once requested medical records have been received, for any identified RADV errors, we conduct two rounds of medical record review by two independent contractors. Medical record review contractors employ certified coders to review medical records. The purpose of the second independent medical record review is to confirm discrepancies found in the initial review. To ensure the integrity of the medical record review process and the accuracy of the medical record review findings, the second medical record review contractor is blind to the findings from the first medical record review contractor when it examines medical records that the first medical record review contractor determined were discrepant. Further, all discrepant records with coding discrepancies are reviewed twice. First they are reviewed by a primary coder and then they are forwarded to a senior-level expert coder for review confirmation. As needed, consultation from physicians is also provided. Finally, we undertake robust medical record coder inter-rater reliability (IRR) testing to ensure that medical record review activity is consistent and the application of CMS RADV coding guidelines are applied uniformly and fairly.

Together in its entirety, we believe the RADV medical record review process is thorough and it affords MA organizations ample opportunity to successfully meet RADV audit standards. We believe that affording MA organizations additional opportunities

for attestation and documentation dispute to meet CMS' RADV medical record documentation standards, beyond those specified at proposed § 422.311(c)(1) and (2) et seq., would be an unnecessary use of government resources that is unlikely to result in any meaningful change in RADV audit results.

Pursuant to our authority to establish MA program standards by regulation at section 1856(b)(1) of the Act and the authority at section 1853(a)(1)(G) of the Act to risk adjust payments for MA organizations, we are adding § 422.311(c)(3) to establish an appeals process whereby RADV payment error calculations may be subject to appeal. Unlike our proposed attestation process described at § 422.311(c)(1) and proposed documentation dispute process describe at § 422.311(c)(2) which afford MA organizations the opportunity to dispute aspects of our medical record review process, the RADV payment error calculation appeal process is specifically designed to afford MA organizations the opportunity to appeal our contract-level RADV payment error calculation. Under the proposed RADV payment error calculation appeal process, we are establishing a three-level appeal process whereby MA organizations may—

- Seek reconsideration;
- Appeal the reconsideration decision to an independent CMS hearing officer; and
- Appeal the decision of the independent CMS hearing officer to the CMS Administrator.

Unlike the proposed attestation and documentation dispute processes described in our proposed regulations at § 422.311(c)(1) and (c)(2), our proposed RADV payment error calculation appeal process has several layers of appeal available to MA organizations. Our proposed dispute processes described at § 422.311(c)(1) and (c)(2) afford MA organizations only one level of dispute consideration because the RADV medical record audit process already provides multiple layers of strong and overlapping review and independence. These measures ensure robust layers of internal checks and balances that help maintain the integrity of the medical record review process. Therefore, we do not believe that the attestation or document dispute processes require additional levels of dispute. Given the complexity of RADV audits in general, and the calculation of RADV-related error rates in particular, we do believe it's prudent to afford appellate MA organizations multiple-layers of RADV-related payment error appeal.

At § 422.311(c)(3)(ii) we specify that MA organizations may not under the RADV payment error calculation appeal process appeal medical record review errors nor may MA organizations seek formal appeal of physician or practitioner signature or credential-related review errors. Medical record review-related issues will be resolved as a result of the rigorous medical record review process and the proposed attestation and documentation dispute processes described earlier in this proposed regulation. In accordance with our proposed regulation at § 422.311(c)(3)(i), the RADV payment error calculation appeals process only applies to errors identified in the RADV payment error calculation. MA organizations cannot utilize the payment error calculation appeal process as a method for submitting any medical records for consideration in the calculation of the payment error. In order to be eligible for RADV payment error calculation appeal, MA organizations must adhere to established RADV audit requirements, including the submission of medical records in the manner and by the deadlines specified by CMS.

Furthermore, MA organizations cannot appeal the CMS' payment error calculation methodology. Our justification for excluding methodological appeals is two-fold. First, the methodology that we employ to calculate RADV payment errors is methodologically sound and academically defensible. We intend to ensure that all MA organizations understand the RADV payment error calculation methodology by providing annual notice to all MA organizations of the methodology that will be employed for calculating Part C payment errors. MA organizations that object to CMS' RADV payment error calculation methodology will be given an opportunity to provide comment to us under the Agency's annual notice of RADV audit methodology. Second, in addition to providing an annual notice of RADV audit methodology, we will provide an expanded explanation of methodology as part of each audit report of findings that we send to MA organizations that undergo RADV audit. Included in this expanded explanation of methodology will be RADV payment error calculation factors unique to each audited MA organization that will enable the MA organization to independently calculate its own RADV payment error.

At § 422.311(c)(3)(iii) and (v), we specify that MA organizations will be notified of their RADV payment error calculation appeal rights at the time

CMS issues a RADV audit report to that organization. MA organizations will have 30 days from the date of this notice to submit a written request for reconsideration of its RADV payment error calculation. A request for reconsideration must specify the issues with which the MA organization disagrees, the reasons for the disagreements and explain why the organization believes the issues are eligible for reconsideration. The request for reconsideration may include additional documentary evidence that the MA organization considers material to the reconsideration, though MA organizations are prohibited from submitting medical record-related evidence such as new or previously submitted medical records or physician or practitioner attestations and from appealing any issues pertaining to the methodology applied in any part of the RADV audit. At § 422.311(c)(3)(iv), we further specify that the MA organization bears the burden of proof to demonstrate that CMS' RADV payment error calculation was clearly incorrect.

We describe the proposed conduct of a RADV payment error calculation reconsideration, the decision of the reconsideration official and the effect of the CMS reconsideration decision official at § 422.311(c)(3)(e) and (f).

At § 422.311(c)(3)(v) and (vi), we describe the first level of RADV payment error calculation appeal, the request for reconsideration of our RADV payment error calculation. Under this process a CMS official or our contractor not otherwise involved in error-rate calculation activity reviews our RADV payment error calculation and any written evidence submitted by the MA organization that pertains to CMS' RADV payment error calculation, recalculates the payment error utilizing our RADV payment error calculation methodology as specified in our standard operating procedures, and renders a determination whether the RADV payment error calculation is accurate. This CMS official or CMS contractor (not otherwise involved in RADV error-rate calculation activity) may calculate and arrive at a different RADV payment error. Whether the official or contractor agrees with our payment error calculation or overturns this calculation and establishes a new RADV payment error, this party's RADV payment error calculation determination is issued to a CMS reconsideration official. The CMS reconsideration official reviews their analysis and makes a determination whether to accept or reject the findings of the CMS official or CMS contractor that recalculated the RADV payment error. In instances when

the CMS official or contractor recommends overturning CMS' RADV payment error calculation and the reviewing CMS reconsideration official agrees with the newly calculated RADV payment error, we issue a reconsideration decision which informs the appealing MA organization in writing of its reconsideration decision, in effect, notifying the MA organization of its new RADV payment error. If the reconsideration official upholds the decision of the CMS official or contractor to sustain our initial RADV payment error calculation, the reconsideration official similarly notifies the appellant MA organization of its determination. In either instance, the decision of the reconsideration official is final and binding unless a request for hearing is filed by CMS or the appellant MA organization.

At § 422.311(c)(4), we propose to allow CMS or MA organizations that are dissatisfied with the decision of the CMS reconsideration official described at § 422.311(c)(3) et seq., to request a second level of RADV payment error calculation appeal, a hearing on their RADV payment error calculation determination. CMS or MA organizations choosing to pursue a hearing must file a request for hearing within 30 days of the date the MA organization receives our written RADV payment error calculation reconsideration decision as described at § 422.311(c)(3)(vi). CMS or MA organizations requesting a hearing must do so in writing, include a copy of the CMS reconsideration official's decision to either uphold or overturn our RADV payment error calculation, and specify the findings or issues in that reconsideration decision that they disagree with and why they disagree with them. The hearing will be conducted by the CMS Office of Hearings and presided over by a CMS Hearing Officer who neither receives testimony nor accepts any new evidence that was not presented with the request for reconsideration of the RADV payment error calculation. The hearing will be held on the record, unless the parties request, subject to the hearing officer's discretion, a live or telephonic hearing. The hearing officer may also schedule a live or telephonic hearing upon their own motion. The CMS hearing officer is limited to the review of the record that was before us when we made both our initial RADV payment error calculation and our reconsidered RADV payment error calculation.

The hearing officer has full power to make rules and establish procedures, consistent with the law, regulations, and

CMS rulings. These powers include the authority to take appropriate action in response to failure of an organization to comply with such procedures.

As described at proposed § 422.311(c)(4)(iv), the CMS hearing officer reviews and decides whether the reconsideration official's decision was correct and notifies CMS and the MA organization in writing of his/her decision, explaining the basis for the decision. In effect, the CMS hearing officer's ruling either upholds or overturns the RADV payment error calculation. The Hearing Officer does not recalculate the error and offer either party an alternative RADV payment error. In instances where the hearing officer overturns the RADV payment error calculation, the hearing officer issues their written determination to CMS and the MA organization, in effect, notifying both parties that we must recalculate the organization's RADV payment error. If the Hearing Officer upholds the decision of the CMS reconsideration official regarding the RADV payment error calculation, the Hearing Officer similarly notifies CMS and the MA organization of his/her determination. The Hearing Officer's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with § 422.311(c) (5).

The third level of RADV payment error calculation appeal that MA organizations can request is discretionary review by the CMS Administrator. We describe this proposed process at § 422.311(c)(5) *et seq.* At this level of appeal, CMS or the MA organization can appeal the decision of the CMS Hearing Officer by requesting that the CMS Administrator review the CMS Hearing Officer's determination. Parties requesting CMS Administrator review would have to request the review within 30 days of receipt of the CMS Hearing Officer's determination. If the Administrator agrees to review the case, the Administrator reviews the Hearing Officer's decision as well as any other information included in the record of the Hearing Officer's decision and determines whether to uphold, reverse, or modify the CMS Hearing Officer's decision. The Administrator's determination is final and binding.

Based on our experience with appeals of MA and Medicare Part D program contract determinations, we have determined that it is necessary for us to establish a "compliance date" to use as a reference point in issuing a ruling regarding RADV audit findings. By way of this proposed regulation at § 422.311(b)(2), we are requiring that the

compliance date for meeting Federal regulations requiring MA organizations to submit medical records for the validation of risk adjustment data, (§ 422.310(e)) also be the due date when MA organizations (or their contractor(s)) selected for RADV audit, must submit medical records to CMS. We will inform an MA organization in writing regarding selection for RADV audit including the due date for submission of medical records. Without a specific date as a reference point for evaluating compliance, MA organizations could choose to assert that while they were unable to meet RADV audit requirements on the date we specified as the due date for medical record submission, they were later able to do so. Under this scenario, organizations would be free to assert the right to submit medical records in place of, or in addition to, records that were, or were not, as the case may be, submitted to us by the RADV audit due date. Accordingly, if we proceeded to conduct our RADV audit, issue a report of findings, and attempt to collect any identified overpayments, affected MA organizations could counter that while they did not have medical records to justify a particular HCC-level payment at the time due, they now have such records. Therefore, we should re-open the audit, review the new medical records and adjust our report of findings accordingly. The medical record review process could continue ad-infinity, preventing us from closing out RADV audits and collecting any identified overpayments.

We welcome comments on all aspects of these proposed rules.

2. Payments to Medicare Advantage Organizations—Actuarial Valuation (§ 422.254)

We propose to amend the regulation to expressly require an actuarial certification for Part C bids. Operationally, we require an actuarial certification to accompany every bid, for both Parts C and D. A qualified Oactuary who is a Member of the American Academy of Actuaries (MAAA) must complete the certification. The objective of obtaining an actuarial certification is to place greater responsibility on the actuary's professional judgment and to hold him/her accountable for the reasonableness of the assumptions and projections. This requirement is already set forth in the part D regulations at § 423.265(c)(3). This proposed change in the part C regulation text will bring the part C regulation at § 422.254(b)(5) in line with current requirements and Part D.

3. Determination of Acceptable Administrative Costs by Cost Contracts and Health Care Prepayment Plans (§ 417.564)

Our requirements for the apportionment and allocation of administrative and general costs for health care prepayment plans (HCPPs) authorized under section 1833(a)(1)(A) of the Act and cost contractors authorized under section 1876 of the Act are set forth at § 417.564. As provided under § 417.802(a), with limited exceptions, allowable costs for HCPP reimbursement are the same as those for reasonable cost HMOs and CMPs as specified in Subpart O of Part 417. Both section 1833(a)(1)(A) of the Act (for HCPPs) and section 1876(h)(2) of the Act (for cost HMOs and CMPs) incorporate the definition of “reasonable cost” in section 1861(v) of the Act, which used to govern reimbursement to providers of services under Part A prior to the enactment of Prospective Payment Systems (PPS). Because that definition was originally established with respect to Original Medicare providers, we believe that it is appropriate to interpret and apply the principles in section 1861(v) in the managed care context. We accordingly propose to revise the regulations governing payments to HCPPs and cost HMOs/CMPs to clarify how we believe the reasonable cost principles in section 1861(v) should apply to HCPPs and HMOs/CMPs by specifying the methodologies that must be used in determining the different allowable administrative costs for both such entities.

We have noted in recent audits of HCPP and section 1876 cost contractors uncertainty regarding what constitutes a “reasonable” level of administrative costs incurred by these entities. In conducting audits, we have not always been able to confirm that HCPP and cost contractors authorized under section 1876 of the Act were calculating their administrative costs in a manner that has allowed us to verify that they have followed appropriate practices.

In order to remove any uncertainty on the part of HCPP and cost contractors authorized under section 1876 of the Act, we propose revising § 417.564(b)(2) to clarify how HCPP and cost contractors authorized under section 1876 of the Act must determine “reasonable” administrative costs. As proposed at § 417.564(b)(2)(iii), personnel costs claimed in administering both HCPP and cost

contracts authorized under section 1876 of the Act must be linked to the specific administrative function performed by persons, at a specific rate of pay, for a specified period of time. We also propose to clarify that this level of information must be available to CMS upon request or in the course of a review. Additionally, we propose revising § 417.564 by adding a new paragraph (c) that specifies that, in order for costs to be considered “reasonable costs” within the meaning of section 1861(v) of the Act, which expressly excludes “incurred cost found to be unnecessary in the efficient delivery of needed health services,” the following costs must be excluded when computing reimbursable administrative costs:

- Donations.
- Fines and penalties.
- Political and lobbying activities.
- Charity and courtesy allowances.
- Spousal education.
- Entertainment.
- Return on equity.

Because we are simply clarifying our reporting and recordkeeping requirements, by clarifying what costs an HCPP may report in its cost report as administrative costs for reimbursement by the government, we do not believe this provision would increase burden or costs for plan sponsors. However, we solicit comment on our assumptions.

4. Calculation of the Minimum Percentage Increase Under Part C (§ 422.306)

Section 5301 of the DRA added section 1853(k) of the Act to create a single rate book for calculating MA payments and applicable adjustments. The DRA also modified the methodology for updating the MA payment rates by adding section 1853(k)(1)(B) of the Act. Beginning in 2007, the statute requires for purposes of calculating the minimum percentage increase rate that the previous year’s benchmarks be updated annually using only the national per capita MA growth percentage as described in section 1853(c)(6) of the Act. Prior to 2007 the minimum percentage increase rate was the greater of 102 percent of the MA capitation rate for the preceding year or the MA capitation rate for the preceding year increased by the national per capita MA growth percentage for the year.

Since the statute, as revised by the DRA, no longer provides for the 2 percent minimum update, we can no longer apply it to the MA rates. The 2 percent minimum update still applies to

the end stage renal disease MA update because the statute at section 1853(a)(1)(H) of the Act provides that ESRD rates are to be calculated in a manner consistent with the way those rates were calculated “under the provisions of [section 1853 of the Act] as in effect before the date of enactment of the MMA.” The pre-2003 version of section 1853 of the Act included the 2 percent minimum update. Therefore, we propose to revise § 422.306 to eliminate the 2 percent minimum update for all rate calculations other than ESRD.

E. Changes To Improve Data Collection for Oversight and Quality Assessment

This section of the rule outlines four proposals related to improving Part C and D data collection for oversight and quality assessment. The first proposal addresses quality improvement projects and data on quality and outcomes measures under Part C. As part of this proposal, we would use data collected by Quality Improvement Organizations for MA quality improvement and performance assessment purposes.

The second proposal addresses payment for beneficiary surveys. We would require, consistent with other surveys under the MA program that MA and Part D sponsoring organizations pay for the data collection costs of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) annual survey beginning in 2011.

Under our third proposal, we propose to require that each Part C and Part D sponsor be subject to an independent yearly audit of Part C and Part D measures (collected pursuant to our reporting requirements) to determine their reliability, validity, completeness, and comparability in accordance with specifications developed by us.

Finally, the last proposal would amend our rules on the collection and use of prescription drug event data for nonpayment-related purposes. Previously our rules addressed only the collection of the original 37 data elements for non-payment related purposes. In this rule, we are proposing to collect all data elements included on the drug event record for non-payment purposes. We also propose to provide for the limited release of plan identifiers to certain government grantees.

For the reasons set forth below, we believe each of these proposals is necessary to ensure continued quality improvement in the Part C and D programs.

TABLE 5—IMPROVE DATA COLLECTION FOR OVERSIGHT AND QUALITY ASSESSMENT

Provision	Part 422		Part 423		Part 480
	Subpart	Section	Subpart	Section	
Requirements for Quality Improvement Programs under Part C.	Subpart D	§ 422.152,	N/A	N/A	§ 480.140.
Require that Sponsors pay for the Consumer Assessment Health Plan Survey (CAHPS).	Subpart D	§ 422.153	Subpart D	§ 423.156	N/A.
Require validation of reporting requirements ..	Subpart D	§ 422.152(b)(5)	Subpart D	§ 423.514	N/A.
Allow collection of all PDE data elements to be collected for non-payment purposes.	N/A	§ 422.516, § 423.514 ..	Subpart D	§ 423.505	N/A.

1. Requirements for Quality Improvement Programs Under Part C (§ 422.152, § 422.153, and § 480.140)

Section 1851(d)(4)(D) of the Act requires us to make available to MA eligible individuals' information comparing MA plan options, including information on plan quality and performance indicators to the extent this information is available. Separately, section 1852(e)(1) of the Act requires that each MA organization have an ongoing quality improvement program for the purpose of improving the quality of care provided to enrollees in each MA plan offered by the MA organization. Section 1852(e)(3)(A) of the Act requires that, as part of this quality improvement program, MA organizations collect, analyze, and report data that permits the measurement of health outcomes and other indices of quality as part of their quality improvement program for their coordinated care plans. To the extent that local PPO, regional PPO, PFFS, and MSA plans have a network of contracted providers, these plan types must meet the same quality improvement requirements as other coordinated care plans.

Section 1852(e)(3)(B)(i) of the Act generally limits the collection of data on quality, outcomes, and beneficiary satisfaction under section 1852(e)(3)(A) to facilitate consumer choice and program administration to "the types of data" that were collected as of November 1, 2003, however, section 1852(e)(3)(B)(ii), titled "Changes in Types of Data," provides for the Secretary to "change the types of data that are required to be submitted under subparagraph (A) after submitting to Congress a report on the reasons for such changes that was prepared in consultation with MA organizations and private accrediting bodies." Section 1852(e)(3)(B)(iii) also makes clear that the limitation in section 1852(e)(3)(B)(i) shall not be construed as "restricting the ability of the Secretary to carry out the duties under section 1851(d)(4)(D)" to

provide beneficiaries with "available" quality information on MA plans.

a. Quality Improvement Programs

The requirement for MA organizations to have ongoing quality improvement programs is codified at § 422.152(a). Under § 422.152(a)(1), MA plans are required to include a chronic care improvement program (CCIP) as part of their quality improvement program that meets the requirements set forth in § 422.152(c). As specified under § 422.152(a)(2), MA organizations are also required to include quality improvement projects as part of their quality improvement program that are expected to have a favorable effect on enrollee health outcomes and enrollee satisfaction, and meet requirements established in § 422.152(d). Under our current regulations at § 422.152(c) and § 422.152(d), MA organizations have flexibility to develop criteria for CCIPs and initiate any quality improvement project that focuses on clinical and non-clinical areas based on the needs of their enrolled population.

Based on our continued experience with the MA program and due to inconsistent methods used across organizations, we are concerned that relying on MA organizations to establish their own CCIPs and quality improvement projects may not lend itself to effectively compare plans by beneficiaries and to manage and report projects. More importantly, we have concerns that these projects are not addressing quality improvement areas that we believe reflect beneficiary needs. For example, some projects may be designed to improve processes only without linking the processes to clinical outcomes. For example, improving the timeliness and effectiveness of referrals to specialists, as measured by process measures, may have little or no impact on improved health outcomes for beneficiaries. We are interested in MA organizations focusing on individual as well as population specific health risk needs (for example, MA organizations' use of data sources internal to their

organizations to identify clinical outcomes that not only fail to meet national averages, but also jeopardize the overall health and quality of life of the beneficiary).

As a result of our concerns, we are proposing to revise § 422.152(a)(1) and § 422.152(a)(2) to require that MA organizations conduct CCIPs in patient populations and quality improvement projects in areas identified by CMS based on our review of data collected from MA organizations and the population served by the plans. We propose to determine what areas would most benefit from quality improvement and will provide guidance on specific quality improvement projects for MA organizations to implement, either based on that organization's specific quality improvement needs, or quality improvement needs for MA plans generally. We also will suggest methods and processes by which to manage a quality improvement project as appropriate.

Using the HPMS, Medicare Managed Care Manual, and other means of communication that CMS determines to be appropriate, we will annually inform MA organizations individually and/or generally which patient populations and areas we have determined would benefit most from a CCIP and quality improvement project, respectively.

b. New Quality Measures

As we strengthen our oversight of quality improvement programs implemented by MA organizations, we believe that there is also a need for us to collect additional data on quality and outcomes measures in order to better track plan performance. We currently collect from MA organizations data on quality, outcomes, and beneficiary satisfaction under Healthcare Effectiveness Data and Information Set (HEDIS®), Health Outcome Survey (HOS), and Consumer Assessment Health Providers Survey (CAHPS®). We anticipate additional collection and reporting of the same types of data on health outcomes and quality measures

that we currently collect as part of these processes.

We believe that the collection of these data is consistent with our authority under section 1852(e)(3)(A) of the Act, and do not believe that the limitation described under section 1852(e)(3)(B) of the Act limits this proposed additional data collection because the data collected would be of the same “type” of data that we currently collect as part of the HEDIS®, HOS, and CAHPS® processes. Examples of additional areas on which we plan to collect data are post-surgical infections or patient falls. Therefore, we are proposing to modify § 422.152(b)(3) and § 422.152(e)(2) to require MA plans to collect, analyze, and report quality performance data identified by CMS that are of the same type of data that plans are currently required to collect and report to CMS. Consistent with the Paperwork Reduction Act, we will provide the public at least two opportunities for public comment before imposing additional quality-related collection and reporting requirements.

c. Use of Quality Improvement Organization Review Information

The mission of the Quality Improvement Organization Program, as authorized under section 1862(g) and Part B of title XI of the Act, is to improve the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries. We contract with one organization in each state, as well as the District of Columbia, Puerto Rico, and the U.S. Virgin Islands, to serve as that state/jurisdiction’s Quality Improvement Organization (QIO) contractor. QIOs are private, mostly not-for-profit organizations, which are staffed by professionals, mostly doctors and other health care professionals, who are trained to review medical care and help beneficiaries with complaints about the quality of care and to implement improvements in the quality of care available throughout the spectrum of care. Over time, QIOs have been instrumental in advancing national efforts to motivate providers in improving the quality of Medicare services, and in measuring and improving outcomes of quality.

Data collected by QIOs to accomplish their mission represent an important tool for CMS in our efforts to improve quality under the MA program. QIOs collect survey, administrative, and medical records data in order to monitor and assess provider performance. These data are frequently required by scope of work contracts administered by CMS to assess whether or not QIOs are meeting performance goals.

Certain QIO data could be used to develop a standardized core set of clinical and non-clinical quality and performance measures that could be applied to all MA plans in order to allow beneficiaries to make better comparisons across all MA plan types and make an informed decision when selecting a plan. These measures could be used to rate plans according to their performance. To support efforts to provide meaningful information to beneficiaries when selecting an MA plan, we also plan to develop minimum performance levels and requirements that address clinical and non-clinical areas. In addition to tracking plan performance, these data could also be used to ensure plan compliance with MA contract requirements and support compliance or enforcement actions against plans that are poor performers on certain quality and performance measures. These data would also allow us to create a competitive value-based purchasing program based on quality of care.

Therefore, we plan to use one particular type of information already collected by QIOs and retool the data elements to make them specific to beneficiaries enrolled in MA plans. This information is quality review study (QRS) information, which is defined in 42 CFR 480.101(b). A QRS is “an assessment, conducted by or for a QIO, of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up.” QRS information means all documentation related to the QRS process. We intend to collect from the QIO only the data that relates to MA plan beneficiaries, providers, practitioners, and services. We could then aggregate the data to the applicable MA plan based on beneficiary enrollment. Accordingly, we are proposing to add a new § 422.153 to indicate that we will collect from the QIOs and use quality review study information that is generated, collected, or acquired by QIOs under part 42 CFR 480. We intend to use these data for the following functions: Enabling beneficiaries to compare health coverage options and select among them, measuring performance under the plan, ensuring compliance with plan requirements under Part 422, and other purposes related specifically to MA plans, as specified by CMS. We will not disclose any beneficiary identifiable information. In addition, we are proposing to amend § 480.140 to add a new paragraph (g), authorizing CMS’s use of quality review study information

solely for the purposes specified in § 422.153.

2. CAHPS Survey Administration Under Parts C and D (§ 417.472, § 422.152, and § 423.156)

In accordance with the 1997 Balanced Budget Act mandate to collect quality assessment data about health plans, we began collecting data in 1998 for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey of enrollees in Medicare Advantage (MA) plans (then called Medicare+Choice plans). In addition, cost contractors under section 1876 of the Act have also been participating in the CAHPS survey process with respect to their enrollees. We have continued to conduct this annual CAHPS survey at no cost to MA organizations or section 1876 cost contractors. After passage of the Medicare Modernization Act (MMA), we began administering a Part D version of this survey in 2007 to Prescription Drug Plans (PDPs) and Medicare Advantage-Prescription Drug Plans (MA-PDs) in accordance with § 423.156 and § 422.152.

Under sections 1857(e) (1) and 1860D–12 of the Act, the Secretary may add additional terms to the contracts with MA organizations and Part D sponsors as deemed necessary and appropriate. Similarly, in the case of cost contracts under section 1876, such new contract terms may be added under section 1876(i)(3)(D). As explained below, we are proposing on the basis of this authority, that MA, Part D, and section 1876 cost contracts will be amended to require MA organizations, Part D sponsors, and cost contractors to pay for the data collection costs of the annual CAHPS survey beginning in 2011.

In the 2010 Call Letter to Part C and D sponsoring organizations, we indicated that all MA and Part D contracts with at least 600 enrollees as of July 1 of the prior calendar year would be required to pay for the data collection costs of the CAHPS survey starting with the administration of the 2011 annual CAHPS survey. This proposal is intended to codify this requirement in the Part C and Part D regulations at § 423.156 and § 422.152, and for cost contractors in § 417.472.

The proposal to require MA organizations, Part D sponsors, and section 1876 cost contractors to pay for the data collection costs of the CAHPS survey would apply only to contracts with 600 or more enrollees. For reasons of statistical precision, a target minimum of 300 or more completed Medicare CAHPS Surveys must be received for each contract. In order to

obtain 300 or more completed surveys, we believe plans must have 600 or more enrollees because some enrollees will not be eligible to receive the survey, such as institutionalized enrollees, and not all enrollees selected to be surveyed will respond to the survey.

It is important to note that we conduct other Medicare quality surveys, such as the Hospital CAHPS and the Medicare Health Outcomes Survey (HOS) for which the MAOs are responsible for the cost of the data collection. This model for data collection is standard industry practice. For example, FEHB plans pay for the administration of the CAHPS survey to their members. The data collection model that we are proposing for CAHPS survey process would use the same model that MAOs currently follow for HOS. The National Committee for Quality Assurance (NCQA) certifies vendors to conduct the HOS survey on behalf of CMS. In 2009, MAOs chose from a list of six approved vendors for HOS. We have been moving toward this model for all of our data collection efforts for beneficiary satisfaction surveys. We propose to use a similar model for the Medicare CAHPS survey where Part C & D contractors and section 1876 cost contractors would select a vendor from a CMS list of approved vendors to conduct the survey on their behalf.

While this proposal would shift the cost of data collection to the eligible Part C and D contractors for the Medicare CAHPS survey (section 1876 cost contractors would be able to claim these costs on their cost reports), with this change the sponsoring organizations will have the flexibility of adding their own questions to the Medicare CAHPS survey. The flexibility to add questions will allow them to get feedback about any contract specific issues.

Under this proposal, the following types of contracts would be amended to include a requirement to administer the CAHPS survey—

- All Coordinated Care contracts, including local and regional preferred provider organizations (PPOs) and contracts with exclusively Special Needs Plans (SNPs) benefit packages;
- Cost contracts under section 1876 of the Act;
- Private-Fee-For Service (PFFS) and Medical Savings Accounts (MSA) contracts; and
- Prescription Drug Plans contracts (PDPs).

All plans under Programs of All Inclusive Care for the Elderly (PACE), HCPP—1833 cost plans, and employer/union only (PDP and PFFS) contracts

are excluded from this CAHPS administration.

Under this proposal, the first survey using the new model of data collection would be conducted in early 2011. Contracts that were in effect on or before January 1, 2010, would use the number of enrollees in a plan as of July 1, 2010 to determine whether they are required to conduct the 2011 CAHPS survey. In late 2010, all MA and Part D contracts that are subject to the CAHPS survey requirement in 2011 would need to select an approved Medicare CAHPS survey vendor to administer the survey.

We note that, in addition to approving a list of survey vendors to conduct the survey on behalf of all MA and Part D contracts, we would select the sample of enrollees to be surveyed for each contract, approve survey vendors, provide oversight of survey vendor activities, analyze the CAHPS data for plan ratings, and produce individual-level reports for quality improvement use by MA and Part D contracts. Vendors will be trained by us to collect and submit data within specified timeframes. If we decide to implement this proposal, we will provide further information regarding access to the listing of approved vendors for the CAHPS survey.

3. Validation of Part C and Part D Reporting Requirements (§ 422.516 and § 423.514)

Under sections 1857(e) and 1860D–12 of the Act, we have the authority to establish information collection requirements with respect to MA organizations and Part D sponsors. Under section 1857(e)(1) of the Act, MA organizations are required to provide the Secretary with such information as the Secretary may find necessary and appropriate. Section 1857(e)(1) of the Act applies to PDPs as indicated in section 1860D–12. Pursuant to our statutory authority, we codified these information collection requirements in regulation at § 422.516 and § 423.514, respectively.

Consistent with our regulatory authority to collect information, we developed specific MA and Part D reporting requirements to assist in monitoring the Part C and D programs and to respond to questions from Congress, oversight agencies, and the public. These inquiries include questions about costs, availability of services, beneficiary use of available services, patient safety, grievance rates, and other factors pertaining to MAOs and PDPs. We began collecting Part D information at the inception of the program. Data collected under the Part D reporting requirements currently

include seventeen measures ranging from access to extended day supplies at retail pharmacies to drug benefit analyses. Over time, we have modified the data elements collected as we gained more experience with the program. The current Part D reporting requirements (OMB 0938–0992) may be accessed at http://www.cms.hhs.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp.

We also require routine reporting of specific data elements by MA organizations. Beginning in January 2009, MA organizations are required to report information across 13 measures ranging from benefit utilization to agent training and testing. Similar to the Part D reporting requirements, these measures are designed to enable us to monitor plan performance and to respond to inquiries. The current Part C reporting requirements (OMB 0938–1054) may be accessed at http://www.cms.hhs.gov/HealthPlansGenInfo/16_ReportingRequirements.asp.

In order for us to use the data provided by MA organizations and PDP sponsors, the data must be accurate, valid, reliable, and comparable across plans. Because we have received data of questionable validity from some Part D sponsors, we stated in the 2010 Call letter (<http://www.cms.hhs.gov/prescriptiondrugcovcontra>) that the agency “has received many inquiries from Congress, oversight agencies, and the public about costs, availability of services, beneficiary use of available services, patient safety, grievance rates, and other factors pertaining to MAOs and PDPs. However, to date, we have not been able to address many of these inquiries due to either an absence of data with respect to MAOs or, despite collecting over three years’ worth of data, data of questionable validity submitted by Part D sponsors.” Accordingly, to meet the goals of data validity reliability, and comparability, we indicated in the Call Letter that, “to better enable CMS to respond to inquiries and manage our programs, sponsoring organizations should undertake a data validation audit on reported Part C and Part D data effective for CY2010.” Given the importance of the new Part C and Part D data reporting requirements, we are proposing to require MAOs and Part D sponsors to undertake an independent data validation audit in accordance with CMS specifications on reported Part C and Part D data that would be effective for CY2011. We believe that only an independent data validation audit conducted by an external entity under contract to the MAO or PDP sponsoring organization would ensure that the

results of the audit are in accordance with CMS specifications, that data used to develop plan performance measures are credible to other stakeholders, and that information used to respond to Congressional and public inquiries are reliable. We therefore propose to amend § 422.516 and § 423.514 to state that each Part C and Part D sponsor be subject to an independent yearly audit of Part C and Part D measures (collected pursuant to our reporting requirements) to determine their reliability, validity, completeness, and comparability in accordance with specifications developed by CMS.

We note that we are working with a contractor to develop data validation specifications to ensure that the goals of reliability, validity, completeness, and comparability are met at the conclusion of the data validation audit. These specifications will focus on how organizations and sponsors compile numerators and denominators, take into account appropriate data exclusions, and verify calculations, computer code, and algorithms. In addition, they will be used to inform how the MAOs, cost plans, and Part D sponsors collect, store, and report data. We expect that these specifications will be utilized by the auditors hired by MAOs and Part D sponsors to conduct the data validation audits, the results of which will be forwarded to us. We expect to make these specifications available on our website for public comment early next year. We solicit comment on this approach.

4. Collection of Additional Part D Claims' Elements for Nonpayment-Related Purposes (§ 423.505)

Section 1860D–12(b)(3)(D) of the Act, which incorporates section 1857(e) of the Act provides the Secretary with authority to include in Part D sponsor contracts any terms or conditions the Secretary deems necessary and appropriate, including requiring the organization to provide the Secretary with such information as the Secretary may find necessary and appropriate. Under this authority, on May 28, 2008 we published a final rule that allowed the Secretary to collect Part D “claims” data from the prescription drug event (PDE) record and use the information gathered for non-payment purposes (73 FR 30664). However, this rule limited what data (hereinafter referred to as PDE elements) we may collect and use for non-payment purposes. The rule also described circumstances under which we may disclose the data to other government and external entities, and the limitations associated with any such release.

In 2006 and 2007 there were 37 PDE elements. In 2008 the number of PDE elements collected was expanded from the original 37 elements to 39 elements. The additional PDE elements are “Estimated Rebate Amount Applied to the Point-of-Sale Price” and “Vaccine Administration Fee.” The “Estimated Rebate Amount applied to the Point-of-Sale Price” is the estimated amount of a rebate that the plan sponsor has elected to apply to the negotiated price as a reduction in the drug price made available to the beneficiary at the point of sale. The “Vaccine Administration Fee” is the amount that is charged for the administration of a vaccine separate from the actual vaccine.

In the 2010 Call Letter to sponsoring organizations we noted that we were planning to add a new (40th) element to the PDE record, referred to as the “Prescription Origin Code.” (at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CallLetter.pdf>). The prescription origin code is designed to capture the frequency with which providers use e-prescribing.

The original Part D claims data proposed rule published on October 18, 2006 (71 FR 61447) did not address the collection, for purposes other than payment, of any additional elements that might be added to the original 37 elements. Rather, in the proposed rule, we only included a discussion of the 37 elements that then comprised the PDE record and proposed that we would collect these 37 PDE elements under section 1860D–12(b)(3)(D) of the Act. As a result, as noted in the May 28, 2008 final rule (73 FR 30667) on Part D claims data, interested parties were not afforded an opportunity to comment on whether new elements that were added to the PDE record for 2008 (or any PDE elements that might be added in the future) should be collected under section 1860D–12(b)(3)(D) of the Act, and, consequently, used or disclosed to other parties for non-payment related purposes.

In this rule, we are now proposing to collect all additional PDE elements beyond the original 37 elements under the same authority described in the May 28, 2008 final rule on Part D claims data (that is, section 1860D–12(b)(3)(D) of the Act). As a result, we would be able to use these data for non-payment related purposes. Similarly, under this proposal, we would be able to release these elements to governmental and external entities, under the authority of section 1106 of the Act, using the same process that we now use to release the original 37 elements as described in the May 28, 2008 final rule, and as updated

by the September 18, 2008 interim final rule that incorporated changes made as a result of section 181 of MIPPA. Thus, in this rule, we propose that the release of any additional PDE data elements collected using our authority under section 1860D–12(b)(3)(D) of the Act would continue to be subject to our minimum necessary data policy, our data sharing procedures, and the encryption of certain identifiers and aggregation of cost data to protect beneficiary confidentiality and commercially sensitive data of Part D sponsors.

This proposal would allow us to collect and use for non-payment-related purposes any data obtained as a result of the addition of new elements to the PDE record without undertaking rulemaking for each additional element added in the future. We believe that the May 28, 2008 of Part D Claims Data final rule (73 FR 30664) resolved any statutory ambiguity surrounding our broad authority to collect PDE data under section 1860D–12(b)(3)(D) of the Act. Accordingly, we may use this same authority to collect additional elements that have been added to the PDE since 2007. Once data have been collected under section 1860D–12(b)(3)(D) of the Act, we may use these data for non-payment related purposes and may release PDE data consistent with our minimum necessary policy and our data procedures.

Elements such as rebates applied at the point-of-sale, vaccine administration, and prescription origin code represent claim-level information that once accessed and analyzed, could provide useful insight into operations of the Part D prescription drug benefit program. For example the prescription origin code could be studied to identify how often electronic prescribing is used in practice, and serve as background for policy proposals to further support this practice in the industry. Accordingly, we believe it is appropriate that these elements should be collected under section 1860D–12(b)(3)(D) of the Act.

For the same reason, we believe it would be appropriate to use our authority under section 1860D–12(b)(3)(D) of the Act to collect for non-payment purposes all elements that may be added to the PDE record in the future. We believe that the ability to analyze new claims-related elements added to the PDE record would increase both specific and general knowledge of Medicare beneficiaries' healthcare and the operation of the Part D program and would aid our ability to conduct program oversight, support operational tasks, and provide more information for use in internal and external healthcare

research studies. Moreover, we would not be required to undertake a separate rulemaking and public comment process each time new elements are added to the PDE record, but rather would automatically begin collecting for non-payment purposes elements added to the PDE record using our authority under section 1860D–12(b)(3)(D) of the Act and § 423.505(f)(3) of the regulations. As a result, we would have the ability to analyze these data for nonpayment related purposes in order to identify operational problems or to support future policy proposals without delay. Moreover, because we do not propose to modify our data sharing processes or our minimum necessary data policy with this proposal, any release of these new elements would be subject to the same protections that currently apply to all other Part D PDE data. Thus, we will continue to—

- Ensure that beneficiary, prescriber, or pharmacy identifiers are not released unless absolutely necessary for a project (for example, to link to another database);

- Encrypt Part D plan identifiers and aggregate cost data elements (ingredient cost, dispensing fee, and sales tax) when sharing PDE data with external requesters; and

- Subject each request to our data sharing procedures which includes ensuring that requestors have the appropriate experience and are working for, or on behalf of, a reputable institution and that, when appropriate, make their project results public. External requests concerning beneficiary identifiable data would continue to be reviewed by the CMS Privacy Board, and would require the requestor to sign a data use agreement.

Accordingly, for the aforementioned reasons, we are proposing to amend § 423.505(f)(3) to include all data elements included in all drug claims for purposes deemed necessary and appropriate by the Secretary and consistent with the Paperwork Reduction Act.

In the May 28, 2008 final rule we deemed it necessary to protect various Part D elements when responding to external research requests (as discussed above). Accordingly, beneficiary ID, plan ID, prescriber ID, and pharmacy ID are encrypted prior to release to external entities. However, in the case of beneficiary ID, prescriber ID, and pharmacy ID, this information may be provided in an unencrypted format when needed to link to another data set.

In contrast, under the current rule, there is no exception to the requirement that plan identifiers be encrypted for all external research requests. Under the current regulation, grantees of HHS agencies are treated as external entities and may not access plan identifiers. In contrast, contractors acting on behalf of HHS are not considered to be external entities and may receive unencrypted plan identifiers when necessary for a particular project, due to the provision in § 423.505(m)(iii)(A) that “all elements on the claim are available to HHS.”

Subsequent to publication of the Part D data rule, we have been made aware by some HHS agencies that a number of their grantees are having difficulty conducting some studies without a Plan ID (for example, studies which examine the extent to which plan choice is influenced by a plan’s name could only be determined using actual plan identifiers). These concerns have arisen at time when healthcare costs and patient outcomes under existing healthcare delivery systems are under great scrutiny, necessitating more research on cost-effective alternatives for healthcare delivery.

We are proposing to revise § 423.505(m)(iii)(C) to permit CMS disclosure to HHS grantees of unencrypted plan identifiers when certain conditions are met. We believe these conditions will mitigate the risk of any unauthorized use or disclosure of commercially sensitive plan information. The conditions we propose be met include—

- The plan identifier is essential to the study and there is no other source of CMS data that would substitute for plan identifiers in order to carry out the study;

- The study is key to the mission of the sponsoring agency;

- The study provides significant benefit to the Medicare program; and

- The requestor attests that any public findings or publications will not identify plans or plan sponsors.

In evaluating requestors’ proposals to determine whether these conditions are met, we propose the following evaluation standards:

- Plan identifier, to evaluate the requestor’s rationale to determine whether an encrypted plan identifier would be sufficient for the study design or if the real identifier is necessary for the study.

- Agency mission, we propose to review the requestor’s agency’s rationale for the study and how the study would help the agency achieve its mission.

- Medicare program benefit, we propose to review the requestor’s rationale for the importance of study findings to the Medicare program.

- Public reporting, we propose to require an attestation from the requestor that the requestor will not identify specific plans or plan sponsors in any public reporting.

We are proposing to provide access to unencrypted plan identifiers to HHS grantees for several reasons. First, some HHS agencies accomplish their mission through grants, rather than contracts, and hence cannot rely on the access that is provided to HHS contractors, which means that HHS agencies have differential access to prescription drug event data. In addition, we believe that research performed by HHS grantees will advance the interests of Medicare beneficiaries, who may also be served by other HHS programs. A number of HHS agencies, such as the National Institutes of Health (NIH) and the Agency for Health Care Research and Quality (AHRQ), provide grants for research on topics such as the utilization, adherence, safety, and effectiveness of medications in the elderly and disabled populations which are of key interest to the Medicare program. We anticipate that such studies will assist health care providers in improving medication use in Medicare beneficiaries over time.

Although our proposal is limited to HHS grantees, we also request comments on whether it would be appropriate to extend this proposal to permit grantees of other Federal agencies to have access to plan identifiers when this access may be necessary for a particular research project and that project otherwise meets the conditions described above.

F. Changes To Implement New Policy

This section addresses two policy proposals. In the area of Part D formulary policy, we propose new regulatory requirements affecting the inclusion of protected drug categories and classes on Part D formularies, following the enactment of MIPPA, which made a number of changes to the Part C and D programs. Under Part C, we propose to revise our rules to allow beneficiaries who elect MSAs as a type of health insurance plan to pay only a pro-rated deductible if their MSA deposit is pro-rated because they enroll after January 1. These revisions are detailed in Table 6.

TABLE 6—REVISIONS TO IMPLEMENT NEW POLICY

Provision	Part 422		Part 423	
	Subpart	Section	Subpart	Section
Clarify the MIPPA 176 “Protected Classes” formulary provision.	N/A	N/A	Subpart C ..	§ 423.120(b)(2)(v).
Pro-rating the Plan Deductible for Part C MSA Enrollments Occurring During an Initial Coverage Election Period.	Subpart C ..	§ 422.103	N/A	N/A.

1. Protected Classes of Concern Under Part D (§ 423.120(b)(2)(v))

As noted previously, the MIPPA was enacted on July 15, 2008. Prior to the passage of MIPPA and before the start of the program, we directed Part D sponsors to include on their formularies all or substantially all drugs in six drug categories (that is, antidepressant; antipsychotic; anticonvulsant; immunosuppressant for transplant rejection; antiretroviral; and antineoplastic categories or classes). This directive was aimed at ensuring a smooth transition of the approximately 6 million dual eligible beneficiaries who were converting from Medicaid drug coverage to Medicare drug coverage at the start of the Part D program.

Although section 1860D–11(i) of the Act prohibits us from establishing a “national formulary,” we have interpreted our obligation under section 1860D–11(e)(2)(D)(i) of the Act not to approve discriminatory benefit designs as providing the authority to set standards for review of formularies. In developing our formulary policy, we have sought to build on a careful balance between ensuring access to drugs for vulnerable populations, while at the same time allowing Part D sponsors the ability to implement drug utilization management processes to achieve cost containment. These standards are contained in Chapter 6 of the Medicare Prescription Drug Benefit Manual located at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/R2PDBv2.pdf>.

Section 176 of MIPPA added a new section 1860D–4(b)(3)(G)(i) to the Act requiring, effective plan year 2010, that the Secretary establish certain categories or classes of drugs that meet two specific statutory specifications: (1) Restricted access to the drugs in the category or class would have major or life threatening clinical consequences for individuals who have a disease or disorder treated by drugs in such category or class; and (2) There is a significant need for such individuals to have access to multiple drugs within a category or class due to unique chemical

actions and pharmacological effects of the drugs within a category or class. In addition, the MIPPA provides the Secretary with the discretion to establish exceptions permitting Part D sponsors to exclude from their formularies, or to otherwise limit access to (including utilization management restrictions or prior authorization), certain Part D drugs from the protected categories and classes.

In the January 16, 2009 **Federal Register** (74 FR 2881), we published the Medicare Advantage and Prescription Drug Programs MIPPA Drug Formulary and Protected Classes Policies interim final rule with comment period that revised the regulations governing the Medicare Part D formularies as a result of MIPPA. We codified the MIPPA provision requiring the inclusion of all drugs from identified “protected categories and classes” on Part D sponsor formularies at § 423.120(b)(2)(v). We also noted in the preamble of the January 16, 2009 IFC that the timing of Part D formulary submissions for 2010 will preclude us from making identification in time for the 2010 contract year. As such, we noted that Part D sponsors must continue to provide coverage of the six classes of clinical concern in contract year 2010, consistent with the policy already in place since 2005. For contract years 2011 and subsequent contract years, we indicated in the preamble that we plan to conduct a comprehensive analysis to—

- Determine which categories and classes of drugs, including which existing six classes of clinical concern, meet the MIPPA requirements for protected categories and classes; and
- Identify any potential exceptions to the requirement that all drugs from protected categories or classes be included on Part D sponsor formularies.

We also specifically noted in the preamble that we are planning a multilevel review process to identify protected categories and classes that would include the following:

- An initial data-driven analysis of widely used treatment guidelines and Part D utilization data; and

- A secondary review by a clinical review panel that will serve to validate the findings of the initial analysis.

We also stated that the second-level expert panel would be “consensus driven” and that “information regarding the independence, potential conflicts of interest, expertise, and balance of the individuals chosen for this panel would be made publicly available.”

We received 30 public comments on the January 16, 2009 IFC. Some commenters suggested an expansion of the current six classes of clinical concern policy, either through the removal of current exceptions or through processes that might broaden the number of protected classes beyond six. Other commenters suggested that the MIPPA was passed in order to codify the current six classes of clinical concern. Still other commenters suggested limiting the protected classes, stating that plans and pharmaceutical benefit managers can only limit beneficiary cost increases through use of formulary and drug utilization management tools. These commenters stated that CMS must carefully weigh increased beneficiary costs against any additional protections that derive from the establishment protected drug classes. Several commenters requested further clarification of terms, such as what we meant by our review of “widely used treatment guidelines” and what is meant by the MIPPA definition of “access to multiple drugs,” with many suggesting different interpretations. Finally, many commenters focused on our process outlined in the January 2009 IFC, with some questioning whether members of the validation review panel would be solicited from experts outside the government under a Federal Advisory Committee Act (FACA) process, whether the representation would include the perspective of beneficiaries, especially groups that advocate for beneficiaries living with specific diseases prevalent among Medicare beneficiaries, and whether the panel would include practicing physicians and specialists with documented

experience in treating Medicare patients in the therapeutic areas under review.

Based on the comments received on the January 16, 2009 IFC, we have decided to revisit section 176 of MIPPA and the “protected classes” for further interpretation and review. While some commenters and a few outside parties have suggested that the Congress’ intention behind section 176 of MIPPA was to codify our preexisting “6 class” policy, we do not believe that the plain reading of the statute supports such an interpretation because the six classes are not expressly identified in the MIPPA. Rather, we continue to believe that various analyses are needed to determine which drug classes meet the MIPPA criteria. Furthermore, varied and conflicting public comments we received on the January 16, 2009 IFC persuade us that the MIPPA criteria are not self implementing and, moreover, the process envisioned in the January 16, 2009 IFC may be unduly burdensome and too unwieldy to permit timely changes in reaction to medical and pharmacological advances. As a result, we are engaging in notice and comment rulemaking to further interpret section 176 of MIPPA.

We believe that the critical policy decision at hand, based on the comments received, is how broadly or narrowly we interpret specific terms in the MIPPA provisions. Interpreted broadly, the provisions in section 176 of MIPPA might easily encompass many classes of drugs and significantly increase costs to the Part D program by eliminating the need for manufacturers to aggressively rebate their products for formulary placement. However, a narrow interpretation of these criteria would reduce the number of classes that are “protected”.

We believe that the plain reading of section 176 of MIPPA does not remove or otherwise revise our transition and coverage determination protections outlined in subparts C and M of part 423, and further explained in Chapters 6 and 18 of the Medicare Prescription Drug Benefit Manual at http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage. These existing protections require Part D sponsors to establish a transition process, consistent with our requirements (which we propose to codify elsewhere in this rule), for issues associated with coverage of non-formulary drugs. They also require a Part D sponsor to establish an exceptions and appeals process, including an expedited request process in urgent situations that allows a beneficiary the right to request a

coverage determination for a non-formulary Part D drug on the basis of medical necessity. Our requirements further include the right of review of a sponsor’s negative determination by an independent review entity in cases of both a standard and expedited appeal.

We believe that it is critically important that section 176 of MIPPA be read in the context of the other protections inherent in the Part D program in order to avoid establishing unnecessary duplicative protections. The current protections already serve as an underlying foundation to ensuring access to needed Part D drugs that do not appear on a Part D plan’s formulary. We therefore propose to amend the regulatory language at § 423.120(b)(2)(v) that was added by the January 16, 2009 IFC in order to reflect the MIPPA protected categories and classes provision in the context of these protections. Specifically, we are proposing to interpret several of the statutory terms in section 176 of MIPPA to better define the scope of the protections under this section of MIPPA. To that end, we are proposing several new definitions at § 423.100.

In order to read section 176 of MIPPA in the context of the existing Part D program, we believe there is a need to interpret the meaning of the term “restricted access” under the first MIPPA criterion in section 1860D–4(b)(3)(G)(i) of the Act, which refers to “restricted access to the drugs in the category or class [having] a major or life threatening clinical consequences for individuals who have a disease or disorder treated by drugs in such category or class.” In theory, lack of access to any drug that is *medically necessary* could result in serious or life-threatening clinical consequences. Thus, one could argue that all prescribed Part D drugs are medically necessary and therefore should be protected. However, we believe that is more appropriate to interpret the MIPPA criteria more narrowly, both to avoid duplicative protections, as mentioned above, as well as to preserve one of the key aspects of the Part D program—namely, that Part D sponsors have the ability to undertake cost containment efforts through formulary design. For this reason, we believe it makes sense to interpret the statutory criteria that will be used to identify protected categories or classes of drugs with these parameters in mind, while seeking to ensure that the protections afforded under section 176 of MIPPA are meaningful. Under this interpretation, therefore, we intend the criteria to apply in those circumstances wherein a short time delay that results from the

application of existing procedures will result in the exacerbation of the enrollee’s underlying disease to an extent that it would cause persistent or permanent damage. For example, a short delay in access to an immunosuppressant to prevent transplant rejection would be more likely to meet the statutory criteria than a short delay in access to a drug intended to increase bone density or treat hyperlipidemia.

Given these considerations, we believe that in light of existing beneficiary protections under Part D, “restricted access” should be construed to occur in the case of someone who, but for the protected classes provision, urgently requires a Part D drug but is waiting for an expedited redetermination by a Part D plan or our independent review entity with respect to coverage of that drug. It is during this period of time—where the beneficiary may urgently need the drug but does not yet have access to it—that is most likely to result in a major or life threatening clinical consequence for beneficiaries who require treatment of a chronic condition or disease and who are going without such medications while awaiting the redetermination. Accordingly, we believe that we must identify drug classes and categories to, in part, address this situation.

To understand how our proposed definition of restricted access fits in context with the rest of the first MIPPA criterion, we believe it is important to have a consistent interpretation of the phrase “major or life threatening clinical consequences.” In thinking about how to define this term, we considered a definition developed by the FDA for new drug and biological products that are being studied for their safety and effectiveness in treating life-threatening or severely debilitating diseases. The definition of *life-threatening* in that context reads as: (1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted; and (2) diseases or conditions with potentially fatal outcomes, where the endpoint of clinical trial analysis is survival (21 CFR 312.81(a)). However, we concluded that this definition is too restrictive for our purposes. Section 176 of MIPPA contemplates ensuring enrollee access to drugs where restricted access “would have *major or life threatening clinical consequences*” (emphasis added). Thus, an interpretation that potentially could exclude “major” clinical consequences that were non-life-threatening would be insufficient. Instead, we believe that the definition of a similar term, “serious

reaction,” found at World Health Organization’s Web site at http://www.who.int/medicines/areas/quality_safety/safety_efficacy/Annex1GlossaryofTerms.pdf is more instructive and more appropriate for addressing the circumstances in which Part D enrollees may face restricted access to medically necessary drugs without a protected class requirement because unlike the FDA definition, it is not limited life-threatening situations, but rather encompasses both major and life-threatening clinical consequences. Therefore, we propose to define major or life threatening clinical consequences in a manner similar to the WHO definition. Specifically, we propose to define “major or life threatening clinical consequences” to mean serious clinical events that arise as a result of not taking a drug that leads to patient hospitalization, or a persistent or significant disability or incapacity, or that result in death.

We note that our proposed definitions with respect to the first criterion of section 176 of MIPPA are intended to provide protection against major or life threatening consequences at a time when other beneficiary protections still would result in a delay in access. We believe that only categories or classes of drugs for which a delay could cause a major or life threatening clinical consequences based on the definitions described above establish the most logical standard for the Part D program given existing beneficiary protections while avoiding potential increased program costs associated with adding duplicative protections.

The second MIPPA criterion requires that “[t]here is a significant need for such individuals to have access to multiple drugs within a category or class due to unique chemical actions and pharmacological effects of the drugs within the category or class, such as drugs used in the treatment of cancer.” To understand how this criterion intersects with the first criterion, one has to understand the meaning of the phrase “significant need for access to multiple drugs.” We believe that this phrase can be interpreted in only two ways: (1) To infer that the statutory phrase means simultaneous use of multiple drugs; or (2) to infer that the phrase means the sequential use of drugs due to a significant likelihood of failure of a specific drug in a class leading to the substitution of another drug or drugs in the same class. To ensure beneficiary protection, we propose to define the term “significant need for access to multiple drugs” to include both readings. Thus, we

propose to define the term to mean instances in which—

- There is a need for simultaneous use of multiple drugs within a drug grouping because such drugs work in combination with each other; or
- There is a strong likelihood of sequential use of drugs within a class or category within a short period of time due to a significant likelihood of failure of a specific drug in a class leading to the substitution of another drug or drugs in the same class. In other words, there is a strong likelihood that a different drug in the same category or class will be needed in a short period of time if the first drug failed due to the unique effects that the drug type may have on an individual. For example, there is a strong likelihood that noncurative chemotherapy will require multiple different drug substitutions as the cancer goes in and out of remission. Second, with respect to duration, we propose that a “short period of time” is a short time frame delay that will result in exacerbation of underlying disease to an extent that persistent and permanent damages will occur.

We propose to define the term “multiple drugs” to mean two or more drugs, and we propose to define the phrase “category or class” for purposes of determining compliance with the rules for protected categories and classes of section 176 of MIPPA as the identification of a drug grouping that is reasonable to identify the applicable drug product. We do not believe this identification is necessarily tied to a specific drug classification system, but rather represents the most specific grouping that is reasonable to identify the applicable drug products. For example, it may include drug groupings based on the USP Model Guidelines, the American Hospital Formulary Service (AHFS) classification, another drug classification system, or some combination thereof to define reasonable groupings of drugs.

Finally, consistent with the statutory authority for the Secretary to identify exceptions to the provision in section 176 of MIPPA, we propose to specify some of the exceptions to the MIPPA provision to include on formulary “all” Part D drugs meeting the two conditions set forth in section 1860D–4(b)(3)(G)(i) of the Act. As we stated in the January 16, 2009 IFC (74 FR 2881) and in our January 28, 2005 Part D final rule (70 FR 4260), inclusion of “all covered Part D drugs” on formulary from a protected class or category does not extend to inclusion of all brand-name drugs and generic versions of the covered drug in question. Under our longstanding interpretation of the term “covered Part

D drug,” and based upon scientific evidence and medical standards of practice, Part D sponsors will only be required to include on their formularies all chemically distinct drugs from the protected classes or categories in order to meet the provision in section 176 of MIPPA. Thus, two drug products that are determined to be therapeutic equivalents by the FDA and identified as such in the FDA’s Orange Book are considered to be the same Part D “drug” and would not be required on all formularies.

We also believe that it is important to consider safety and general drug and population applicability issues in the context of the new protections under section 176 of MIPPA. Although, as noted above, we believe that section 176 of MIPPA is intended to provide additional beneficiary protections, we believe it would be imprudent to interpret these new protections in such a way that they interfere with existing protections intended to promote safety and efficacy. For example, we believe that it is appropriate for Part D sponsors to establish edits for safety and that our policies not interfere with basic drug utilization management edits that sponsors apply at point-of-sale to ensure that adverse events do not occur. Such edits must be consistent with FDA labeling to ensure that they are based on scientific evidence and medical standards of practice. Indeed, we believe that any interpretation of section 176 of MIPPA that interferes with a plan’s ability to impose safety edits would defeat the very purpose of section 176 of MIPPA.

In order to minimize confusion about the scope of the protections under section 176 of MIPPA, we clarify that the formulary requirements set forth in section 1860D–4(b)(3)(G)(ii) of the Act apply only to Part D drugs; therefore, drugs that are not Part D drugs need not be included on a plan’s formulary, even if a particular non-Part-D drug might otherwise be included in a protected class or category under section 176 of MIPPA. In other words, the MIPPA protections do not apply to non-Part D drugs and their exclusion from the formulary requirements is not based on our exceptions authority under section 1860D–4(b)(3)(G)(iii) of the Act. Further, we do not require now as part of our six class policy, and would not require under the authority of section 176 of MIPPA, the inclusion of drugs that have been historically paid for under Part B (for example, “incident to” drugs supplied and administered by physicians during patient visit and paid for under Part B) or whose regulatory status under the definition of a Part D

drug at § 423.100 is not known. Given the fact that these drugs are not covered under Part D today, we believe their lack of presence on plan formularies would not disrupt access. We further believe that requiring the inclusion of these drugs on the formulary when they are not payable under Part D would lead to beneficiary confusion, particularly with respect to drugs with an unknown approval status. For these reasons, we are proposing to exclude drugs with very limited applicability to the Medicare Part D population and non-Part D drugs from the formulary requirements under section 176 of MIPPA.

Therefore, we have added a new paragraph to § 423.120(b)(2) to clarify exceptions to the inclusion of all drugs meeting the criteria under section 176 of MIPPA. Under § 423.120(b)(2)(vi), exceptions would include the following:

- Drug products that are determined to be therapeutic equivalents under the FDA's Orange Book;
- Edits that limit the quantity of drugs due to safety; and
- Other drugs that we may specify through a process that is based upon scientific evidence and medical standards of practice (and, in the case of antiretroviral medications, is consistent with the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents) and which permits public notice and comment.

We welcome comment on these proposed definitions and clarifications.

As noted previously, we now believe that the process outlined in the January 16, 2009 IFC may be too burdensome to pursue. One practical concern with that process is one of timing. We no longer consider it feasible by contract year 2011 to complete the process outlined in the January 16, 2009 IFC, in which we would—(1) contract with an organization to complete a data-driven analysis to identify possible protected classes and exceptions under the MIPPA; (2) decide on the composition, independence, expertise, potential conflicts of interest, and balance of individuals chosen to participate in the second-level validation panel that would arrive a consensus-driven set of recommendations; and (3) complete notice-and-comment rulemaking to both identify the protected categories or classes and to establish exceptions. Additionally, periodic updates and adjustments to the protected categories and classes, as well as to the exceptions, would take longer to implement if the process contemplated in the preamble

were followed every year or some periodic timeframe thereafter.

We continue to believe that the best way to determine which drug classes meet the MIPPA criteria is through a data-driven process, which includes an analysis of prescription drug event data, a review of widely used treatment guidelines, validation of the results by an expert committee of clinicians, and acceptance by the Secretary. By widely used treatment guidelines, we mean clinical literature that we consider to represent best practices. We envision these would include references in such sources as the Cochrane database and the AHRQ National Guideline Clearinghouse (NGC), and to include literature referred to in the Part D statutory compendia. (For more information on the Cochrane database and the NGC are see their Web sites at <http://www.cochrane.org/reviews> and <http://www.guideline.gov/>, respectively.) Therefore, it is our expectation that we will undertake the following multilevel process, which we again state is critical to any future identification of protected formulary classes under the Part D program:

- Commence an initial data-driven analysis of widely used treatment guidelines and Part D utilization data to identify the following:
 - ++ Possible categories and classes of drugs, including those of the existing six classes of clinical concern, that meet the requirements for protected categories and classes; and
 - ++ Any potential exceptions to the requirement that all drugs from protected categories or classes be included on Part D sponsor formularies.

We note that a review of treatment guidelines along with the review of the prescription drug event data will provide us with the necessary data to make informed decisions on the identification of MIPPA protected classes to present to the Secretary.

- Arrange for a secondary review by a group of government clinicians that will serve to validate the findings of the initial analysis. We believe that an expert Government panel will best assist us in appropriately weighing the data derived from the initial analysis against the statutory requirements to identify protected categories or classes of drugs in which “access to multiple drugs within a category or class” is needed because “major or life threatening clinical consequences” may arise if access is restricted. Furthermore, we believe the expert panel will be well positioned to consider the data that may suggest possible exceptions and consider this data in light of the protected categories or classes in order

to identify exceptions that are based upon available scientific evidence and medical standards of practice. Moreover, an expert panel of government physicians and pharmacists will obviate any problems surrounding independence of clinical judgment and potential conflicts of interest.

- Present recommendations to the Secretary of HHS of the drug classes or categories, and any recommended exceptions.

We note that the main difference between these data-driven process described here and the process outlined in the January 16, 2009 IFC is the composition of the clinical committee that will serve a validation review. As we noted above, an expert panel composed solely of government physicians and pharmacists would obviate any problems surrounding independence of clinical judgment and potential conflicts of interest, and would simplify the process compared to an external panel commissioned under the FACA.

With regard to the designation of the drug classes themselves and the manner in which they are announced, we believe there are two options and solicit comment on which option the public believes will allow us to make timely determinations in a transparent manner.

Option 1: Announce protected classes through subregulatory guidance (for example, the Call Letter) that provides a notice and comment process but does not entail full notice and comment rulemaking.

One option would be to promulgate regulations that set forth the criteria we would use to identify the protected classes and to apply those criteria as part of the data analysis and validation process described above, but to announce the protected classes that result from this process through subregulatory guidance, such as CMS's annual Call Letter to Part D plans, or alternatively through a separate **Federal Register** notice. Under either vehicle, we would invite comment prior to the final announcement of the protected classes and exceptions thereto, and prior to finalizing any changes to the protected classes or exceptions. We believe this approach represents a more simplified and streamlined process. We further believe that this simplified and streamlined process would provide ample opportunity for public input and adequate protection of the public interest in the determination of the protected classes and any exceptions thereto.

Furthermore, we believe that this process also is consistent with other processes we use to make similar

determinations. For example, under Medicare Part B, coverage of off-label use of anticancer therapies may include uses that are supported by certain drug compendia. In the CY 2008 Medicare Physician Fee Schedule final rule, we implemented a new process to make changes to the list of Part B-accepted compendia. This process involves posting materials on the CMS website, soliciting comment, and announcing final decision through nonregulatory means.

Option 2—Announce the protected classes through formal notice and comment rulemaking.

A second option would be to undertake the clinical and data driven review process described above and after promulgating regulations addressing the criteria for identifying the protected classes, implement the proposed protected classes themselves through notice and comment rulemaking, consistent with our proposal in the January 16, 2009 IFC.

We welcome comments on these two approaches for soliciting public comment and announcing the protected categories or classes of drugs required for inclusion on Part D sponsor formularies. We note that, given the implementation timeframes discussed above, as well as the need to ensure consistency in formulary coverage as we complete our analysis to implement the requirements of section 1860D-4(b)(3)(G)(i) of the Act, we will retain our existing six classes of clinical concern contained in Chapter 6 of the Medicare Prescription Drug Benefit Manual (section 30.2.5) for contract year 2010. We further note that any decisions with respect to the retention of these classes for the 2011 contract year will be made either through a separate rulemaking that identifies the MIPPA

protected classes and any exceptions thereto and/or as part of the 2011 Call Letter to Part D plans.

2. Pro-rating the Plan Deductible for Part C MSA Enrollments Occurring During an Initial Coverage Election Period (§ 422.103)

Section 1851(a)(2)(B) of the Act establishes Medicare Medical Savings Account (MSA) plans as a type of health insurance plan that combines both a tax advantaged savings account and a high-deductible health insurance policy. Under this MA plan option, Medicare pays the MA organization offering the MA plan the premium amount charged by the organization for a high-deductible insurance policy and the remainder of the MA payment amount is deposited in the enrollee's savings account. If an individual enrolls in such a plan mid-year, a pro-rated share corresponding to the number of months remaining in the calendar year is placed into the individual's savings account. As provided under § 422.103(d), however, beneficiaries newly eligible for Medicare who enroll in MSAs midyear pursuant to an initial coverage election period (ICEP) are currently required to pay a full deductible for the calendar year. For example, an enrollee whose 65th birthday is in May and who chooses to enroll May 1 will be given 8/12ths of the deposit that has been approved for the plan for the year, but this enrollee is required to pay the full deductible approved for the plan for the entire calendar year. An enrollee whose 65th birthday is later in the year could enroll, for example, on September 1 and would receive a pro-rated deposit representing only 4/12ths of the year; however, this enrollee would also be required to pay the full calendar year deductible.

We are proposing to interpret the deductible requirement as implicitly applying only for the number of months in which a beneficiary is enrolled in the MSA plan, and accordingly are proposing to revise § 422.103(d) to allow beneficiaries who enroll during the year as ICEP enrollments to pay only a pro-rated deductible consistent with the pro-rated deposit they receive. This rule would also apply to disabled enrollees under age 65 who become eligible for Medicare during the year. Interested beneficiaries may inquire with potential MSA plans about their options prior to enrollment, and, upon enrollment, would receive a confirmation of enrollment letter that would inform them of both their pro-rated deposit amount and their pro-rated deductible.

G. Changes To Clarify Various Program Participation Requirements

We have worked with sponsoring organizations to implement and operationalize the Medicare Advantage and Prescription Drug Benefit Programs over the past 4 years. As part of this partnership, we have implemented operational and/or policy guidance via HPMS memoranda or manual instruction to assist sponsoring organizations in ensuring the proper and efficient administration of the Part C and D programs. The proposed regulations in this section either clarify existing regulations or implement new requirements consistent with existing policy guidance, to assist sponsoring organizations with attaining the goals envisioned by the Congress when the legislation implementing the Medicare Advantage and Prescription Drug Benefit programs was first passed. These clarifications are detailed in Table 7.

TABLE 7—CLARIFICATIONS OF VARIOUS SPONSOR PROGRAM PARTICIPATION REQUIREMENTS

Provision	Part 422		Part 423	
	Subpart	Section	Subpart	Section
Clarify what we mean by uniform benefits	Subpart C ..	§ 422.100(d)	Subpart C ..	§ 423.104.
Ensure security of personal health information and other personally identifiable information.	Subpart K ..	§ 422.504	Subpart K ..	§ 423.505.
Require plans to report other payer information to support coordination of benefits (COB).	Subpart C ..	§ 422.108	Subpart C ..	§ 423.464.
Visitor/Traveler Benefit under Part C for the Purpose of Extending Enrollment up to 12 Months.	Subpart B ..	§ 422.74	N/A	N/A.
Codify authority to establish (MTM) Program requirements.	N/A	N/A	Subpart D ..	§ 423.153(d).
Clarify Pharmacy & Therapeutics (P&T) Committee requirements.	N/A	N/A	Subpart C ..	§ 423.120.
Generic equivalent disclosure	N/A	N/A	Subpart C ..	§ 423.132.
Application of access standards at application level.	N/A	N/A	Subpart C ..	§ 423.120.
Standard Timeframe for coverage requirements ...	N/A	N/A	Subpart M ..	§ 423.568.
Clarify Novation requirements	N/A	N/A	Subpart L ...	§ 423.551.

TABLE 7—CLARIFICATIONS OF VARIOUS SPONSOR PROGRAM PARTICIPATION REQUIREMENTS—Continued

Provision	Part 422		Part 423	
	Subpart	Section	Subpart	Section
Cost Contract Program revisions: Appeals and Marketing Requirements.	Subpart O ..	§ 417.428	N/A	N/A.
		§ 417.492		
		§ 417.494		
		§ 417.500		
		§ 417.640		

1. Uniform Benefits Under Parts C and D (§ 422.100(d) and § 423.104)

Section 1852(d)(1)(A) of the Act requires a Medicare Advantage (MA) organization offering a plan to select the providers from whom the benefits under the plan are provided so long as the organization makes such benefits available and accessible to each individual electing the plan within the plan's service area with reasonable promptness and in a manner which assures continuity in the provision of benefits. Section 1860D–2(a) of the Act defines qualified prescription drug coverage to mean access to standard or actuarially equivalent prescription drug coverage and access to negotiated prices (in accordance with section 1860D–2(d) of the Act). We codified these sections in our regulations at § 422.100(d) and § 423.104(b).

Both sections currently require that either an MA organization or PDP sponsor offering a plan must offer that plan to all eligible beneficiaries residing in the plan's service area, or for MA organizations, a subset of the plan's service area. We further interpret section 1860D–2(a) of the Act as requiring the provision of uniform premiums and benefits.

We have provided guidance to Part D sponsors on several occasions indicating that varying cost-sharing or premiums, including waiving cost-sharing or premiums, violates the uniform benefit requirements at § 423.104(b) because doing so results in the Part D sponsor's plan not providing uniform premiums and benefits to all eligible beneficiaries within its service area. We have further informed Part D sponsors that their failure to collect cost-sharing at the time the service is provided or to attempt to collect cost-sharing or bill cost-sharing to the appropriate party (either a beneficiary or another payer) after the fact is in violation of the uniform benefit provisions set forth in the current regulation at § 423.104(b).

However, we believe that § 423.104(b) is not clear in regard to the PDP sponsor's imposition of uniform premiums and cost-sharing. Therefore, we propose to revise § 423.104(b) to

mirror the language at § 422.100 to specify that Part D sponsors apply uniform premiums and cost-sharing.

2. Ensuring the Security of Personal Health Information and Other Personally Identifiable Information (§ 422.504 and § 423.505)

In the contract provisions sections of subpart K of parts 422 and 423, we specify that MAOs and Part D sponsors must permit access to their facilities by the Secretary or his or her designee. Access to facilities must be granted in connection with the Secretary's right to evaluate through audit, inspection, or other means MAO and Part D sponsor compliance with Medicare contract requirements, including the quality, appropriateness, and timeliness of services.

We interpret the Secretary's right to audit or inspect compliance with MA and Part D program regulations to include evaluation of compliance with CMS requirements for maintaining the privacy and security of personal health information and other personally identifiable information of Medicare enrollees. In order to clarify our policy that beneficiaries' personal health information and other personally identifiable information must remain secure, we propose to revise § 422.504 and § 423.505 to make this interpretation explicit. In a related change, we propose to clarify that we interpret the term "facilities" to include an MAO's or Part D sponsor's computer or other electronic systems. We would implement these proposed changes at § 422.504(e)(1)(ii) and § 423.505(e)(1)(ii). We are also proposing conforming changes to the contract requirements related to downstream entities at § 422.504(i)(2)(i) and § 423.505(i)(2)(i), respectively. Note that while we do not believe our authority extends to accessing the facilities of downstream entities, we may review systems and computer-generated information from downstream entities for compliance with privacy and security requirements. Such information includes, but is not limited to, backup tapes, print outs of

screen shots, CDs, and similar information.

We encourage the use of computerized and electronic systems by MAOs and Part D sponsors. We are aware, however, of the additional potential for security and privacy breaches in a computerized/electronic context. Our proposed changes are designed to ensure that beneficiaries' protected health information and personally identifiable information associated with their enrollment remain private and secure.

3. Requirement for Sponsoring Organizations Under Parts C and D To Report Other Payer Information to the Coordination of Benefits Contractor (§ 422.108 and § 423.464)

Section 1852(a)(4) of the Act provides that an MA organization may charge or authorize a provider to seek reimbursement for services from a beneficiary or third party to the extent that payment is made secondary under section 1862(b)(2) of the Act. Section 1860D–2(a)(4) of the Act extends the Medicare secondary payer (MSP) procedures applicable to MA organizations under section 1852(a)(4) of the Act to Part D sponsors and their provision of qualified prescription drug coverage. This authority is implemented for MA organizations in § 422.108 and for Medicare PDPs in § 423.462, as well as in CMS manuals.

MA organizations are responsible for identifying payers that are primary to Part C of Medicare, determining the amounts payable by those payers, and for coordinating the benefits the plan offers with the benefits of such payers. Additionally, MA organizations must take into account Part C costs that could have been recovered or avoided due to MSP when determining costs in the base period. MA organizations must account for Part C MSP amounts in one of three ways. MA organizations must—

- Recover from liable third parties;
- Avoid Part C costs by directing providers to bill liable third parties directly; or
- Account for Part C costs that could have been recovered or avoided, but that were actually not recovered or avoided,

by not including them in Part C base period costs.

MA organizations and PDPs are required to follow the same rules regarding—

- Their responsibilities under the MSP statutory and regulatory provisions;
- Collection of payment from insurers, group health plans and large group health plans, the enrollee, or other entities for covered Part D drugs; and
- The interaction of MSP rules with State laws.

Sections 1860D–23 and 1860D–24 of the Act also require a Part D sponsor to coordinate with SPAPs, as well as other drug plans, including Medicaid programs, group health plans, FEHBP, military coverage, and other plans or programs providing prescription drug coverage. To support the required benefit coordination, section 1860D–2(b)(4)(D)(ii) of the Act permits Part D sponsors to request information on third party insurance from beneficiaries. The authority for COB, as well as for information collection from beneficiaries is implemented for prescription drug sponsors in § 423.464 and in the Coordination of Benefits chapter of the Medicare Prescription Drug Benefit Manual.

The growing number of CMS data sharing agreements with other payers has improved the volume and quality of other payer information available to MA organizations and prescription drug sponsors on the COB data file from CMS. New mandatory insurer reporting of MSP group health plan coverage, liability insurance, no-fault insurance and workers' compensation, required by section 111 of the Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Extension Act of 2007 (Pub. L. 110–173), will further expand the other payer information available for MA organization and PDP MSP procedures and for Part D sponsor coordination of benefits. (*See* 42 U.S.C. 1395y(b)(7) and (8).) Most insurers will need to report their own coverage already. It is only when an MA organization becomes aware of coverage that is primary to Medicare offered by another insurer that it will need to report under this rule. In addition to these advances, we continue to seek improvements to the quality of the MSP and COB information we report to MA organizations and Part D sponsors. We believe the best means to accomplish this is to rely primarily on the most reliable sources of other coverage information. Based on our experience, these sources tend to be the other insurers.

However, MA organizations and PDP sponsors will on occasion continue to receive information about other coverage from their enrollees, as well as other sources. While our MA program policy does not currently include reporting requirements, Part D subregulatory policy guidance, reflected in section 50.2 of the Coordination of Benefits chapter of the Prescription Drug Benefit Manual, requires that PDP sponsors submit other coverage information that is brought to their attention within 30 days of receipt to the CMS COB Contractor for verification and application of the verified data to our data systems.

Given the importance of the other payer information to MA organization and PDP MSP procedures and for prescription drug program coordination of benefits, we propose to require the reporting of other coverage information in § 422.108 for MA organizations and § 423.462 and § 423.464 for PDP sponsors. Given concerns regarding the quality of the information, we propose to limit the information reported to that which is reported to the sponsor as being inconsistent with existing information on the COB file.

Specifically, we propose to include in regulatory text the requirement that MA organizations and Part D sponsors, upon being notified of credible new information regarding other payers or changes to existing other payer information, report this information to the CMS COB Contractor in accordance with the processes and timeframes established by CMS. By “credible” we mean information that is consistent with conventions for how group health insurance coverage is identified, for instance including the name and address of the insurance company and the policy identification number. We also propose to extend the reporting requirements to MA organizations as they relate to other primary payers. We note that Medicare MA organizations and Part D sponsors should never be reported to CMS as a “primary” payer. In the absence of another (that is, non-Medicare) primary payer, the MA organization or Part D plan is always primary. This is not to say that if an enrollee has primary individual or employer group coverage through the same insurer or organization through which they also have MA or Part D coverage, such primary coverage should not be reported. In fact, such coverage must be reported. However, reporting Medicare itself as primary serves no purpose and merely causes confusion.

The proposed changes described in this section of the proposed rule would impose a new requirement on MA

organizations but would not change current MSP and coordination of benefits policy for the prescription drug program.

4. Visitor/Traveler Benefit Under Part C for the Purpose of Extending Enrollment Up to 12 Months (§ 422.74)

Under our authority to establish special rules for the enrollment of beneficiaries in MA plans at section 1851(b) of the Act, we had previously described in the Medicare Advantage regulations a visitor/traveler (V/T) benefit. Specifically, § 422.74(d)(4)(iii) established an exception to our disenrollment requirements, under which a plan member must be disenrolled when out of the service area for more than 6 months. Under this exception, MA plans may offer their enrollees extended enrollment in the plan when they are out of the plan service area, but within the United States, from 6 to 12 months if the plan covers services other than emergent, urgent, maintenance and post stabilization, and renal dialysis services. Section 422.74(d)(iii) establishes that an MAO can offer a “visitor” or “traveler” type program which would allow its enrollees to remain enrolled in the plan while out of the plan's service area for up to 12 months. We note that Medicare-covered services can only be covered within the United States. Although we stated in the preamble of the Medicare+Choice program; Managed Care Provisions final rule, published in the August 22, 2003 **Federal Register** (68 FR 50848), that the visitor or traveler program must cover “the full range of services available to other members,” we did not specify in regulation text what we intended by “full range of services.”

Given the lack of specificity in our regulations, we have received a number of questions since that time regarding what services must be covered through a V/T program if an MA plan wishes to retain members up to 12 months when those members are residing outside the service area. We propose to amend § 422.74(d)(4)(iii) to specify that an MAO may offer an extended enrollment V/T option under an MA plan if that plan furnishes all plan covered services—that is, Medicare Parts A and B services and all mandatory and optional supplemental benefits—at in-network cost-sharing levels consistent with Medicare access and availability requirements at § 422.112. An MAO offering a V/T benefit under an MA plan must make the option available to all plan enrollees. Specifically, the V/T benefit must be available to all plan enrollees who are temporarily in the

areas where the V/T benefit is offered for the 6–12 months the member is in the area.

5. Medication Therapy Management Programs Under Part D (§ 423.153(d))

Section 1860D–4(c)(1)(c) of the Act requires Part D sponsors to establish Medication Therapy Management programs (MTMP) and section 1860D–4(c)(2) of the Act requires MTMPs to be designed to ensure, with respect to targeted beneficiaries described in section 1860D–4(c)(2)(A)(ii) of the Act, that covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events. These requirements are codified at § 423.153(d) of the Part D regulations.

Section 423.153(d)(1) requires each Part D sponsor to establish a MTMP that is designed to ensure that covered Part D drugs (as defined in § 423.100) prescribed to targeted beneficiaries are appropriately used to optimize therapeutic outcomes through improved medication use; designed to reduce the risk of adverse events for targeted beneficiaries; furnished by a pharmacist or other qualified provider; and allowed to distinguish between services provided in ambulatory and institutional settings. Section 423.153(d)(2) defines targeted beneficiaries as enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual costs for covered Part D drugs that exceed a predetermined level as specified by the Secretary.

In the original Part D final rule (that is, the January 28, 2005 final rule), we did not identify specific medication therapy management (MTM) requirements beyond those contained in the Act because there was insufficient industry experience and no widely accepted standard practices for MTMPs. Moreover, we also believed that in the future outcomes measures would provide the best method for evaluating MTMPs and promoting the most effective programs. However, given the experience garnered from the first few years for the Part D program, and as we still await further development of MTMP outcomes measures that can serve the Part D program, we have determined that it necessary to have more specific Part D MTMP requirements for enrollment methods, targeting procedures, and MTM services. Accordingly, in the 2010 Call Letter, we included policy guidance regarding the implementation of MTMPs. This policy guidance reflects common practices among Part D

MTMPs that were derived from our extensive review of MTMP applications, plan-reported data, exploratory research on MTM, informal interviews with Part D sponsors, and other relevant literature and data. In this rule, we are proposing to codify this policy guidance in § 423.153(d). We believe the proposed changes to the MTMP requirements will promote greater consistency across the Part D program that will allow for better evaluation and comparison of MTMPs when outcomes measures become available.

Specifically, in accordance with sections 1860D–4(c)(1)(C) and 1860D–4(c)(2) of the Act, we propose to add the following requirements:

- Part D sponsors shall use only an opt-out method for MTMP enrollment;
- Part D sponsors shall target beneficiaries for MTMP enrollment at least quarterly during each plan year; and
- Part D sponsors shall offer a minimum level of MTM services for each beneficiary enrolled in the MTMP that includes interventions for both, beneficiaries and prescribers, annual comprehensive medication reviews, and quarterly targeted medication reviews.

In addition, we are proposing to revise the requirements for targeting beneficiaries who have multiple chronic diseases and take multiple Part D drugs by specifying the maximum number of multiple chronic diseases and multiple Part D drugs that Part D sponsors may establish as a minimum threshold for satisfying their MTMP targeting criteria.

We propose adding § 423.153(d)(1)(v) to require Part D sponsors to enroll beneficiaries in their MTMPs using an opt-out method of enrollment only. Under this proposal, a beneficiary that meets the targeting criteria would be auto-enrolled into the MTMP and considered to be enrolled unless the he or she declines enrollment. This opt-out method of enrollment is currently the preferred method of enrollment among Part D sponsors, used by approximately 85 percent of current MTMPs, and has increased enrollment of targeted beneficiaries into MTMPs. As a result, we believe that requiring an opt-out method of enrollment will provide more beneficiaries with access to MTM services.

We also propose adding § 423.153(d)(1)(vi) to require Part D sponsors to target beneficiaries for enrollment in the MTMP at least quarterly during each plan year. Currently, more than 95 percent of Part D sponsors target beneficiaries for enrollment in their MTMPs on a daily, weekly, monthly, or quarterly basis. We believe that making this a requirement

for all Part D sponsors will allow more Medicare beneficiaries to have access to the MTMP earlier in the year. Part D sponsors also can promote continuity of care by identifying current MTMP enrollees towards the end of a plan year who will qualify for MTMP enrollment in the next plan year. This practice would allow the Part D sponsors to have such beneficiaries enrolled in their MTMP at the beginning of the next plan year.

We also propose adding § 423.153(d)(1)(vii) to require Part D sponsors to offer a minimum level of MTM services for each beneficiary enrolled in the MTMP that includes interventions for both beneficiaries and prescribers; annual comprehensive medication reviews; and quarterly targeted medication reviews. In 2008, approximately 90 percent of Part D MTMPs provided interventions targeting both beneficiaries and prescribers. Our proposed requirement that MTMPs include interventions for both beneficiaries and prescribers does not mean, however, that all interventions must target both the beneficiary and the prescriber. Instead, Part D sponsors must determine if the beneficiary, prescriber, or both should be targeted for any specific intervention or interventions. Prescriber interventions may be passive (for example, faxed or mailed) and should be targeted to resolve potential medication-related issues or other opportunities to optimize medication use.

Furthermore, while Part D sponsors may incorporate passive or “lower touch” beneficiary interventions, such as education newsletters, drug utilization review (DUR) edits, refill reminders, and medication lists into their MTMPs, where appropriate, these passive interventions cannot be the sole offerings. Part D sponsors must also offer MTM services to beneficiaries that include an interactive component, continued monitoring, and follow-up when necessary. In addition, Part D sponsors should have procedures in place to follow-up with beneficiaries that do not respond to initial offers for MTM services.

Under this proposal, Part D sponsors would also be required to offer an annual comprehensive medication review (CMR) to all targeted beneficiaries. With the exception of targeted beneficiaries in long-term care settings, the CMR would be required to include an interactive, person-to-person consultation performed by a pharmacist or other qualified provider. A CMR is a review of a beneficiary’s medications including prescription medications,

over-the-counter (OTC) medications, herbal therapies and dietary supplements intended to aid in assessing medication therapy, and optimizing patient outcomes. The review of the beneficiary's medication may be performed concurrently with the beneficiary consultation or prior to the consultation by a qualified provider or computerized clinical algorithm. The consultation must be a real-time interaction that is provided either face-to-face or via an alternative interactive method such as the telephone. Finally, the beneficiary must receive a written summary of the CMR and consultation that may include such things as a medication record, reconciled medication list, action plan, or recommendations for monitoring, education, or self management.

In addition to the annual CMR, under this proposal, Part D sponsors would be required to perform targeted medication reviews for all beneficiaries enrolled in the MTMP no less often than quarterly. These targeted reviews would focus on assessing medication use since the CMR and determining if any issues that were identified during the CMR remain unresolved or if any new drug therapy issues have arisen. The Part D sponsor must assess the findings of these reviews to determine if a follow-up intervention is necessary with either the prescriber or beneficiary. Unlike the CMR, these interventions are not required to be interactive although it should be considered when appropriate.

Consistent with section 1860D-4(c)(2)(ii)(A) of the Act, Part D sponsors must target beneficiaries who have multiple chronic diseases for MTM services. In the original rule, we left the determination of "multiple" and "chronic disease" entirely to the Part D sponsors. In 2008, approximately 85 percent of Part D MTMPs targeted beneficiaries with a minimum of two or three chronic diseases. Based upon our experience with Part D MTMPs since the beginning of the Part D program, we issued guidance in 2009 to clarify the range and types of diseases that will satisfy this requirement beginning in 2010.

In this rule, we propose to revise § 423.153(d)(2)(i) to specify that the minimum number of multiple chronic diseases for targeted beneficiaries be no more than three. Under the proposed revision to § 423.153(d)(2)(i), we would require Part D sponsors to define the minimum threshold for "multiple" for purposes of targeting beneficiaries as no more than three chronic diseases. Therefore, Part D sponsors would be permitted to set their minimum threshold at two or three and target

beneficiaries with at least two chronic diseases or at least three chronic diseases.

Under this proposed revision to § 423.153(d)(2)(i), Part D sponsors may continue to target any chronic diseases or limit MTMP enrollment to enrollees having specific chronic diseases. However, beginning in 2010, CMS guidance specifies, at a minimum, that Part D sponsors should target at least four of seven core chronic diseases that we have identified as prevalent in the Medicare population based upon the analysis of the RxHCC Risk Adjustment model, posing a risk to the Medicare Trust Fund, and reflecting the most common diseases targeted by Part D MTMPs in general. The seven chronic diseases are hypertension, heart failure, diabetes, dyslipidemia, respiratory disease, bone disease-arthritis, and mental health diseases such as depression, schizophrenia, and bipolar disorder. In determining whether a beneficiary meets the minimum number of multiple chronic diseases to be targeted for MTM services, a beneficiary could have any combination of the chronic diseases targeted by the Part D sponsor.

Consistent with section 1860D-4(c)(2)(ii)(II) of the Act, plan sponsors must target beneficiaries taking multiple covered Part D drugs for MTM services. In the original Part D rule, we left the determination of "multiple" entirely to the Part D sponsors. Based upon our experience and extensive analysis of the Part D MTMPs since the beginning of the Part D program, we issued guidance in 2009 to clarify the range that plan sponsors should consider in order to satisfy the statutory requirement beginning in 2010. Specifically, we noted that Part D sponsors should define "multiple" for purposes of satisfying this requirement as no more than eight Part D drugs as the minimum number of multiple Part D drugs. Consistent with this policy guidance, we now propose to revise § 423.153(d)(2)(ii) to specify that no more than eight multiple Part D drugs be established as a minimum for targeted beneficiaries. Therefore, Part D sponsors would be permitted to set this minimum threshold for MTMP eligibility at any number equal to or between two and eight.

Under section 1860D-4(c)(2)(ii)(III) of the Act, plans must target beneficiaries that are likely to incur annual costs for covered Part D drugs that exceed a level specified by CMS. In the 2010 Call Letter, we specified a new, lower three thousand dollar threshold. Moving forward, we believe that it makes more sense to establish a dollar threshold

based upon a benchmark that is tied to the Part D benefit. We believe that the initial coverage limit (ICL) for the Part D defined standard benefit provides a logical benchmark for the MTMP because it ensures that Part D sponsors will always be able to target enrollees at risk of entering the coverage gap. Accordingly, in this rule, we propose to revise § 423.153(d)(2)(iii) to specify that targeted beneficiaries must be likely to incur costs for covered Part D drugs that exceed the ICL for the Part D defined standard benefit for the applicable Part D plan year.

6. Formulary Requirements—Development and Revision by a Pharmacy and Therapeutics Committee (§ 423.120)

Section 1860D-4(b)(3)(A) of the Act requires Part D sponsors to use a pharmacy and therapeutics (P&T) committee to develop and review the formulary if the Part D sponsor uses a formulary. In developing and reviewing the formulary, section 1860D-4(b)(3)(B) of the Act requires the P&T committee to base clinical decisions on the strength of scientific evidence and standards of practice, including accessing peer-reviewed medical literature, such as randomized clinical trials, pharmaco-economic studies, outcomes research data, and on such other information as the committee determines to be appropriate. The P&T committee must also consider whether the inclusion of a particular Part D drug in a formulary or formulary tier has any therapeutic advantages in terms of safety and efficacy. We codified these requirements at § 423.120(b)(1).

In the preamble to the January 28, 2005 final rule (70 FR 4193) and subsequent formulary guidance, we distinguished between the roles of the P&T committee in determining which drugs are placed on a formulary versus the application of utilization management tools that are applied to the drugs placed on the formulary. Specifically, we said that the P&T committee recommendations regarding which Part D drugs are placed on a formulary are binding on the Part D sponsor while recommendations regarding utilization management tools such as prior authorization (PA), step therapy, and quantity limits are advisory only and not binding on the Part D sponsor. We made this distinction because we believed that the placement of a drug on the formulary was the primary clinical decision in developing a formulary while the application of utilization management tools, although clinically justified, required the consideration of additional

financial and benefit design criteria that went beyond the scope of the P&T committee role. Consequently, we believed it was only necessary for the P&T committee to review for clinical appropriateness Part D sponsor policies that guide utilization management processes and codified this requirement in § 423.120(b)(vi).

We have gained a better understanding of the formulary development process since the beginning of the Part D program and now recognize that the application of PA criteria, step therapy, and quantity limits are as important to the clinical soundness of a formulary as the drugs that are included. Access to Part D drugs may be influenced as much by the application of PA criteria, step therapy requirements, or quantity limit restrictions as it can be by exclusion of a Part D drug from a Part D formulary. For example, one formulary could list twice as many drugs as another formulary but if all the additional drugs on the second formulary are subject to PA requirements, overall access to Part D drugs may be the same under both formularies. For this reason, our formulary review process has not been limited to evaluating the number and types of drugs on Part D formularies but also includes the review of the specific PA criteria, step therapy requirements, and quantity limit restrictions that are applied within the Part D formularies. Therefore, in accordance with section 1860D-4(b)(3)(A) and (b)(3)(B) of the Act, we propose adding new paragraph § 423.120(b)(1)(ix) to require Part D P&T committees to review and approve all clinical PA criteria, step therapy protocols, and quantity limit restrictions applied to each covered Part D drug.

PA criteria, step therapy requirements, and quantity limits directly affect beneficiary access to formulary drugs. Because P&T committees must review and approve all drugs before they may be added to a formulary, we also believe it is necessary that all PA criteria, step therapy protocols, and quantity limits be approved by P&T committees prior to their application to formulary drugs. We continue to recognize that the decision to apply such utilization management tools is not based solely upon clinical considerations and, therefore, remains the responsibility of the Part D sponsors. However, we believe this new requirement adds a necessary beneficiary protection by ensuring that independent clinical experts have reviewed and approved each application of these utilization management tools for clinical appropriateness. It is our understanding

that this is standard practice for P&T committees, and therefore, do not believe this requirement creates an additional burden.

Finally, we do not believe it is necessary for P&T committees to review and approve administrative PA criteria such as those used to make “B vs. D” determinations. Only PA criteria that require clinical information and justification require the review and approval of the P&T committee.

7. Generic Equivalent Disclosure Under Part D (§ 423.132)

Section 1860D-4(k)(1) of the Act requires a Part D sponsor to have each of their network pharmacies inform enrollees of any difference between the price of the drug(s) they are purchasing via the plan and the price of the lowest priced therapeutically equivalent generic product available to the pharmacy. Section 1860D-4(k)(2)(A) of the Act requires that this information be provided at the time of purchase except for purchases delivered by mail when it must be provided at the time of delivery. Under section 1860D-4(k)(2)(B) of the Act the Secretary has the authority to waive this requirement for certain entities in certain cases as specified in § 423.132(c).

In § 423.132(d), we specified that for enrollees in long-term care pharmacy settings, the timing portion of the disclosure requirement (that is, the requirement that the enrollee be informed at time of purchase) may be waived. Accordingly, sponsors are required to disclose the differential (if any) in pricing for long-term care network pharmacies by requiring that this information be provided in the explanation of benefits (EOB).

Over time, we have heard from sponsors, as well as pharmaceutical benefit managers on behalf of sponsors, that providing this information in the EOB is unworkable from a plan operational standpoint. Primarily, this is due to the fact that information on generic pricing can—and often does—vary day to day; thus, sponsors cannot accurately reflect the differential within a monthly EOB. Additionally, sponsors have pointed out that they would need to program the generic equivalent prices for all drugs specific to a particular LTC’s contracted reimbursement rate into their systems to populate electronically on the EOB, which represents a significant programming and financial burden.

We also believe the generic equivalent information provided on the EOB is of no value to the long-term care beneficiary. In the LTC setting, the beneficiary receives the medication after

the prescription drug claim has been submitted by the LTC pharmacy and processed by the Part D sponsor. Therefore, the ability of the beneficiary to make changes at the point-of-service based upon information provided on the EOB is simply not feasible. Unlike the enrollee standing at the retail pharmacy counter at time of service, enrollees in long-term care institutions have limited opportunities to affect a switch to a lower-priced generic substitute before dispensing. Because of this limitation, we have not enforced this regulatory requirement and have not included model language that addresses this requirement in the EOB.

For the aforementioned reasons, we are proposing to revise § 423.132(c) by adding long-term care network pharmacies to the list of entities for which from the public disclosure requirement is waived, and revise § 423.132(d) to remove the requirement that long-term care network pharmacies provide the pricing differential information in enrollees’ EOBs.

8. Access to Covered Part D Drugs (§ 423.120)

The statute at sections 1860D-4(b)(1)(C) and 1860D-21(c)(1) of the Act establishes the standards for convenient access for network pharmacies for PDP sponsors and other Part D sponsors. This section of the statute requires that the sponsor of a PDP shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access consistent with the rules established by the Secretary, and as long as they are no less favorable than the TRICARE pharmacy access standards.

A TRICARE contractor is required to maintain a pharmacy network sufficient to meet the following minimum beneficiary access standards on an overall basis—Urban: a pharmacy within 2 miles of 90 percent of the beneficiaries; Suburban: a pharmacy within five miles of 90 percent of the beneficiaries; and Rural: a pharmacy within fifteen miles of 70 percent of the beneficiaries. We adopted into regulation these standards, but instead of specifying them at the contract or PDP sponsor level, erroneously established them at the plan level. Specifically, in § 423.120(a) of the regulation, which describes the requirements to assure pharmacy access, we inadvertently used the term “plans” instead of the correct terminology of PDP sponsor or other Part D sponsors. This error is problematic when considering the definitions outlined in

§ 422.2 (for MA) and § 423.4 (for Part D) because the term “plan” is intended to mean a specific benefit package offered to beneficiaries living in a geographic area. For any given service area, Part D sponsors frequently offer multiple plans under one contract with CMS, and any given plan may be offered within a subset of the Part D sponsor’s total service area.

Our intention has always been to ensure adequate access to Part D covered drugs at sponsor level, not at the plan level. For one, the statute explicitly states that access should be ensured at the PDP sponsor level. Further, assessing adequacy of pharmacy access is one of the most critical steps in the Part D application review process and determining access to Part D covered drugs at the plan level is not possible during application review. This is because plan service areas (potentially subsets of Part D sponsor or organization service areas) are not determined until the time of the bid submission, which occurs after applications are reviewed. However, sponsor service areas are known at the time of application submission. Our proposed correction would align our regulations with the intent of the statute with regard to the level of analysis that should be conducted for access to Part D drugs, namely at the Part D sponsor level, rather than at the plan level.

We note that as a practical matter and consistent with the current drafting of the regulation, if the Part D sponsor’s entire service area is larger than one State, we will continue to ensure access at no greater than the State level for multi-state regions. This approach is necessary to ensure that pharmacies are not unduly clustered in one part of the region. Accordingly, based on the preceding rationale, we are proposing to revise the text of the regulation that discusses pharmacy access in § 423.120(a)(10 through (a)(7) to refer to PDP sponsors, MA organizations offering local and regional MA–PD plans, and cost contracts rather than plans. Additionally, since § 423.120(a) (defining access requirements for Part D drugs) references a definition provided in § 423.112(a) (establishment of PDP service areas), it is necessary to correct the terminology in that location as well. Therefore, we propose to revise § 423.112(a) to specify the establishment of service areas for PDP sponsors.

9. Standard Timeframe and Notice Requirements for Coverage Determinations Under Part D (§ 423.568)

Section 1860D–4(g) of the Act requires Part D plan sponsors to establish procedures for processing

requests for coverage determinations and redeterminations. Those procedures must apply to Part D plan sponsors in the same manner as such requirements apply to MA organizations with respect to organization determinations and reconsiderations. In accordance with section 1860D–4(g) of the Act, § 423.568 establishes the standard timeframe and notice requirements for coverage determinations. However, that section does not explain the method for filing such requests. We originally omitted these instructions from § 423.568 because § 422.568 does not dictate the method for filing requests for standard organization determinations. However, elsewhere in this rule, we are proposing to revise § 422.568 of the MA regulations by adding a new paragraph (a) clarifying the method for filing requests for standard organization determinations. The proposal requires MA organizations to accept standard organization determination requests orally and in writing, except for standard requests for payment, which must be submitted in writing unless the MA organization adopts a voluntary policy of accepting oral payment requests. Because section 1860D–4(g) of the Act requires Part D plan sponsors to meet the requirements for Part D coverage determinations in the same manner as such requirements apply to MA organizations for organization determinations, we propose to make a corresponding change to § 423.568 and require Part D plan sponsors to accept standard coverage determination requests orally and in writing. This proposed change would not apply to standard requests for payment, which must be submitted in writing unless the plan sponsor adopts a policy for accepting those requests orally.

In addition to this technical change, we propose to revise the timeframe for a Part D plan sponsor to notify an enrollee of a payment determination in § 423.568(b). The regulation currently requires that a plan sponsor notify the enrollee of its determination no later than 72 hours after receipt of the request. We propose to revise the provision to require Part D plan sponsors to process requests for payment no later than 14 calendar days after receipt of the request, and also make payment no later than 14 calendar days after receiving the request when a plan sponsor’s decision is partially or fully favorable.

As noted above, section 1860D–4(g) of the Act requires Part D plan sponsors to meet the requirements for Part D coverage determinations in the same manner as such requirements apply to MA organizations with respect to

organization determinations. The MA regulations under § 422.568 distinguish between how requests for benefits not yet received and requests for payment are processed by MA plans. The rules pertaining to requests involving benefits not yet received are contained in paragraph (a), while paragraph (b) contains the rules for processing requests for payment. In accordance with section 1860D–4(g) of the Act, this distinction was carried over to Part D in current § 423.568(a) and (b).

We received a comment on the Application of Certain Appeals Provisions to the Medicare Prescription Drug Appeals Process proposed rule (73 FR 14342), published in the March 17, 2008 **Federal Register**, recommending that we revise § 423.568(b) of the existing regulations by lengthening the timeframe for making standard coverage determinations involving requests for reimbursement submitted by enrollees. Although the comment was outside the scope of the Part D appeals-related proposals in the March 17, 2008 proposed rule, we believe the commenter’s suggestion merits consideration, as discussed in detail below.

The commenter contends that the existing 72-hour requirement for making a determination on an enrollee’s request for reimbursement constitutes an unprecedented and overly burdensome timeframe, and the only way a Part D plan sponsor can meet the regulatory timeframe is by making an adverse coverage determination (that is, deny the request for payment). Thus, the existing requirement in effect forces an enrollee into the Part D appeals process, even though in the vast majority of such situations, the claim will eventually be paid within the 30-day timeframe for effectuating a coverage determination. The commenter recommended that we revise § 423.568(b) to extend the timeframe for making a coverage determination on a request for payment from 72 hours to 30 days.

As the commenter indicates, § 423.568(b) sets forth the coverage determination and notification requirements in situations (generally involving non-network pharmacies) where an enrollee has already obtained a drug and subsequently makes a request to the Part D plan sponsor for payment. Existing § 423.568(b) requires a Part D plan sponsor to make this coverage determination and notify the enrollee of its determination no later than 72 hours after receiving such a payment request. Although the regulations do not specify a timeframe for making payment to the enrollee when the plan determines the drug in

question should be covered, plans are directed by manual guidance that such payment should be made within 30 days of the request. We note that the 30-day effectuation timeframe comports with the established requirements in § 423.636 for effectuating redeterminations or reconsiderations involving requests for payment. It also generally parallels the prompt payment provisions that apply under § 422.520 and § 422.568 of the MA program.

The intent of these provisions was to ensure enrollees receive a prompt response to requests for payment while still giving plans a reasonable amount of time to process the payment. However, in practice, we agree that the 72-hour timeframe for making a coverage determination in these situations may be quite difficult for Part D plan sponsors to meet. Requests for reimbursement are generally submitted by mail in paper form, and must be identified as reimbursement requests, transferred from the mailroom to the reimbursement processing department, and then manually entered and adjudicated by Part D plan sponsors outside of the usual online real-time electronic claims processing procedures. We also note that under these circumstances, information that Part D plan sponsors need to make meaningful determinations with respect to a request (which is readily available on electronic claims) may be missing from the member-submitted paper claim. Finally, the Part D plan sponsor must notify the enrollee of its determination within 72 hours. Thus, as the commenter asserts, in practice the only way to meet the 72-hour coverage determination timeframe often may be to make a negative coverage determination, at least initially, which is clearly not in the best interests of the enrollee. This initial negative determination can be particularly confusing to an enrollee in situations where a Part D plan sponsor subsequently determines that the reimbursement request should be paid and remits payment to the enrollee, frequently within a few days of the initial negative determination.

As previously stated, the current regulations do not establish a timeframe for effectuating payment, and our manual guidance establishes a 30-day timeframe for doing so. Thus, even when a Part D plan sponsor completes the process above and issues a coverage determination within 72 hours, it is under no obligation to make payment any sooner than 30 calendar days after receiving the request. While we recognize that receiving Part D coverage decisions as soon as possible is important, an enrollee who is requesting

reimbursement already has the needed prescription drug in hand. Thus, we believe it is more important for him or her to receive the actual payment as soon as possible, rather than simply a determination as to whether payment will or will not be made.

Therefore, we believe it would be in the best interests of enrollees to modify the requirements of § 423.568(b) by extending the timeframe for making coverage determinations with respect to requests for payment in such a way as to avoid confusion but also ensure that enrollees receive payment as soon as possible. Based on our experience and previous discussions with Part D plan sponsors, we have determined that Part D sponsors generally are capable of making such payments within a 14-day period following receipt of a reimbursement request, as opposed to the 30-day period recommended by the commenter. Therefore, we propose revising § 423.568(b) to require Part D plan sponsors to take the following actions: (1) Make a coverage determination on a request for payment and notify the enrollee of its determination no later than 14 calendar days after receipt of a request for reimbursement, and (2) for favorable coverage determinations, make payment no later than 14 calendar days after receipt of the reimbursement request. We believe these changes will establish a more reasonable standard for the adjudication of paper claims, as well as ensure faster payments to enrollees who submit these requests. Thus, this change will better serve both plans and their members. As a result of changes proposed elsewhere in this rule, if adopted, these new requirements regarding the timeframe for processing requests for payment would appear at § 423.568(c) of the regulations.

Our last proposed change to § 423.568 involves adding new paragraphs (d) and (e), which will explain the form and content of favorable coverage determination decisions. In § 423.568(d), we propose requiring plan sponsors to send written notice of fully favorable decisions to enrollees. We also propose to allow plan sponsors the option of providing the initial notice orally so long as a written follow-up notice is sent to within 3 calendar days of the oral notification. In § 423.568(e), we propose to require notice of fully favorable decisions to include the conditions of the approval in a readable and understandable manner.

Adding further requirements regarding the form and content of favorable determination decisions to the Part D regulations is necessary because prescription drugs are often provided to

beneficiaries on a recurring basis (unlike most MA services which are generally provided to beneficiaries only once), and requiring plans to provide the terms of an approval in writing helps ensure continuity of care for Medicare beneficiaries who receive prescription drugs under Part D. The prescription may be subject to prior authorization or some other rule which needs to be met before a prescription can be refilled. Also, a prescription may only be approved for a specific period of time and refills may not be authorized. In those situations, it is important for the enrollee to know the conditions (for example, duration, limitations, and coverage rules for refills) of the approval before he or she needs to refill the prescription, so he or she can work with his or her physician to secure prior approval for additional refills, obtain an exception, or switch to an appropriate alternative prescription if necessary. Otherwise, the enrollee may experience a break in coverage if he or she attempts to fill a prescription and is told for the first time at the pharmacy that the prescription cannot be filled because it is subject to a coverage rule or additional refills have not been authorized. We believe the proposed changes to the notice requirements for favorable coverage determinations will help to ensure that enrollees and their physicians or other prescribers have the information they need in order maintain the continuity of prescription drug treatment.

10. Expediting Certain Coverage Determinations (§ 423.570)

Consistent with the proposed revisions to § 423.568, we propose to make a technical change to § 423.570 by revising the cross reference to § 423.568(a) to § 423.568(b).

11. Timeframes and Notice Requirements for Expedited Coverage Determinations (§ 423.572)

In accordance with section 1860D-4(g) of the Act, § 423.572 establishes the timeframe and notice requirements for expedited coverage determinations. Section 423.572(c)(1) requires Part D plan sponsors to include the specific reasons for any expedited decision (whether favorable or adverse) in its decision notice, and paragraph (c)(2) addresses the content of adverse decision notices. However, § 423.572 does not include any content requirements for favorable expedited decisions. Consistent with our rationale for adding form and content requirements for favorable standard coverage determination decisions, we believe form and content requirements

for favorable expedited coverage determinations are important beneficiary protections that will help to ensure that enrollees are able to maintain continuity in their prescription drug treatment. Therefore, we propose to revise § 423.572(b) by requiring plan sponsors to send written notice of fully favorable expedited decisions to enrollees, and allowing plan sponsors the option of providing the initial notice orally so long as a written follow-up notice is sent to the enrollee within three calendar days of the oral notification. We also propose to add paragraph (c)(2), which requires notice of a fully favorable expedited decision to provide the conditions of the approval in a readable and understandable manner.

We are also proposing in § 423.572(c)(2)(i) to require plan sponsors to issue adverse expedited coverage determination decisions using CMS approved language in readable and understandable form. Section 423.568(d) requires plan sponsors to use approved notices for adverse standard coverage determinations, and a parallel instruction for adverse standard and expedited coverage determinations is contained in subregulatory guidance. We developed Form CMS-10146 for use when plan sponsors issue adverse coverage determinations and, in our subregulatory guidance, we instruct plan sponsors to use that form when issuing adverse standard and expedited coverage determination decisions. Our proposed change in § 423.572(c)(2)(i) would reconcile this discrepancy in the regulations. We note that the proposed change does not create an additional burden for plan sponsors because sponsors already submit Form CMS-10146 to CMS for approval for adverse standard coverage determination decisions and, consistent with our subregulatory guidance, we expect plan sponsors to also use Form CMS-10146 for adverse expedited coverage determination decisions.

12. Clarify Novation Agreements Under Part D (§ 423.551)

Section 1860D-12(b) (1) of the Act provides the Secretary with the authority to enter into contracts with PDP sponsors. Additionally, section 1860D-12(b)(3)(B) of the Act grants the Secretary the authority to amend or modify these contracts in accordance with the furtherance of the purpose of the Act.

Consistent with the above-stated authority, we have implemented contracting regulations including § 423.551 of the Part D regulations, which provide for the novation of a PDP

sponsor contract in the event of a change of ownership involving a PDP sponsor. A change of ownership prompting the execution of a novation agreement is appropriate when a PDP sponsor is acquired or when it no longer can or wants to continue to participate in the PDP program. In the latter instance, a change of ownership can provide both the holder of the contract and CMS with an opportunity to transfer the ownership of the contract to a different entity with little or no disruption to the enrolled beneficiaries when the original entity faces difficulties (for example, financial, administrative) in operating its PDP contract. A change in ownership of the PDP line of business, which is recognized by CMS when we agree to a novation of the existing PDP sponsor contract, in this instance promotes the efficient and effective administration of the PDP program.

However, over the past few years several PDP sponsors have requested CMS approval of transactions that involve the sale of a piece of the sponsor's contract with CMS or less than the full line of PDP business [all PDP contracts held by that PDP sponsor]. For example, several PDP sponsors who have missed the LIS benchmark for a particular region requested to novate that portion of their contract to another PDP who met the benchmark in the region.

However, our policy goals are not served when a sponsor is simply using the novation process to pick and choose which markets it wishes to serve at any given time and to profit from its exit from a given PDP region when a simple nonrenewal for that region is an option available to the sponsor. Novations are not intended to be an instrument for moving LIS beneficiaries when a particular sponsor has missed the benchmark. Rather, we have a reassignment process for moving LIS beneficiaries to sponsors who have met benchmark for the new contract year.

Accordingly, we propose to revise § 423.551 and add new paragraph § 423.551(g) to restrict the situations in which we will agree to a PDP sponsor contract novation to those transfers involving the selling of the sponsor's entire line of PDP business, which would include all PDP sponsor contracts held by the legal entity. We believe that allowing the spin-off of just one contract (when the PDP sponsor has more than one PDP contract) or pieces of a single contract can have a negative impact on beneficiary election rights.

We are recommending becoming more prescriptive in this area because our experience gained over the first 4 years

of the program indicates this is necessary for the reasons stated above. The proposed change would also create consistency between the MA program and the PDP program, because the MA program only allows novations that include the entire MA line of business (that is, all MA contracts held by a single legal entity). We invite comments from sponsors and the industry about this proposed change, and suggestions on other options which would accomplish the same policy goals.

13. Cost Contract Program Revisions: Appeals and Marketing Requirements (§ 417.428, § 417.494, § 417.500, and § 417.640)

Although the cost contract program authorized under section 1876 of the Act and the health care prepayment plan (HCPP) programs authorized under section 1833 of the Act are based on reasonable costs, these programs have important elements in common with the MA program. As in the case of MA coordinated care plans, and unlike original Medicare, cost contractors authorized under section 1876 of the Act and HCPPs employ networks of providers and deliver services through a managed care model. However, unlike MA plans, enrollees under cost contracts authorized under section 1876 of the Act and HCPPs are not "locked in" to their plans networks, and can always receive any service through Original Medicare if they pay original Medicare cost sharing.

In the case of cost contracts authorized under section 1876 of the Act, the MA statute specifically recognized the parallels between contracts authorized under section 1876 of the Act and MA contracts, providing in section 1856(b)(2) of the Act that MA standards "shall be based on standards established under section 1876 to carry out analogous provisions of such section." Indeed, many of the original Part C regulations borrowed wholesale from the provisions in section 1876 of the Act and codified in Part 417. Using already established programs as the basis for new but related programs is common practice, one of the most recent examples of which is the Part D prescription drug benefit program. The MMA directed that fundamental aspects of the program, such as enrollment and payment policies, be similar to those of the MA program.

There are several MA program requirements that we believe are appropriate to apply to cost contracts. In the case of contracts authorized under section 1876 of the Act, because section 1876 of the Act contains similar statutory language to that in Part C for

MA contracts, this language provides clear authority to impose the same policies to both types of contracts. We have expressly done this in past regulations. For example, given the similarities between the statutory language in sections 1876(c)(5) and 1852(g) of the Act, and the procedures for an independent review entity that existed in part 417 before Part C was enacted, we revised the part 417 beneficiary appeals regulations governing cost contract appeals authorized under section 1876 of the Act simply to incorporate the Part C beneficiary appeals regulations in part 422. MA contracts and cost contracts authorized under section 1876 of the Act similarly have had largely the same process concerning appeals of contract determinations, sanctions, and civil money penalties (CMPs). More recently, however, these processes have diverged, especially since the publication of final regulations revising the contract determination, sanctions, and CMP processes for MA organizations on December 5, 2007 (72 FR 68700 through 68741). Similarly, the marketing requirements for cost contracts, which at one time largely mirrored the MA requirements, have diverged. This is especially true since publication of our final regulations implementing significant changes to marketing standards, agent/broker compensation, and other marketing changes in 2008. As a result, there is sometimes confusion over which marketing requirements cost contract plans must follow.

Therefore, we are proposing in this rule, under the authority under section 1876(i)(3)(D) of the Act to impose "other terms and condition" under contracts authorized by the statute that the Secretary finds "necessary and appropriate," and in implementation of the provisions authorized by section 1876 of the Act set forth below, to apply the following MA program requirements to cost contracts authorized under section 1876 of the Act:

- Under the authority in section 1876(i)(1) of the Act to terminate or nonrenew contracts and the authority in section 1876(i)(6) of the Act to impose intermediate sanctions and CMPs, the MA program requirements on appeals processes for contract determinations and intermediate sanctions. (To the extent that the CMP in section 1876(i)(6)(B) and (C) of the Act differ from those under Part C, the penalty amounts under section 1876 of the Act would continue to control); and
- Under the authority in section 1876(c)(3)(C) of the Act to regulate marketing of plans authorized under

section 1876 of the Act and ensure that marketing material is not misleading, the MA program requirements for marketing to cost contract plans.

We discuss the above proposals for cost contracts authorized under section 1876 of the Act in greater detail in the sections that follow.

14. Appeals Processes for Contract Determinations, Intermediate Sanctions, and Civil Money Penalties

The policy reasons we gave in our December 2007 final rule for revising the contract determination and appeals processes for MA plans apply equally to cost contracts authorized under section 1876 of the Act. By extending the MA and Part D requirements regarding these processes to cost contracts authorized under section 1876 of the Act and organizations that have both MA and contracts authorized under section 1876 of the Act will also have a more efficient and clear path for appealing contract determinations, intermediate sanctions, and CMPs.

We are proposing to revise the following sections of the current contract requirements provisions of Part 417 authorized at section 1876 of the Act to specify that, with respect to appeals of contract determinations, intermediate sanctions and CMPs, cost contracts authorized under section 1876 of the Act would follow the provisions applicable to MA organizations at, respectively, Subpart N and Subpart T of part 422. With respect to appeals of intermediate sanctions, we are proposing to revise § 417.500 of the cost contracts requirements authorized under section 1876 of the Act to make these consistent, with the exception of some CMP amount provisions, with the sanctions processes for MA organizations. We discuss the proposed changes below.

a. Contract Determinations (§ 417.492 and 417.494)

Previous to the implementation of the contract determination requirements in the December 2007 final rule, the cost contracts authorized under section 1876 of the Act and MA plan contract determination requirements were very similar. Although we did not apply the provisions of the December 2007 regulations to cost contracts authorized under section 1876 of the Act at that time, we believe that it makes sense to do so now for the same reasons we made changes to the MA processes at that time.

As a result, we propose in § 417.492(b)(2), concerning notice of appeal rights, and § 417.494, concerning notice of termination, to require cost

contract plans to follow the contract determination appeal procedures under Subpart N of Part 422.

b. Civil Money Penalties (§ 417.500)

Currently, the regulations governing cost contracts authorized under section 1876 of the Act do not set forth a formal process for appealing CMPs. We propose these plans would follow the same requirements for CMP appeals that MA organizations follow. As a result, we propose to revise § 417.500 to require cost contracts authorized under section 1876 of the Act to follow the MA programs requirements for appeals of CMPs at Subpart T of Part 422. The appeals process for CMPs specified at Subpart T allows for a hearing by an Administrative Law Judge (ALJ) and a review of the ALJ's decision by the Departmental Appeals Board. In proposed new paragraph (c), we specify that the amount of CMPs a cost contract may be assessed is governed by section 1876(i)(6)(B) of the Act, not by the provisions in part 422 of the MA program regulations.

c. Intermediate Sanctions (§ 417.500)

Our proposed revision to the cost contracts regulations authorized under section 1876 of the Act would ensure that these contracts follow the same requirements for intermediate sanctions appeals specified in § 422.750 through § 422.764 of the MA program regulations (subpart O).

These sections concern—

- Types of intermediate sanctions and CMPs (§ 422.750);
- Bases for intermediate sanctions and CMPs (§ 422.752);
- Procedures for imposing intermediate sanctions and CMPs (§ 422.656);
- Collection of CMPs (§ 422.758);
- Settlement of penalties (§ 422.762); and
- Other applicable provisions (§ 422.764).

As noted above, with respect to determinations of the amount of CMPs, the provisions in section 1876(i)(6)(B) and (C) of the Act would govern such amounts.

15. Extending MA Marketing Requirements to Cost Program Plans (§ 417.428)

In 2008, we published several marketing-related regulations that significantly revised the marketing requirements for MA organizations and Part D sponsors. In the Medicare Advantage and Prescription Drug Benefit Programs; Final Marketing Provisions final rule, published in the September 18, 2008 **Federal Register** (73

FR 54208 through 54223), we discussed exclusively the marketing and established marketing standards including prohibiting soliciting door-to-door or through other unsolicited means for Medicare beneficiaries. A second regulation, the Revisions to the Medicare Advantage and Prescription Drug Benefit Programs IFC, also published in the September 18, 2008 **Federal Register** (73 FR 54226 through 54254), added requirements limiting agent and broker commissions. A third regulation, the Revisions to the Medicare Advantage and Prescription Drug Benefit Programs; Clarification of Compensation Plans IFC, published in the November 14, 2008 **Federal Register** (73 FR 67406 through 67414), clarified and augmented the agent broker requirements as specified. The new marketing regulations resulted in the creation of a new subpart V in parts 422 and 423. Although many of these provisions reflect or implement statutory provisions applicable only to MA plans and Part D plans, many of these same provisions were initially proposed under our broad authority to regulate marketing and impose new contract terms. As noted above, under this latter authority, we propose to amend § 417.428, which governs 1876 cost contract program marketing requirements, to require cost contract plans to follow the MA marketing requirements in § 422.2260 *et seq.* (Subpart V). We discuss the proposed marketing changes in the sections below.

a. Definitions Concerning Marketing Materials (§ 422.2260)

We are proposing that cost contracts authorized under section 1876 of the Act follow the same standards as MAOs under § 422.2260. Thus, cost contract plan marketing materials would include any materials which—

- Promote the cost contract, or any cost contract plan offered by the cost contract;
- Inform Medicare beneficiaries that they may enroll, or remain enrolled in, a cost contract plan offered by the cost contract;
- Explain the benefits of enrollment in a cost contract plan, or rules that apply to enrollees; and
- Explain how Medicare services are covered under a cost contract plan, including conditions that apply to such coverage.

b. Review and Distribution of Marketing Materials (§ 422.2262)

We propose that cost contracts authorized under section 1876 of the Act plan program marketing materials

be subject to the same marketing review guidelines and timelines as MA plans at § 422.2262. While section 1876(c)(3)(C) of the Act, like section 1851(h) of the Act, provides that marketing materials must be provided to CMS for review prior to use, and generally provides that such materials may be used after 45 days if we do not disapprove them, section 1876(c)(3)(C) of the Act does not include the shorter, 10-day timeframe that applies under section 1851(h)(5) of the Act in the case of marketing materials using model language. However, we believe that as long as material is submitted to CMS prior to use, we can authorize use by an earlier timeframe than that provided for under the applicable statute, or for use under conditions established by CMS for “deemed” approval under the file and use policy or as discussed in section II.G.15.d. of this proposed rule. Therefore, notwithstanding the differences in statutory language between sections 1876(c)(3)(C) and 1851(h) of the Act, we propose that the part 417 marketing regulations be revised to provide that cost contracts plans authorized under section 1876 of the Act submit all such marketing materials to CMS at least 45 days before the date planned for distribution (10 days if plans use CMS model language, without any modifications), and that file and use materials, as designated by CMS under the MA marketing regulations, may be released 5 days following their submission to CMS.

c. Guidelines for CMS Review (§ 422.2264)

In our proposal to apply the same standards to cost contract plans as currently applied to MAOs at § 422.2264, cost contractors authorized under section 1876 of the Act would be required to comply with MA regulations that specify the information that cost contract plans must include in marketing materials, and specify that the cost contract plan must notify the general public concerning the plan’s enrollment period. Under section 1876(i)(3)(D) of the Act, we also propose that in markets with a significant non-English speaking population, cost contract plans be required to provide materials in the language of these individuals.

d. Deemed Approval (§ 422.2266)

We propose to specify that if we have not disapproved the distribution of marketing materials or forms submitted by a cost contract plan in an area, we are deemed not to have disapproved the distribution in all other areas covered by the cost contract plan and cost contract

except with regard to any portion of the material or form that is specific to the particular area, as provided under § 422.2266.

e. Standards for MA Organization Marketing (§ 422.2268)

MA marketing standards we propose to extend to cost contract plans include the following provisions at § 422.2268:

- Plans may not offer gifts to potential enrollees, unless the gifts are of nominal (as defined in the CMS Marketing Guidelines) value, are offered to all potential employees without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.
- Plans may not market any health care-related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.
- Plans may not market additional health-related lines of plan business not identified prior to an in-home appointment without a separate appointment that may not be scheduled until 48 hours after the initial appointment.
- Plans may not use a plan name that does not include the plan type. The plan type should be included at the end of the plan name.

f. Licensing of Marketing Representatives and Confirmation of Marketing Resources (§ 422.2272)

As is the case currently for MAOs, we propose that cost contract plans authorized under section 1876 of the Act, consistent with § 422.2272:

- Demonstrate to CMS’ satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.
- Establish and maintain a system for confirming that enrolled beneficiaries have, in fact, enrolled in the plan, and understand the rules applicable under the plan.
- Employ as marketing representatives only individuals who are licensed by the State to conduct marketing activities (as defined in the Medicare Marketing Guidelines) in that State, and whom the cost program has informed that State it has appointed, consistent with the appointment process provided for under State law.

g. Broker and Agent Requirements (§ 422.2274)

Under section 1876(i)(3)(D) of the Act, we propose applying the MA limits on independent agent and broker compensation at § 422.2274 to 1876 cost

contract plans. As with MA plans, compensation would be based on a 6-year compensation cycle. Agents and brokers would receive initial compensation (first year of the cycle) with compensation over each of the successive 5 years to be no more and no less than 50 percent of the initial

aggregate compensation paid for the enrollment. If an enrollee moves to plan type distinct from the one in which he or she is currently enrolled, the agent/broker would receive an initial commission and the cycle would begin anew. Distinct plan types include MA, MA-PD, PDP, and cost contract plans

authorized under section 1876 of the Act.

H. Changes To Implement Corrections and Other Technical Changes

We propose six technical changes in this section outlined below.

TABLE 8—CHANGES TO IMPLEMENT CORRECTIONS AND OTHER TECHNICAL CHANGES

Provision	Part 422		Part 423	
	Subpart	Section	Subpart	Section
Applications of Subpart M to Health Care Prepayment Plans.	Subpart M ..	§ 417.840	N/A	N/A.
Generic Notice Requirements	Subpart M ..	§ 422.622, § 422.626	N/A	N/A.
Revision to Definition of Gross Covered Prescription Drug Costs.	N/A	N/A	Subpart G ..	§ 423.308.
Application Evaluation Procedures	Subpart K ..	§ 422.502(c) through (d)	Subpart K ..	§ 423.503(c) through (d).
Intermediate Sanctions	Subpart O ..	§ 422.750(a)	Subpart O ..	§ 423.750(a).
Basis for Imposing Intermediate Sanctions and Civil Money Penalties.	Subpart O ..	§ 422.752	Subpart O ..	§ 423.752.

1. Application of Subpart M to Health Care Prepayment Plans (§ 417.840)

As part of the January 28, 2005 Medicare Advantage (MA) final rule, we required cost plans (HMOs), including HCPPs, established under section 1876 of the Act (Part E) and regulated under Part 417, to follow the MA appeals requirements in Subpart M of Part 422. While the MA beneficiary appeals provisions in section 1852(g) of the Act and cost-HMO-CMP beneficiary appeals provisions in section 1876(c)(5) of the Act do not apply to HCPP enrollees, HCPP enrollees retain the general right to appeal Medicare coverage decisions consistent with section 1869 of the Act. In applying the MA appeals procedures to HCPPs by regulation, we adapted and implemented section 1869 appeal rights in the HCPP context. The regulations implementing section 1869 for services received on a fee-for-service basis through original Medicare do not address the case of services furnished by an HCPP in the managed care context.

Because HCPPs only provide Part B services, in our January 28, 2005 final rule (70 FR 4194), we limit the applicability of Subpart M to HCPP enrollees to only those provisions affecting Part B services. However, in doing so we inadvertently failed to include fast-track appeal rights regarding services provided by a (Part B) comprehensive outpatient rehabilitation facility (CORF). The proposed revision corrects this oversight, and ensures that HCPP enrollees have access to fast-track appeals for CORF services furnished by an HCPP. This would also effectuate for HCPP enrollees the fast track appeal

rights provided for under section 1869 of the Act.

2. Generic Notice Delivery Requirements (§ 422.622 and § 422.626)

We propose making two technical revisions in § 422.622 and § 422.626 to ensure that the MA regulations accurately state when plans and providers are responsible for delivering certain notices to enrollees. Section 422.622, states that when a QIO determines that an enrollee may remain in an inpatient setting, the MA organization must again provide the enrollee with a copy of the Important Message from Medicare (IM) when the enrollee no longer requires inpatient hospital care. However, the IM form instructions make clear that the IM is always delivered by a hospital. Similarly, in § 422.626, the current regulations make delivery of the Notice of Medicare Noncoverage (NOMNC) the MA organization's responsibility. Again, the form instructions for the NOMNC clearly state that the notice is to be delivered by the provider. Accordingly, we propose replacing "MA organization" with "hospital" in § 422.622, and "provider" in § 422.626.

3. Revision to Definition of Gross Covered Prescription Drug Costs (§ 423.308)

On January 12, 2009, we published a final rule (74 FR 1494) that included revisions to the definition of "gross covered prescription drug costs" in the Part D regulations at § 423.308. In amending § 423.308, we made a technical error in the definition of "gross covered prescription drug costs" (74 FR 1545) by referencing "negotiated

prices", the prices made available to Part D beneficiaries at network pharmacies, and not also referencing "usual and customary prices", the prices for drugs purchased at out-of-network pharmacies. When we revised the definition of "gross covered prescription drug costs" our intent was to clarify that Part D sponsors must use the amount received by the dispensing pharmacy or other dispensing provider as the basis for determining the drug costs that must be reported to us. The use of the term "negotiated prices" as defined at § 423.100 (74 FR 1544) in the definition of "gross covered prescription drug costs" clarifies this requirement with regards to covered Part D drugs purchased at network pharmacies. However, by not also referencing "usual and customary prices" for covered Part D drugs purchased at out-of-network pharmacies, we inadvertently omitted from the definition of "gross covered prescription drug costs" the share of drug costs actually paid by Part D sponsors to out-of-network pharmacies.

Section 1860D-15(b)(3) of the Act defines "gross covered prescription drug costs" as "the costs incurred under the [Part D] plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs * * *." These costs include costs incurred for covered Part D drugs at out-of-network pharmacies, as well as costs incurred at network pharmacies. Therefore, we are proposing to revise the definition of "gross covered prescription drug costs" to correctly reference both "negotiated prices" paid to network pharmacies and "usual and customary prices" paid to out-of-network pharmacies. Specifically,

we are proposing to replace the term “negotiated price” with the term “actual cost,” which is defined at § 423.100 as “the negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of-network pharmacy consistent with § 423.124(a).” Thus, with this correction, the definition of gross covered prescription drug costs would include “the share of actual costs (as defined by § 423.100 of this part) actually paid by the Part D plan that is received as reimbursement by the pharmacy or other dispensing entity* * *.”

4. Application Evaluation Procedures (§ 422.502(c) and (d) and § 423.503(c) and (d))

Section 1857(a) of the Act provides the Secretary with the authority to enter into contracts with MA organizations, and section 1860D–12(b) (1) of the Act provides the Secretary with the authority to enter into contracts with PDP sponsors. Sections 422.502 and 423.503 provide the evaluation and determination procedures for approving or denying a contract application. We are proposing two amendments to these regulations in § 422.502(c) and (d), and § 423.503(c) and (d).

Currently, § 422.502(c)(3)(iii) and § 423.503(c)(3)(iii) state that if we deny the application, it gives written notice to the contract applicant indicating the applicant’s right to request reconsideration. In the December 5, 2007 final rule, we modified the appeal rights for initial applications and eliminated the reconsideration process. However, in the final regulations we did not update § 422.502(c)(3)(iii) and § 423.503(c)(3)(iii) to state that the applicant has a right to request a hearing and as a result the existing regulations incorrectly provide for a right to reconsideration. Therefore, at § 422.502(c)(3)(iii) and § 423.503(c)(3)(iii) we are proposing to make a technical correction and delete the language “right to reconsideration” and replace it with “right to request a hearing”.

Sections 422.502(d) and 423.503(d) currently provide that we have the ability to oversee the sponsoring organization’s continued compliance with the requirements and that if the sponsoring organization no longer meets those requirements, we will terminate the contract in accordance with § 422.510 and § 423.509. This regulation is not an appropriate regulation for a section dedicated to the evaluation and determination procedures for approving or denying a contract application.

Therefore, we are proposing to delete § 422.502(d) and § 423.503(d). The deletion of this language should not in any way be interpreted as limiting our ability to oversee a sponsoring organization’s compliance with our requirements as outlined at § 422.504 and § 423.505 or our ability to terminate a contract when a sponsoring organization no longer meets requirements as outlined in § 422.510(a) and § 423.509(a).

5. Intermediate Sanctions (§ 422.750(a) and § 423.750(a))

Sections 1857(g) and 1860D–12 of the Act provide the Secretary the ability to impose intermediate sanctions on sponsoring organizations. Section 422.750 and § 423.750 provide the types of intermediate sanctions that we may impose. Those intermediate sanctions are suspension of enrollment, suspension of payment, and suspension of all marketing activities. We are proposing to make technical changes to each intermediate sanction regulation to more accurately reflect the statute.

We are first proposing to change § 422.750(a)(1) and § 423.750(a)(1), which currently state that we may impose an intermediate sanction that requires the suspension of enrollment of Medicare beneficiaries. This regulation, as currently written, does not adequately reflect the statutory language which specifies that the enrollment suspension applies to the sponsoring organization’s enrollment of Medicare beneficiaries. Therefore, we are proposing to amend § 422.750(a)(1) and § 423.750(a)(1) to add language which makes it explicit that the suspension of enrollment applies to suspension of the sponsoring organization’s enrollment of Medicare beneficiaries.

We also are proposing to change the language of § 422.750(a)(2) and § 423.750(a)(2), which currently states that we may impose a suspension of payment to the sponsoring organization for Medicare beneficiaries who are enrolled in the MA plan. This language does not conform to the statutory language at section 1857(g)(2)(C) of the Act which states suspension of payment may be imposed for individuals enrolled after the date the Secretary notifies the organization of the imposition of an intermediate sanction. Therefore, we are amending § 422.750(a)(2) and § 423.750(a)(2) to add language that specifically states a suspension of payment applies to Medicare beneficiaries enrolled after the date we notify the organization of the intermediate sanction.

We are also proposing changes to § 422.750(a)(3) and § 423.750(a)(3),

which currently states that we may impose an intermediate sanction that requires the suspension of all marketing activities to Medicare beneficiaries by a sponsoring organization for specified MA or Part D “plans.” The use of the words “for specified” MA or Part D “plans” does not conform to the statutory language that applies intermediate sanctions at the organization level. Therefore, we are amending § 422.750(a)(3) and § 423.750(a)(3) to conform to the statutory language by deleting the words “for specified MA or Part D plans.”

6. Basis for Imposing Intermediate Sanctions and Civil Money Penalties (§ 422.752 and § 423.752)

Sections 1857(g) and 1860D–12 of the Act provide a list of bases for intermediate sanctions and civil money penalties. Existing regulations at § 422.752(a) and § 423.752(a) provide a similar list of bases for intermediate sanctions and civil money penalties. However, the language provided in § 422.752(a)(1), (3), and (4) and § 423.752(a)(1), (3), and (4) does not adequately conform to the statutory language in section 1857(g)(1)(A), (C), and (D) of the Act, respectively. Specifically, section 1857(g)(1) of the Act states the Secretary may impose an intermediate sanction if it determines that the sponsoring organization: (A) Fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual; (C) acts to expel or to refuse to re-enroll an individual in violation of the provisions of this part; and (D) engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services. To ensure accuracy, consistency and uniformity we are making conforming changes to our regulation at § 422.752(a)(1), (3), and (4) and § 423.752(a)(1), (3), and (4) to more accurately reflect the statutory language.

First, § 422.752(a)(1) states that we may impose an intermediate sanction if the sponsoring organization fails substantially to provide, to a sponsoring organization enrollee, medically necessary services that the organization is required to provide (under law or under the contract) to a sponsoring organization enrollee, and that failure

adversely affects (or is substantially likely to adversely affect) the enrollee. This language is slightly different than the language provided in the statute at section 1857(g)(1)(A) of the Act. Therefore, we are proposing to amend § 422.752(a)(1) and § 423.752(a)(1) to conform with the statutory language and state that we may impose an intermediate sanction if the sponsoring organization fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual.

Second, § 422.752(a)(3) and § 423.752(a)(3) states that we may impose an intermediate sanction if the sponsoring organization expels or refuses to reenroll a beneficiary in violation of the provisions of this part. This language does not include the word "acts" to expel which is mentioned in the statute at section 1857(g)(1)(C) of the Act. Therefore, we are proposing to amend § 422.752(a)(3) and § 423.752(a)(3) to conform with the statutory language and state that we may impose an intermediate sanction if the sponsoring organization "acts" to expel or refuses to re-enroll a beneficiary in violation of the provisions of this part.

Third, § 422.752(a)(4) and § 423.752(a)(4) states that we may impose an intermediate sanction if the sponsoring organization engages in any practice that could reasonably be expected to have the effect of denying or discouraging enrollment of individuals whose medical condition or history indicates a need for substantial future medical services. This language does not match the exact language contained in section 1857(g)(1)(D) of the Act. Therefore, we are proposing to amend § 422.752(a)(4) and § 423.752(a)(4) to conform with the statutory language and state that we may impose an intermediate sanction if the sponsoring organization engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services.

We are also proposing to make conforming changes to § 422.752(c) and § 423.752(c). Currently § 422.752(c)(1) and § 423.752(c)(1) state that we may impose civil money penalties for any of the determinations at § 422.510(a) and § 423.509(a), except § 422.510(a)(4) and § 423.509(a)(4). Also, § 422.752(c)(2)(ii)

and § 423.752(c)(2)(ii) state that OIG may impose civil money penalties for a determination made pursuant to § 422.510(a)(4) and § 423.509(a)(4). Since we are proposing elsewhere in these proposed regulations to redesignate § 422.510(a)(4) and § 423.509(a)(4) to § 422.510(a)(2)(iii) and § 423.509(a)(2)(iii), we need to conform § 422.752 and § 423.752 to these changes. Therefore, for regulations § 422.752(c)(1), § 422.752(c)(2)(ii), § 423.752(c)(1), and § 423.752(c)(2)(ii) we are proposing to delete the reference to § 422.510(a)(4) and § 423.509(a)(4) and replace them with a reference to § 422.510(a)(2)(iii) and § 423.509(a)(2)(iii).

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

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

A. ICRs Regarding Basic Contract Requirements (§ 417.472)

Proposed § 417.472(i) states that HMO or CMP must comply with the requirements at § 422.152(b)(5). Proposed § 417.472 states that all coordinated care contracts (including local and regional PPOs and contracts with exclusively SNP benefit packages, cost contracts under section 1876 of the Act, private fee-for-service contracts, and MSA contracts with 600 or more enrollees in July of the prior year) must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of MA plan

enrollees in accordance with CMS specifications and submit the survey data to CMS. The burden associated with the requirement in § 417.472(i) and (j) is detailed in our discussion of § 422.152(b)(5).

B. ICRs Regarding Apportionment and Allocation of Administrative and General Costs (§ 417.564)

We are not imposing any new reporting requirements. We are simply clarifying what costs an HCPP may report in its cost report as administrative costs for reimbursement from the government. We do not believe that our proposal will result in additional burden on cost plans; therefore, we have not incorporated a burden increase in the PRA section. However, we solicit comment on our burden estimates.

C. ICRs Regarding Medicare Secondary Payer (MSP) Procedure (§ 422.108 and § 423.462)

Section 422.108(b)(3) proposes that MA organizations must coordinate benefits to Medicare enrollees with the benefits of the primary payers, including reporting, on an ongoing basis, information obtained in accordance with requirements in paragraphs (b)(1) and (b)(2) of this section in accordance with CMS instructions. Similarly, § 423.462 proposed that Part D plan sponsors must report creditable new or changed primary payer information to the CMS Coordination of Benefits Contractor in accordance with the processes and timeframes specified by CMS. The burden associated with this requirement is the time and effort necessary to report the specified information to CMS on an ongoing basis. We estimate that 624 MA organizations and 456 Part D plan sponsors must comply with these requirements, a total of 1,080 entities. We also estimate that, on average, each entity will produce one report thereby yielding a total of 1,080 reports annually for involved entities. It will take each entity an average of 2,885 hours to report the required information to CMS. The estimated annual burden associated with these requirements is 3,115,800 hours. The cost associated with meeting these requirements is \$77.9 million.

D. ICRs Regarding Disclosure Requirements (§ 422.111)

Proposed § 422.111 states that we may require an MA organization to self-disclose to its enrollees or potential enrollees, the MA organization's performance and contract compliance deficiencies in a manner specified by CMS. The burden associated with this

requirement is the time and effort necessary for an MA organization to make the aforementioned disclosures. We have not accounted for the burden associated with this provision for two reasons. First, we may require organizations that are under enforcement actions to disclose their compliance deficiencies in a letter to their existing members. However, the number of organizations that receive enforcement actions per year does not exceed the PRA threshold of 10. Based on past history and experience, we have not imposed intermediate sanctions on more than 10 plans in a given year. For example, there have been a total of 4 organizations with intermediate sanctions imposed this year which is the highest number of intermediate sanctions imposed during the past 4 years. Second, for organizations that are not under enforcement action, we may require them to disclose compliance and performance deficiencies but only in their existing marketing or enrollment materials sent to current and potential enrollees. There will be no requirement for them to submit additional materials to enrollees. We solicit comment on whether these provisions could impact 10 or more plans and whether these burdens should be accounted for under the PRA.

E. ICRs Regarding Quality Improvement Program (§ 422.152)

Proposed § 422.152(b)(3)(ii) states that MA coordinated care plans must collect, analyze and report quality performance data identified by CMS that are of the same type as those specified under paragraph (b)(3)(i) of this section. The burden associated with these requirements is the time and effort necessary for an MA coordinated care plan to collect, analyze and report quality performance data to CMS. We estimate that it will require 1,000 hours per MA coordinated care plan to comply with these requirements. There are 624 MA coordinated care plans. The estimated annual burden associated with these requirements is 624,000 hours. The estimated annual cost associated with these requirements is \$36.9 million.

Proposed § 422.152(b)(5) requires that all coordinated care contracts (including local and regional PPOs and contracts with exclusively SNP benefit packages, cost contracts under section 1876 of the Act, private fee-for-service contracts, and MSA contracts with 600 or more enrollees in July of the prior year) must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare

CAHPS satisfaction survey of MA plan enrollees in accordance with CMS specifications, and submit the survey data to CMS. The burden associated with this requirement is the time and effort necessary to conduct the CAHPS survey and submit the corresponding data to CMS. While this requirement is subject to the PRA, the associated burden is currently approved under OMB control number 0938-0732.

Proposed § 422.152(e)(2)(ii) states that MA organizations offering an MA regional plan or local PPO plan must collect, analyze and report quality performance data identified by CMS that are of the same type as those described under § 422.152(e)(2)(i). The burden associated with these requirements is the time and effort necessary for an MA organization offering an MA regional plan or local PPO plan to collect, analyze and report quality performance data to CMS. We estimate that it will require 54 hours per MA organization to comply with these requirements; there are 509 organizations offering an MA regional plan or local PPO. The estimated annual burden associated with these requirements is 27,486 hours. The estimated annual cost associated with these requirements is \$3.1 million.

F. ICRs Regarding RADV Audit Dispute and Appeal Processes (§ 422.311)

Proposed § 422.311(c)(1) discusses the attestation process with regard to the RADV audit dispute and appeal processes. Specifically, proposed § 422.311(c)(1)(i)(A) states that subsequent to the conduct of a RADV audit, MA organizations may submit CMS-generated attestations from physician/practitioner(s) in order to dispute signature or credential related RADV errors. Proposed § 422.311(c)(1)(iv)(A) states that CMS notifies an MA organization of their RADV audit status, we will provide the attestation forms and submission instructions. As stated in proposed § 422.311(c)(1)(iv)(B), MA organizations are required to submit the attestation to CMS at the same time that the MA organization is required to submit related medical records for RADV audits.

The burden associated with the requirements in this section is the time and effort necessary for MA organizations to complete the CMS-generated attestations and to submit the related documentation to CMS. While these requirements are subject to the PRA, we believe the associated burden is exempt from the PRA under 5 CFR 1320.3(h)(1). As stated in 5 CFR 1320.3(h)(1), information does not

generally include items in the following categories, which include but are not limited to affidavits, oaths, affirmations and certifications, provided that they entail no burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument. Similarly, we believe the burden associated with the aforementioned information collection requirements is exempt from the PRA under 5 CFR 1320.4. Information collected during the conduct of an administrative action or audit is not subject to the PRA.

Proposed § 422.311(c)(2) states that an MA organization may choose to dispute CMS' operational processing of RADV medical records using a CMS-administered documentation dispute process.

Proposed § 422.311(c)(2)(iii)(B) states that MA organizations have 30 days from the date of issuance of the RADV audit report to request a documentation dispute. Proposed § 422.311(c)(2)(iv) outlines the documentation dispute review and notification procedures. The burden associated with the requirements in this section is the time and effort necessary for an MA organization to request a documentation dispute. While this requirement is subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.4. Information collected during the conduct of an administrative action or audit is not subject to the PRA.

Proposed § 422.311(c)(3) describes the RADV payment error appeal process. Specifically, proposed § 422.311(c)(3)(iii) states that at the time CMS issues its RADV audit report, we notify affected MA organizations in writing of their appeal rights around the RADV payment error calculation. The MA organizations have 30 days from the date of this notice to submit a written request for reconsideration of its RADV payment error calculation. The burden associated with this requirement is the time and effort necessary for an MA organization to draft and submit a redetermination request that contains the content specified in proposed § 422.311(c)(3)(v). While this requirement is subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.4. Information collected during the conduct of an administrative action or audit is not subject to the PRA.

Proposed § 422.311(c)(4) states that an MA organization that is dissatisfied with the written decision of the CMS reconsideration official is entitled to a hearing as provided in this section. The organization's request for a hearing must be made in writing and filed with CMS

within 30 days of the date CMS and the MA organization receive CMS' written reconsideration decision. The reconsideration request must contain the information listed in proposed § 422.311(c)(4)(ii). The burden associated with this requirement is the time and effort necessary for an MA organization to draft and submit a hearing request. While this requirement is subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.4. Information collected during the conduct of an administrative action or audit is not subject to the PRA.

G. ICRs Regarding Application Requirements (§ 422.501 and § 423.502)

Proposed § 422.501(b) and proposed § 423.502(b) require that an organization submitting an application under this section for a particular contract year must first submit a completed Notice of Intent to Apply by the date established by CMS. We will not accept applications from organizations that do not submit a timely Notice of Intent to Apply. The purpose of these requirements is to facilitate CMS systems access earlier so that the contract number may be given out and applications may be submitted electronically. While the burden associated with the requirements contained in proposed § 422.501(b) and proposed § 423.502(b), the Notice of Intent to Apply, is subject to the PRA, the burden associated with these requirements is already approved under the OMB control numbers for the Part C and Part D applications, 0938–0935 and 0938–0936, respectively.

Section 422.501(c) and § 423.502(c) propose to revise the current regulation, making clear the application standards for becoming an MA organization or Part D plan sponsor. Specifically, proposed § 422.501(c) and § 423.502(c) would require that applicants complete all parts of a certified application. The burden associated with the aforementioned requirements is the time and effort necessary for an applicant to complete all parts of a certified Part C or Part D application. While the burden associated with the requirements contained in proposed § 422.501(c) and proposed § 423.502(c) is subject to the PRA, the burden associated with these requirements is already approved under OMB control numbers for the Part C and Part D applications, 0938–0935 and 0938–0936, respectively.

The costs associated with submitting the applications approved under 0938–0935 and 0938–0936 are \$864,600 and \$655,559, for MA plans and Part D plan sponsors, respectively.

H. ICRs Regarding General Provisions (§ 422.503 and § 423.504)

Section 422.503(b)(4)(vi) and § 423.504(b)(4)(vi) propose to expand on the existing requirements by providing clarification and additional guidance with respect to the requirements for developing, implementing and maintaining effective compliance programs. We believe the requirements contained in § 422.503(b)(4)(vi) and § 423.504(b)(4)(vi) will assist sponsoring organizations further improving their existing compliance programs. While these requirements are subject to the PRA, we believe the associated burden is part of usual and customary business practices and thereby exempt under 5 CFR 1320.3(b)(2). However, we solicit comment on our assessment and whether these burdens are, in fact, part of usual and customary business practices.

I. ICRs Regarding Contract Provisions (§ 422.504 and § 423.505)

Proposed § 422.504 and § 423.505 explicitly state our existing authority to find sponsors out of compliance with either MA requirements, Part D requirements, or both when the sponsor's performance represents an outlier relative to the performance of other sponsors. Specifically, proposed § 422.504(e)(2) and § 423.505(e)(2) state that HHS, the Comptroller General or their designees have the right to audit, evaluate, and inspect any books, contracts, computer or other electronic systems, including medical records and documentation of the first tier, downstream, and related to our contract with the MA organization. These proposed sections contain recordkeeping requirements. The burden associated with proposed § 422.504(e)(2) and § 423.505(e)(2) is the time and effort necessary for MA organizations or Part D sponsors to maintain the information on file and make it available to CMS upon request. While these requirements are subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(b)(2). However, we solicit comment on our assessment and whether these burdens are, in fact, part of usual and customary business practices.

J. ICRs Regarding Nonrenewal of Contract (§ 422.506 and § 423.507)

Proposed § 422.506 and § 423.507 contain notification requirements for MA organizations and Part D plan sponsors. Section 422.506(a)(2) and § 423.507(a)(2) propose to require that when an organization does not intend to

renew its contract, it must notify each Medicare enrollee by mail at least 90 calendar days before the date on which the nonrenewal is effective. An organization would also have to provide information about alternative enrollment options by complying with at least one of the requirements specified in proposed § 422.506(a)(2)(ii) or § 423.507(a)(2)(ii). In addition, proposed § 422.506(b)(2) and § 423.507(b)(2) state that an organization notify each Medicare enrollee by mail at least 90 calendar days before the date on which the nonrenewal is effective, or at the conclusion of the appeals process if applicable.

The burden associated with the aforementioned requirements is the time and effort necessary for an organization to notify its Medicare enrollees by mail at least 90 calendar days before the date on which the nonrenewal is effective, or at the conclusion of the appeals process if applicable. While this requirement is subject to the PRA, we are unable to accurately quantify the burden because we cannot estimate the number of organizations that may not renew their contracts from year to year. We believe that less than 10 contracts will be terminated on an annual basis; however, we welcome public comments on these information collection requirements and whether the PRA would apply. We will reevaluate this issue in the final rule stage of rulemaking.

K. ICRs Regarding Request for Hearing (§ 422.662 and § 423.651)

With respect to Medicare contract determinations and appeals, § 422.662 and § 423.651 propose the requirements for submission methods and time for filing requirements for MA organizations and Part D plan sponsors that want to request a hearing for a determination under appeal. The request for hearing must be submitted in writing and must be filed within 15 calendar days after the receipt of the notice of the contract determination or intermediate sanction. The PRA is not applicable to this proposal because there are no additional requirements for sponsoring organizations. This is an existing regulation and we are only modifying the language "after receipt of the hearing decision" to conform to other regulations.

L. ICRs Regarding Time and Place of Hearing (§ 422.670 and § 423.655)

Proposed § 422.670 and § 423.655 state that CMS, an MA organization or a Part D plan sponsor may request an extension by filing a written request no later than 5 calendar days prior to the scheduled hearing. The burden

associated with these requirements is the time and effort necessary for an MA organization or a Part D plan sponsor to submit a written extension request to the presiding hearing officer. While this requirement is subject to the PRA, we believe the associated burden is exempt from the PRA as stated under 5 CFR 1320.4. Information collected during the conduct of an administrative action is not subject to the PRA.

M. ICRs Regarding Review by the Administrator (§ 422.692 and § 423.666)

Proposed § 422.692 and § 423.666 state that CMS, an MA organization or a PDP plan sponsor that has received a hearing decision may request a review by the Administrator within 15 calendar days after receipt of the hearing decision. The burden associated with these requirements is the time and effort necessary to submit a request for the Administrator to review a hearing decision. The PRA is not applicable to this proposal because there are no additional requirements for sponsoring organizations. This is an existing regulation and we are only modifying the language “after receipt of the hearing decision” to conform to other regulations.

N. ICRs Regarding Procedures for Imposing Intermediate Sanctions and Civil Monetary Penalties (§ 422.756 and § 423.756)

Proposed § 422.756 and § 423.756 state before CMS imposes intermediate sanctions, MA organizations and Part D plan sponsors may request a hearing before a CMS hearing officer. A written request must be received by the designated CMS office within 15 calendar days of the receipt of the notice of sanction. The burden associated with these requirements is the time and effort necessary to draft and submit a hearing request to the designated CMS office. The PRA is not applicable to this proposal because there are no additional requirements for sponsoring organizations. This is an existing regulation and we are only modifying the language “after receipt of the hearing decision” to conform to other regulations.

O. ICRs Regarding Disclosure of Part D Plan Information (§ 423.128)

Proposed § 423.128 states that we may require a Part D plan sponsor to self-disclose to its enrollees or potential enrollees, the Part D plan sponsor's performance and contract compliance deficiencies in a manner specified by CMS. We believe the burden associated with this requirement is the time and effort necessary for a Part D plan

sponsor to disclose the aforementioned information. We do not believe the PRA is applicable for this proposal for two reasons.

First, we may require organizations that are under enforcement actions to disclose their compliance deficiencies in a letter to their existing members. Based on past history and experience, we have not imposed intermediate sanctions on more than 10 plans in a given year. For example, there have been a total of 4 organizations with intermediate sanctions imposed this year which is the highest number of intermediate sanctions imposed during the past 4 years. We believe the burden associated with the requirement is not subject to the PRA under 5 CFR 1320.3(c), which defines the agency collection of information subject to the requirements of the PRA as information collection imposed on 10 or more persons within any 12-month period. This information collection does not impact 10 or more entities in a 12-month period. However, we welcome public comments on this issue. We will reevaluate this issue in the final rule stage of rulemaking.

Second, for organizations that are not under enforcement action, we may require them to disclose compliance and performance deficiencies but only in their existing marketing or enrollment materials sent to current and potential enrollees.

While we do not believe this additional disclosure would increase burden or costs to organizations, we solicit comment on our burden estimates and assumptions.

P. ICRs Regarding Consumer Satisfaction Surveys (§ 423.156)

Proposed § 423.156 requires Part D contracts with 600 or more enrollees as of July of the prior year to contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of Part D plan enroll enrollees in accordance with CMS specifications and submit the survey data to CMS. The burden associated with this requirement is the time and effort necessary to conduct the CAHPS survey and submit the corresponding data to CMS. While this requirement is subject to the PRA, the associated burden is currently approved under OMB control number 0938–0732.

Q. ICRs Regarding Validation of Part C and Part D Reporting Requirements (§ 422.516 and § 423.514)

We propose to amend § 422.516 and § 423.514 to state that each Part C and

Part D sponsor be subject to an independent yearly audit of Part C and Part D measures (collected pursuant to our reporting requirements) to determine their reliability, validity, completeness, and comparability in accordance with specifications developed by CMS. The burden associated with this proposed provision is the time and effort of the MA organizations and Part D sponsors in procuring an auditor and in supporting the auditor as well as the time and effort of the auditor in conducting the yearly audit. We estimate that the total yearly hourly burden for procuring and supporting the auditor is equal to the number of sponsors (710) × the average estimated hours per sponsor (120). This equals 85,200 hours. We estimated that the average number of hours for the auditor to conduct an audit was 304. The total estimated hours to conduct audits across all sponsors would then be $710 \times 304 = 215,840$. The total hours would be $85,200 + 215,840 = 301,040$. The estimated annual cost associated with these requirements is \$45.6 million.

R. ICRs Regarding Drug Utilization Management, Quality Assurance, and Medication Therapy Management Programs (MTMPs) (§ 423.153)

The proposed revisions to § 423.153 state that Part D plans must offer a minimum level of medication therapy management services for each beneficiary enrolled in the MTMP that includes but is not limited to annual comprehensive medication reviews with written summaries. The comprehensive medical review must include an interactive, person-to-person consultation performed by a pharmacist or other qualified provider unless the beneficiary is in a long-term care setting. Additionally, there must be quarterly targeted medication reviews with follow-up interventions when necessary.

The burden associated with these requirements is the time and effort necessary for a Part D sponsors (both MA-PDs and PDPs) to conduct the medical reviews with written summaries. We estimate that each medical review will take an average of 30 minutes to conduct. Similarly, we estimate that there will be 1,875,000 reviews conducted by 456 Part D sponsors on an annual basis. The total annual burden associated with this requirement is 937,500 hours.

S. ICRs Regarding Timeframes and Notice Requirements for Standard Coverage Determinations (§ 423.568)

If a Part D plan sponsor makes a completely favorable standard decision under paragraph (b) of this section, it must give the enrollee written notice of the determination. The initial notice may be provided orally, so long as a written follow-up notice is sent within 3 calendar days of the oral notification.

The burden associated with the requirement proposed in paragraph (d) is the time and effort necessary for a Part D plan sponsor to notify an enrollee (and the prescribing physician or other prescriber involved, as appropriate) in writing of completely favorable standard decision for benefits. We estimate that each year, the 456 Part D plan sponsors will issue a total of approximately 760,411 written favorable standard notifications for benefits. We further estimate that it will take a Part D plan sponsor 30 minutes to distribute a single notice. The estimated annual burden associated with the requirement in proposed § 423.568(d) is 380,206 hours. The estimated annual cost associated with these requirements is \$15.2 million.

T. ICRs Regarding Timeframes and Notice Requirements for Expedited Coverage Determinations (§ 423.572)

If a Part D plan sponsor makes a completely favorable expedited decision under paragraph (b) of this section, it must give the enrollee written notice of the determination. The initial notice may be provided orally, so long as a written follow-up notice is sent within 3 calendar days of the oral notification. The burden associated with the requirements listed in § 423.572(b) is the time and effort necessary for a Part D plan sponsor to notify an enrollee (and the prescribing physician or other prescriber involved, as appropriate) in writing of completely favorable expedited decision. We estimate that

each of the 456 Part D plan sponsors will issue an average of 87,103 written favorable expedited notifications per year. We further estimate that it will take a Part D plan sponsor 30 minutes to distribute a single notice. The estimated annual burden associated with the requirement in § 423.572(b) is 43,552 hours. The estimated annual cost associated with these requirements is \$15.2 million.

U. ICRs Regarding Access to Covered Part D Drugs (§ 423.120)

Proposed § 423.120(b)(iv) would require sponsors to provide enrollees with appropriate notice regarding their transition process within a reasonable amount of time after providing a temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules). The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to provide a notice to beneficiaries regarding the transition process. We estimate this would result in 1.35 million notices that would take an average of 15 minutes to prepare. We then estimate the total burden to be 337,500 hours.

Proposed § 423.120(c)(3) would require Part D sponsors to contractually mandate that their network pharmacies submit claims electronically to the Part D sponsor or its intermediary on behalf of the beneficiary whenever feasible unless the enrollee expressly requests that a particular claim not be submitted to the Part D sponsor or its intermediary. Proposed § 423.120(c)(3) would require the approximately 28 pharmacy claims processors currently responsible for the electronic adjudication of pharmacy benefits to change their RxBIN or RxBIN and RxPCN combination if such identifiers are not already unique to its Medicare

line of business, and the Part D cardholder identification number if it is not already unique to each Medicare Part D enrollee. We estimate the annual hourly burden to be 1,380 hours per processor to make the coding changes necessary to implement this requirement. There are an estimated 28 processors. At an estimated \$150 cost per hour for the fully loaded labor of a computer programmer, we estimate the yearly burden to be 38,640 hours for CY 2010. This is a one-time only burden for programming.

The estimated annual cost associated with requirements associated with the transition process is \$6.8 million.

V. ICRs Regarding Timeframes and Responsibility for Making Redeterminations (§ 423.590)

Proposed § 423.590(d)(2) states that if a Part D plan sponsor first notifies an enrollee of an adverse or favorable expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification. The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to follow up an initial oral notification to an enrollee with a written notification. We estimate that each of the 456 Part D plan sponsors will have to distribute approximately 95 notices for an estimated annual number of 43,320 responses. Similarly, we estimate that the work will be conducted at a rate of \$40 per hour. The estimated annual cost associated with this requirement is \$1.733 million.

W. Annual Information Collection Burden

Table 9 shows our estimates of the annual reporting and recordkeeping burden based on the discussion detailed in sections III.A. through III.V. of this proposed rule.

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TABLE 9--Estimated Annual Reporting, Recordkeeping and Cost Burdens

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burdens per Response (hours)	Total Annual Burden (hours)	Total Annual Cost Burden (\$ in millions)	Hourly Labor Cost of Reporting	Total Labor Cost of Reporting (\$ in millions)	Total Capital/Maintenance Costs (\$ millions)	Total Costs (\$ millions)
§422.108 and §423.462	0938-New	1,080	1,080	2,885	3,115,800	77.9	25	77.9	0	77.9
§422.152 (b)(3)(ii)	0938-New	624	624	1,000	624,000	36.9	59.13	36.9	0	36.9
§422.152(b)(5)	0938-0732	660,000	660,000	0.33	217,800	0	0	0	0	0
§422.152(c)(2)(ii)	0938-New	509	509	54	27,486	3.1	112.78	3.1	0	3.1
§422.501	0938-0935	291	291	32.8	9,547	0.9	90.56	0.9	0	0.9
§423.502	0938-0936	453	453	26.3	11,919	0.7	55.00	0.7	0	0.7
§423.156	0938-0732	660,000	660,000	0.33	217,800	0.0	0.00	0.0	0	0.0
§422.516 and §423.514	0938-New	710	710	425	301,840	45.6	151.07	45.6	0	45.6
§422.568 and §423.568	0938-New	1,080	21,232	0.5	10,616	0.4	40	0.4	0	0.4
§423.568	0938-New	456	760,411	0.5	380,206	15.2	40	15.2	0	15.2
§423.120(b)(iv)	0938-New	456	1,350,000	0.15	337,500	6.8	20.15	6.8	0	6.8
§423.120(c)(3)	0938-New	28	28	1380	38,640	0	0	0	5.8	5.8
§423.153	0938-New	456	1,875,000	0.5	937,500	112.5	120	112.5	0	112.5
§423.590	0938-New	456	43,550	1	43,550	1.7	40	1.7	0	1.7
§423.572	0938-0976	758	290,344	0.5	145,172	15.2	104.70	15.2	0	15.2
Total/Average					6,419,376	316.8	49.35	316.8	5.8	322.6

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. E-mail comments to the Office of Information and Regulatory Affairs, Office of Management and Budget to oir_submission@omb.eop.gov or fax comments to 202-395-7285. Please reference this rule (CMS-4085-P) and mark your comments to the attention of CMS desk officer.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

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

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by

nonprofit status or by having revenues of \$7.0 million to \$34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. MA organizations and Part D sponsors, the only entities that will be affected by the provisions of this rule, are not generally considered small business entities. They must follow minimum enrollment requirements (5,000 in urban areas and 1,500 in non-urban areas) and because of the revenue from such enrollments, these entities are generally above the revenue threshold required for analysis under the RFA. While a very small rural plan could fall below the threshold, we do not believe that there are more than a handful of such plans. A fraction of MA organizations and sponsors are considered small businesses because of their non-profit status. For an analysis to be necessary, however, 3 to 5 percent of their revenue would have to be affected by the provisions. We do not believe that this threshold would be reached by the proposed requirements. Therefore, the Secretary has determined that this proposed rule will not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact 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 we believe and the Secretary has determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 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. That threshold level is currently \$133 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.

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.

Because there are costs to plans and sponsors associated with several provisions of this rule, we indicate general areas affected and specify the costs associated with these. For specific burden associated with the requirements and the bases for our estimates, see section III. of this proposed rule.

We estimate this rule is “economically significant” as measured by the \$100 million threshold, and hence a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis.

B. Increase in Costs to MA Organizations and Part D Sponsors

The provisions of this proposed rule would require MA organizations and Part D sponsors an estimated cost of approximately \$321.68 million for CY 2010. We believe the following requirements will result in monetized transfers from the Federal Government to MA organizations and Part D sponsors between 2011 and 2015. Risk Adjustment Validation (Part 422), Quality Improvement program (§ 422.152), Medicare Secondary Payer Procedures (§ 422.108), Validation of Reporting Requirements (§ 422.516 and § 423.514), the Quality Improvement Program and Consumer Satisfaction Surveys (§ 422.152 and § 423.156), Providing Written Notifications (§ 422.568(e)), Organization Determinations, Transition Process Notice (§ 423.120), Standard Timeframe and Notice Requirements for Coverage Determinations (§ 423.568), Drug Utilization Management, Quality Assurance, and Medication Therapy Management Programs (§ 423.153), and Pharmacy Use of Standard Technology under Part D (§ 423.120(c)(3)). We believe that the MIPPA 176 provision will result in savings. However, the MIPPA 176 provision will not take effect until CY 2011. Most of the proposed changes do not require additional data collection or reporting burden but rather involve clarification or codification of current policy. The economic impact will be funded through monetized transfers from the Federal government to health plans and through increases in beneficiary premiums. We expect that these expenses will be largely reflected in higher bid prices. Given that there are approximately 27 million PDP enrollees and an additional 8 million MA

enrollees, the impact on the premium per enrollee will be minimal. In CY 2010, the estimated cost is

approximately \$3.2 million, translating to under \$10.00 per enrollee. The affect on the monthly premium would be less

than \$1.00. The estimated impact on enrollees would appear to be negligible.

TABLE 10—ESTIMATED COSTS AND SAVINGS BY PROVISION FOR CYS 2010–2015

[\$ in millions]

	Calendar year						
	2010	2011	2012	2013	2014	2015	2010–2015
RADV	\$3.98	\$3.98	\$3.98	\$3.98	\$3.98	\$3.98	\$23.88
Quality	36.9	36.9	36.9	36.9	36.9	36.9	221.4
MSP	77.9	77.9	77.9	77.9	77.9	77.9	467.4
Validation of Reporting Requirements	45.6	45.6	45.6	45.6	45.6	45.6	273.6
CAHPS	0.0	3.1	3.1	3.1	3.1	3.1	15.5
Written Notifications	17.0	17.0	17.0	17.0	17.0	17.0	102.0
MIPPA 176	0.0	–90.0	–210.0	–300.0	–340.0	–380.0	–1,320.0
Organization Determinations	15.2	15.2	15.2	15.2	15.2	15.2	91.2
Transition Process	6.8	6.8	6.8	6.8	6.8	6.8	40.8
Drug Utilization Management	112.5	112.5	112.5	112.5	112.5	112.5	675.0
Pharmacy Use of Standard Technology	5.8	0.0	0.0	0.0	0.0	0.0	5.8
Total Cost/Savings	321.68	228.98	108.98	18.98	–21.02	–61.02	596.58

C. Expected Benefits

Beginning in CY 2014, we expect net savings due to the combined impact of these new proposed provisions. We expect that the net impact across the 6-year period from CY 2010 through CY 2015 will be a cost of \$596.58 million.

Many of the new requirements involve clarifications of existing regulations and policies. As such, they should help plans to improve their administrative operational functions which will streamline the Medicare Prescription Drug program and strengthen beneficiary protections within the program. Specifically, we believe that the proposed requirements will improve coordination of care, increase quality of data reporting, increase ability to comply with existing regulations and policies, enhance appeal and grievance procedures, and curtail illegal marketing practices. Additional benefits include clarification of timeframes and notification requirements. Some of the new requirements may lead to changes in health plan service areas.

We anticipate that several of the proposed requirements will be beneficial to PBMs when assisting Part D sponsors with administering the Part D benefit. Proposed codification of transition process requirements and establishment of protected classes will assist PBMs in applying the Part D requirements consistently across Part D plans and managing the Part D sponsor's benefit packages more efficiently. Establishing cut-off limits for coordination of benefits and requiring Part D sponsors to report other payer information in a timely fashion to CMS' COB contractors will improve the administrative burden of the payment

reconciliation process. The technical correction to the definition of gross covered prescription drug costs will also help PBMs with calculating a beneficiary's gross covered prescription drug costs.

D. Analysis by Provision

With regard to part 422, Risk Adjustment Data Validation (RADV), we estimate that we will audit approximately 110 MA organizations for risk adjustment data validation (RADV) in FYs 2010 and 2011. We estimate that at least 50 percent of these organizations—55 MA organizations—will pursue one of the options presented in these proposed rules for disputing or appealing their RADV audit findings—via attestation, documentation dispute, or RADV payment error calculation appeal. Our experience to date indicates that approximately 25 percent of HCCs audited under RADV audit procedures result in signature and credential-related medical record review errors. Each MA organization that undergoes a RADV audit is on average asked to validate approximately 700 HCCs for 200 beneficiaries selected for audit.

Since signature and credential-related errors comprise such a large overall percentage of RADV error, there is clearly an incentive for MA organizations to submit attestations along with medical records missing signatures/credentials to avoid incurring a RADV audit error. With approximately 110 organizations expected to undergo RADV audit annually, we can estimate that MA organizations will seek to produce roughly 19,250 attestations (or 175 attestations per audit). We estimate that it will take 1 hour to prepare and submit one attestation to CMS. This

equates to 19,250 burden hours at approximately \$59.20/hour (based on U.S. Department of Labor statistics for hourly wages for management analysts)—or, an aggregate annual dollar burden on the MA industry of \$1,139,600. RADV audit statistics to date indicate that approximately 55 percent of RADV audit errors are of the type that may be eligible for documentation dispute. Clearly there is a financial incentive for MA organizations to pursue documentation dispute in an attempt to avoid incurring a RADV audit error. Utilizing the same statistics regarding the number of organizations that we expect to undergo RADV audit annually (that is, 110 organizations), we estimate that 100 percent of these organizations will pursue documentation dispute. Each MA organization that undergoes RADV audit is on average asked to validate approximately 700 HCCs for 200 beneficiaries audited. Therefore, we can expect each organization that undergoes RADV audit to pursue documentation dispute for 385 HCCs. This equates to an overall volume of 42,350 document dispute requests annually. We estimate that it will take approximately 1 hour to prepare the necessary documentation to dispute one HCC via documentation dispute. This equates to 42,350 burden hours at approximately \$59.20/hour (based on U.S. Department of Labor (DOL) statistics for hourly wages for management analysts) or an aggregate annual dollar burden on the MA industry of \$2,507,120.

Finally, regarding requests for RADV payment error calculation appeals, based upon existing RADV audit data, we estimate that 100 percent of MA organizations that undergo RADV audit

We are also proposing to require in § 422.152 that each MAO contract conduct CCIPs in patient populations and quality improvement projects in areas identified by CMS and also collect and report new quality measures. The mean estimated burden per contract as indicated in section III. of this proposed rule is 1,000 hours. The estimated mean cost per hour for these contracts is \$59.20 (wages, fringe benefits, and overhead). The mean cost per contract is: $1,000 \times \$59.20 = \$59,200$. Since the number of contracts is estimated to be 624, the overall estimated cost across all contracts is: $624 \times \$59,200 = \$36,940,800$.

Regarding the Medicare Secondary Payer (MSP) Procedures (§ 422.108), in 2007 original Medicare estimated total savings due to MSP at \$6.5 billion. This included \$2.9 billion recovered or avoided for working-aged individuals, \$1.9 billion for working-disabled individuals, \$877 million for workers' compensation, \$278 million for ESRD beneficiaries, and another \$485 million recovered or avoided for liability and other insurers. In 2007, there were approximately 8.5 million MA enrollees and 44 million total Medicare enrollees (an MA penetration rate of approximately 19 percent). The \$6.5 billion in MSP savings can be attributed to 35.5 million original Medicare enrollees, which equates to approximately \$183 per original Medicare enrollee that can be attributed to MSP savings. In 2009 MA penetration is higher, with approximately 11 million MA enrollees out of approximately 45 million total Medicare enrollees—or about 24 percent MA penetration. We assume a similar MSP rate for MA enrollees as obtains in original Medicare, and therefore project total savings from MSP in the MA program in 2007 as close to \$1.5 billion and by 2010 at approximately \$2 billion.

The estimated impact of MSP on 624 MA organizations and 456 PDPs based on 3.1158 million burden hours at approximately \$25/hour (based on U.S. Department of Labor (DOL) statistics for the hourly wages of claims analysts of \$22.20/hour and for management analysts of \$59.20/hour), is approximately \$77.9 million. We expect an MA organization to use approximately 1.5 FTEs to implement Part C MSP procedures related to avoiding costs, reporting data, and collecting from liable third parties related to MSP. We expect the work mix to be completed approximately 90 percent by the claims analyst and 10 percent by the management analyst.

We note that MAOs claim expenses related to MSP recoveries as part of their

administrative overhead. MA organizations that faithfully pursue and recover from liable third parties will have lower medical expenses. Lower medical expenses make such plans more attractive to enrollees. The lower the medical expenses in an MA plan, the higher the potential rebate. The rebate is calculated as the difference between the cost of Medicare benefits and the benchmark for that plan. The benchmark is a fixed amount. Therefore, as the cost of Medicare benefits go down (with the benchmark remaining constant), the larger the rebate. Therefore, as more MSP dollars are collected or avoided, medical expense go down and rebates go up, allowing the sponsoring MA organization to offer potential enrollees additional non-Medicare benefits funded by rebate dollars. Such non-Medicare benefits include reductions in cost sharing. Since cost sharing is generally expressed as a percentage of medical costs, such cost sharing will also be proportionally lower as overall medical costs go down—providing MA organizations offering such plans with an additional competitive edge.

Regarding validation of reporting requirements (§ 422.516 and § 423.514), the main focus will be on how the sponsor collects, stores, and reports the new Part C and Part D data requirements. Standards and procedures will also focus on how sponsors compile data, and verify calculations, computer code, and algorithms. The estimated mean hourly burden per affected part C and Part D sponsor to procure an auditing organization and to support the auditing organization in its data collection efforts including staff interviews is 120 hours as indicated in section III. of this proposed rule. We believe the auditor that is hired by the plan will typically have a team consisting of a management analyst, two senior auditors, a senior claims analyst, a senior statistician, an IT systems analyst, a computer programmer, and a word processor. We used May 2008 wage statistics supplied by the Department of Labor, Bureau of Labor Statistics to develop estimates of direct wages. We also added fringe benefits, overhead costs, and general and administrative expenses using percentages that are consistent with CMS contracts. Based on our experience and in consultant with program experts, we developed an estimate of the hourly burden. The estimated mean cost per hour for these sponsors is \$43.14 (wages, fringe benefits, and overhead). The estimated mean number of hours per sponsor is 120. The mean cost per

sponsor to procure and support the auditor is therefore: $120 \times \$43.14 = \$5,177$. Since the number of sponsors is estimated to be 710, the overall estimated cost across all sponsors to do the work involved in procuring and supporting the auditing contractors is: $710 \times \$5,177 = \$3,675,670$.

The total estimated burden hours related to the time and effort for all auditing organizations to perform the annual audit for both Part C and Part D data validation is estimated to be 215,840. The mean cost per hour (includes direct wages, fringe benefits, overhead costs, general and administrative expenses, and fee) is estimated to be \$194.21. Therefore, the estimated annual cost for auditing contracts involving all 710 sponsors is: $215,840 \times \$194.21 = \$41,918,287$. The total estimated annual cost for auditing contracts and for the procurement and audit support time and effort of the sponsors is: $\$41,918,287 + 3,675,670 = \$45,593,956$. The auditing costs will be allowable costs in the plan's bid.

We are also proposing that beginning in 2011 MA organizations and Part D sponsors will begin paying for the data collection costs of the CAHPS annual survey. Data collection is to be performed by a contractor hired by the MAO or part D sponsor. The mean estimated burden per contract as indicated in section III. of this proposed rule is 51 hours. The estimated mean cost per contract is \$5,023. The overall estimated annual cost across 624 contracts is: $624 \times \$5,023 = \$3,134,352$.

Regarding written notices of a favorable standard coverage determination (§ 423.568(d)), the burden is the time and effort necessary for each of an estimated 456 PDP sponsors to disclose the necessary information in writing to an enrollee. (Note: plan sponsors have always been required to formulate a decision and notify the enrollee of that decision, so the additional burden is only related to communicating the favorable decision in writing). We estimated an annual burden of 380,206 hours. At an estimated cost of \$40.00 per hour (salary/wages, fringe benefits, overhead), the estimated total annual cost of this proposed change is \$15,208,240.

The burden associated with providing written notice of a favorable expedited coverage determination (§ 423.572(b)) is the time and effort necessary for each of an estimated 456 PDP sponsors to disclose the necessary information in writing to an enrollee (given that plan sponsors have always been required to formulate favorable and adverse expedited decisions, notify enrollees of

those decisions, and follow-up in writing if the decision is adverse, the additional burden is only related to communicating the favorable decision in writing).

The total estimated annual burden associated with this requirement was 43,550 hours. At an estimated cost of \$40.00 per hour, the estimated total annual cost of this proposed change is \$1,742,000. Therefore, the total estimated annual cost for these two provisions is \$15,208,240 + \$1,742,000 = \$16,950,240. The total estimated annual cost for years 2010–2015 is \$102 million.

Additionally, regarding written notices, proposed § 423.590(d)(2) states that if a Part D plan sponsor first notifies an enrollee of an adverse or favorable expedited redetermination decision orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification. The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to notify an enrollee (and the prescribing physician or other prescriber involved, as appropriate) in writing of an adverse or favorable expedited redetermination decision. We estimate that each year the 456 Part D plan sponsors will issue a total of about 21,232 written adverse and favorable expedited notifications. We further estimate that it will take a Part D plan sponsor 30 minutes to distribute a single notice. The estimated annual burden associated with the requirement in § 423.590(d)(2) is 10,616 hours. At an estimated cost of \$40.00 per hour, the estimated total annual cost of this proposed change is \$424,640. The total estimated annual cost for years 2010–2015 is \$2.5 million.

With regard to standard timeframes and notice requirements for organization determinations (§ 422.568 and § 423.568), the total estimated annual burden is 380,206 hours. At an estimated average hourly cost of \$40.00, the total annual estimated cost for CY 2010 is \$15,208,240.

Regarding the MIPPA 176 protected drug class provisions, we project that future utilization and hence future costs will be lower than estimated in the Medicare Advantage and Prescription Drug Programs: MIPPA-Related Marketing Revisions interim final rule with comment period published in the January 16, 2009 Federal Register (74 FR 2881). This is because the proposed provisions may be somewhat more restrictive than those in the January 16, 2009 IFC. That is, in the January 16, 2009 IFC, we had not proposed definitions of associated with MIPPA protected classes criteria. The

definitions, as outlined in this proposed rule, provide further precision with respect to the MIPPA criteria leading to a reduced likelihood of certain disease categories qualifying as protected classes.

The FY 2010 President's Budget estimated cost of this provision was about \$4.9 billion for FYs 2010 through 2019. This is the amount that was built into our FY 2010 budget projections. The revised cost estimate is roughly \$1.6 billion over the same period. As a result, the modifications made in the rule will save Part D an estimated \$3.3 billion for FYs 2010 through 2019 relative to our current Budget baseline.

Regarding the Transition Process (§ 423.120), proposed § 423.120 would require sponsors to provide enrollees with appropriate notice regarding their transition process within a reasonable amount of time after providing a temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules). We estimated the annual hourly burden to be 337,500 hours in section III. of this proposed rule. At an estimated average \$20 cost per hour for the fully loaded labor of an administrative assistant, we estimate the yearly cost to be \$6,750,000 in CY 2010.

Regarding drug utilization management, quality assurance, and medication therapy management programs (MTMPs), proposed § 423.153 states that Part D plans must offer a minimum level of medication therapy management services for each beneficiary enrolled in the MTMP that includes but is not limited to annual comprehensive medication reviews with written summaries. We estimated that the total annual burden associated with this requirement is 937,500 hours. At an average cost of \$120 per hour, we estimate the yearly cost to be \$112,500,000.

Regarding the Use of Standardized Technology under Part D (§ 423.120) requirements, we estimated an annual burden of 38,640 hours, with a cost of \$150 per hour. The estimated one time cost impact for CY 2010 is \$5.80 million.

E. Anticipated Effects

1. Effects of Cap on Out-of-Pocket Costs and Cost Sharing Amounts

We are proposing to establish and require local MA plans to have an annual catastrophic cap on members out-of-pocket cost sharing and that we will also establish limits on the cost sharing amounts that MA plans can

impose for Part A and B services. These proposed changes are significant in that they will help beneficiaries to understand and anticipate their possible health care expenditures. However, we do not believe these changes will by themselves have a significant impact on either plan participation or plan costs. We will set the parameters for the cost sharing and spending cap and this should make it easier for MA plans to compete on a level playing field and as previously noted enhance transparency for prospective enrollees. We note that while there will be cost sharing limits and a catastrophic cap. We are not setting a cap on the monthly plan premium beyond the overall actuarial limit (determined annually by CMS) on the amount of cost sharing that MA plans may impose on its enrollees. In other words, MA plans will still have the option of collecting the maximum allowed actuarial amount of cost sharing from beneficiaries in terms of premium, and costs sharing amounts for plan covered benefits.

2. Alternatives Considered

a. Strengthening CMS' Ability To Take Timely, Effective Contract Determinations or Intermediate Sanctions (Part C & D)

We are proposing to modify the regulations to more clearly and accurately clarify our existing statutory authority to terminate a contract. The existing enumerated list of determinations that could support a decision to terminate a contract is not all inclusive. Therefore, we are proposing to remove the enumerated list. Also, we are proposing to revise the regulatory language to clarify that failure to comply with any of the regulatory requirements contained in parts 422 and 423 or failure to meet our performance requirements, may constitute a basis for CMS to determine that the MA Organization or Part D sponsor meets the requirements for contract termination in accordance with the statutory standard. We considered modifying or adding to the existing list of determinations that could support termination (which included 12 items in parts 422 and 11 items in parts 423). However, we believe that continuing to add to the existing list may fail to make sufficiently clear to sponsoring organizations that all violations of our regulations and/or contract and performance requirements may be used to support a termination decision.

b. Changing the Standards of Review, Clarifying the Standard of Proof and Burden of Proof for Appeals, and Modifying the Conduct of Hearing for Contract Decisions (Including Denials of Initial Applications to Contract, Service Area Expansions for Existing Contracts, Contract Non-Renewals and Terminations, and Intermediate Sanctions)

We are proposing to change the standards of review and clarify the standard of proof when an appeal of a contract determination or intermediate sanction is requested and an evidentiary hearing is conducted. The current standards of review require the hearing officer to determine whether the sponsoring organization can demonstrate “substantial compliance” with Part C and/or Part D requirements on the “earliest of” the following three dates: The date the organization received written notice of contract determination or intermediate sanction, the date of the most recent onsite audit, or the date of the alleged breach of current contract or past substantial noncompliance. In practice, these standards of review (“substantial compliance” and “earliest of test”) have led to confusion among parties to the hearing and have been difficult for the hearing officer to apply. Additionally, though the existing regulations explicitly state that the sponsoring organization bears the burden of proof, it does not provide the standard of proof that is to be applied by the hearing officer. Therefore, we are proposing to delete the “substantial compliance” and “earliest of” test and revise the regulations to explicitly state the standard of proof and provide clear standards of review for each type of contract determination or intermediate sanction.

First, we are proposing to explicitly state that the hearing officer must apply the “preponderance of the evidence” standard of proof when weighing the evidence at all hearings for contract determinations or intermediate sanctions. Second, we are proposing to clarify the standards of review, which vary according to the type of contract determination or intermediate sanction. In particular, the proposed change makes the distinction between how the evidentiary standard of review is to be applied to appeals of CMS determinations involving Part C or D contract qualification applications, those involving the termination or non-renewal of a Part C or D sponsor contract, and those involving the imposition of intermediate sanctions. Finally, we are proposing to clarify that

because the sponsoring organization bears the burden of proof, under any briefing schedule determined by the hearing officer, it must first present evidence and argument to the hearing officer before we present our evidence and argument. We considered leaving the existing regulations unchanged.

c. Clarify That CMS May Require a “Test Period” During an Enrollment/Marketing Sanction

We are proposing to provide that in instances where an enrollment and/or marketing suspension has been imposed, we may determine that it is appropriate to subject the MA organization or Part D sponsor to a “test period” whereby the organization or sponsor will, for a limited time, engage in marketing activities and/or accept enrollments in order to assist us in making a determination as to whether the bases for the sanctions have been corrected and are not likely to recur. Currently, our experience has shown that we are limited in our ability to adequately determine if marketing and enrollment deficiencies have been corrected while marketing and enrollment sanctions are in place. If the test of the Part D sponsor or MA organization’s marketing/enrollment processes reveals that deficiencies have not been corrected and/or are likely to recur, the sanction will continue to remain in place.

We considered leaving the existing regulations unchanged. However, we believe this proposal will strengthen our ability to adequately assess compliance with our requirements. The proposal will also help us to avoid situations where, because we do not have the ability to perform adequate testing of an organization’s systems/processes (such as information systems testing) to ensure the deficiencies have been corrected, we lift a sanction and then find that we have to re-engage in the statutory and regulatory process for reinstating the sanction.

d. Right for CMS To Require an Independent Audit of Sponsoring Organizations Under Intermediate Sanction

We are proposing that we have the flexibility to require certain Part D sponsors and MA organizations, under intermediate sanctions, to hire an independent auditor to evaluate whether the bases for a sanction have been corrected and are not likely to recur before we come to a determination as to whether lifting of the sanction would be appropriate. The independent auditor would be hired by the sponsoring organization and work in

accordance with CMS specifications in order to provide accurate and reliable information to CMS. This would benefit the sponsoring organization by improving the process for removing a sanction, which may reduce the duration of the sanction. A similar approach is used by the Office of Inspector General (OIG) in their Corporate Integrity Agreements and/or Self-Disclosure Protocol processes.

We considered leaving the regulations unchanged. This existing regulatory scheme requires us to rely solely on its internal resources to assess whether the underlying deficiencies that form the basis of an intermediate sanction have been corrected and are not likely to recur. Given our experience with the nature and extent of some compliance deficiencies (for example, those caused by information technology issues or lack of adequate internal controls) and the need to obtain the level of skill and experience necessary to conduct an exhaustive audit and verification of the correction of these deficiencies, we believe this additional flexibility and access to expertise (such as a qualified independent auditor) is appropriate and will benefit both plan sponsors and CMS.

Another option considered is not requiring certain sponsoring organizations to hire an independent auditor. Instead, we would consider using results obtained by an independent auditor hired under a sponsoring organization’s own initiative to evaluate its compliance with our requirements. We may consider the sponsoring organization’s initiative to obtain an independent audit similar to a “safe harbor” and may be afforded some weight in CMS’ determination of whether the bases for the sanction have been corrected and are not likely to recur. We invite comments from sponsors and the industry about this alternative proposal and suggestions on other options we could implement to accomplish the desired outcome.

e. The Ability for CMS To Require Sponsors To Disclose to Current and Potential Enrollees Compliance and Performance Deficiencies

We are proposing to require certain sponsors to disclose their current compliance and/or performance deficiencies to existing and potential enrollees. This disclosure option could be exercised by CMS either when a sponsor is sanctioned or when a sponsor’s compliance deficiencies rise to a certain level such that we make the determination that existing or potential enrollees should be notified of these deficiencies. This level of transparency

will provide additional incentives for sponsors to make improvements to their operations and also provide relevant information to beneficiaries and the public concerning plan choices.

We considered not adding this disclosure authority to the existing regulations. However, we believe this change is necessary to provide us with another tool to strengthen our compliance and oversight authority and provide appropriate transparency concerning compliance and/or performance deficiencies to beneficiaries and the public.

f. Section 176 of the MIPPA—Formulary and Protected Classes Requirements (Part D)

The critical policy decision was how broadly or narrowly we interpret specific terms in the MIPPA provisions. Interpreted broadly, the provisions in section 176 of the MIPPA might easily encompass many classes of drugs and significantly increase costs to the Part D program by eliminating the need for manufacturers to aggressively rebate their products for formulary placement. Only a narrow interpretation of these criteria would limit the number of classes “protected” under MIPPA.

g. Reducing Duplicative and Low Enrollment Plans (Parts C & D)

We are proposing to implement regulations to reduce duplicative benefit packages based upon our authority to add such additional terms to its contracts with Medicare Advantage organizations or Part D plan sponsors as we “may find necessary and

appropriate” as specified in section 1857(e)(1) of the Act (see also section 1860D–12(b)(3)(D) of the Act (incorporating section 1857(e)(1) of the Act by reference for Part D.) In addition, we are using our authority under section 1860D–11(d)(2)(B) of the Act as further support for our authority to propose regulations imposing “reasonable minimum standards” on Part D sponsors.

One alternative would be to make no changes to our current regulations regarding bid submission and review and to continue our current efforts to eliminate duplicative or low enrollment plan options. However, since our current regulations do not explicitly address the issue of eliminating duplicative or low enrollment plans, we believe that codifying our authority to do so will provide us with more leverage over plans during the bid submissions, review, negotiation, and approval processes.

Another alternative would be to provide more detail in regulation text regarding the specific criteria we would use to eliminate duplicative or low enrollment plan options. We believe addressing the issue generally in regulations text, but containing most of the discussion regarding specific criteria to the preamble, maintains our flexibility to adjust our review processes and criteria consistent with current market trends.

h. Validation of Part C and Part D Reporting Requirements

Several of the proposed changes do involve costs to MAOs and Part D

sponsors. One such regulatory change was the audit requirement of Part C and Part D measures. We considered not requiring an audit. However, because we believe that an audit is required to ensure that the Part C and Part D measures are consistent with our specifications, are reliable, valid, and comparable, and are credible to stakeholders, this alternative was rejected. A second such regulatory change was requiring MAOs and Part C sponsors to assume a portion of the cost of the annual CAHPs survey that would result from hiring contractors to conduct the data collection. We considered not requiring MAOs and Part C sponsors to hire contractors to perform the CAHPs data collection. However, we rejected this alternative, because we believe that the benefits obtained through this regulatory change outweigh the costs incurred by the MAOs and Part C sponsors.

F. Accounting Statement

As required by OMB Circular A–4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), in the Table 13, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule. Table 13 provides our best estimate of the costs and savings as a result of the changes.

TABLE 13—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM CY 2010 TO CY 2015
[\$ in millions]

Category	Transfers			
	Year dollar	Units discount rate		Period covered
		7%	3%	
Annualized Monetized Transfers	2009	\$–204.45	\$–213.23	CYs 2010–2015
From Whom to Whom?	Federal Government to MAO and Part D Sponsors.			
Annualized Costs to MAOs and Part D Sponsors	2009	\$319.51	\$319.46	CYs 2010–2015

G. Conclusion

We expect that the cost of implementing these provisions will be \$321.68 million in CY 2010. Sponsors will experience additional costs which they are likely to pass on to us through direct subsidy payments and to beneficiaries through increases in premiums as reflected in their bids. Beginning in CY 2013, we expect that these provisions will generate a net

savings on an annual basis. For the entire estimated time period, CY 2010 through 2015, we expect the overall impact to be a cost of \$596.58 million.

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

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs—health, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health Maintenance Organizations (HMO), Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 480

Health care, Health professions, Health records, Peer Review Organizations (PRO), Penalties, Privacy, and Reporting and recordkeeping requirements.

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

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

1. The authority citation for part 417 continues to read as follows:

Authority: 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 417.428 is revised to read as follows:

§ 417.428 Marketing activities.

(a) With the exception of § 422.2276 of this chapter, the procedures and requirements relating to marketing requirements set forth in subpart V of part 422 of this chapter also apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(b) In applying those provisions, references to part 422 of this chapter must be read as references to this part, and references to MA organizations as references to HMOs and CMPs.

Subpart L—Medicare Contract Requirements

3. Section 417.472 is amended by adding paragraphs (i) and (j) to read as follows:

§ 417.472 Basic contract requirements.

* * * * *

(i) The HMO or CMP must comply with the requirements at § 422.152(b)(5).

(j) All coordinated care contracts (including local and regional PPOs and contracts with exclusively SNP benefit packages, cost contracts under section 1876 of the Act, private fee-for-service contracts, and MSA contracts with 600 or more enrollees in July of the prior year) must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of MA plan enrollees in accordance with CMS specifications and submit the survey data to CMS.

4. Section 417.492 is amended by revising paragraph (b)(2) to read as follows:

§ 417.492 Nonrenewal of contract.

* * * * *

(b) * * *

(2) *Notice of appeal rights.* CMS gives the HMO or CMP written notice of its right to appeal the nonrenewal decision, in accordance with part 422 subpart N of this chapter, if CMS's decision was based on any of the reasons specified in § 417.494(b).

5. Section 417.494 is amended by revising paragraph (b)(2) to read as follows:

§ 417.494 Modification or termination of contract.

* * * * *

(b) * * *

(2) If CMS decides to terminate a contract, it sends a written notice informing the HMO or CMP of its right to appeal the termination in accordance with part 422 subpart N of this chapter.

* * * * *

6. Section 417.500 is revised to read as follows:

§ 417.500 Intermediate sanctions for and civil monetary penalties against HMOs and CMPs.

(a) Except as provided in paragraph (c) of this section, the rights, procedures, and requirements related to intermediate sanctions and civil money penalties set forth in part 422 subparts O and T of this chapter also apply to Medicare contracts with HMOs or CMPs under sections 1876 of the Act.

(b) In applying paragraph (a) of this section, references to part 422 of this chapter must be read as references to this part and references to MA organizations must be read as references to HMOs or CMPs.

(c) In applying paragraph (a) of this section, the amounts of civil money penalties that can be imposed are governed by section 1876(i)(6)(B) and

(C) of the Act, not by the provisions in part 422 of this chapter.

Subpart O—Medicare Payment: Cost Basis

7. Section 417.564 is amended by adding new paragraphs (b)(2)(iii) and (c) to read as follows:

§ 417.564 Apportionment and allocation of administrative and general costs.

* * * * *

(b) * * *

(2) * * *

(iii) For the costs incurred under paragraphs (b)(1)(i) through (iv) of this section that include personnel costs, the organization must be able to identify the person hours expended for each administrative task and the rate of pay for those persons performing the tasks. Administrative tasks performed and rate of pay for the persons performing those tasks must match in terms of the skill level needed to accomplish those tasks. This information must be made available to CMS upon request.

(c) *Costs excluded from administrative costs.* In accordance with section 1861(v) of the Act, the following costs must be excluded from administrative costs:

- (1) Donations.
- (2) Fines and penalties.
- (3) Political and lobbying activities.
- (4) Charity or courtesy allowances.
- (5) Spousal education.
- (6) Entertainment.
- (7) Return on equity.

Subpart R—Medicare Contract Appeals

8. Section § 417.640 is revised to read as follows:

§ 417.640 Applicability.

(a) The rights, procedures, and requirements relating to contract determinations and appeals set forth in part 422 subpart N of this chapter also apply to Medicare contracts with HMOs or CMPs under section 1876 of the Act.

(b) In applying paragraph (a) of this section, references to part 422 of this chapter must be read as references to this part and references to MA organizations must be read as references to HMOs or CMPs.

§ 417.642 through § 417.694 [Removed]

9. Remove § 417.642 through § 417.694.

Subpart U—Health Care Prepayment Plans

10. Section 417.840 is revised to read as follows:

§ 417.840 Administrative review procedures.

The HCPP must apply § 422.568 through § 422.626 of this chapter to—
(a) Organization determinations and fast-track appeals that affect its Medicare enrollees; and
(b) Reconsiderations, hearings, Medicare Appeals Council review, and judicial review of the organization determinations and fast-track appeals specified in paragraph (a) of this section.

PART 422—MEDICARE ADVANTAGE PROGRAM

11. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

- 12. Section 422.2 is amended by—
 - A. Adding the definitions of “Attestation process,” “documentation dispute process,” and “Hierarchical condition categories.”
 - B. Revising the definition of “Point of service.”
 - C. Adding the definitions of “RADV payment error calculation appeal process” and “Risk adjustment data validation (RADV) audit.”
 - D. Revising the introductory text of the definition of “Service area”.
 - E. Adding the definition of “The one best medical record”.

The additions and revision read as follows:

§ 422.2 Definitions.

Attestation process means a CMS-developed RADV audit-related dispute process that enables MA organizations undergoing RADV audit to submit CMS-generated and physician practitioner signed attestations for medical records with missing or illegible signatures or credentials. Physicians/practitioners who documented health care services in the specific medical record under RADV review will be allowed to attest that they provided and documented the health care services evidenced in the specific medical record.

* * * * *

Documentation dispute process means a dispute process that enables MA organizations that have undergone a RADV audit to dispute medical record discrepancies that pertain to incorrect ICD–9–CM coding by allowing affected MA organizations to submit formal written disputes regarding discrepancy findings for the initial medical record

that an organization submitted for HCC validation.

* * * * *

Hierarchical condition categories (HCC) means disease groupings consisting of disease codes (currently ICD–9–CM codes) that predict average healthcare spending. HCCs represent the disease components of the enrollee risk score that are applied to MA payments.

* * * * *

Point of service (POS) means a benefit option that an MA HMO plan can offer to its Medicare enrollees as an additional, mandatory supplemental, or optional supplemental benefit. Under the POS benefit option, the HMO plan allows members the option of receiving specified services outside of the HMO plan’s provider network. In return for this flexibility, members typically have higher cost-sharing requirements for services received and, when offered as a mandatory or optional supplemental benefit, may also be charged a premium for the POS benefit option.

* * * * *

RADV payment error calculation appeal process means an administrative process that enables MA organizations that have undergone RADV audit to appeal the CMS calculation of an MA organization’s RADV payment error.

* * * * *

Risk adjustment data validation (RADV) audit means a CMS-administered payment audit of a Medicare Advantage (MA) organization that ensures the integrity and accuracy of risk adjustment payment data.

* * * * *

Service area means a geographic area that for local MA plans is a county or multiple counties, and for MA regional plans is a region approved by CMS within which an MA-eligible individual may enroll in a particular MA plan offered by an MA organization. Facilities in which individuals are incarcerated are not included in the service area of an MA plan. Each MA plan must be available to all MA-eligible individuals within the plan’s service area. In deciding whether to approve an MA plan’s proposed service area, CMS considers the following criteria: * * *

* * * * *

The one best medical record for the purposes of Medicare Advantage Risk Adjustment Validation (RADV) is defined as: the clinical documentation for a single encounter for care (that is, a physician office visit, an inpatient hospital stay, or an outpatient hospital visit) that occurred for one patient during the data collection period. The single encounter for care must be based

on a face-to-face encounter with a provider deemed acceptable for risk adjustment and documentation of this encounter must be reflected in the medical record.

- 13. Amend § 422.4 by—
 - A. Revising paragraphs (a)(1)(v) and (a)(2)(i)(A).
 - B. Redesignating paragraph (a)(2)(i)(B) as paragraph (a)(2)(i)(C).
 - C. Adding new paragraphs (a)(2)(i)(B) and (a)(3)(iv).

The revisions and additions read as follows:

§ 422.4 Types of MA plans.

* * * * *

- (a) * * *
- (1) * * *
- (v) A PPO plan is a plan that—
 - (A) Has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;
 - (B) Provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers;
 - (C) Only for purposes of quality assurance requirements in § 422.152(e), is offered by an organization that is not licensed or organized under State law as an HMO; and
 - (D) Does not permit prior notification for out-of-network services—that is, a reduction in the plan’s standard cost-sharing levels when the out-of-network provider from whom an enrollee is receiving plan-covered services voluntarily notifies the plan prior to furnishing those services, or the enrollee voluntarily notifies the PPO plan prior to receiving plan-covered services from an out-of-network provider.
- (2) * * *
- (i) * * *
- (A) Pays at least for the services described in § 422.101, after the enrollee has incurred countable expenses (as specified in the plan) equal in amount to the annual deductible specified in § 422.103(d);
- (B) Does not permit prior notification—that is, a reduction in the plan’s standard cost-sharing levels when the provider from whom an enrollee is receiving plan-covered services voluntarily notifies the plan prior to furnishing those services, or the enrollee voluntarily notifies the MSA plan prior to receiving plan-covered services from a provider; and
- (3) * * *
- (iv) Does not permit prior notification—that is, a reduction in the plan’s standard cost-sharing levels when the provider from whom an enrollee is receiving plan-covered services

voluntarily notifies the plan prior to furnishing those services, or the enrollee voluntarily notifies the PFFS plan prior to receiving plan-covered services from a provider.

* * * * *

Subpart B—Eligibility, Election, and Enrollment

14. Section 422.74 is amended by revising paragraphs (d)(1)(i)(B) and (d)(4)(iii) to read as follows:

§ 422.74 Disenrollment by the MA organization.

* * * * *

- (d) * * *
(1) * * *
(i) * * *

(B) Providing the individual with a grace period, that is, an opportunity to pay past due premiums in full. The length of the grace period must be at least 2 months, beginning on the first day of the month for which the premium is unpaid.

* * * * *

- (4) * * *

(iii) *Exception.* If the MA plan offers a visitor/traveler benefit when the individual is out of the service area but within the United States (as defined in § 400.200 of this chapter) for a period of consecutive days longer than 6 months but less than 12 months, the MA organization may elect to offer to the individual the option of remaining enrolled in the MA plan if—

(A) The individual is disenrolled on the first day of the 13th month after the individual left the service area (or residence, if paragraph (d)(4)(i)(B) of this section applies);

(B) The individual understands and accepts any restrictions imposed by the MA plan on obtaining these services while absent from the MA plan's service area for the extended period, consistent with paragraph (d)(4)(i)(C) of the section;

(C) The MA organization makes this visitor/traveler option available to all Medicare enrollees who are absent for an extended period from the MA plan's service area. MA organizations may limit this visitor/traveler option to enrollees who travel to certain areas, as defined by the MA organization, and who receive services from qualified providers who directly provide, arrange for, or pay for health care; and

(D) The MA organization furnishes all Medicare Parts A and B services and all mandatory and optional supplemental benefits at the same cost sharing levels as apply within the plan's service area; and

(E) The MA organization furnishes the services in paragraph (D) of this

paragraph consistent with Medicare access and availability requirements at § 422.112 of this part.

* * * * *

Subpart C—Benefits and Beneficiary Protections

15. Section 422.100 is amended by adding new paragraphs (f)(4) and (f)(5) to read as follows:

§ 422.100 General requirements.

* * * * *

- (f) * * *

(4) All local MA plans must establish an out-of-pocket maximum for Medicare A and B services that is no greater than the annual limit set by CMS.

(5) Cost sharing for Medicare A and B services does not exceed levels annually determined by CMS to be discriminatory.

* * * * *

16. Section 422.103 is amended by adding a new paragraph (d)(3) to read as follows:

§ 422.103 Benefits under an MA MSA plan.

* * * * *

- (d) * * *

(3) Is pro-rated for enrollments occurring during a beneficiary's initial coverage election period as described at § 422.62(a)(1) of this part.

* * * * *

17. Section 422.105 is amended by revising paragraphs (b), (c), and (f) to read as follows:

§ 422.105 Special rules for self-referral and point of service option.

* * * * *

(b) *Point of service option.* As a general rule, a POS benefit is an option that an MA organization may offer in an HMO plan to provide enrollees with additional choice in obtaining specified health care services. The organization may offer A POS option—

(1) Before January 1, 2006, under a coordinated care plan as an additional benefit as described in section 1854(f)(1)(A) of the Act;

(2) Under an HMO plan as a mandatory supplemental benefit as described in § 422.102(a); or

(3) Under an HMO plan as an optional supplemental benefit as described in § 422.102(b).

(c) *Ensuring availability and continuity of care.* An MA HMO plan that includes a POS benefit must continue to provide all benefits and ensure access as required under this subpart.

* * * * *

(f) *POS-related data.* An MA organization that offers a POS benefit

through an HMO plan must report enrollee utilization data at the plan level by both plan contracting providers (in-network) and by non-contracting providers (out-of-network) including enrollee use of the POS benefit, in the form and manner prescribed by CMS.

18. Section 422.108 is amended by revising paragraph (b)(3) to read as follows:

§ 422.108 Medicare secondary payer (MSP) procedures.

* * * * *

- (b) * * *

(3) Coordinate its benefits to Medicare enrollees with the benefits of the primary payers, including reporting, on an ongoing basis, information obtained related to requirements in paragraphs (b)(1) and (b)(2) of this section in accordance with CMS instructions.

* * * * *

19. Section 422.111 is amended by adding a new paragraph (g) to read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(g) CMS may require an MA organization to self-disclose to its enrollees or potential enrollees, the MA organization's performance and contract compliance deficiencies in a manner specified by CMS.

20. Section 422.112 is amended by adding a new paragraph (a)(10) to read as follows:

§ 422.112 Access to services.

* * * * *

- (a) * * *

(10) *Prevailing patterns of community health care delivery.* Coordinated care and PFFS MA plans that meet Medicare access and availability requirements through direct contracting network providers must do so consistent with the prevailing community pattern of health care delivery in the areas where the network is being offered. Factors making up community patterns of health care delivery that CMS will use as a benchmark in evaluating a proposed MA plan health care delivery network include, but are not limited to—

(i) The number and geographical distribution of eligible health care providers available to potentially contract with an MAO to furnish plan covered services within the proposed service area of the MA plans.

(ii) The prevailing market conditions in the service area of the MA plan. Specifically, the number and distribution of health care providers contracting with other health care plans (both commercial and Medicare) operating in the service area of the plan.

(iii) Whether the service area is comprised of rural or urban areas or some combination of the two.

(iv) Whether the MA plan's proposed provider network meet Medicare time and distance standards for member access to health care providers including specialties.

(v) Other factors that CMS determines are relevant in setting a standard for an acceptable health care delivery network in a particular service area.

* * * * *

Subpart D—Quality Improvement

21. Section 422.152 is amended by—

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

B. Redesignating paragraph (b)(3)(ii) as paragraph (b)(3)(iii).

C. Adding new paragraph (b)(3)(ii).

D. Adding new paragraph (b)(5).

F. Redesignating paragraphs (e)(2)(ii) and (e)(2)(iii) as paragraphs (e)(2)(iii) and (e)(2)(iv), respectively.

H. Adding a new paragraph (e)(2)(ii).

The revisions and additions read as follows:

§ 422.152 Quality improvement program.

(a) * * *

(1) Have a chronic care improvement program that meets the requirements of paragraph (c) of this section concerning elements of a chronic care program and addresses populations identified by CMS based on a review of current quality performance;

(2) Conduct quality improvement projects that can be expected to have a favorable effect on health outcomes and enrollee satisfaction, meet the requirements of paragraph (d) of this section, and address areas identified by CMS; and

* * * * *

(b) * * *

(3) * * *

(ii) Collect, analyze, and report quality performance data identified by CMS that are of the same type as those under paragraph (b)(3)(i) of this section.

* * * * *

(5) All coordinated care contracts (including local and regional PPOs and contracts with exclusively SNP benefit packages, cost contracts under section 1876 of the Act, private fee-for-service contracts, and MSA contracts with 600 or more enrollees in July of the prior year) must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of MA plan enrollees in accordance with CMS specifications, and submit the survey data to CMS.

* * * * *

(e) * * *

(2) * * *

(ii) Collect, analyze, and report quality performance data identified by CMS that are of the same type as those described under paragraph (e)(2)(i) of this section.

* * * * *

22. Section 422.153 is added to read as follows:

§ 422.153 Use of quality improvement organization review information.

CMS will acquire from quality improvement organizations (QIOs) as described in part 480 of this chapter quality review study information as defined in § 480.101(b) and subject to the requirements in § 480.140(g). CMS will acquire this information, as needed, and use it for the following limited functions:

(a) Enable beneficiaries to compare health coverage options and select among them.

(b) Evaluate plan performance.

(c) Ensure compliance with plan requirements under this part.

(d) Develop payment models.

(e) Other purposes related to MA plans as specified by CMS.

23. Section 422.156 is amended by revising paragraphs (b)(7) and (f) to read as follows:

§ 422.156 Compliance deemed on the basis of accreditation.

* * * * *

(b) * * *

(7) The requirements listed in § 423.165 (b)(1) through (3) for MA organizations that offer prescription drug benefit programs.

* * * * *

(f) *Authority.* Nothing in this subpart limits CMS' authority under subparts K and O of this part, including but not limited to, the ability to impose intermediate sanctions, civil money penalties, and terminate a contract with an MA organization.

Subpart F—Submission of Bids, Premiums, and Related Information and Plan Approval

24. Section 422.254 is amended by adding new paragraphs (a)(4) and (b)(5) to read as follows:

§ 422.254 Submission of bids.

* * * * *

(a) * * *

(4) *Substantial differences between bids.* An MA organization's bid submissions must reflect differences in benefit packages and plan costs that CMS determines to represent substantial

differences relative to a sponsor's other bid submissions.

* * * * *

(b) * * *

(5) *Actuarial valuation.* The bid must be prepared in accordance with CMS actuarial guidelines based on generally accepted actuarial principles.

(i) A qualified actuary must certify the plan's actuarial valuation (which may be prepared by others under his or her direction or review).

(ii) To be deemed a qualified actuary, the actuary must be a member of the American Academy of Actuaries.

(iii) Applicants may use qualified outside actuaries to prepare their bids.

* * * * *

25. Section 422.256 is amended by adding a new paragraph (b)(4) to read as follows:

§ 422.256 Review, negotiation, and approval of bids.

* * * * *

(b) * * *

(4) *Substantial differences between bids.*

(i) *General.* CMS approves a bid only if it finds that the benefit package and plan costs represented by that bid are substantially different from the MA organization's other bid submissions. In order to be considered "substantially different," each bid must be significantly different from other plans of its plan type with respect to premiums, benefits, or cost-sharing structure.

(ii) Transition period for MA organizations with new acquisitions. After a 2-year transition period, CMS approves a bid offered by an MA organization (or by a parent organization to that MA organization) that recently purchased (or otherwise acquired or merged with) another MA organization only if it finds that the benefit package and plan costs represented by that bid are substantially different, as provided under paragraph (b)(4)(i) of this section, from any benefit package and plan costs represented by another bid submitted by the same MA organization (or parent organization to that MA organization).

* * * * *

Subpart G—Payments to Medicare Advantage Organizations

26. Section 422.306 is amended by revising paragraph (a) to read as follows:

§ 422.306 Annual MA capitation rates.

* * * * *

(a) *Minimum percentage increase rate.* The annual capitation rate for each MA local area is equal to the minimum percentage increase rate, which is the

annual capitation rate for the area for the preceding year increased by the national per capita MA growth percentage (defined at § 422.308(a)) for the year, but not taking into account any adjustment under § 422.308(b) for a year before 2004.

* * * * *

27. A new § 422.311 is added to read as follows.

§ 422.311 RADV audit dispute and appeal processes.

(a) *Risk Adjustment Data Validation (RADV) audits.* In accordance with § 422.2 and § 422.310 *et seq.*, CMS annually conducts RADV audits to ensure risk adjusted payment integrity and accuracy.

(b) *RADV audit results.*

(1) MA organizations that undergo RADV audits will be issued an audit report post medical record review that describes the results of the RADV audit as follows:

(i) Detailed enrollee-level information relating to confirmed enrollee HCC discrepancies.

(ii) The contract-level RADV payment error estimate in absolute dollars.

(iii) The contract-level payment adjustment amount to be made in absolute dollars.

(iv) An approximate timeframe for the payment adjustment.

(v) An enrollee-level description of HCC-level discrepancies that will be eligible for dispute.

(vi) A description of the MA organization's RADV audit appeal rights.

(2) *Compliance date.* The compliance date for meeting RADV medical record submission requirements for the validation of risk adjustment data is the due date when MA organizations selected for RADV audit must submit medical records to CMS or its contractors.

(c) *RADV audit dispute and appeal processes.*

(1) *Attestation process.*

(i) MA organizations—

(A) May submit CMS-generated attestations from physician/practitioner(s) in order to dispute signature or credential-related RADV errors.

(B) That submit CMS-generated attestations must do so in accordance with the rules under this section.

(C) Are not obligated to submit attestations to CMS.

(ii) *RADV audit-related errors eligible for attestation process.* CMS will only accept an attestation to support a physician or outpatient medical records with missing or illegible signatures or missing or illegible credentials or both.

(iii) *RADV audit-related errors ineligible for attestation process.*

(A) Attestations from providers, for the purpose of resolving coding discrepancies or other medical record documentation, will not be permitted.

(B) The introduction of new HCCs for payment that were not previously identified by CMS for RADV audit will not be eligible for attestation.

(C) Inpatient provider-type medical records are not eligible for attestation.

(iv) *Manner and timing of a request for attestation.*

(A) At the time CMS notifies an MA organization that it has been selected for RADV audit, CMS provides the MA organization with the attestation forms and instructions regarding the submission of attestations.

(B) If an organization decides to submit attestations completed by physicians or other practitioners, the MA organization must submit the attestations to CMS at the same time that the MA organization is required to submit related medical records for RADV audit.

(v) *Attestation content.* An attestation must accompany and correspond to the medical record submitted for RADV audit and must meet the following requirements:

(A) Only CMS-generated attestations will be accepted by CMS.

(B) The CMS attestation form may not be altered unless otherwise instructed and agreed-upon in writing by CMS.

(C) Attestations must be completed and be signed and dated by the RADV-physician/practitioner whose medical record accompanies the attestation.

(D) Attestations must be based upon medical records that document face-to-face encounters between beneficiaries and RADV-eligible physicians/practitioners.

(vi) *Attestation review and determination procedures.*

(A) CMS reviews each submitted attestation to determine if it meets CMS requirements and is acceptable for use during the medical record review.

(B) CMS provides written notice of its determination(s) regarding submitted attestations to the MA organization at the time CMS issues its RADV audit report.

(vii) *Effect of CMS' attestation determination.* CMS' attestation determination is final and binding.

(2) *Documentation dispute process.*

An MA organization may choose to dispute CMS' operational processing of RADV medical records using a CMS-administered documentation dispute process.

(i) *RADV-related errors eligible for documentation dispute process.* The

documentation dispute process will apply only to the operational processing of those medical records selected for RADV audit. In order to be eligible for documentation dispute, medical records have to have been submitted to CMS by the CMS-established deadline.

(ii) RADV-related audit errors ineligible for documentation dispute process.

(A) Medical record coding discrepancies.

(B) MA organizations may not use the documentation dispute process to submit new medical records in place of previously-submitted medical records.

(C) MA organizations may not use the documentation dispute process to introduce new HCCs for payment that were not earlier identified by CMS for audit.

(D) MA organizations may not submit medical records for HCCs that were in error because the MA organization failed to meet the medical record submission deadline established by CMS.

(iii) *Manner and timing of a request for documentation dispute.*

(A) At the time CMS issues its RADV audit report to affected MA organizations, CMS notifies affected MA organizations of any RADV errors that are eligible for documentation dispute.

(B) MA organizations have 30 days from date of issuance of the RADV audit report to request documentation dispute.

(iv) *Documentation dispute review and notification procedures.*

(A) CMS reviews documentation submitted by MA organizations to determine whether it supports overturning errors listed in the MA organization's RADV audit report.

(B) CMS provides written notice of its determination(s) to the MA organization and notifies the MA organization of its aggregate determinations regarding overturning errors listed in the MA organization's RADV audit report and recalculating the MA organization's RADV payment error.

(v) *Effect of CMS documentation dispute determination.* CMS' documentation dispute determination is final and binding.

(3) *RADV payment error calculation appeal process.*

(i) MA organizations may appeal CMS' RADV payment error calculation.

(ii) RADV payment error-related issues ineligible for appeal.

(A) MA organizations may not appeal RADV medical record review-related errors.

(B) MA organizations may not appeal physician/practitioner signature or credential-related medical record review errors.

(C) MA organizations may not introduce new HCCs to CMS for payment consideration in the context of their RADV payment error calculation appeal.

(D) MA organizations may not appeal RADV errors that result from an MA organization's failure to submit a medical record.

(E) MA organizations may not appeal CMS' RADV payment error calculation methodology.

(iii) *Manner and timing of a request for appeal.*

(A) At the time CMS issues its RADV audit report, CMS notifies affected MA organizations in writing of their appeal rights around the RADV payment error calculation.

(B) MA organizations have 30 days from the date of this notice to submit a written request for reconsideration of its RADV payment error calculation.

(iv) *Burden of proof.* The MA organization bears the burden of proof in demonstrating that CMS failed to follow its stated RADV payment error calculation methodology.

(v) *Content of request.* The written request for reconsideration must specify the issues with which the MA organization disagrees and the reasons for the disagreements.

(A) Excluding evidence pertaining to issues described at § 422.311(c) (1) and (2), the written request for reconsideration may include additional documentary evidence the MA organization wishes CMS to consider.

(B) CMS does not accept reconsiderations for issues with the methodology applied in any part of the RADV audit.

(vi) *Conduct of written reconsideration.*

(A) In conducting the written reconsideration, CMS reviews all of the following information:

(1) The RADV payment error calculation.

(2) The evidence and findings upon which they were based.

(3) Any other written evidence submitted by the MA organization.

(B) CMS ensures that a third party—either within CMS or a CMS contractor—not otherwise involved in the RADV payment error calculation reviews the written request for reconsideration.

(C) The third party recalculates the payment error in accordance with CMS RADV payment calculation procedures described in CMS' RADV payment error calculation standard operating procedures.

(D) The third party described in paragraph (B) of this paragraph provides his or her determination to a CMS

reconsideration official not otherwise involved in the RADV payment error calculation to review the reconsideration determination.

(vii) *Decision of the CMS reconsideration official.* The CMS reconsideration official informs the MA organization and CMS in writing of the decision of the CMS reconsideration official.

(viii) *Effect of the CMS reconsideration official.* The written reconsideration decision is final and binding unless a request for a hearing is filed by CMS or the appellant MA organization in accordance with paragraph (c)(4) of this section.

(4) *Right to a hearing.* CMS or an MA organization dissatisfied with the written decision of the CMS reconsideration official is entitled to a hearing as provided in this section.

(i) *Manner and timing for request.* A request for a hearing must be made in writing and filed with CMS within 30 days of the date CMS and the MA organization receives CMS' written reconsideration decision.

(ii) *Content of request.* The written request for hearing must include a copy of the written decision of the CMS reconsideration official and must specify the findings or issues in the reconsideration decision with which either CMS or the MA organization disagrees and the reasons for the disagreement.

(iii) *Hearing procedures.*

(A) The hearing will be held on the record, unless the parties request, subject to the hearing officer's discretion, a live or telephonic hearing. The hearing officer may schedule a live or telephonic hearing on his/her own motion.

(B) The hearing is conducted by an official from the CMS' Office of Hearings (CMS Hearing Officer) who neither receives testimony nor accepts any new evidence that was not presented with the request for reconsideration. The CMS Hearing Officer is limited to the review of the record that was before CMS when CMS made its initial RADV payment error calculation determination and when the CMS reconsideration official issued the written reconsideration decision.

(C) The hearing officer has full power to make rules and establish procedures, consistent with the law, regulations, and CMS rulings. These powers include the authority to dismiss the appeal with prejudice or take any other action which the hearing officer considers appropriate for failure to comply with such rules and procedures.

(iv) *Decision of the CMS Hearing Officer.* The CMS Hearing Officer

decides whether the reconsideration official's decision was correct, and sends a written decision to CMS and the MA organization, explaining the basis for the decision.

(v) *Effect of the Hearing Officer's decision.* The Hearing Officer's decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (c)(5) of this section.

(5) *Review by the CMS Administrator.* (i) At his or her discretion, the CMS Administrator can choose to either review or not review a case.

(ii) CMS or an MA organization that has received a Hearing Officer decision upholding or overturning a CMS initial or reconsideration-level RADV payment error calculation determination may request review by the Administrator within 30 days of receipt of the Hearing Officer's decision.

(iii) If the CMS Administrator chooses to review the case, the CMS Administrator reviews the Hearing Officer's decision, any written documents submitted by CMS or the MA organization to the Hearing Officer, as well as any other information included in the record of the Hearing Officer's decision and determines whether to uphold, reverse, or modify the Hearing Officer's decision.

(iv) The Administrator's determination is final and binding.

Subpart K—Contracts With Medicare Advantage Organizations

28. Section 422.501 is amended by—
A. Redesignating paragraphs (b) through (e) as paragraphs (c) through (f), respectively.

B. Adding a new paragraph (b).

C. Revising newly redesignated paragraph (c)(1) introductory text and paragraph (c)(2).

The addition and revisions read as follows:

§ 422.501 Application requirements.

* * * * *

(b) *Completion of a notice of intent to apply.*

(1) An organization submitting an application under this section for a particular contract year must first submit a completed Notice of Intent to Apply by the date established by CMS. CMS will not accept applications from organizations that do not first submit a timely Notice of Intent to Apply.

(2) Submitting a Notice of Intent to Apply does not bind that organization to submit an application for the applicable contract year.

(c) * * *

(1) In order to obtain a determination on whether it meets the requirements to

become an MA organization and is qualified to provide a particular type of MA plan, an entity, or an individual authorized to act for the entity (the applicant) must fully complete all parts of a certified application, in the form and manner required by CMS, including the following:

* * * * *

(2) The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, all the requirements described in this part.

* * * * *

29. Section 422.502 is amended by—
A. Revising paragraphs (a)(1), (a)(2), and (b).

B. Adding a new paragraph (c)(2)(iii).

C. Revising paragraph (c)(3)(iii).

D. Removing paragraph (d).

The revisions read as follows:

§ 422.502 Evaluation and determination procedures.

(a) * * *

(1) With the exception of evaluations conducted under paragraph (b) of this section, CMS evaluates an application for an MA contract solely on the basis of information contained in the application itself and any additional information that CMS obtains through other means such as on-site visits.

(2) After evaluating all relevant information, CMS determines whether the applicant's application meets all the requirements described in this part.

(b) *Use of information from a current or prior contract.* If an MA organization fails during the 14 months preceding the deadline established by CMS for the submission of contract qualification applications to comply with the requirements of the Part C program under any current or prior contract with CMS under title XVIII of the Act or fails to complete a corrective action plan during the 14 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application based on the applicant's failure to comply with the requirements of the Part C program under any current or prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(c) * * *

(2) * * *

(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 the applicant does not appear qualified to contract as an MA organization or has not provided enough information to allow CMS to evaluate the application, CMS will deny the application.

(3) * * *

(iii) The applicant's right to request a hearing in accordance with the procedures specified in subpart N of this part.

30. Section 422.503 is amended by—

A. Revising paragraph (b)(4)(vi).

B. Adding new paragraph (b)(7).

The revisions and addition read as follows:

§ 422.503 General provisions.

* * * * *

(b) * * *

(4) * * *

(vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements:

(A) Written policies, procedures, and standards of conduct that—

(1) Articulate the organization's commitment to comply with all applicable Federal and State standards;

(2) Describe compliance expectations as embodied in the standards of conduct,

(3) Implement the operation of the compliance program;

(4) Provide guidance to employees and others on dealing with potential compliance issues;

(5) Identify how to communicate compliance issues to appropriate compliance personnel;

(6) Describe how potential compliance issues are investigated and resolved by the organization; and

(7) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.

(B) The designation of a compliance officer and a compliance committee who report directly to the organization's chief executive or other senior administrator.

(1) The compliance officer, vested with the day-to-day operations of the compliance program, must be an employee of the MA organization.

(2) The compliance officer and the compliance committee must periodically report directly to the governing body of the MA organization on the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.

(3) The governing body of the MA organization must be knowledgeable about the content and operation of the compliance program and must exercise reasonable oversight with respect to the implementation and effectiveness of the compliance programs.

(C)(1) Each MA organization must establish and implement effective training and education between the compliance officer and organization employees, the MA organization's chief executive or other senior administrator, managers and governing body members, and the MA organization's first tier, downstream, and related entities. Such training and education must occur at a minimum annually and must be made a part of the orientation for a new employee, new first tier, downstream and related entities, and new appointment to a chief executive, manager, or governing body member.

(2) First tier, downstream, and related entities who have met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program are deemed to have met the training and educational requirements for fraud, waste, and abuse.

(D) Establishment and implementation of effective lines of communication, ensuring confidentiality, between the compliance officer, members of the compliance committee, the MA organization's employees, managers and governing body, and the MA organization's first tier, downstream, and related entities. Such lines of communication must be accessible to all and allow compliance issues to be reported including a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified.

(E) Well-publicized disciplinary standards through the implementation of procedures which encourage good faith participation in the compliance program by all affected individuals. These standards must include policies that:

(1) Articulate expectations for reporting compliance issues and assist in their resolution,

(2) Identify noncompliance or unethical behavior; and

(3) Provide for timely, consistent, and effective enforcement of the standards when noncompliance or unethical behavior is determined.

(F) Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the MA organization, including first tier entities', compliance with CMS

requirements and the overall effectiveness of the compliance program.

(G) Establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.

* * * * *

(7) Not have terminated a contract by mutual consent under which, as a condition of the consent, the MA organization agreed that it was not eligible to apply for new contracts or service area expansions for a period of 2 years per § 422.508(c) of this subpart.

* * * * *

31. Section 422.504 is amended by—
A. Redesignating paragraph (e)(1)(ii) and (e)(1)(iii) as paragraph (e)(1)(iii) and (e)(1)(iv), respectively.

B. Adding a new paragraph (e)(1)(ii).
C. Revising newly redesignated paragraph (e)(1)(iii).

D. Revising paragraph (i)(2)(i).
E. Add a new paragraph (m).

The additions and revisions read as follows:

§ 422.504 Contract provisions.

* * * * *

(e) * * *
(1) * * *

(ii) Compliance with CMS requirements for maintaining the privacy and security of personal health information and other personally identifiable information of Medicare enrollees;

(iii) The facilities of the MA organization to include computer and other electronic systems; and

* * * * *

(i) * * *
(2) * * *

(i) HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, computer or other electronic systems, including medical records and documentation of the first tier, downstream, and related to CMS' contract with the MA organization.

* * * * *

(m)(1) CMS may determine that an MA organization is out of compliance with Part C when the organization fails to meet performance standards articulated in the Part C statutes, regulations, or guidance.

(2) If CMS has not already articulated a measure for determining

noncompliance, CMS may determine that a MA organization is out of compliance when its performance represents an outlier relative to the performance of other MA organizations.

- 32. Section 422.506 is amended by—
A. Revising paragraph (a)(2)(ii).
B. Removing paragraph (a)(2)(iii).
C. Revising paragraph (a)(3)(i).
D. Adding a new paragraph (b)(1)(iv).
E. Revising paragraph (b)(2)(ii).
F. Removing paragraph (b)(2)(iii).
G. Revising paragraph (b)(3).

The revisions and addition read as follows:

§ 422.506 Nonrenewal of contract.

(a) * * *
(2) * * *

(ii) Each Medicare enrollee by mail at least 90 calendar days before the date on which the nonrenewal is effective. The MA organization must also provide information about alternative enrollment options by doing one or more of the following:

(A) Provide a CMS approved written description of alternative MA plan options available for obtaining qualified Medicare services within the beneficiaries' region.

(B) Place outbound calls to all affected enrollees to ensure beneficiaries know who to contact to learn about their enrollment options.

(3) * * *

(i) The MA organization notifies its Medicare enrollees in accordance with paragraph (a)(2)(ii) of this section; and

(b) * * *
(1) * * *

(iv) The contract must be nonrenewed as to an individual MA plan if that plan does not have a sufficient number of enrollees to establish that it is a viable independent plan option.

(2) * * *

(ii) To each of the MA organization's Medicare enrollees by mail at least 90 calendar days before the date on which the nonrenewal is effective, or at the conclusion of the appeals process if applicable.

(3) *Opportunity to develop and implement a corrective action plan.*

(i) Before providing a notice of intent of nonrenewal of the contract, CMS will provide the MA organization with a notice specifying the deficiencies and reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that form the basis for the determination to non-renew the contract.

(ii) CMS affords the MA organization with at least 30 calendar days in which to develop and implement a corrective action plan to correct the deficiencies

that formed the basis for the determination to non-renew the contract.

(iii) The MA organization is solely responsible for the identification, development, and implementation of its corrective action plan and for demonstrating to CMS that the underlying deficiencies have been corrected within the time period specified by CMS in the notice requesting corrective action.

* * * * *

33. Section 422.508 is amended by adding paragraph (c) to read as follows:

§ 422.508 Modification or termination of contract by mutual consent.

* * * * *

(c) *Agreement to limit new MA applications.* As a condition of the consent to a mutual termination CMS will require, as a provision of the termination agreement language prohibiting the MA organization from applying for new contracts or service area expansions for a period of 2 years, absent circumstances warranting special consideration.

34. Section 422.510 is amended by revising paragraphs (a), (b) introductory text, (b)(2)(i), (b)(2)(ii), and (c) to read as follows:

§ 422.510 Termination of contract by CMS.

(a) *Termination by CMS.*

(1) CMS may at any time terminate a contract if CMS determines that the MA organization meets any of the following:

(i) Has failed substantially to carry out the contract.

(ii) Is carrying out the contract in a manner that is inconsistent with the efficient and effective administration of this part.

(iii) No longer substantially meets the applicable conditions of this part.

(2) CMS may determine, in

accordance with paragraph (a)(1) of this section, that a basis exists to terminate an MA organization's contract if—

(i) The MA organization fails to comply with any of the regulatory requirements contained in this part or part 423 of this chapter or both;

(ii) The MA organization fails to meet CMS performance requirements in carrying out the regulatory requirements contained in this part or part 423 of this chapter or both including, but not limited to, when CMS determines that an analysis of data related to the organization's performance indicates it is an outlier relative to that of other organizations; or

(iii) There is credible evidence to show that the MA organization has committed or participated in false, fraudulent, or abusive activities

affecting the Medicare, Medicaid, or other State or Federal health care programs, including submission of false or fraudulent data.

(b) *Notice.* If CMS decides to terminate a contract it gives notice of the termination as follows:

(1) * * *

(2) *Expedited termination of contract by CMS.* (i) If CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the MA organization, the effective date of termination will be specified, in writing, by CMS.

(ii) If a termination is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the MA organization covering the period of the month following the contract termination.

* * * * *

(c) Opportunity to develop and implement a corrective action plan.

(1) *General.* (i) Before providing a notice of intent to terminate the contract, CMS will provide the MA organization with a notice specifying the deficiencies and reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that form the basis for the determination to terminate the contract.

(ii) CMS affords the MA organization with at least 30 calendar days in which to develop and implement a corrective action plan to correct the deficiencies that formed the basis for the determination to terminate the contract.

(iii) The MA organization is solely responsible for the identification, development, and implementation of its corrective action plan and for demonstrating to CMS that the underlying deficiencies have been corrected within the time period specified by CMS in the notice requesting corrective action.

(2) *Exceptions.* If CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the MA organization, the MA organization will not be provided with an opportunity to develop and implement a corrective action plan prior to termination.

* * * * *

35. Section 422.516 is amended by—
A. Revising the section heading.
B. Adding a new paragraph (g).

The revision and addition to read as follows:

§ 422.516 Validation of Part C reporting requirements.

* * * * *

(g) *Data validation.* Each Part C sponsor must subject information collected under paragraph (a) of this section to a yearly independent audit to determine their reliability, validity, completeness, and comparability in accordance with specifications developed by CMS.

Subpart M—Grievances, Organization Determinations, and Appeals

36. Section 422.561 is amended by revising the definition of “Representative” to read as follows:

§ 422.561 Definitions.

* * * * *

Representative means an individual appointed by an enrollee or other party, or authorized under State or other applicable law, to act on behalf of an enrollee or other party involved in the grievance or appeal. Unless otherwise stated in this subpart, the representative will have all the rights and responsibilities of an enrollee or party in filing a grievance, and in obtaining an organization determination or in dealing with any of the levels of the appeals process, subject to the applicable rules described in part 405 of this chapter.

37. Section 422.566 is amended by revising paragraph (b)(4) to read as follows:

§ 422.566 Organization determinations.

* * * * *

(b) * * *

(4) Discontinuation or reduction of a service or an authorized course of treatment.

* * * * *

38. Section 422.568 is amended by—
A. Redesignating paragraphs (a) through (f) as paragraphs (b) through (g), respectively.

B. Adding a new paragraph (a).

C. Revising newly redesignated paragraph (e).

The addition and revision read as follows:

§ 422.568 Standard timeframes and notice requirements for organization determinations.

(a) *Method and place for filing a request.* An enrollee must ask for a standard organization determination by making a request with the MA organization or, if applicable, to the entity responsible for making the determination (as directed by the MA organization), in accordance with the following:

(1) The request may be made orally or in writing, except as provided in paragraph (a)(2) of this section.

(2) Requests for payment must be made in writing (unless the MA organization or entity responsible for making the determination has implemented a voluntary policy of accepting oral payment requests).

* * * * *

(e) *Written notice for MA organization denials.*

(1) If an MA organization decides to deny a service or payment in whole or in part, or discontinue or reduce the level of care for an authorized course of treatment, the organization must give the enrollee written notice of the determination.

(2) If an enrollee requests an MA organization to provide an explanation of a practitioner’s denial of an item or service, in whole or in part, the MA organization must give the enrollee a written notice.

* * * * *

39. Section 422.574 is amended by revising paragraph (a) to read as follows:

§ 422.574 Parties to the organization determination.

* * * * *

(a) The enrollee (including his or her representative);

* * * * *

40. Section 422.622 is amended by revising paragraph (f)(3) to read as follows:

§ 422.622 Requesting immediate QIO review of the decision to discharge from the inpatient hospital.

* * * * *

(f) * * *

(3) If the QIO determines that the enrollee still requires inpatient hospital care, the hospital must provide the enrollee with a notice consistent with § 422.620(c) of this subpart when the hospital or MA organization once again determines that the enrollee no longer requires inpatient hospital care.

* * * * *

41. Section 422.624 is amended by revising paragraph (c)(1) to read as follows:

§ 422.624 Notifying enrollees of termination of provider services.

* * * * *

(c) * * *

(1) The enrollee (or the enrollee’s representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents; and

* * * * *

42. Section 422.626 is amended by—

A. Redesignating paragraph (f) as paragraph (g).

B. Redesignating paragraph (e)(5) as paragraph (f) and revising the newly redesignated paragraph (f).

The revisions read as follows:

§ 422.626 Fast-track appeals of service terminations to independent review entities (IREs).

* * * * *

(f) *Responsibilities of the provider.* If an IRE reverses an MA organization's termination decision, the provider must provide the enrollee with a new notice consistent with § 422.624(b) of this subpart.

* * * * *

Subpart N—Medicare Contract Determinations and Appeals

43. Section 422.644 is amended by revising paragraph (c) to read as follows:

§ 422.644 Notice of contract determination.

* * * * *

(c) *CMS-initiated terminations.*

(1) *General rule.* CMS mails notice to the MA organization 90 calendar days before the anticipated effective date of the termination.

(2) *Exception.* For terminations where CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the MA organization, CMS notifies the MA organization of the date that it will terminate the MA organization's contract.

* * * * *

44. Section § 422.660 is revised to read as follows:

§ 422.660 Right to a hearing, burden of proof, standard of proof, and standards of review.

(a) *Right to a hearing.* The following parties are entitled to a hearing:

(1) A contract applicant that has been determined to be unqualified to enter into a contract with CMS under Part C of Title XVIII of the Act in accordance with § 422.501 and § 422.502.

(2) An MA organization whose contract has been terminated under § 422.510 of this part.

(3) An MA organization whose contract has not been renewed under § 422.506 of this part.

(4) An MA organization who has had an intermediate sanction imposed in accordance with § 422.752(a) through (b) of this part.

(b) *Burden of proof, standard of proof, and standards of review at a hearing.*

(1) During a hearing to review a contract determination as described at

§ 422.641(a) 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 § 422.501 and § 422.502 of this part.

(2) During a hearing to review a contract determination as described at § 422.641(b) of this subpart, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.506 of this part.

(3) During a hearing to review a contract determination as described at § 422.641(c) of this subpart, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.510 of this part.

(4) During a hearing to review the imposition of an intermediate sanction as described at § 422.750 of this part, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.752 of this part.

(c) *Timing of favorable decisions.* Notice of any decision favorable to the MA organization appealing a determination that it is not qualified to enter into a contract with CMS must be issued by September 1 for the contract in question to be effective on January 1 of the following year.

45. Section 422.662 is amended by revising paragraphs (a) and (b) to read as follows:

§ 422.662 Request for hearing.

(a) *Method and place for filing a request.* (1) A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or MA organization that was the party to the determination under the appeal.

(2) The request for the hearing must be filed in accordance with the requirements specified in the notice.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 calendar days after the receipt of the notice of the contract determination or intermediate sanction.

* * * * *

46. Section 422.664 is amended by revising paragraph (b)(2) to read as follows:

§ 422.664 Postponement of effective date of a contract determination when a request for a hearing is filed timely.

* * * * *

(b) * * *

(2) If CMS determines that a delay in termination, resulting from compliance

with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of individuals enrolled with the MA organization, the date of termination will not be postponed if the MA organization requests a hearing.

47. Section 422.670 is revised to read as follows:

§ 422.670 Time and place of hearing.

(a) The hearing officer—

(1) Fixes a time and place for the hearing, which is not to exceed 30 calendar days after the receipt of the request for the hearing; and

(2) Sends written notice to the parties that informs the parties of the general and specific issues to be resolved, the burden of proof, and information about the hearing procedure.

(b)(1) The hearing officer may, on his or her own motion, change the time and place of the hearing.

(2) The hearing officer may adjourn or postpone the hearing.

(c)(1) The MA organization or CMS may request an extension by filing a written request no later than 5 calendar days prior to the scheduled hearing.

(2) When either the MA organization or CMS requests an extension, the hearing officer will provide a one-time 15 calendar day extension.

(3) Additional extensions may be granted at the discretion of the hearing officer.

48. Section 422.676 is amended by revising paragraph (d) to read as follows:

§ 422.676 Conduct of hearing.

* * * * *

(d) The MA organization bears the burden of going forward and must first present evidence and argument before CMS presents its evidence and argument.

49. Section 422.682 is revised to read as follows:

§ 422.682 Witness lists and documents.

Witness lists and documents must be identified and exchanged at least 5 calendar days before the scheduled hearing.

50. Section 422.692 is amended by revising paragraphs (a) and (c) to read as follows:

§ 422.692 Review by the Administrator.

(a) *Request for review by Administrator.* CMS or an MA organization that has received a hearing decision may request a review by the Administrator within 15 calendar days after receipt of the hearing decision as provided under § 422.690(b). Both the MA organization and CMS may provide

written arguments to the Administrator for review.

* * * * *

(c) *Notification of Administrator determination.* The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days after receipt of request for review. If the Administrator declines to review the hearing decision or the Administrator does not make a determination regarding review within 30 calendar days, the decision of the hearing officer is final.

* * * * *

51. Section 422.696 is amended by revising the section heading and paragraph heading for paragraph (a) to read as follows:

§ 422.696 Reopening of a contract determination or decision of a hearing officer or the Administrator.

(a) *Contract determination.* * * *

* * * * *

Subpart O—Intermediate Sanctions

52. Section 422.750 is amended by revising paragraph (a) to read as follows:

§ 422.750 Types of intermediate sanctions and civil money penalties.

(a) The following intermediate sanctions may be imposed and will continue in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur:

(1) Suspension of the MA organization's enrollment of Medicare beneficiaries.

(2) Suspension of payment to the MA organization for Medicare beneficiaries enrolled after the date CMS notifies the organization of the intermediate sanction.

(3) Suspension of all marketing activities to Medicare beneficiaries by an MA organization.

* * * * *

53. Section 422.752 is amended by—

A. Revising paragraphs (a) introductory text, (a)(1), (a)(3), and (a)(4).

B. In paragraph (c)(1), removing the cross-reference “422.510(a)(4)” and adding the cross-reference “§ 422.510(a)(2)(iii) of this part” in its place.

C. In paragraph (c)(2)(iii), removing the phrase “pursuant to 422.510(a)(4)” and adding the phrase “under § 422.510(a)(2)(iii) of this part” in its place.

The revisions read as follows:

§ 422.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) *All intermediate sanctions.* For the violations listed in this paragraph, CMS may impose one or more of the sanctions specified in § 422.750(a) of this subpart on any MA organization with a contract. The MA organization may also be subject to other remedies authorized under law.

(1) Fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has the substantial likelihood of adversely affecting) the individual.

* * * * *

(3) Acts to expel or refuses to re-enroll a beneficiary in violation of the provisions of this part.

(4) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services.

* * * * *

54. Section 422.756 amended by—

A. Revising paragraph (b).
B. Removing paragraph (c).
C. Redesignating paragraphs (d) through (f) as paragraphs (c) through (e), respectively.

D. Revising the newly redesignated paragraphs (c)(1) and (c)(3).

The revisions read as follows:

§ 422.756 Procedures for imposing intermediate sanctions and civil money penalties.

* * * * *

(b) *Hearing.* (1) The MA organization may request a hearing before a CMS hearing officer.

(2) A written request must be received by the designated CMS office within 15 calendar days after the receipt of the notice.

(3) A request for a hearing under § 422.660 does not delay the date specified by CMS when the sanction becomes effective.

(4) The MA organization must follow the right to a hearing procedure as specified at § 422.660 through § 422.684.

(c) *Effective date and duration of sanction.* (1) *Effective date.* The effective date of the sanction is the date specified by CMS in the notice.

* * * * *

(3) *Duration of sanction.* The sanction remains in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have

been corrected and are not likely to recur.

(i) CMS may require that the MA organization hire an independent auditor to provide CMS with additional information to determine if the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur. The independent auditor must work in accordance with CMS specifications and must be willing to attest that a complete and full independent review has been performed.

(ii) In instances where marketing or enrollment or both intermediate sanctions have been imposed, CMS may require an MA organization to market or to accept enrollments or both for a limited period of time in order to assist CMS in making a determination as to whether the deficiencies that were the bases for the intermediate sanctions have been corrected and are not likely to recur.

(A) If, following this time period, CMS determines the deficiencies have not been corrected or are likely to recur, the intermediate sanctions will remain in effect until such time that CMS is assured the deficiencies have been corrected and are not likely to recur.

(B) The MA organization does not have a right to a hearing under § 422.660(a)(4) of this part to challenge CMS' determination to keep the intermediate sanctions in effect.

* * * * *

Subpart V—Medicare Advantage Marketing Requirements

55. Section 422.2260 is amended by revising paragraph (5)(vii) of the definition of “Marketing materials” to read as follows:

§ 422.2260 Definitions concerning marketing materials.

* * * * *

(5) * * *

(vii) *Membership activities—Current enrollee communication materials.* Current enrollee communication materials include any informational materials that are—

(A) Targeted to current enrollees; and
(B) Customized or limited to a subset of enrollees or apply to a specific situation; or

(C) Cover claims processing or other operational issues.

56. Section 422.2262 is amended by—

A. Revising paragraphs (a)(1) and (b).
B. Adding new paragraphs (c) and (d).

The revisions and additions read as follows:

§ 422.2262 Required use of standardized model materials.

(a) * * *

(1) Except as provided in paragraph (b) of this section, an MA organization may not distribute any marketing materials (as defined in § 422.2260 of this subpart), or election forms, or make such materials or forms available to individuals eligible to elect an MA organization unless—

(i) At least 45 days (or 10 days if using certain types of marketing materials that use, without modification, proposed model language and format, including standardized language and formatting, as specified by CMS) before the date of distribution the MA organization has submitted the material or form to CMS for review under the guidelines in § 422.2264 of this subpart; and

(ii) CMS does not disapprove the distribution of new material or form.

* * * * *

(b) *File and use.* The MA organization may distribute certain types of marketing material, designated by CMS, 5 days following their submission to CMS if the MA organization certifies that in the case of these marketing materials, it followed all applicable marketing guidelines and, when applicable, used model language specified by CMS without modification.

(c) *Standardized model marketing materials.* When specified by CMS, organizations must use standardized formats and language in model materials.

(d) *Current enrollee communication materials.* Current enrollee communication materials may be reviewed by CMS, which may upon review determine that such materials must be modified, or may no longer be used.

PART 423—MEDICARE PROGRAM; MEDICARE PRESCRIPTION DRUG PROGRAM

57. 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

58. Section 423.34 is revised to read as follows:

§ 423.34 Enrollment of low-income subsidy eligible individuals.

(a) *General rule.* CMS must ensure the enrollment into Part D plans of low-income subsidy eligible individuals who fail to enroll in a Part D plan.

(b) *Definitions.*

Full-benefit dual-eligible individual. For purposes of this section, a full-benefit dual eligible individual means an individual who is—

(1) Determined eligible by the State for—

(i) Medical assistance for full-benefits under Title XIX of the Act for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act; or

(ii) Medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) for any month if the individual was eligible for medical assistance in any part of the month.

(2) Eligible for Part D in accordance with § 423.30(a) of this subpart.

Low-income subsidy-eligible individual. For purposes of this section, a low-income subsidy eligible individual means an individual who meets the definition of full subsidy eligible (including full benefit dual eligible individuals) or other subsidy eligible in § 423.772 of this part.

(c) *Reassigning low-income subsidy-eligible individuals.* Notwithstanding § 423.32(e) of this subpart, during the annual coordinated election period, CMS may reassign certain low-income subsidy-eligible individuals in another PDP if CMS determines that the further enrollment is warranted.

(d) *Enrollment rules.*

(1) *General rule.* Except for low-income subsidy eligible individuals who are qualifying covered retirees with a group health plan sponsor as specified in paragraph (d)(3) of this section, CMS enrolls those individuals who fail to enroll in a Part D plan into a PDP offering basic prescription drug coverage in the area where the beneficiary resides that has a monthly beneficiary premium amount that does not exceed the low-income subsidy amount (as defined in § 423.780(b) of this part). In the event that there is more than one PDP in an area with a monthly beneficiary premium at or below the low-income premium subsidy amount, individuals are enrolled in such PDPs on a random basis.

(2) *Individuals enrolled in an MSA plan or one of the following that does not offer a Part D benefit.* Low-income subsidy eligible individuals enrolled in an MA private fee-for-service plan or cost-based HMO or CMP that does not offer qualified prescription drug coverage or an MSA plan and who fail to enroll in a Part D plan must be enrolled into a PDP plan as described in paragraph (d)(1) of this section.

(3) *Exception for individuals who are qualifying covered retirees.*

(i) Full benefit dual eligible individuals who are qualifying covered retirees as defined in § 423.882 of this part, and for whom CMS has approved the group health plan sponsor to receive the retirement drug subsidy described in subpart R of this part, also are automatically enrolled in a Part D plan, consistent with this paragraph, unless they elect to decline that enrollment.

(ii) Before effectuating such an enrollment, CMS provides notice to such individuals of their choices and advises them to discuss the potential impact of Medicare Part D coverage on their group health plan coverage. The notice informs individuals that they will be deemed to have declined to enroll in Part D unless they affirmatively enroll in a Part D plan or contact CMS and confirm that they wish to be auto-enrolled in a PDP. Individuals who elect not to be auto-enrolled, may enroll in Medicare Part D at a later time if they choose to do so.

(iii) All other low-income subsidy eligible beneficiaries who are qualified covered retirees are not enrolled by CMS into PDPs.

(e) *Declining enrollment and disenrollment.* Nothing in this section prevents a low-income subsidy eligible individual from—

(1) Affirmatively declining enrollment in Part D; or

(2) Disenrolling from the Part D plan in which the individual is enrolled and electing to enroll in another Part D plan during the special enrollment period provided under § 423.38.

(f) *Effective date of enrollment for full-benefit dual eligible individuals.* Enrollment of full-benefit dual eligible individuals under this section must be effective as follows:

(1) January 1, 2006 for individuals who are full-benefit dual-eligible individuals as of December 31, 2005.

(2) The first day of the month the individual is eligible for Part D under § 423.30(a)(1) for individuals who are Medicaid eligible and subsequently become newly eligible for Part D under § 423.30(a)(1) on or after January 1, 2006.

(3) For individuals who are eligible for Part D under § 423.30(a)(1) of this subpart and subsequently become newly eligible for Medicaid on or after January 1, 2006, enrollment is effective with the first day of the month when the individuals become eligible for both Medicaid and Part D.

(g) *Effective date of enrollment for non-full-benefit dual-eligible individuals who are low-income subsidy-eligible individuals.* The

effective date for non-full-benefit dual-eligible individuals who are low-income subsidy-eligible individuals is no later than the first day of the second month after CMS determines that they meet the criteria for enrollment under this section.

59. Section 423.38 is amended by revising paragraph (c)(4) to read as follows:

§ 423.38 Enrollment periods.

* * * * *

(c) * * *

(4) The individual is a full-subsidy eligible individual or other subsidy-eligible individual as defined in § 423.772 of this part.

* * * * *

60. Section 423.44 is amended by—

A. Redesignating paragraphs (d)(1)(iii) and (d)(1)(iv) as paragraphs (d)(1)(iv) and (d)(1)(v), respectively.

B. Adding a new paragraph (d)(1)(iii).

C. Redesignating the introductory text of paragraph (d)(5) as paragraph (d)(5)(i).

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

The revisions and additions read as follows:

§ 423.44 Involuntary disenrollment by the PDP.

* * * * *

(d) * * *

(1) * * *

(iii) The PDP sponsor provides the individual with a grace period, that is, an opportunity to pay past due premiums in full. The grace period must—

(A) Be at least 2 months; and

(B) Begin on the first day of the month for which the premium is unpaid.

* * * * *

(5) * * *

(ii) *Special rule.* If the individual has not moved from the PDP service area, but has been absent from the service area for more than 12 consecutive months, the PDP sponsor must disenroll the individual from the plan effective on the first day of the 13th month after the individual left the service area.

* * * * *

Subpart C—Benefits and Beneficiary Protections

61. Section 423.100 is amended by adding the definitions of “Drug category or class,” “Major or life threatening clinical consequences,” “Multiple drugs,” “Restricted access,” and “Significant need for access to multiple drugs” to read as follows:

§ 423.100 Definitions.

* * * * *

Drug category or class means, for the purpose of § 423.120(b)(2)(v) of the subpart, the identification of a drug grouping that is reasonable to identify the applicable drug products.

* * * * *

Major or life threatening clinical consequences means consequences in which serious clinical events may arise as a result of not taking a drug that can lead to patient hospitalization, or a persistent or significant disability or incapacity, or that can result in death.

Multiple drugs mean two or more Part D drugs.

* * * * *

Restricted access means, for the purposes of § 423.120(b)(2)(v)(A) of this subpart, an enrollee who but for § 423.120(b)(2)(v) of this subpart urgently requires a Part D drug but is waiting for an expedited redetermination by a Part D plan or an CMS independent review entity with respect to coverage of that drug.

* * * * *

Significant need for access to multiple drugs means instances in which —

(1) There is a need for simultaneous use of drugs within a drug grouping because such drugs work in combination with each other; or

(2) There is a strong likelihood of sequential use of drugs within a class or category within a short period of time due to the unique effects the drugs have on various individuals.

* * * * *

62. Section 423.104 is amended by—

A. Revising paragraph (b).

B. Adding a new paragraph (d)(2)(iii).

The revision and addition read as follows:

§ 423.104 Requirements related to qualified prescription drug coverage.

* * * * *

(b) *Availability of prescription drug plan.* A PDP sponsor offering a prescription drug plan must offer the plan—

(1) To all Part D eligible beneficiaries residing in the plan’s service area; and

(2) At a uniform premium, with uniform benefits and level of cost-sharing throughout the plan’s service.

* * * * *

(d) * * *

(2) * * *

(iii) Tiered cost sharing under paragraph (d)(2)(ii) of this section may not exceed levels annually determined by CMS to be discriminatory.

* * * * *

63. Section 423.112 is amended by revising paragraph (a) to read as follows:

§ 423.112 Establishment of prescription drug plan sponsor service areas.

(a) *Service area for prescription drug plan sponsors.* The service area for a prescription drug plan sponsor other than a fallback prescription drug plan sponsor consists of one or more PDP regions as established under paragraphs (b) and (c) of this section.

* * * * *

64. Section 423.120 is amended by—

A. Revising paragraph (a).

B. Redesignating paragraph (b)(1)(ix) as paragraph (b)(1)(x).

C. Adding a new paragraph (b)(1)(ix).

D. Revising paragraph (b)(2)(v).

E. Adding new paragraph (b)(2)(vi).

F. Revising paragraph (b)(3).

G. Redesignating paragraph (c) as paragraph (c)(1).

H. Adding new paragraphs (c)(2) through (c)(4).

The revisions and additions read as follows:

§ 423.120 Access to covered Part D drugs.

(a) *Assuring pharmacy access—(1) Standards for convenient access to network pharmacies.* Except as provided in paragraph (a)(7) of this section, a Part D sponsor (as defined in § 423.4 of this part) must have a contracted pharmacy network consisting of retail pharmacies sufficient to ensure that, for beneficiaries residing in each State in a PDP sponsor’s service area (as defined in § 423.112(a) of this part), each State in a regional MA-organization’s service area (as defined in § 422.2 of this part), the entire service area of a local MA organization (as defined in § 422.2 of this chapter) or the entire geographic area of a cost contract (as defined in § 417.401 of this chapter) all of the following requirements are satisfied:

(i) At least 90 percent of Medicare beneficiaries, on average, in urban areas served by the Part D sponsor live within 2 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(ii) At least 90 percent of Medicare beneficiaries, on average, in suburban areas served by the Part D sponsor live within 5 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(iii) At least 70 percent of Medicare beneficiaries, on average, in rural areas served by the Part D sponsor live within 15 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(2) *Applicability of some non-retail pharmacies to standards for convenient access.* Part D sponsors may count

I/T/U pharmacies and pharmacies operated by Federally Qualified Health Centers and Rural Health Centers toward the standards for convenient access to network pharmacies in paragraph (a)(1) of this section.

(3) *Access to non-retail pharmacies.* A Part D sponsor's contracted pharmacy network may be supplemented by non-retail pharmacies, including pharmacies offering home delivery via mail-order and institutional pharmacies, provided the requirements of paragraph (a)(1) of this section are met.

(4) *Access to home infusion pharmacies.* A Part D sponsor's contracted pharmacy network must provide adequate access to home infusion pharmacies consistent with written policy guidelines and other CMS instructions. A Part D plan must ensure that such network pharmacies, at a minimum meet all the following requirements:

(i) Are capable of delivering home-infused drugs in a form that can be administered in a clinically appropriate fashion.

(ii) Are capable of providing infusible Part D drugs for both short-term acute care and long-term chronic care therapies.

(iii) Ensure that the professional services and ancillary supplies necessary for home infusion therapy are in place before dispensing Part D home infusion drugs.

(iv) Provide delivery of home infusion drugs within 24 hours of discharge from an acute care setting, or later if so prescribed.

(5) *Access to long-term care pharmacies.* A Part D sponsor must offer standard contracting terms and conditions, including performance and service criteria for long-term care pharmacies that CMS specifies, to all long-term care pharmacies in its service area. The sponsor must provide convenient access to long-term care pharmacies consistent with written policy guidelines and other CMS instructions.

(6) *Access to I/T/U pharmacies.* A Part D sponsor must offer standard contracting terms and conditions conforming to the model addendum that CMS develops, to all I/T/U pharmacies in its service area. The sponsor must provide convenient access to I/T/U pharmacies consistent with written policy guidelines and other CMS instructions.

(7) *Waiver of pharmacy access requirements.* CMS waives the requirements under paragraph (a)(1) of this section in the case of either of the following:

(i) An MA organization or cost contract (as described in section 1876(h) of the Act) that provides its enrollees with access to covered Part D drugs through pharmacies owned and operated by the MA organization or cost contract, provided the organization's or plan's pharmacy network meets the access standard set forth—

(A) At § 422.112 of this chapter for an MA organization; or

(B) At § 417.416(e) of this chapter for a cost contract.

(ii) An MA organization offering a private fee-for-service plan described in § 422.4 of this chapter that—

(A) Offers qualified prescription drug coverage; and

(B) Provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies and without charging cost-sharing in excess of that described in § 423.104(d)(2) and (d)(5).

(8) Pharmacy network contracting requirements. In establishing its contracted pharmacy network, a Part D sponsor offering qualified prescription drug coverage—

(i) Must contract with any pharmacy that meets the Part D sponsor's standard terms and conditions; and

(ii) May not require a pharmacy to accept insurance risk as a condition of participation in the Part D sponsor's contracted pharmacy network.

(9) *Differential cost-sharing for preferred pharmacies.* A Part D sponsor offering a Part D plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs obtained through a preferred pharmacy relative to the copayments or coinsurance applicable for such drugs when obtained through a non-preferred pharmacy. Such differentials are taken into account in determining whether the requirements under § 423.104(d)(2) and (d)(5) and § 423.104(e) are met. Any cost-sharing reduction under this section must not increase CMS payments to the Part D plan under § 423.329.

(10) *Level playing field between mail-order and network pharmacies.* A Part D sponsor must permit its Part D plan enrollees to receive benefits, which may include a 90-day supply of covered Part D drugs, at any of its network pharmacies that are retail pharmacies. A Part D sponsor may require an enrollee obtaining a covered Part D drug at a network pharmacy that is a retail pharmacy to pay any higher cost-sharing applicable to that covered Part D drug at the network pharmacy that is a retail pharmacy instead of the cost-sharing

applicable to that covered Part D drug at the network pharmacy that is a mail-order pharmacy.

(b) * * *

(1) * * *

(ix) Reviews and approves all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered Part D drug.

* * * * *

(2) * * *

(v) Beginning with contract year 2011, except as provided in paragraph (b)(2)(vi) of this section, a Part D sponsor's formulary will include all Part D drugs in a category or class for which both of the following apply:

(A) Restricted access to the drugs in the category or class would have major or life threatening clinical consequences for individuals who have a disease or disorder treated by drugs in such category or class; and

(B) There is a significant need for such individuals to have access to multiple drugs within a category or class due to unique chemical actions and pharmacological effects of the drugs within a category or class.

(vi) Exceptions to paragraph (b)(2)(v) of this section are as follows:

(A) Drug products that are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations," also known as the Orange Book).

(B) Utilization management processes that limit the quantity of drugs due to safety.

(C) Other drugs that CMS specifies through a process that is based upon scientific evidence and medical standards of practice (and, in the case of antiretroviral medications, is consistent with the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents) and which permits public notice and comment.

(3) *Transition process.* A Part D sponsor must provide for an appropriate transition process for enrollees prescribed Part D drugs that are not on its Part D plan's formulary (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a plan's utilization management rules). The transition process must:

(i) Be applicable to all of the following:

(A) New enrollees into Part D plans following the annual coordinated election period.

(B) Newly eligible Medicare enrollees from other coverage.

(C) Individuals who switch from one plan to another after the start of the contract year.

(D) Current enrollees remaining in the plan affected by formulary changes.

(ii) Ensure access to a temporary supply of drugs within the first 90 days of coverage under a new plan. This 90-day timeframe applies to retail, home infusion, long-term care and mail-order pharmacies,

(iii) Ensure the provision of a temporary fill when an enrollee requests a fill of a non-formulary drug during the time period specified in paragraph (ii) of this paragraph (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules).

(A) In the outpatient setting, the one-time, temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) must be for at least 30 days of medication, unless the prescription is written by a prescriber for less than 30 days and requires the Part D sponsor to allow multiple fills to provide up to a total of 30 days of medication.

(B) In the long-term care setting, the temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) must be for up to 90 days in 31-day supply increments (unless the prescription is written for less than 31 days).

(iv) Ensure written notice is provided to each affected enrollee within 3 business days of the temporary fill.

(v) Ensure that reasonable efforts are made to notify prescribers of affected enrollees who receive a transition notice under paragraph (b)(3)(iv) of this section.

(c) * * *

(2) When processing Part D claims, a Part D sponsor or its intermediary must comply with the electronic transaction standards established by 45 CFR 162.1102. CMS will issue guidance on the use of conditional fields within such standards.

(3) A Part D sponsor must require its network pharmacies to submit claims to the Part D sponsor or its intermediary whenever the card described in paragraph (c)(1) of this section is presented or on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted to the Part D sponsor or its intermediary.

(4) A part D sponsor must assign a unique—

(i) Part D BIN or RxBIN and Part D processor control number (RxPCN) combination to its Medicare line of business; and

(ii) Part D cardholder identification number (RxID) to each Medicare Part D enrollee to clearly identify Medicare Part D beneficiaries.

65. Section 423.128 is amended by adding a new paragraph (f) to read as follows:

§ 423.128 Dissemination of Part D plan information.

* * * * *

(f) *Disclosure requirements.* CMS may require a Part D plan sponsor to disclose to its enrollees or potential enrollees, the Part D plan sponsor's performance and contract compliance deficiencies in a manner specified by CMS.

66. Section 423.132 is amended by—

A. Revising the introductory text of paragraph c.

B. In paragraphs (c)(2) and (c)(3), removing the “;” and adding a “.” in its place.

C. In paragraph (c)(4), removing “; and” and adding a “.” in its place.

D. Redesignating paragraph (c)(5) as (c)(6).

E. Adding a new paragraph (c)(5).

F. Revising paragraph (d).

The revisions and additions read as follows:

§ 423.132 Public disclosure of pharmaceutical prices for equivalent drugs.

* * * * *

(c) Waiver of public disclosure requirement. CMS waives the requirement under paragraph (a) of this section in any of the following cases:

* * * * *

(5) A long-term care network pharmacy.

(d) *Modification of timing requirement.* CMS modifies the requirement under paragraph (b) of this section under circumstances where CMS deems compliance with this requirement to be impossible or impracticable.

Subpart D—Cost Control and Quality Improvement Requirements

67. Section 423.153 is amended by—

A. Adding paragraphs (d)(1)(v) through (vii).

B. Revising paragraph (d)(2).

The additions and revisions read as follows:

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

* * * * *

(d) * * *

(1) * * *

(v) Must enroll targeted beneficiaries using an opt-out method of enrollment only.

(vi) Must target beneficiaries for enrollment in the MTMP at least quarterly during each plan year.

(vii) Must offer a minimum level of medication therapy management services for each beneficiary enrolled in the MTMP that includes all of the following:

(A) Interventions for both beneficiaries and prescribers.

(B) Annual comprehensive medication reviews with written summaries. The comprehensive medical review must include an interactive, person-to-person consultation performed by a pharmacist or other qualified provider unless the beneficiary is in a long-term care setting.

(C) Quarterly targeted medication reviews with follow-up interventions when necessary.

(2) *Targeted beneficiaries.* Targeted beneficiaries for the MTMP described in paragraph (d)(1) of this section are enrollees in the sponsor's Part D plan who—

(i) Have multiple chronic diseases, with three chronic diseases being the maximum number a Part D plan sponsor may require for targeted enrollment;

(ii) Are taking multiple Part D drugs, with eight Part D drugs being the maximum number of drugs a Part D plan sponsor may require for targeted enrollment; and

(iii) Are likely to incur costs for covered Part D drugs that exceed the initial coverage limit for the Part D defined standard benefit for the applicable Part D plan year.

* * * * *

68. Section 423.156 is revised to read as follows:

§ 423.156 Consumer satisfaction surveys.

Part D contracts with 600 or more enrollees as of July of the prior year must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of Part D plan enrollees in accordance with CMS specifications and submit the survey data to CMS.

69. Section 423.165 is amended by—

A. Removing paragraph (b)(4).

B. Revising paragraph (f).

The revision reads as follows:

§ 423.165 Compliance deemed on the basis of accreditation.

* * * * *

(f) *Authority.* Nothing in this limits CMS' authority under subparts K and O

of this part, including, but not limited to the ability to impose intermediate sanctions, civil money penalties, and terminate a contract with a Part D plan sponsor.

Subpart F—Submission of Bids and Monthly Beneficiary Premiums: Plan Approval

70. Section 423.265 is amended by revising paragraph (b) to read as follows:

§ 423.265 Submission of bids and related information.

* * * * *

(b) *Bid submission.* (1) General. Not later than the first Monday in June, each potential Part D sponsor must submit bids and supplemental information described in this section for each Part D plan it intends to offer in the subsequent calendar year.

(2) *Substantial differences between bids.* Potential Part D sponsors' bid submissions must reflect differences in benefit packages and plan costs that CMS determines to represent substantial differences relative to a sponsor's other bid submissions. In order to be considered "substantially different," each bid must be significantly different from the sponsor's other bids with respect to beneficiary out-of-pocket costs and formulary structures.

* * * * *

71. Section 423.272 is amended by adding a new paragraph (b)(3) to read as follows:

§ 423.272 Review and negotiation of bid and approval of plans submitted by potential Part D sponsors.

* * * * *

(b) * * *

(3) *Substantial differences between bids—(i) General.* CMS approves a bid only if it finds that the benefit package and plan costs represented by that bid are substantially different as provided under § 423.265 (b)(2) of this subpart from the benefit package represented by another bid submitted by the same Part D sponsor.

(ii) *Transition period for PDP sponsors with new acquisitions.* After a 2-year transition period, as determined by CMS, CMS approves a bid offered by a PDP sponsor (or by a parent organization to that PDP sponsor) that recently purchased (or otherwise acquired or merged with) another Part D sponsor if it finds that the benefit package and plan costs represented by that bid are substantially different from any benefit package and plan costs represented by another bid submitted by the same Part D sponsor (or parent organization to that Part D sponsor).

* * * * *

Subpart G—Payments to Part D Plan Sponsors for Qualified Prescription Drug Coverage

§ 423.308 [Amended]

72. Section 423.308 is amended in paragraph (1) of the definition of "gross covered prescription drug costs" by removing the phrase "The share of negotiated prices" and adding in its place "The share of actual costs".

Subpart J—Coordination Under Part D Plans With Other Prescription Drug Coverage

73. Section 423.462 is amended by—
A. Redesignating the existing text as paragraph (a).

B. Adding a paragraph heading for paragraph (a) and new paragraph (b).
The additions read as follows:

§ 423.462 Medicare secondary payer procedures.

* * * * *

(a) *General rule.* * * *

(b) *Reporting requirements.* A Part D sponsor must report credible new or changed primary payer information to the CMS Coordination of Benefits Contractor in accordance with the processes and timeframes specified by CMS.

74. Section 423.464 is amended by adding new paragraphs (a)(3), (e)(1)(vi), and (g) to read as follows:

§ 423.464 Coordination of benefits with other providers of prescription drug coverage.

(a) * * *

(3) Retroactive claims adjustments, underpayment reimbursements, and overpayment recoveries as described in paragraph (g) of this section and § 423.466(a) of this subpart.

* * * * *

(e) * * *

(1) * * *

(vi) Does not engage in midyear plan or noncalendar year plan enrollment changes on behalf of a substantial number of its members when authorized to do so on the beneficiary's behalf.

* * * * *

(g) *Responsibility to account for other providers of prescription drug coverage when a retroactive claims adjustment creates an overpayment or underpayment.* When a Part D sponsor makes a retroactive claims adjustment, the sponsor has the responsibility to account for SPAPs and other entities providing prescription drug coverage in reconciling the claims adjustments that create overpayments or underpayments. In carrying out these reimbursements and recoveries, Part D sponsors must also account for payments made, and for

amounts being held for payment, by other individuals or entities. Part D sponsors must have systems to track and report adjustment transactions and to support all of the following:

(1) Adjustments involving payments by other plans and programs providing prescription drug coverage have been made.

(2) Reimbursements for excess cost-sharing and premiums for low-income subsidy eligible individuals have been processed in accordance with the requirements in § 423.800(c).

(3) Recoveries of erroneous payments for enrollees as specified in § 423.464(f)(4) have been sought.

75. A new § 423.466 is added to subpart J to read as follows:

§ 423.466 Timeframes for coordination of benefits.

(a) *Retroactive claims adjustments, underpayment refunds, and overpayment recoveries.* Whenever a sponsor receives information that necessitates a retroactive claims adjustment, the sponsor must process the adjustment and issue refunds or recovery notices within 45 days of the sponsor's receipt of complete information regarding claims adjustment.

(b) *Coordination of benefits.* Part D sponsors must coordinate benefits with SPAPs, other entities providing prescription drug coverage, beneficiaries, and others paying on the beneficiaries' behalf for a period not to exceed 3 years from the date on which the prescription for a covered Part D drug was filled.

Subpart K—Application Procedures and Contracts With PDP Sponsors

76. Section 423.502 is amended by—
A. Redesignating paragraphs (b) through (d) as (c) through (e), respectively

B. Adding a new paragraph (b).

C. Revising newly redesignated paragraph (c)(1) introductory text and paragraph (c)(2).

The addition and revisions reads as follows:

§ 423.502 Application requirements.

* * * * *

(b) *Completion of a notice of intent to apply.*

(1) An organization submitting an application under this section for a particular contract year must first submit a completed Notice of Intent to Apply by the date established by CMS. CMS will not accept applications from organizations that do not submit a timely Notice of Intent to Apply.

(2) Submitting a Notice of Intent to Apply does not bind that organization to submit an application for the applicable contract year.

(c) * * *

(1) In order to obtain a determination on whether it meets the requirements to become a Part D plan sponsor, an entity, or an individual authorized to act for the entity (the applicant), must fully complete all parts of a certified application in the form and manner required by CMS, including the following:

* * * * *

(2) The authorized individual must describe thoroughly how the entity is qualified to meet the all requirements described in this part.

* * * * *

77. Section 423.503 is amended by—
A. Revising paragraphs (a)(1), (a)(2), and (b).

B. Adding a new paragraph (c)(2)(iii).

C. Revising paragraph (c)(3)(iii).

D. Removing paragraph (d).

The revisions and addition read as follows:

§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.

* * * * *

(a) * * *

(1) With the exception of evaluations conducted under paragraph (b) of this section, CMS evaluates an entity's application solely on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits.

(2) After evaluating all relevant information, CMS determines whether the application meets all the requirements described in this part.

(b) *Use of information from a current or prior contract.* If a Part D plan sponsor fails during the 14 months preceding the deadline established by CMS for the submission of contract qualification applications (or in the case of a fallback entity, the previous 3-year contract) to comply with the requirements of the Part D program under any current or prior contract with CMS under title XVIII of the Act or fails to complete a corrective action plan during the 14 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application based on the applicant's failure to comply with the requirements of the Part D program under any current or prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(c) * * *

(2) * * *

(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 the applicant does not appear qualified to contract as a Part D plan sponsor or has not provided enough information to allow CMS to evaluate the application, CMS denies the application.

(3) * * *

(iii) The applicant's right to request a hearing in accordance with the procedures specified in subpart N of this part.

78. Section 423.504 is amended by—

A. Revising paragraph (b)(4)(vi).

B. Redesignating paragraph (b)(6) as paragraph (b)(7).

C. Adding a new paragraph (b)(6).

The revisions and addition read as follows:

§ 423.504 General provisions.

* * * * *

(b) * * *

(4) * * *

(vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct noncompliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements:

(A) Written policies, procedures, and standards of conduct that—

(1) Articulate the Part D plan sponsor's commitment to comply with all applicable Federal and State standards;

(2) Describe compliance expectations as embodied in the standards of conduct;

(3) Implement the operation of the compliance program;

(4) Provide guidance to employees and others on dealing with potential compliance issues;

(5) Identify how to communicate compliance issues to appropriate compliance personnel;

(6) Describe how potential compliance issues are investigated and resolved by the Part D plan sponsor; and

(7) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.

(B) The designation of a compliance officer and a compliance committee

who report directly to the Part D plan sponsor's chief executive or other senior administrator.

(1) The compliance officer, vested with the day-to-day operations of the compliance program, must be an employee of the Part D plan sponsor.

(2) The compliance officer and the compliance committee must periodically report directly to the governing body of the Part D plan sponsor on the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.

(3) The governing body of the Part D plan sponsor must be knowledgeable about the content and operation of the compliance program and must exercise reasonable oversight with respect to the implementation and effectiveness of the compliance programs.

(C)(1) Each Part D plan sponsor must establish, implement and provide effective training and education for its employees including, the chief executive and senior administrators or managers; governing body members; and first tier, downstream, and related entities.

(2) The training and education must occur at a least annually and be a part of the orientation for new employees including, the chief executive and senior administrators or managers; governing body members; and first tier, downstream, and related entities.

(D) Establishment and implementation of effective lines of communication, ensuring confidentiality, between the compliance officer, members of the compliance committee, the Part D plan sponsor's employees, managers and governing body, and the Part D plan sponsor's first tier, downstream, and related entities. Such lines of communication must be accessible to all and allow compliance issues to be reported including a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified.

(E) Well-publicized disciplinary standards through the implementation of procedures which encourage good faith participation in the compliance program by all affected individuals. These standards must include policies that—

(1) Articulate expectations for reporting compliance issues and assist in their resolution;

(2) Identify non-compliance or unethical behavior; and

(3) Provide for timely, consistent, and effective enforcement of the standards when non-compliance or unethical behavior is determined.

(F) Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the Part D plan sponsors, including first tier entities', compliance with CMS requirements and the overall effectiveness of the compliance program.

(G) Establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.

* * * * *

(6) Not have terminated a contract by mutual consent under which, as a condition of the consent, the Part D plan sponsor agreed that it was not eligible to apply for new contracts or service area expansions for a period up to 2 years per § 423.508(e) of this subpart.

* * * * *

79. Section 423.505 is amended by—

A. Redesignating paragraph (e)(1)(ii) and (e)(1)(iii) as paragraph (e)(1)(iii) and (e)(1)(iv), respectively.

B. Adding a new paragraph (e)(1)(ii).

C. Revising newly redesignated paragraph (e)(1)(iii).

D. Revising paragraph (f)(3) introductory text.

E. Revising paragraphs (i)(2)(i) and (m)(1)(iii)(C).

F. Add a new paragraph (n).

The additions and revisions read as follows:

§ 423.505 Contract provisions.

* * * * *

(e) * * *

(1) * * *

(ii) Compliance with CMS requirements for maintaining the privacy and security of personal health information and other personally identifiable information of Medicare enrollees;

(iii) The facilities of the Part D sponsor to include computer and other electronic systems; and

* * * * *

(f) * * *

(3) All data elements included in all its drug claims for purposes deemed necessary and appropriate by the Secretary, including, but not limited to the following:

* * * * *

(i) * * *

(2) * * *

(i) HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, computer or other electronic systems, including medical records and documentation of the first tier, downstream, and related to CMS' contract with the Part D sponsor.

* * * * *

(m)(1) * * *

(iii) * * *

(C) Plan identifier elements on the claim are encrypted or unavailable for release to external entities with the exception of HHS grantees that CMS determines meet all of the following criteria:

(1) The plan identifier is essential to the study.

(2) The study is key to the mission of the sponsoring agency.

(3) The study provides significant benefit to the Medicare program.

(4) The requestor attests that any public findings or publications will not identify plans.

* * * * *

(n)(1) CMS may determine that a Part D plan sponsor is out of compliance with a Part D requirement when the sponsor fails to meet performance standards articulated in the Part D statutes, regulations, or guidance.

(2) If CMS has not already articulated a measure for determining noncompliance, CMS may determine that a Part D sponsor is out of compliance when its performance represents an outlier relative to the performance of other Part D sponsors.

80. Section 423.507 is amended by—

A. Revising paragraph (a)(2)(ii).

B. Removing paragraph (a)(2)(iii).

C. Adding a new paragraph (b)(1)(iii).

D. Revising paragraph (b)(2)(ii).

E. Removing (b)(2)(iii).

F. Redesignating paragraph (b)(2)(iv) as (b)(2)(iii).

G. In newly redesignated paragraph (b)(2)(iii), removing the reference "paragraphs (b)(2)(ii) and (iii) of this section" and add the reference "paragraph (b)(2)(ii) of this section" in its place.

H. Revising paragraph (b)(3).

The revisions and addition read as follows:

§ 423.507 Nonrenewal of a contract.

(a) * * *

(2) * * *

(ii) Each Medicare enrollee by mail at least 90 calendar days before the date on which the nonrenewal is effective. The sponsor must also provide information about alternative enrollment options by doing one or more of the following:

(A) Provide a CMS approved written description of alternative PDP plan options available for obtaining qualified prescription drug coverage within the beneficiaries' region.

(B) Place outbound calls to all affected enrollees to ensure beneficiaries know who to contact to learn about their enrollment options.

* * * * *

(b) * * *

(1) * * *

(iii) The contract must be nonrenewed as to an individual PDP if that plan does not have a sufficient number of enrollees to establish that it is a viable independent plan option.

(2) * * *

(ii) To each of the Part D plan sponsor's Medicare enrollees by mail at least 90 calendar days before the date on which the nonrenewal is effective, or at the conclusion of the appeals process if applicable.

* * * * *

(3) *Opportunity to develop and implement a corrective action plan.* (i)

Before providing a notice of intent of nonrenewal of the contract, CMS will provide the Part D plan sponsor with a notice specifying the deficiencies and reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that form the basis for the determination to non-renew the contract.

(ii) CMS affords the Part D plan sponsor at least 30 calendar days in which to develop and implement a corrective action plan to correct the deficiencies that formed the basis for the determination to nonrenew the contract.

(iii) The Part D plan sponsor is solely responsible for the identification, development, and implementation of its corrective action plan and for demonstrating to CMS that the underlying deficiencies have been corrected within the time period specified by CMS in the notice requesting corrective action.

* * * * *

81. Section 423.508 is amended by adding a new paragraph (e) to read as follows:

§ 423.508 Modification or termination of contract by mutual consent.

* * * * *

(e) *Agreement to limit new Part D applications.* As a condition of the consent to a mutual termination, CMS will require, as a provision of the termination agreement language prohibiting the Part D plan sponsor from applying for new contracts or service area expansions for a period up to 2 years, absent circumstances warranting special consideration.

82. Amend § 423.509 by revising paragraphs (a), introductory text of paragraph (b), (b)(2), and (c) to read as follows:

§ 423.509 Termination of contract by CMS.

(a) *Termination by CMS.*

(1) CMS may at any time terminate a contract if CMS determines that the Part D plan sponsor meets any of the following:

(i) Has failed substantially to carry out the contract.

(ii) Is carrying out the contract in a manner that is inconsistent with the efficient and effective administration of this part.

(iii) No longer substantially meets the applicable conditions of this part.

(2) CMS may determine, in accordance with paragraph (a)(1) of this section, that a basis exists to terminate a Part D sponsor's contract if—

(i) The Part D plan sponsor fails to comply with any of the regulatory requirements contained in this part.

(ii) The Part D plan sponsor fails to meet CMS performance requirements in carrying out the regulatory requirements contained in this part, including, but not limited to, when CMS determines that an analysis of data related to the sponsor's performance indicates it is an outlier relative to that of other sponsors; or

(iii) There is credible evidence to show that the Part D plan sponsor has committed or participated in false, fraudulent, or abusive activities affecting the Medicare, Medicaid, or other State or Federal health care programs, including submission of false or fraudulent data.

(b) *Notice.* If CMS decides to terminate a contract it gives notice of the termination as follows:

* * * * *

(2) *Expedited termination of contract by CMS.* (i) If CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the Part D plan sponsor the effective date of termination will be specified, in writing, by CMS.

(ii) If a termination is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the Part D plan sponsor covering the period of the month following the contract termination.

* * * * *

(c) *Opportunity to develop and implement a corrective action plan.*

(1) *General.* (i) Before providing a notice of intent to terminate the contract, CMS will provide the Part D plan sponsor with a notice specifying the deficiencies and reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that form the basis for the determination to terminate the contract.

(ii) CMS will afford the Part D plan sponsor at least 30 calendar days in which to develop and implement a corrective action plan to correct the deficiencies that formed the basis for the determination to terminate the contract.

(iii) The Part D plan sponsor is solely responsible for the identification, development, and implementation of its corrective action plan and for demonstrating to CMS that the underlying deficiencies have been corrected within the time period specified by CMS in the notice requesting corrective action.

(2) *Exceptions.* If CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the Part D plan sponsor, the Part D plan sponsor will not be provided with an opportunity to develop and implement a corrective action plan prior to termination.

* * * * *

83. Section 423.514 is amended by—

A. Revising the section heading.

B. Adding a new paragraph (g).

The revision and addition to read as follows:

§ 423.514 Validation of Part D reporting requirements.

* * * * *

(g) *Data validation.* Each Part D sponsor must subject information collected under paragraph (a) of this section to a yearly independent audit to determine its reliability, validity, completeness, and comparability in accordance with specifications developed by CMS.

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

84. Section 423.551 is amended by adding a new paragraph (g) to read as follows:

§ 423.551 General provisions.

* * * * *

(g) *Sale of beneficiaries not permitted.*

(1) CMS will only recognize the sale or transfer of an organization's entire PDP line of business, consisting of all PDP contracts held by the PDP sponsor.

(2) CMS will not recognize or allow a sale or transfer that consists solely of the sale or transfer of individual beneficiaries, groups of beneficiaries enrolled in a pharmacy benefit package, or one contract if the sponsor holds more than one PDP contract.

Subpart M—Grievances, Coverage Determinations, and Appeals

85. Section 423.568 is revised to read as follows:

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

(a) *Method and place for filing a request.* An enrollee must ask for a standard coverage determination by making a request with the Part D plan sponsor in accordance with the following:

(1) Except as specified in paragraph (a)(2) of this section, the request may be made orally or in writing.

(2) Requests for payment must be made in writing (unless the Part D plan sponsor has implemented a voluntary policy of accepting oral payment requests).

(b) *Timeframe for requests for drug benefits.* When a party makes a request for a drug benefit, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request, or, for an exceptions request, the physician's or other prescriber's supporting statement.

(c) *Timeframe for requests for payment.* When a party makes a request for payment, the Part D plan sponsor must notify the enrollee of its determination and make payment (when applicable) no later than 14 calendar days after receipt of the request.

(d) *Written notice for favorable decisions by a Part D plan sponsor.* If a Part D plan sponsor makes a completely favorable decision under paragraph (b) of this section, it must give the enrollee written notice of the determination. The initial notice may be provided orally, so long as a written follow-up notice is sent within 3 calendar days of the oral notification.

(e) *Form and content of the approval notice.* The notice of any approval under paragraph (d) of this section must explain the conditions of the approval in a readable and understandable form.

(f) *Written notice for denials by a Part D plan sponsor.* If a Part D plan sponsor decides to deny a drug benefit, in whole or in part, it must give the enrollee written notice of the determination.

(g) *Form and content of the denial notice.* The notice of any denial under paragraph (f) of this section must meet the following requirements:

(1) Use approved notice language in a readable and understandable form.

(2) State the specific reasons for the denial.

(i) For drug coverage denials, describe both the standard and expedited redetermination processes, including the enrollee's right to, and conditions for, obtaining an expedited redetermination and the rest of the appeals process.

(ii) For payment denials, describe the standard redetermination process and the rest of the appeals process.

(3) Inform the enrollee of his or her right to a redetermination.

(4) Comply with any other notice requirements specified by CMS.

(h) *Effect of failure to meet the adjudicatory timeframes.* If the Part D plan sponsor fails to notify the enrollee of its determination in the appropriate timeframe under paragraphs (b) or (c) of this section, the failure constitutes an adverse coverage determination, and the plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

86. Section 423.570 is amended by revising paragraph (d)(1) to read as follows:

§ 423.570 Expediting certain coverage determinations.

* * * * *

(d) * * *

(1) Make the determination within the 72 hour timeframe established in § 423.568(b) for a standard determination. The 72 hour period begins on the day the Part D plan sponsor receives the request for expedited determination, or, for an exceptions request, the physician's or other prescriber's supporting statement.

* * * * *

87. Section 423.572 is amended by revising paragraphs (b) and (c) to read as follows:

§ 423.572 Timeframes and notice requirements for expedited coverage determinations.

* * * * *

(b) *Confirmation of oral notice.* If the Part D plan sponsor first notifies an enrollee of an adverse or favorable expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(c) *Content of the notice of expedited determination.* (1) If the determination is completely favorable to the enrollee,

the notice must explain the conditions of the approval in a readable and understandable form.

(2) If the determination is not completely favorable to the enrollee, the notice must—

(i) Use approved language in a readable and understandable form;

(ii) State the specific reasons for the denial;

(iii) Inform the enrollee of his or her right to a redetermination;

(iv) Describe—

(A) Both the standard and expedited redetermination processes, including the enrollee's right to request an expedited redetermination;

(B) Conditions for obtaining an expedited redetermination; and

(C) Other aspects of the appeal process.

* * * * *

88. Section 423.590 is amended by—

A. Redesignating paragraph (d)(2) as paragraph (d)(3).

B. Adding a new paragraph (d)(2).

C. Revising the introductory text of paragraph (g).

D. Adding a new paragraph (h).

The revisions and additions read as follows:

§ 423.590 Timeframes and responsibility for making redeterminations.

* * * * *

(d) * * *

(2) *Confirmation of oral notice.* If the Part D plan sponsor first notifies an enrollee of an adverse or favorable expedited redetermination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

* * * * *

(g) *Form and content of an adverse redetermination notice.* The notice of any adverse determination under paragraphs (a)(2), (b)(2), (d)(1) or (d)(2) of this section must—

* * * * *

(h) *Form and content of a completely favorable redetermination notice.* The notice of any completely favorable determination under paragraphs (a)(1), (d)(1) or (d)(2) of this section must explain the conditions of the approval in a readable and understandable form.

Subpart N—Medicare Contract Determinations and Appeals

89. Section 423.642 is amended by revising paragraph (c) to read as follows:

§ 423.642 Notice of contract determination.

* * * * *

(c) *CMS-initiated terminations—(1) General rule.* CMS mails notice to the Part D plan sponsor 90 calendar days

before the anticipated effective date of the termination.

(2) *Exception.* For terminations where CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the Part D plan sponsor, CMS notifies the Part D plan sponsor of the date that it will terminate the Part D plan sponsor's contract.

* * * * *

90. Section 423.650 is revised to read as follows:

§ 423.650 Right to a hearing, burden of proof, standard of proof, and standards of review.

(a) *Right to a hearing.* The following parties are entitled to a hearing:

(1) A contract applicant that has been determined to be unqualified to enter into a contract with CMS under Part D of Title XVIII of the Act in accordance with § 423.502 and § 423.503 of this part.

(2) A Part D sponsor whose contract has been terminated under § 423.509 of this part.

(3) A Part D sponsor whose contract has not been renewed in accordance with § 423.507 of this part.

(4) A Part D sponsor who has had an intermediate sanction imposed in accordance with § 423.752(a) and (b) of this part.

(b) *Burden of proof, standard of proof, and standard of review at hearing.*

(1) During a hearing to review a contract determination as described at § 423.641(a) 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 § 423.502 and § 423.503 of this part.

(2) During a hearing to review a contract determination as described at § 423.641(b) of this part, the Part D plan sponsor has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 423.507 of this part.

(3) During a hearing to review a contract determination as described at § 423.641(c) of this subpart, the Part D plan sponsor has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 423.509 of this part.

(4) During a hearing to review the imposition of an intermediate sanction as described at § 423.750 of this part, the Part D sponsor has the burden of proving by a preponderance of the

evidence that CMS' determination was inconsistent with the requirements of § 423.752 of this part.

(c) Timing of favorable decision. Notice of any decision favorable to the Part D sponsor appealing a determination that it is not qualified to enter into a contract with CMS must be issued by September 1 for the contract in question to be effective on January 1 of the following year.

* * * * *

91. Section 423.651 is amended by revising paragraphs (a) and (b) to read as follows:

§ 423.651 Request for hearing.

(a) *Method and place for filing a request.* (1) A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or Part D plan sponsor that was the party to the determination under the appeal.

(2) The request for the hearing must be filed in accordance with the requirements specified in the notice.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 calendar days after the receipt of the notice of the contract determination or intermediate sanction.

* * * * *

92. Section 423.652 is amended by revising paragraph (b)(2) to read as follows:

§ 423.652 Postponement of effective date of a contract determination when a request for a hearing is filed timely.

* * * * *

(b) * * *

(2) If CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of individuals enrolled with the Part D plan sponsor, the date of termination will not be postponed if the Part D plan sponsor requests a hearing.

* * * * *

93. Section 423.655 is revised to read as follows:

§ 423.655 Time and place of hearing.

(a) The hearing officer—

(1) Fixes a time and place for the hearing, which is not to exceed 30 calendar days after the receipt of request for the hearing;

(2) Sends written notice to the parties that informs the parties of the general and specific issues to be resolved, the burden of proof, and information about the hearing procedure.

(b)(1) The hearing officer may, on his or her own motion, change the time and place of the hearing.

(2) The hearing officer may adjourn or postpone the hearing.

(c)(1) The Part D plan sponsor or CMS may request an extension by filing a written request no later than 5 calendar days prior to the scheduled hearing.

(2) When either the Part D plan sponsor or CMS requests an extension the hearing officer will provide a one-time 15-calendar day extension.

(3) Additional extensions may be granted at the discretion of the hearing officer.

94. Section 423.658 is amended by revising paragraph (d) to read as follows:

§ 423.658 Conduct of hearing.

* * * * *

(d) The Part D sponsor bears the burden of going forward and must first present evidence and argument before CMS presents its evidence and argument.

95. Section 423.661 is revised to read as follows:

§ 423.661 Witnesses lists and documents.

Witness lists and documents must be identified and exchanged at least 5 calendar days prior to the scheduled hearing.

96. Section 423.666 is amended by revising paragraphs (a) and (c) to read as follows:

§ 423.666 Review by the Administrator.

(a) *Request for review by Administrator.* CMS or a Part D plan sponsor that has received a hearing decision may request a review by the Administrator within 15 calendar days after receipt of the hearing decision as provided under § 423.665(b) of this subpart. Both the Part D plan sponsor and CMS may provide written arguments to the Administrator for review.

* * * * *

(c) *Notification of Administrator determination.* The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days after receipt of request for review. If the Administrator declines to review the hearing decision or the Administrator does not make a determination regarding review within 30 calendar days, the decision of the hearing officer is final.

* * * * *

97. Section 423.668 is amended by revising the section heading and the paragraph heading for paragraph (a) to read as follows:

§ 423.668 Reopening of a contract determination or decision of a hearing officer or the Administrator.

(a) *Contract determination.* * * *

* * * * *

Subpart O—Intermediate Sanctions

98. Section 423.750 is amended by revising paragraph (a) to read as follows:

§ 423.750 Types of intermediate sanctions and civil money penalties.

(a) The following intermediate sanctions may be imposed and will continue in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur:

(1) Suspension of the Part D plan sponsor's enrollment of Medicare beneficiaries.

(2) Suspension of payment to the Part D plan sponsor for Medicare beneficiaries enrolled after the date CMS notifies the organization of the intermediate sanction.

(3) Suspension of all marketing activities to Medicare beneficiaries by a Part D plan sponsor.

* * * * *

99. Section 423.752 is amended by—

A. Revising the paragraphs (a) introductory text, (a)(1), (a)(3), and (a)(4).

B. In paragraph (c)(1), removing the cross-reference “423.509(a)(4)” and adding the cross-reference “§ 422.509(a)(2)(iii) of this part” in its place.

C. In paragraph (c)(2)(ii), removing the phrase “pursuant to 423.509(a)(4)” and adding the phrase “under § 422.509(a)(2)(iii) of this part” in its place.

§ 423.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) *All intermediate sanctions.* For the violations listed in this paragraph (a), CMS may impose one or more of the sanctions specified in § 423.750(a) of this subpart on any Part D plan sponsor with a contract. The Part D plan sponsor may also be subject to other remedies authorized under law.

(1) Fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has the substantial likelihood of adversely affecting) the individual.

* * * * *

(3) Acts to expel or refuses to re-enroll a beneficiary in violation of the provisions of this part.

(4) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services.

* * * * *

100. Section 423.756 is amended by—

- A. Revising paragraph (b).
B. Removing paragraph (c).
C. Redesignating paragraphs (d) through (f) as paragraphs (c) through (e), respectively.

D. Revising the newly redesignated paragraphs (c)(1) and (c)(3).

The revisions read as follows:

§ 423.756 Procedures for imposing intermediate sanctions and civil money penalties.

(b) Hearing. (1) The Part D plan sponsor may request a hearing before a CMS hearing officer.

(2) A written request must be received by the designated CMS office within 15 calendar days after the receipt of the notice.

(3) A request for a hearing under § 423.650 of this part does not delay the date specified by CMS when the sanction becomes effective.

(4) The Part D plan sponsor must follow the right to a hearing procedure as specified at § 423.650 through § 423.662 of this part.

(c) * * *

(1) Effective date. The effective date of the sanction is the date specified by CMS in the notice.

* * * * *

(3) Duration of sanction. The sanction remains in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur.

(i) CMS may require that the Part D plan sponsor hire an independent auditor to provide CMS with additional information to determine if the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur. The independent auditor must work in accordance with CMS specifications and must be willing to attest that a complete and full independent review has been performed.

(ii) In instances where marketing or enrollment or both intermediate sanctions have been imposed, CMS may require a Part D plan sponsor to market or to accept enrollments or both for a limited period of time in order to assist CMS in making a determination as to whether the deficiencies that were the bases for the intermediate sanctions

have been corrected and are not likely to recur.

(A) If, following this time period, CMS determines the deficiencies have not been corrected or are likely to recur, the intermediate sanctions will remain in effect until such time that CMS is assured the deficiencies have been corrected and are not likely to recur.

(B) The Part D plan sponsor does not have a right to a hearing under § 423.650(a)(4) of this subpart to challenge CMS' determination to keep the intermediate sanctions in effect.

* * * * *

Subpart P—Premium and Cost-Sharing Subsidies for Low-Income Individuals

101. Section 423.773 is amended by revising paragraph (c)(2) to read as follows:

§ 423.773 Requirements for eligibility.

* * * * *

(c) * * *

(2) CMS notifies an individual treated as a full-subsidy eligible under this paragraph (c) that he or she does not need to apply for the subsidies under this subpart, and, at a minimum, is deemed eligible for a full subsidy as follows:

(i) For an individual deemed eligible between January 1 and June 30 of a calendar year, the individual is deemed eligible for a full subsidy for the remainder of the calendar year.

(ii) For an individual deemed eligible between July 1 and December 31 of a calendar year, the individual is deemed eligible for the remainder of the calendar year and the following calendar year.

* * * * *

Subpart V—Part D Marketing Requirements

102. Section 423.2260 is amended by revising paragraph (5)(vii) of the definition "Marketing materials" to read as follows:

§ 423.2260 Definitions concerning marketing materials.

* * * * *

Marketing materials. * * *

(5) * * *

(vii) Membership activities. Current enrollee communication materials include any informational materials that are—

(A) Targeted to current enrollees, and
(B) Customized or limited to a subset of enrollees or apply to a specific situation; or

(C) Cover claims processing or other operational issues.

* * * * *

103. Section 423.2262 is amended by—

- A. Revising paragraph (a)(1)(i).
B. Adding new paragraphs (c) and (d) to read as follows:

§ 423.2262 Review and distribution of marketing materials.

* * * * *

(a) * * *

(1) * * *

(i) At least 45 days (or 10 days if using certain types of marketing materials that use, without modification, proposed model language and format, including standardized language and formatting, as specified by CMS) before the date of distribution, the Part D sponsor submits the material or form to CMS for review under the guidelines in § 423.2264 of this subpart; and

* * * * *

(c) Standardized model marketing materials. When specified by CMS, organizations must use standardized formats and language in model materials.

(d) Current enrollee communication materials. Current enrollee communication materials may be reviewed by CMS, which may upon review determine that such materials must be modified, or may not longer be used.

PART 480—ACQUISITION, PROTECTION, AND DISCLOSURE QUALITY IMPROVEMENT ORGANIZATION REVIEW INFORMATION

104. The authority citation for part 480 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

105. Section 480.140 is amended by adding a new paragraph (g) to read as follows.

§ 480.140 Disclosure of quality review study information.

* * * * *

(g) The QIO must disclose quality review study information with identifiers of MA plan beneficiaries, providers, practitioners, and services to CMS when CMS requests this information for the sole purpose of conducting activities related to MA organizations as described in § 422.153 of this chapter.

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

Dated: August 13, 2009.

Charlene Frizzera,

*Acting Administrator, Centers for Medicare
& Medicaid Services.*

Approved: September 1, 2009.

Kathleen Sebelius,

Secretary.

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