

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, 423, and 480

[CMS-4085-F]

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: Final rule.

SUMMARY: This final rule makes revisions to the regulations governing 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 revisions strengthen various program participation and exit requirements; strengthen beneficiary protections; ensure that plan offerings to beneficiaries include meaningful differences; improve plan payment rules and processes; improve data collection for oversight and quality assessment, implement new policies and clarify existing program policy.

DATES: *Effective Date:* These regulations are effective on June 7, 2010. However, we note that because health and drug plans under the Part C and D programs operate under contracts with CMS that are applicable on a calendar year basis, the provisions will not be applicable prior to contract year January 1, 2011, except where otherwise noted.

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- AO Accrediting Organization
 ADS Dispensing System
 AEP Annual Enrollment Period
 AHFS American Hospital Formulary Service
 AHFS-DI American Hospital Formulary Service—Drug Information
 AHRQ Agency for Health Care Research and Quality
 ALJ Administrative Law Judge
 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
 CCS Certified Coding Specialist
 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
 CPC Certified Professional Coder
 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 General Accounting Office
 HCPCP 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
 IVC Initial Validation Contractor
 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
 PPACA Patient Protection and Affordable Care Act (Pub. L. 111-148)
 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
 RADV Risk Adjustment Data Validation
 RAPS Risk Adjustment Payment System
 RHIA Registered Health Information Administrator
 RHIT Registered Health Information Technician
 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

SUPPLEMENTARY INFORMATION:

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.

Generally, the provisions enacted in the MMA took effect 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). While the provisions of the final rule did not govern plan payment or benefits until January 1, 2006, given the fact that provisions relating to applications, marketing, contracts, and the new bidding process for the MA and Part D programs, many provisions in these final rules became effective on March

22, 2005, 60 days after publication of the rule.

As we have gained experience with the MA program and the prescription drug benefit program, we periodically 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).

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 discussed above, the MMA, enacted on December 8, 2003, added a new "Part D" to the Medicare statute (sections 1860D-1 through 42 of the Act) creating the Medicare Prescription Drug Benefit Program, and made significant changes to the M+C program.

Also as noted above, MIPPA, enacted on July 15, 2008, addressed a number of provisions impacting the Part C and D programs, including provisions impacting marketing under both programs which were implemented in regulations published in the **Federal Register** on September 18, 2008 (73 FR 54208), a final rule effective October 1, 2008, that paralleled provisions in MIPPA, and in the same issue of the **Federal Register** (73 FR 54226), 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).

In October 22, 2009 **Federal Register** (74 FR 54634), we published a proposed rule (file code CMS-4085-P), hereinafter referred to as the October 22, 2009 proposed rule) addressing additional policy clarifications under the Part C and D programs. As noted when issuing this proposed rule, we believe that additional programmatic and operational changes 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.

Indeed, one of the primary reasons set forth in the preamble for issuing the October 22, 2009 proposed rule was to address beneficiary concerns associated with the annual task of selecting one plan from so many options. We noted that while it is clear that 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, some have suggested that a significant numbers of beneficiaries are confused by the array of choices and find it difficult to make enrollment decisions that are best for them. Moreover, experience has shown that organizations submitting bids under Part C and D to offer multiple plans have not consistently submitted plan benefit designs that were significantly different from each other, which can add to beneficiary confusion. In this rule, we finalize a number of proposals to the way we administer the Part C and D programs to promote beneficiaries making the best plan choice that suits their needs. Although we believe these provisions will go a long way to further that goal, we are committed to additional explorations of ways to

structure choices for seniors to aid them in making better plan choices, and will continue to evaluate program changes in this area.

We also proposed additional provisions aimed at strengthening existing beneficiary protections, improving payment rules and processes, enhancing our ability to pursue data collection for oversight and quality assessment, strengthening formulary policy, and finalizing a number of clarifications and technical corrections to existing policy. Except as noted or otherwise modified, we finalize these requirements in this rule.

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances.

This final rule has been published within the 3-year time limit imposed by section 902 of the MMA, and thus is in accordance with the Congress' intent to ensure timely publication of final regulations.

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111-148) was enacted. Several provisions of this public law affect the Part C and D programs. In sections II.B. and II.F. of this final rule, we provide a discussion of the effects of two of these provisions on our proposed policies regarding MA cost sharing and "protected classes" of drugs under Part D, respectively.

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

We received approximately 114 items of timely correspondence containing comments on the October 22, 2009 proposed rule. Commenters included health and drug plan organizations, insurance industry trade groups, pharmacy associations, pharmaceutical benefit manager (PBM) organizations, provider associations, representatives of hospital and long term care institutions, drug manufacturers, mental health and disease specific advocacy groups,

beneficiary advocacy groups, researchers, and others.

In this final rule, we address all timely comments and concerns on the policies included in the proposed rule. We note that there were several comments submitted that were outside the scope of the proposals set forth in the proposed rule and, as such, we do not address them within this final rule. Generally, the commenters supported our efforts to improve plan offerings by the same sponsor that are meaningfully different from each other in order to support improved beneficiary decision making and our efforts to clarify and codify existing policy through rulemaking.

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 finalizes a number of proposed revisions 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. Additionally, 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 set forth below, we are finalizing 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.

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. Clarify programmatic elements that are “deemable”	Subpart C ..	§ 422.112	N/A	N/A.
Procedures for termination and Nonrenewals: Part C and D	Subpart D ..	§ 422.156(b)(7), § 422.156(f).	Subpart D ..	§ 423.165(b), § 423.165(f).
Intermediate Sanctions: procedures for imposing civil and money penalties.	Subpart K ...	§ 422.510(c)(1), § 422.506(b)(3).	Subpart K ...	§ 423.509(c)(1), § 423.507(b)(3).
Contract Termination	Subpart O ..	§ 422.756	Subpart O ..	§ 423.756.
Proper request for hearings	Subpart K ...	§ 422.510(a)	Subpart K ...	§ 423.509(a).
Burden of Proof, Standard of Proof, Standard of Review and Conduct of Hearing.	Subpart N ..	§ 422.662	Subpart N ..	§ 423.651.
Postponement of effective date of determination when a request is being filed.	Subpart N ..	§ 422.660, § 422.676(d).	Subpart N ..	§ 423.650, § 423.658(d).
Extending timeframe for contract determination hearings	Subpart N ..	§ 422.664	Subpart N ..	§ 423.652.
Appeal times: require each party provide witness list and documents 5 calendar days before hearing.	Subpart N ..	§ 422.670	Subpart N ..	§ 423.655.
Appeal times: require request for a review by the administrator must be received with 15 days after receipt of hearing decision.	Subpart N ..	§ 422.682	Subpart N ..	§ 423.661.
Contract redeterminations and reopening	Subpart N ..	§ 422.692(a)	Subpart N ..	§ 423.666(a).
Mutual termination of contract	Subpart N ..	§ 422.692(a) § 422.696	Subpart N ..	§ 423.668.
	Subpart K ...	§ 422.503(b)(6)	Subpart K ...	§ 423.504(b)(6).

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

Under the authority of section 1871(a)(1) of the Act, which authorizes us to prescribe such regulations as may be necessary to carry out the administration of the Medicare program, we proposed an administrative requirement in the October 22, 2009 proposed rule for both the Part C and D programs related to the application submission to qualify as MA and PDP sponsor contractors. We specifically proposed in § 422.501 and § 423.502 to codify our existing guidance that initial applicants and existing contractors seeking to expand complete a nonbinding Notice of Intent to Apply.

We noted that as a result of the fully electronic submission process and restrictions on access to the CMS Health Plan Management System (HPMS), every applicant must complete a Notice of Intent to Apply as described in the HPMS memo dated October 10, 2008. This includes both initial applicants and current contractors seeking to expand their organizations’ service area and current contractors adding a Special Needs Plan (SNP) or an Employer Group/Union-Sponsored Waiver Plan (EGWP) to their existing contract.

We also noted that 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.

In this final rule, we address comments received and finalize this provision with modification. As explained below, we modified § 422.503(b)(2) and § 423.502 (b)(2) to clearly indicate that the decision not to submit an application after submission of a notice of intent will not result in any compliance consequences.

Comment: Several commenters supported this provision.

Response: We appreciate the commenters support of our proposal.

Comment: Some commenters were concerned about the due date of the Notice of Intent to Apply and wanted exceptions to allow CMS the flexibility to accept notice of intent after the due date. Some commenters were particularly concerned about special need plans offered in conjunction with Medicaid. Commenters also urged CMS to provide organizations adequate time to make the decision whether to apply and stated that some organizations may not consider submitting an application at the time notices are due.

Response: As stated in the proposed regulation at § 422.503(b)(2) and § 423.503(b)(2), the Notice of Intent to

Apply does not bind the organization to submit an application. For this reason, we do not believe it is necessary to be flexible with the due date of the notice of intent. Organizations are free to submit a Notice of Intent to Apply and then consider whether or not to submit an application without risking any negative consequences from CMS. We also believe that the notice of intent requirement will benefit applicants as it will serve as a 3-month advance reminder to begin preparation for their submission. We anticipate that the additional lead time will result in more successful applications.

Comment: One commenter questioned whether the three month lead time is necessary, particularly for existing sponsors, to ensure timely connectivity to CMS systems.

Response: Our preparation for the receipt of applications is a process that can take up to 3 months. We encourage interested parties to see the October 2, 2009 HPMS memo for an example of the timeline from submission of the Notice of Intent to Apply to the application submission.

Comment: One commenter wanted CMS to add language indicating that for those notices of intent that do not result in the submission of an application, lack of submission would not be considered as part of any punitive evaluation.

Response: As we stated in the October 2009 proposed rule, the Notice of Intent

to Apply does not bind the organization to submit an application. We want to make clear that the submission of a notice of intent without a subsequent application submission would present no risk of reprimand or sanction by us. For this reason, we are modifying § 422.503(b) and § 423.502 (b) to clearly indicate that the decision not to submit an application after submission of a notice of intent will not result in any compliance consequences.

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)

In the October 2009 proposed rule, we proposed a single clarification that applies to both MA organizations and Part D sponsors related to our application evaluation procedures and appeals of our determinations regarding applications. At § 422.502 and § 423.503, we specifically proposed to make explicit that we will approve only those applications that demonstrate that they meet all (not substantially all) Part C and D program requirements.

We noted that the application process under Part C and D requires an applicant to submit for our review a combination of attestations that it will comply with stated program requirements, as well as submit 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. We proposed at § 422.501(c)(1) and (2), § 422.502(a)(2), § 423.502(c)(1) and (2), and § 423.503(a)(2) to require that applicants demonstrate that they meet all requirements outlined in the MA organization and Part D sponsor applications.

We simplified the application evaluation process under § 422.502(a)(1) and § 423.503(a)(1) by limiting the evaluation of an entity's application to information contained in the application and any additional information that we obtain through onsite visits. As we noted in the proposed rule, limiting our review to this information ensures that we will afford all applicants (numbering in the hundreds each of the last 4 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 also proposed to clarify 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. We clarified § 422.502(c)(2) and § 423.503(c)(2) by proposing to add 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 or has not provided enough information to allow us to evaluate the application, we will deny the application.

Further, we noted that consistent with the revisions to § 422.650(b)(2) and § 423.660(b)(2), which are discussed elsewhere in this final 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. Allowing for such a submission and review of such information as part of the hearing would, in effect, extend the deadline for submitting an approvable application. In this final rule, we adopt these provisions as proposed. *Comment:* A number of commenters expressed support for all areas of this provision.

Response: We appreciate the commenters support of our proposal.

Comment: Many commenters urged CMS to be flexible and allow for unique circumstances. Several commenters noted that SNPs have only limited ability to influence the terms and timelines that State Medicaid agencies follow in executing the SNP agreements.

Response: We design our solicitations to ensure that all organizations have a fair opportunity to demonstrate their qualifications for an MA or PDP contract. As noted in the preamble to the October 2009 proposed rule, allowing exceptions to requirements to address unique circumstances would undermine the need for a uniform application process applied fairly to all applicants. With respect to Medicaid agency contracts, we may require that organizations submit those documents as part of an application to qualify to offer a SNP plan. When we include that requirement in a particular year's SNP application, we have determined that organizations can reasonably be expected to obtain the executed agreements in time for us to determine that it is qualified to operate a SNP during the coming contract year. We do

not anticipate the need to provide any flexibility on this particular matter.

Comment: One commenter stated that the "all" standard is not practical given that there is not a narrative of requirements in the applications, but a series of attestations and tables (with detailed requirements stated in regulations and CMS subregulatory guidance).

Response: We believe the "all" standard is practical. Applicants receive enough information to successfully apply and are given two opportunities with instructions to cure deficiencies. While we advise that applicants should be familiar with Part C and D program regulations and guidance, in most instances they are not required to describe how their organization will meet a requirement; rather they simply attest that they will meet the requirement. Therefore, an explanation of all the program requirements in the application is not necessary for organizations to submit successful Part C or D applications to us.

Comment: Several commenters stated that CMS has been unclear in its previous deficiency responses to applicants and that it has been difficult to obtain guidance from CMS. Commenters urged CMS to provide clear rules and be consistent. In light of the inconsistencies with which applications are reviewed, one commenter recommended using a standard that emphasizes the materiality of the requirements that sponsors must meet.

Response: We agree that in order for applicants to have a consistent understanding of the expectations on which we base our contract approval and denials, we must ensure the clarity and transparency of the program requirements and review criteria. Applicants receive up to three communications which explain our application requirements and provide clear instructions on how to be a successful applicant. Organizations that fail to completely and accurately apply receive a courtesy e-mail explaining the deficiencies and are given an opportunity to cure. Organizations that are still deficient after the initial opportunity to cure receive a notice of intent to deny and are given another opportunity to cure. All application communications include contact information for CMS subject matter specialists. We are always willing to work with applicants to ensure a complete understanding of program and contracting requirements.

Comment: One commenter stated that the applicants that have disagreed with CMS' network adequacy determinations have been reluctant to seek re-

evaluation of their network adequacy in specific counties because of the possibility that CMS will confirm its original finding and deny the entire application. A denial of one county in one state could result in the denial of an entire application. To address this problem, the commenter recommended that CMS revise its policy to provide that an applicant for a network-based plan or service area expansion (SAE) may drop a county or portion of its service area that has been identified in the intent to deny notice after receiving CMS' final decision based upon the additional information submitted by the organization.

Response: We afford sponsors multiple opportunities during the application review process for applicants to modify their proposed service area. However, when we conduct our final review of an application prior to the issuance of a notice of intent to deny, we must make the reasonable assumption, for the sake of consistency, that the applicant seeks approval for its entire proposed service area, not some portion that the applicant will identify at a later date. Therefore, we will not allow applicants to modify their service areas after they have received a final notice of denial of their application from us.

Comment: One commenter recommended that CMS explicitly provide in the regulation for a process to permit applicants to cure deficiencies identified by CMS subsequent to the issuance of the notice of intent to deny; and that if such an opportunity is not provided, CMS should base any denial notice only on issues raised in the notice of intent to deny and not on deficiencies that are identified later in the application review process.

Response: When we have discovered a deficiency after we have issued a notice of intent to deny, we have not disapproved that application based on the failure to correct the new deficiency. Rather, we approve the application (assuming all corrections have been made based on deficiencies identified in the Notice of Intent to Deny), but communicate to the applicant that the newly identified deficiency must be corrected prior to executing a Medicare contract. If the issue is not so corrected, it immediately becomes the subject of a CMS contract compliance action.

Comment: One commenter requested that we clarify the type of information gained via the onsite visits and how this information will be used in evaluation of applications.

Response: We clarify, that we limit our application reviews (with the exception of the past performance

analysis) to the materials organizations submit in response to the annual solicitations. We would also make clear that we retain our authority to conduct site visits to conduct compliance and monitoring activities.

Comment: One commenter noted that it would be beneficial to sponsors if CMS provided a tool that allows sponsors to self-determine network adequacy. The commenter stated that the CMS network adequacy standards are subject to reviewer discretion and stated that this ambiguity is unfair when the sponsor must identify, negotiate, and complete contract terms, sometimes with multiple entities, within a 10-day period.

Response: We have developed standardized network criteria and an automated review process that we will use, starting with the contract year 2011 application cycle, to review network adequacy. Applicants may request exceptions where they do not meet the standardized criteria for individual provider types in individual counties under limited, defined circumstances. We believe these changes will increase the consistency and transparency of network reviews.

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

As described in the existing provisions at § 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. In the October 22, 2009 proposed rule, we proposed to modify these provisions at § 422.502(b) and § 423.503(b) to clarify that we will review past performance across any and all of the contracts held by the applicant, by specifically revising the language 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 clarified that the period that will be examined for past performance problems will 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.

In making these proposed changes, we noted that 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, consistent with the proposed changes to § 422.503(b), § 422.508(c), § 423.504(b), and § 423.508(e), we indicated that the 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) is 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 us throughout the upcoming contract year. In such instances, we noted that we could simply leave the contract in place and take enforcement actions against the organization. However, under such an approach, we would knowingly be permitting beneficiaries to remain enrolled with an organization that cannot effectively deliver the benefit. Instead, we indicated our preference to act in the best interests of the beneficiaries by agreeing with the organization to terminate its contract and work with the organization to make certain that beneficiaries receive uninterrupted access to Medicare services through another MA organization, PDP sponsor, or original Medicare. We are adopting these proposed changes without further modification in this final rule.

Comment: Several commenters expressed their support for our use of the past performance review authority to ensure that underperforming sponsors are not permitted to expand their participation in the Part C and D programs.

Response: We appreciate the commenters' support.

Comment: Several commenters requested that CMS more clearly articulate the methodology it will apply to past performance reviews conducted under this regulatory provision. For example, commenters were interested in knowing the relative weights CMS will

be assigning to different types of compliance actions (such as, corrective action plan requests, warning letters) and whether we will afford organizations the opportunity to correct deficiencies before CMS makes past performance determinations.

Response: We expect to make past performance methodology available through publication in our manuals. We believe that the manuals provide us and sponsors with the best available avenue for providing such detailed information and making updates to it as we continue to gain more experience with conducting past performance analysis. Given that, we note that the information on which we will base our past performance analysis has already been made available to organizations. For example, at any time an organization can review its own record of compliance correspondence received from us to get a sense of the degree to which the organization should be concerned about the likelihood that CMS would deny an application for a new contract.

We believe that questions regarding corrective action opportunities are not relevant to our process for reviewing past performance in making application determinations. The purpose of the past performance review is to determine whether the sponsor has demonstrated, over a 14-month period, whether it has operated its Part C or D contract in a manner that suggests that it is generally meeting and capable of meeting program requirements and that new Medicare business would not jeopardize that status. While some organizations take corrective action to address any and all compliance issues prior to the expiration of the 14-month review period, such corrective action would not change the fact that during that period of time, the organization demonstrated a pattern of noncompliance that may raise questions about its ability to take on new Medicare business.

Comment: Some commenters advised that the 14-month review period is too long, while others stated that a longer period (for example, 3 years) would provide a more comprehensive view of a sponsor's contract performance.

Response: We believe that the 14 month look-back provides an adequate amount of time for us to review an MA organization's or Part D sponsor's performance and the choice of 14 months as the look-back period was not arbitrary. As we noted previously, and in the proposed rule, 14 months covers the period spanning the start of the previous contract year to the time we receive applications for the following contract year. To shorten that time period to, say, 12 months would leave

a gap in our past performance review. Similarly, limiting the period to the 14-month timeframe gives sponsors and organizations the opportunity and incentive to promptly establish a positive compliance track record so that the next CMS past performance review will find them eligible for additional Part C or Part D business.

Comment: Several commenters asked that CMS indicate whether the withdrawal from all or part of a service area, non-renewal of one or more plans (on the Part C or Part D sponsor's initiative), withdrawal of an application or bid, or termination of a contract after it has been executed would be counted against an organization for purposes of past performance analysis.

Response: We would not consider a sponsor-initiated non-renewal of all or a portion of an MA or PDP sponsor contract as an indication of poor contract performance. (However, under separate regulatory authority sponsors that non-renew their contracts may not be permitted to reenter the program for a period of 2 years.) We would treat non-renewed plan benefit packages similarly, assuming the organization had met the Part C or D requirements for providing timely notice to us and our enrollees. We do not consider the withdrawal of an application for qualification as Medicare contractor or of a bid prior to the publication of the annual benchmark calculation as relevant to a performance evaluation.

We do look unfavorably on organizations that withdraw bids after the benchmark has been announced. Also, we consider the termination of a contract for an upcoming benefit year after the organization has executed the contract as a failure to meet Part C and D program requirements. Accordingly, organizations should expect that these occurrences would be considered against them when we evaluate their past contract performance.

Comment: Several commenters offered suggestions on factors CMS should take into consideration when developing and applying our past performance review methodology. These included accounting for distinctions between national and local organizations, beneficiary impact of noncompliance (or lack thereof), unique characteristics of SNP plans, and whether difficulties in an organization's operation of a contract can be attributed to an entire organization or are limited to operation of only one or more of its contracts.

Response: As noted previously, we plan to address issues raised by some of the commenters more fully in guidance issued through our manual update

process. At this time, we can provide a general discussion of some of the principles we intend to apply to the development of our past performance methodology. We are cognizant of the variety of products offered by Medicare contractors, and when an element of our past performance evaluation is affected by the unique feature of a particular plan type, we will adjust the application of our methodology as appropriate. We also want to emphasize that we intend to be conservative in our determinations. We expect to use our authority under this provision to exclude only those organizations demonstrating a pattern of poor performance. Finally, we acknowledge that not all types of noncompliance will be given equal weight, and our methodology will assign weights to different measures based on factors such as beneficiary impact or program stability.

Comment: A number of commenters suggested that CMS provide the results of its past performance analysis prior to the due dates for the submission of notices of intent to apply or for the applications for contract qualification.

Response: We will explore the feasibility of providing a preliminary analysis in response to sponsors' requests. However, we note that such a report would not be final, and in no case would even a preliminary report be available before December of each year.

Comment: A number of commenters requested assurance that the past performance review described previously in this final rule and in the October 2009 proposed rule would not include information concerning a sponsor's performance under contracts other than those governing Medicare managed care and prescription drug plan operations (such as, Medicaid, QIC contracts).

Response: Absent extraordinary circumstances, we plan to limit our past performance review to the operations of organizations in the performance of their Part C and D contracts only.

Comment: One commenter objected to CMS' use of past performance analysis asserting that is equivalent to taking a second punitive action for a single instance of noncompliance.

Response: In this final rule, we are clarifying the scope of our existing authority and we do not believe it is equivalent to an additional compliance or enforcement action taken against any of the organization's existing Medicare contracts. Our denial of an application based on an applicant's past contract performance is a reflection of our belief that an organization demonstrating significant operational difficulties

should focus on improving its existing operations before expanding into new types of plan offerings or additional service areas. Such a determination has no impact, punitive or otherwise, on a sponsor's current Medicare contract rights and obligations.

Comment: One commenter requested that organizations be permitted to attest that they will meet all Part C or D program requirements as of no earlier than January 1 of the upcoming contract year, as organizations are focused on enrollment and readiness activities prior to that date.

Response: This comment concerns an aspect of the Part C and D application and contracting processes unrelated to our exercise of the past performance review authority. Thus, it is outside the scope of our proposal, and we will not address it here.

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)

In the October 22, 2009 proposed rule, we clarified our authority to find organizations or sponsors out of compliance with MA and Part D requirements. We noted that under the authority of Sections 1857(e)(1) and 1860D-12(b)(3)(D) of the Act, the Secretary may 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." Additionally, under that authority, CMS established § 422.516 and § 423.514, which support the submission of Part C and D Reporting Requirements. We clarified that the data acquired through the reporting requirements are often used for the purpose of monitoring an organization's or sponsor's continued compliance with MA and Part D requirements. We also explained that 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.

As part of the proposed rule, we added 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 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. In this final rule, we adopt the provisions as proposed.

Comment: Some commenters supported this provision, specifically the development of consistent performance data evaluation processes.

Response: We appreciate the comments.

Comment: Many commenters recommended that CMS not use outlier data to make compliance determinations for a variety of reasons. Some commenters believed that CMS should only use specific, previously articulated criteria to determine non-compliance. Other commenters stated that the outlier analysis is arbitrary, inconsistent, and capricious at least in part because it would result in CMS holding sponsors to standards that are developed simply by measuring sponsors' performance relative to each other, not what is actually required to comply with Part C and D program requirements. One commenter noted that such an approach is inconsistent with the operation of a program where Medicare sponsor contracts are not awarded on a competitive basis. Still other commenters recommended that if an outlier analysis is used, it should only be used as a means by which CMS identifies plans in need of improvement not as a determination of non-compliance.

Response: We appreciate these comments, but we maintain our belief that outlier analysis remains a valid method for identifying non-compliant plan sponsors and a valuable tool in our efforts to monitor hundreds of contracting organizations in a timely and effective manner. Technically, the Part C and D regulations require 100 percent compliance with all program requirements. We acknowledge that it can be impractical to hold sponsors to such an absolute standard. When attempting to establish an acceptable level of noncompliance, it makes sense for us to compare a sponsor's performance to that of its peers. Such outlier analysis gives us a sense of the general performance capabilities of a set of sponsors. From such an analysis it is reasonable, in most instances, for us to conclude that organizations whose performance trails that of other similarly situated sponsors are not making reasonable efforts to provide an acceptable level of service to their enrollees. As we noted in the discussion of our proposed rule, inherent in the use

of outlier analyses to evaluate compliance is the application of the well-accepted principle that we should look to evolving industry standards to establish program requirements.

We recognize our obligation, as both a business partner and a regulatory agency, to use the outlier analysis tool in a manner that is fair to sponsors and is legally supportable. For example, we want to reassure organizations that we understand that effective outlier analysis is concerned not just with which organizations' performance scores are lower than others, but also with the degree to which some sponsors may trail their peers. Therefore, an outlier analysis does not by definition and in every case result in a finding of non-compliance. Also, we remind organizations that we have adopted over the last several years, a graduated system of compliance notices, and we expect that in the large majority of instances, we will make organizations aware of their non-compliance with an outlier-based standard through the lower-level types of notice. These are the types of notices issued in the earlier stages of CMS' compliance efforts and would afford organizations reasonable opportunities to take corrective action. Finally, we are committed to publishing regularly outlier-based performance standards, as they are developed, in guidance materials, including our program manuals, HPMS memoranda, and our annual call letter, and to update these standards over time. Further, compliance communications to sponsors concerning an area of noncompliance where the basis for the finding relied on outlier analysis include an explicit description of the methodology employed to make such a determination.

Comment: Many commenters requested that CMS compare like plans with respect to several identifiers, including: plan types (with particular consideration given to SNPs), size, market conditions, open vs. closed formularies, and age of enrollees. Some commenters noted that meaningful comparisons across sponsors might be difficult.

Response: Where appropriate, we compare like sponsors and frequently take enrollment (both numbers and types of beneficiaries, such as LIS-eligible) into consideration. Identifiers that the commenters mentioned are taken into consideration as part of our data analysis. Our goal is to do meaningful analysis that can aid us in identifying potential weaknesses.

Comment: Several commenters were concerned with how CMS will conduct outlier analysis and requested that CMS

define and develop standardized methods for determining outliers. One commenter recommended that CMS work with the industry to establish methods for outlier analysis. Another commenter recommended that the methodology should include different weights assigned to measures based on the magnitude of beneficiary impact and program integrity. One commenter requested that the outlier analysis be done at the contract level as opposed to the plan benefit package (PBP) level. Another commenter recommended that CMS be specific about whether compliance action would be taken for first-time outliers or only for sponsors with a history of being an outlier.

Response: We understand the importance of working with the industry to establish methodologies and do so where appropriate. For example, we have and will continue to share drafted or proposed plan rating (star ratings) measures and their analyses. Comments from sponsors are reviewed and considered as we finalize those measures. The Part C and D reporting requirements also undergo similar public comment periods.

The issue of assigning different weights to measures is not relevant here as the proposed change concerns the use of outlier analysis for particular, not aggregated, operational requirements. We incorporate weighting into our analysis of sponsors' overall contract performance. This analysis is typically done at the contract level at least in part because we collect data at that level, not the PBP level.

As discussed previously, we account for whether a sponsor is a first-time or repeat outlier when it determines the type of compliance notice to issue. Depending on the circumstances, organizations identified as first-time outliers may receive only a notice of noncompliance, while those that are repeat outliers may receive a CAP request or be subject to an enforcement action.

Comment: Several commenters urged CMS to make the outlier methodology available to all sponsors through, for example, the Call Letter or Technical Specifications. Many of these commenters requested an opportunity to review and comment on the methodology. A couple of commenters were concerned about CMS' use of outlier analysis and being able to predict how other sponsors will perform to ensure that their own performance is aligned and compliant.

Response: Where appropriate, we will make methodologies available to sponsors, as we discussed earlier in our response to comment on this proposal.

An example of the importance we place on the need for clarity and transparency is the fact that we currently make available our methodologies in the technical specifications for the Reporting Requirements and the plan ratings (star ratings). In another example, we recently (January 2010) released an HPMS memo and incorporated into the Part D manual a comprehensive description of our outlier methodology for ensuring appropriate access to home infusion pharmacies. In an effort toward complete transparency, we also provided the underlying data and necessary information for Part D sponsors to conduct their own independent analyses on this topic.

Comment: Many commenters noted that there are reasons other than non-compliance that may result in a sponsor being an outlier. Outlier, by definition, means that there will always be a sponsor underperforming.

Response: We acknowledge that outlier status does not necessarily mean non-compliance. We review the list of statistical outliers and set thresholds on a number of factors for the purposes of identifying potential compliance problems. This is consistent with our goal to do meaningful analysis that can aid in identifying potential weaknesses. Most often, a sponsor will receive a request for information, as opposed to a compliance letter, to help us better understand why that particular sponsor was an outlier. These requests frequently result in the sponsor gaining a better understanding of our requirements and promote program improvement.

Comment: There were a few comments on the validity of current analyses performed by CMS. Some commenters discussed their observation that the findings resulting from some of CMS' outlier analyses methodology may penalize some organizations unfairly because—(1) the underlying data on which the analysis was based was flawed; or (2) analyses based on self-reported data may indicate that one sponsor is reporting data more accurately than its peers. A commenter noted that the compliance letters that result from outlier analysis come months after the data has been collected and that there is little opportunity for an organization to correct its performance. A few commenters requested that CMS give sponsors the opportunity to appeal or explain the outlier status to CMS.

Response: We are always open to information and feedback from sponsors on our analyses and make corrections to our compliance determinations where

the new information supports such a step. We also note that we are developing requirements concerning sponsors submitting audited data to address the concerns about data accuracy that the commenters raise.

Comment: One commenter believed that the annual audits and the outlier analyses appear to be duplicative.

Response: We use audits, outlier analysis, and other methods to ensure compliance with program requirements and to help identify potential compliance problems. Audits and outlier analyses are two distinct monitoring methods that utilize different sources of information and apply different types of analyses to evaluate sponsors' compliance with program requirements. Audits represent an in-depth review of selected sponsor's documentation related to the operation of their Medicare contracts. Outlier analysis, by contrast, consists of an agency review of performance data (generated by CMS or the sponsor) across all contracting organizations which results in the identification of potential noncompliance and the need for further investigation.

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

In the October 2009 proposed rule, we proposed to modify the language at § 422.503(b)(4)(vi) and § 423.504(b)(4)(vi) to explicitly provide clarification as to what constitutes an "effective" compliance program. We also proposed clarifying language for each of the required elements of an effective compliance program in order to assist sponsoring organizations with implementing more effective compliance programs and to more clearly articulate our expectations.

We proposed to add language to the first element at § 422.503(b)(4)(vi)(A) and § 423.504(b)(4)(vi)(A) to require that written policies and procedures must describe a commitment to comply with all Federal and State standards, 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.

The second element requires a sponsoring organization to have a compliance officer and committee accountable to senior management. We proposed to add language at § 422.503(b)(4)(vi)(B) and § 423.504(b)(4)(vi)(B) that the

compliance officer must be employed by the sponsoring organization, and the compliance officer and committee must periodically report directly to the governing body and that body must be knowledgeable about the compliance program and exercise reasonable oversight over the implementation and effectiveness of the program.

The third element requires the sponsoring organization to have an effective training and education program. We proposed to add language at § 422.503(b)(4)(vi)(C) and § 423.504(b)(4)(vi)(C) to specify several key groups and individuals (the chief executive or other senior administrator, managers, and governing body members) among the sponsoring organization's employees who are required to have compliance training and education. We also proposed to add language 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 appointments of a chief executive, manager, or governing body member. The required compliance training must include training regarding the prevention and detection of fraud, waste and abuse. We proposed to add that providers who have met the requirement for fraud, waste and abuse training and education through enrollment into the Medicare program are deemed to have met that portion of the training and education requirement.

We noted that, in some instances, a particular pharmacy or other provider may contract with dozens of MA or PDP plans, each of which is required by the existing language at § 422.503(b)(4)(vi)(C) and § 423.504(b)(4)(vi)(C), read literally, to provide the required fraud, waste and abuse prevention and detection training to the pharmacy, or other provider, and its staff. Since we did not intend to require duplicative training, we offered two options in our proposed rule. One option was that the sponsoring organization "assures" or "obtains an assurance" that the first tier, downstream, and related entity has received such training. Another option was to leave existing language unchanged, but issue interpretive guidance on this point. We requested workable suggestions to assure that our objective is met, while eliminating unnecessary duplication.

The fourth element requires a sponsoring organization to have effective lines of communication. We proposed to add language at § 422.503(b)(4)(vi)(D) and § 423.504(b)(4)(vi)(D) that requires that

these lines of communication be confidential and accessible to all employees and allow for compliance issues to be reported anonymously and in good faith as issues are identified.

The fifth element requires a sponsoring organization to enforce standards through well-publicized disciplinary guidelines. We proposed to add language at § 422.503(b)(4)(vi)(E) and § 423.504(b)(4)(vi)(E) that more specifically described 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.

The sixth element requires a sponsoring organization to have procedures for internal monitoring and auditing. We proposed to add 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 sponsoring organization's compliance with our requirements and overall effectiveness of the compliance program. We also proposed to add language that these audits should include the sponsoring organization's first tier entities.

The seventh element requires a sponsoring organization to have procedures for ensuring prompt responses to detected offenses. We proposed to add 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.

We are adopting all of these proposed changes into the final rule without further modification with the exception of changes made to § 422.502(b)(4)(vi)(B), § 423.504(b)(4)(vi)(B) and § 423.504(b)(4)(vi)(C), to provide that the compliance officer must be an employee of the sponsoring organization, parent organization or corporate affiliate and clarify that he or she may not be an employee of a first

tier, downstream or related entity of the sponsoring organization and must be accountable to the governing board of the sponsoring organization. In addition, at § 423.504(b)(4)(vi)(C)(3), we adopt a new regulation for the Part D program to specify that first tier, downstream, and related entities that have met the fraud, waste, and abuse certification requirements through enrollment into the fee-for-service Medicare program and accreditation as a durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) supplier are deemed to have met the fraud, waste and abuse training and educational requirements.

We received the following comments on the first element, which requires written policies and procedures:

Comment: Two commenters raised concerns about the resources necessary to satisfy our requirements related to written policies and procedures. One commenter stated that sponsoring organizations are currently spending significant time and resources drafting and redrafting policies and procedures and are still uncertain if these policies and procedures will cover the items we expect to be covered in requisite detail. Both commenters suggested that we release our audit worksheets which outline CMS's expectations for the contents of policies and procedures, which would allow sponsoring organizations to tailor their policies and procedures accordingly. Additionally, one commenter suggested that CMS should not be dictating the scope or components of such policies and disagreed with our inclusion of more "prescriptive standards" into the regulatory text and alternatively suggested that certain requirements be issued through subregulatory guidance.

Response: Our proposals are intended to significantly strengthen our oversight of compliance programs, and provide more specificity and clarity to sponsoring organizations with regard to what we expect to see when we review a compliance program. We believe the proposals we have made are important changes and are necessary to maintain consistency and promote appropriate focus on these requirements and that going through the rulemaking process is the best way to promote these goals. We also believe that the proposed changes to the first element provide important information as to what we consider a framework for an effective compliance program. We do not intend to be prescriptive as to the choice of particular processes or procedures, only to provide the minimum amount of information we would expect to see in a comprehensive set of written policies,

procedures and standards of conduct. With respect to the comment regarding releasing audit materials, we must balance the goals of transparency regarding our audit program with the goals of conducting an effective evaluation of whether organizations have in fact instituted effective compliance programs (and not just “paper” compliance programs). To the extent that sponsoring organizations are looking to tailor their policies and procedures for compliance programs to materials released by us, they should be looking to our regulations, including the changes made by this final rule, and any subregulatory guidance issued by CMS, and not documents related to our audit program, as these may only be a subset of CMS’ larger set of requirements.

We received the following comments regarding our proposed revisions to the second element, which addresses the designation of a compliance officer and a compliance committee who report directly to the organization’s chief executive or other senior management:

Comment: Commenters expressed concern with CMS’ proposal to require that the compliance officer, vested with day to day operations of the compliance program, be an employee of the sponsoring organization. Commenters recommended that CMS broaden this portion of the provision to permit the compliance officer to be employed by the sponsoring organization or an affiliate in its corporate group. These commenters indicated that “the entity who employs the compliance officer is a corporate structure issue that may have no effect or bearing on the issues of accountability and oversight.” One commenter further insisted that in instances when related entities are MA organizations and PDP sponsors who hold separate contracts with CMS, having one centralized compliance officer is not only effective and efficient, but it also promotes consistency with respect to the implementation of the compliance program across the contracting entities. Several commenters also stated that having the compliance officer at a parent or affiliated group level would not lessen the accountability of the compliance officer with respect to each entity.

Response: We agree that having a compliance officer being employed at a parent company or corporate affiliate may not necessarily lessen the accountability of the compliance officer to the governing body of the sponsoring organization. Our proposal was intended to provide further clarity on how sponsoring organizations can meet the key requirement of having a compliance officer and compliance

committee that is accountable to the governing body of the sponsoring organization. We have issued extensive subregulatory guidance on this issue, both in the 2007 call letter and in Chapter 9 of the Medicare Prescription Drug Benefit Manual (“Chapter 9”). This guidance was issued in part in response to us learning that sponsoring organizations were subcontracting the compliance officer function to their first tier, downstream and related entities. We do not view subcontracting that function as an acceptable alternative for a number of reasons, including the potential for conflicts of interest that would exist by virtue of the compliance function residing in a subcontracted entity that is being paid by the entity whose compliance the subcontractor is charged with monitoring. As a result of the comments received, we are modifying the language in this final rule to provide that the compliance officer must be an employee of the sponsoring organization, parent organization or corporate affiliate and to provide that the compliance officer may not be an employee of a first tier, downstream or related entity of the sponsoring organization.

Comment: Proposed sections § 422.503(b)(4)(vi)(B)(2) and § 423.504(b)(4)(vi)(B)(2) specify that the compliance officer and committee must periodically report to the governing body of the sponsoring organization on the activities and status of the compliance program. One commenter emphatically supported CMS’ proposal to strengthen the compliance program by increasing the requirements with respect to interaction with the executive leadership and board members. One commenter recommended that CMS revise the language of this provision to state that the compliance officer and committee, “or their delegate”, report directly to the governing body. Lastly, one commenter stated that although they supported CMS’ goal of ensuring sponsoring organizations’ senior leadership and governing body are informed of key developments, the commenter opposed CMS dictating internal reporting obligations and reporting structures.

Response: We disagree with the suggestion to add “or their delegate” to the language at § 422.503 (b)(4)(vi)(B)(2) and § 423.504(b)(4)(vi)(B)(2), which would expand the scope of individuals who could provide periodic reports to the governing body of the sponsoring organization. The purpose of this provision is to ensure communication between the compliance officer, committee and the governing board. We do not intend that this reporting

responsibility be delegated to someone other than the compliance officer as that would defeat the purpose of the proposed provision. Therefore, we will not be incorporating the commenter’s suggested change into the final rule.

We also do not believe that the proposed regulatory language in this section results in CMS dictating to MA organizations and Part D sponsors their internal reporting obligations and reporting structures. The proposed language does not specify the means or manner in which the report should be communicated to the governing body, nor does it provide specific requirements as to how often such reports are made.

We received the following comments concerning our proposed changes to the third compliance program element, which—(1) states that sponsoring organizations must establish and implement effective training and education between the compliance officer and the sponsoring organization’s employees, governing board, first tier, downstream and related entities; (2) specifies that this training and education must occur at a minimum annually and must be made a part of new employee orientation; and (3) provides deeming of fraud, waste and abuse educational requirements to first tier, downstream and related entities who have met the fraud, waste and abuse certification requirements though Medicare program enrollment:

Comment: Some commenters stated that organizations should have the flexibility to modify and tailor the training for the governing body so that it is not a replication of the training needed for front line staff, and expressed specific concern with CMS requiring training of the governing body annually. Additionally, several commenters stated that requiring sponsoring organizations to conduct compliance training at new employee orientations and annually thereafter is administratively and financially burdensome, and may even result in organizations having to conduct such training on a weekly basis. Commenters made numerous recommendations, including providing sponsoring organizations with flexibility in determining the appropriate level and timing of training depending on the audience; modifying the education and training requirements to apply to only those involved in the administration of the Medicare Advantage and Part D lines of business within the organization; clarifying that the annual education and training requirement is limited to general compliance training, and does not include the specialized

training that sponsoring organizations have to implement in accordance with Chapter 9; and the suggestion that CMS develop a Web-based compliance training tool or certify an independent industry entity to provide consistent and efficient compliance training; and finally, providing additional clarification on the required training for downstream entities.

Response: We believe that the proposed regulatory language allows organizations the flexibility to tailor the content of the training and many aspects of how the training is provided. We have not specified the manner in which the training would be provided at new employee orientations, or to senior leadership or members of the governing body upon their appointment to these positions. Organizations can decide to provide new employees with a copy of the organization's compliance policies and procedures and ask new employees to attest that they have been provided with a copy and have read the material. We do not believe that such a requirement is overly burdensome or difficult for sponsoring organizations to implement.

We also do not believe that it is appropriate to clarify in regulation text that we are referring to general versus specific compliance training, as discussed in Chapter 9. The proposed language makes no reference to the training being specialized and we believe that the regulatory language should be left general as the level of training and education will vary depending on the level and responsibilities of the person receiving the training. We believe that the proposal is sufficiently clear in its description of what is expected of the sponsoring organization in the implementation of its compliance training and education program and the requirements are reasonable. If we determine in the future that further guidance is necessary, we will issue subregulatory guidance.

Lastly, in response to those commenters who suggested that CMS develop a Web-based compliance training tool, we have determined that additional analysis needs to be undertaken and additional information sought before providing guidance on how training of first tier, downstream, and related entities is to be provided and the content managed. Additional clarification will be issued in subregulatory guidance.

Comment: Some commenters stated that requiring sponsoring organizations to conduct compliance training for all delegated entities (first tier, downstream and/or related) or insuring that all

delegated entities conduct such training on their own imposes a significant burden on sponsoring organizations.

Response: In response to those commenters who stated that requiring that first tier, downstream and related entities to receive compliance training is overly burdensome, we would like to reiterate that this is an existing requirement, not a proposed new requirement. We agree that duplicative training is inefficient and we believe that commenters have offered valuable suggestions. After reviewing these comments and recommendations, we have determined that additional analysis needs to be undertaken and additional information sought before providing guidance on how training of first tier, downstream, and related entities is to be provided and the content managed. Additional clarification will be issued in subregulatory guidance.

Comment: Commenters also suggested striking the word "effective" from the language of this section which specifies that the sponsoring organization must establish, implement and provide "effective" training and education. Alternatively the commenter requested that CMS at least clarify how we would determine if training were "effective" and clarify CMS' definition of sufficient oversight.

Response: The use of the term "effective" is existing regulatory language and has already gone through notice and comment rulemaking. "Effective" is not a new requirement, therefore, we do not believe it is necessary to remove the word "effective" from this regulatory provision.

Comment: Commenters suggested that CMS consider revising the requirement that fraud, waste, and abuse training and education occur at least annually and be a part of the orientation for a new employee, new first tier, downstream and related entities, and new appointments to chief executive, manager or governing body member. Commenters believe that CMS should require that training only at the time of initial hire or when there are significant changes in the laws and regulations related to fraud, waste, and abuse.

Response: We disagree and believe that annual training is a necessary component of an effective compliance program that addresses the detection, correction, and prevention of fraud, waste, and abuse in the MA and Part D programs. The intent of this regulation is to codify the existing CMS expectation that fraud, waste and abuse training be provided at a minimum on an annual basis, which is contained in Chapter 9 of the Prescription Drug

Benefit Manual (Part D Program to Control Fraud, Waste, and Abuse). Chapter 9 can be viewed at: http://www.cms.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf. We recognize that Chapter 9 was specifically developed for Part D (prescription drug plan) sponsors. In previous guidance, we have directed MA organizations to apply the provisions of Chapter 9 to Part C (Medicare Advantage) programs as well. We are in the process of updating this document to specifically address any particular Part C measures for detecting and preventing fraud, waste, and abuse.

Comment: Several commenters expressed support for our proposed revisions to § 422.503 (b)(4)(vi)(C)(2), which clarify that first tier, downstream, and related entities who have met the fraud, waste, and abuse certification requirements through enrollment into the fee-for-service Medicare program are deemed to have met the training and educational requirements for fraud, waste, and abuse under this rule. One commenter disagreed with the proposed revision.

Response: We believe that the proposed regulatory language eliminates redundant certification made when these entities enroll in the Medicare program. We also wish to clarify that the reference to deeming in this regulation is distinct from the MA deeming and accreditation program described at § 422.156, § 422.157, and § 422.158.

Comment: A number of commenters recommended that CMS extend the regulatory change proposed for the Part C program at § 422.503(b)(4)(vi)(C) to the Part D program at § 423.504(b)(4)(vi)(C). The commenters noted that Part D first tier, downstream, and related entities that have enrolled in the Medicare program as a supplier of Part B covered medications or as a supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) go through the same application and certification process as MA providers. They contend that including Part D providers in this deeming would ensure the requirements for Part D sponsors will be identical to those for MA organizations and would reduce unnecessary additional burden.

Response: We agree with the commenters and have adopted a new regulation for the Part D program at § 423.504(b)(4)(vi)(C)(3) to specify that first tier, downstream, and related entities who have met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program accreditation as a DMEPOS supplier are deemed to have met the

training and educational requirements for fraud, waste, and abuse training. We wish to clarify that the reference to deeming in this regulation is distinct from the Part D deeming and accreditation program described at § 423.165, § 423.168, and § 423.171.

We received the following responses to our request for comments on whether or how to best revise the requirement that first tier, downstream, and related entities receive training in how to prevent and identify fraud, waste, and abuse to address the issue of duplication of training for providers or entities that contract with multiple MA organizations or Part D sponsors:

Comment: Several commenters recommended requiring MA organizations and Part D sponsors to create training materials or approve first tier, downstream, and related entity-created materials and require attestations that the training was provided to all appropriate parties. These commenters noted that in order to avoid duplicative training, all sponsoring organizations would be required to accept attestations from their first tier, downstream, and related entities that they completed training provided by any other sponsoring organization in order to fulfill this requirement. Commenters also suggested that another option to ensure consistent training content and minimize duplication is for CMS to create a standardized training and require all sponsoring organizations to use it for training their first tier, downstream, and related entities. Commenters also recommended that CMS permit first tier, downstream, and related entities to create and implement their own training programs and attest to their contracting MA organizations and/or Part D sponsors that they have fulfilled the training requirement.

Response: We believe the commenters have offered valuable suggestions. After reviewing these comments and recommendations, we have determined that additional analysis needs to be undertaken and additional information sought before providing guidance on how training of first tier, downstream, and related entities is to be provided and the content managed. Additional clarification will be issued in subregulatory guidance.

Comment: A few commenters requested that CMS provide more specificity regarding which entities must complete fraud, waste, and abuse training. These commenters believe that CMS should limit the training requirement for first tier, downstream and related entities to only staff of those entities that are involved in patient care

and/or claims submission, and should not require administrative or retail clerk/cashier staff to complete the training.

Response: The requirement for fraud, waste, and abuse training applies to all MA organization and Part D sponsor employees (including chief executive or other senior administrator, managers and governing body members) and first tier, downstream and related entities. We will issue additional clarification in subregulatory guidance.

The fourth element requires a sponsoring organization to have effective lines of communication. We did not receive comments regarding this element.

We received the following comment concerning the proposed revisions to the fifth compliance program element which details a sponsoring organization's obligation to ensure its compliance program has well publicized disciplinary standards.

Comment: The commenter requested that CMS provide guidance regarding its expectations as to sponsoring organization's enforcement of disciplinary standards, and asked for clarification as to whether a policy identifying the different types of disciplinary actions a sponsoring organization may impose would be sufficient to meet the requirement.

Response: We believe that our proposal is sufficiently detailed to provide sponsoring organizations with necessary guidance on how to implement an effective compliance program.

We received the following comment regarding the proposed revisions to the sixth compliance program element concerning requirements for sponsoring organizations monitoring and identification of compliance risks.

Comment: A commenter requested that CMS specify that its reference to external audits, especially of first tier entities, does not require sponsoring organizations to hire an independent, external auditor to perform this function but rather that sponsoring organizations may undertake the auditing of these contractors through their internal audit units.

Response: Our expectation, when referring to a sponsoring organization conducting an external audit of itself or a first tier entity, was that that sponsoring organization would utilize an auditor who is external of both the sponsoring organization and the first tier entity being audited.

Comment: A commenter recommended that CMS share its preamble language that further defines the expectations for an effective

compliance program with other areas of the Federal government, such as the Department of Defense, so that all government contractors will have the same compliance program expectations.

Response: We believe that this comment is outside the scope of this regulation.

The seventh element requires a sponsoring organization to have procedures for ensuring prompt responses to detected offenses. We did not receive comments regarding this element.

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

In the October 22, 2009 proposed rule (74 FR 54644), we requested comments on proposed criteria for determining whether an MA plan network meets the network availability and accessibility requirement in section 1852(d)(1) of the Act. As we discussed in the proposed rule, we have developed an automated system for reviewing network adequacy on a continuing basis based on the elements that we have determined reasonably reflect community patterns of health care delivery. As we noted in the proposed rule, our operational experience has demonstrated that the concept of community patterns of health care delivery provides a useful benchmark for measuring a proposed provider network, because it allows for varying geographical and regional conditions to be taken into consideration in determining what constitutes "reasonable" access in a given area.

In the proposed rule, we described the elements of community patterns of health care delivery that we proposed to include in our evaluations of provider networks, and stated that our goal was to make the standard of community patterns of care more transparent and consistent across the country. Specifically, we proposed adding a new paragraph (a)(10) to § 422.112 to specify the factors comprising community patterns of health care delivery that we would 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 proposed providing more detail about how we would operationalize these requirements through subregulatory guidance (for example, the annual Call Letter). We solicited comment on whether our proposed regulatory provisions are sufficiently clear and whether clarification should be provided through regulation or subregulatory guidance, such as the annual Call Letter.

After considering all the timely comments we received on our proposal, we are adopting § 422.112(a)(10) without modification in this final rule.

Comment: Many commenters expressed concern that the proposed CMS approach to evaluating network adequacy based on community patterns of care would be too limiting, and would not allow organizations sufficient flexibility to develop networks in rural areas or areas with unique conditions. Several commenters were concerned that CMS' interpretation of what constitutes community patterns of care would result in an approach that would not adequately take into account special plan-specific factors, such as the size of a plan or the quality of its providers. Also, a number of commenters were concerned that unique characteristics of a particular community, such as provider willingness to contract, would not be captured in the CMS network adequacy standards. One commenter expressed concern that the proposed requirements for network adequacy appear to encourage a fee-for-service and fragmented care model based on geographic access rather than a defined network of high quality primary care practices, supported by a limited network of sub-specialists. One commenter was concerned that CMS would only use the prevailing community standard of care to evaluate network adequacy, citing as an example a plan with a network that did not meet the prevailing community standard of care but was nevertheless adequate or even better in terms of the access it actually provides health care services to enrollees.

Response: In developing standards for network adequacy we chose the overarching principle of community patterns of care because it is a robust model that allows CMS the necessary flexibility to develop standards that can be adapted to the significant variations that exist in health care delivery in the United States. Our proposed regulation outlined the broad elements that we have found from years of experience to be relevant in evaluating a particular community pattern of care. However, we are cognizant of the fact that there exist a number of unique local circumstances related to such factors as geography, market conditions, and provider availability. Accordingly, this final rule codifies an approach to determining network adequacy that builds on our experience with evaluating health plan provider networks but is also flexible enough to adapt to evolving and unique local market conditions. The automated process we have established to assess network adequacy is likely to be refined as we gain more experience, and maintaining flexibility in our regulatory requirements for network adequacy supports this goal. We also note that the automated system we are using does not specify the providers with which a plan contracts. Rather, it furnishes a benchmark so we can determine if a plan's provider network is adequate given the availability of providers in the area where the plan is being offered and the expected enrollment in the plan. In other words, our standards address the relative size and scope of an acceptable MA provider network given the community patterns of care. However, MA plans still have discretion to select the providers they contract with as long as that network is adequate to meet the health care needs of its enrollees. In addition, we will have an exceptions process by which plans can highlight special circumstances that affect their ability to meet our access standards.

Comment: Many commenters had very detailed, specific questions about our automated system for assessing network adequacy, and much of this feedback has already been provided to CMS through other mechanisms. For example, one commenter asked for certain adjustments to the ratio of providers to beneficiaries. Other comments questioned how CMS would implement various features of network adequacy and whether they would be codified in regulations text.

Response: As noted previously, we have developed and implemented automated systems to evaluate the network adequacy of MA plans. As part of that implementation, we have

provided considerable subregulatory guidance regarding implementation of community patterns of care through this automated process. An example of this subregulatory guidance is the provision of time and distance standards (available on the CMS Web site) by category of health care provider for a number of rural and metropolitan counties throughout the United States. Because we did not propose to incorporate the technical specifics of our automated system into regulation text, we believe it is most appropriate to address specific technical suggestions in the context of implementing and fine-tuning the automated network adequacy system.

Comment: Several commenters expressed concern about how CMS would implement time and distance standards for determining network access. One commenter asked that CMS be mindful of the impact of imposing time and distance standards equally among different types of providers. One commenter stated that the prevailing 30 minute/30 mile access to services standards need to be fine-tuned specifically for urban, rural, and other medically underserved areas. Other comments included recommendations to establish separate and distinct network adequacy standards for Parts A and Part B services, as well as standard for measuring network adequacy in rural areas for services that are only in hospitals.

Response: As noted in the October 22, 2009 proposed rule, we have historically used the 30 minute/30 mile access to services as a rough standard for evaluating provider networks. However, we agree that this standard is not sufficiently nuanced to stand on its own, and does not fully address our needs. Our operational experience has demonstrated that the concept of community patterns of health care delivery furnishes a more useful benchmark for measuring a proposed provider network because it allows for varying geographical and regional conditions to be taken into consideration.

Comment: One commenter asked CMS to consider Medicaid provider networks as part of the assessment of network adequacy for dual eligible integrated products. This commenter also suggested comparing contracting rates across plans serving duals as an additional measure of network adequacy. In addition, the commenter suggested that a comparison of the plan's provider availability to those actually open to new Original Medicare enrollees might indicate the value of the plan to potential enrollees. Another

commenter asked that CMS include in its regulation defining network adequacy the following factors derived from the Medicaid access standards under § 438.206: (1) The mode of transportation used by Medicare beneficiaries, particularly those who are dually eligible and those who rely on transportation for the disabled; (2) whether the location furnishes physical access for enrollees with disabilities; and (3) delivery of services in a culturally competent manner.

Response: We recognize that special needs plans (SNPs) that specifically serve the dual eligible population have unique requirements. It is for that reason that in 2011, SNPs that exclusively serve the dual eligible population will be required to have contracts with State Medicaid agencies where they operate. While transportation is not a Medicare covered benefit, it is our expectation that MA plans' facilities are available and accessible to plan enrollees.

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

In the October 2009 proposed rule, we proposed to clarify what regulatory requirements are "deemable" for MA organizations that offer prescription drug benefit programs by modifying the language at § 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). In addition, we proposed modification to § 422.156(f) and § 423.165(f) to add language clarifying that CMS may use its statutory authority to impose intermediate sanctions and civil money penalties (CMPs), initiate contract terminations, and perform evaluations and audits of a sponsoring organization's records, facilities and operations, notwithstanding our deeming provisions. We also proposed to remove language at § 423.165(b)(4) regarding programs to protect against fraud, waste and abuse from the items listed as deemable program requirements. After considering the comments we received in response to these proposals, we are adopting all of these proposals without further modification into this final rule.

Comment: One commenter asked if CMS will create an avenue for accrediting organizations who are currently approved under the Medicare Advantage program to apply for deeming under the Prescription Drug program.

Response: Our proposal did not address the process for becoming an accrediting organization. Any

organization that wishes to be an accrediting organization for the Medicare Prescription Drug program must first apply and be approved by CMS in accordance with existing requirements.

Comment: One commenter asked if we will define possible roles and responsibilities for accrediting organizations under the revised Part D monitoring and oversight audit program.

Response: Our proposal did not address the Part D accrediting process and we do not intend to address this process in this final rule. We will evaluate whether or not there is a need to release more detailed information in the future through subregulatory guidance or other appropriate means.

Comment: One commenter indicated that Part D plan sponsors have not been given information on accrediting organizations that could grant plans deemed status for Part D. The commenter further recommended that there be an opportunity to work with us to identify accredited organizations for pharmacy benefit manager operations in order to simplify the audit process.

Response: Our proposal did not address the Part D accrediting process and we do not intend to address this process in this final rule. However, as of the date of the publication of this regulation, CMS has not approved any accrediting organizations to grant deemed status for Part D sponsors. We will evaluate whether or not there is a need to release more detailed information in the future through subregulatory guidance or other appropriate means.

Comment: We received a few comments indicating that the regulatory provisions provided in this section should be further clarified either through rulemaking or subregulatory guidance.

Response: We will evaluate whether or not there is a need to release more detailed information in the future through subregulatory guidance or other appropriate means.

Comment: One commenter suggested that we provide clarification on the criteria we would use to determine whether to perform evaluations, conduct audits, or impose sanctions or civil money penalties relative to a sponsoring organization's compliance with deemable requirements.

Response: Our proposal did not intend to modify or affect the manner in which CMS conducts compliance evaluations, audits or the process for imposing intermediate sanctions. These processes are not directly affected by whether the underlying subject of the deficiency is a deemable requirement.

Comment: One commenter encouraged us to consider adding additional deemable requirements based on differences between the Part D program and the Part C program.

Response: We have been granted limited statutory authority regarding what specific requirements are deemable. Our proposals reflect our current statutory authority.

Comment: One commenter requested that since the fraud, waste and abuse program was being removed as a deemable requirement we consider allowing "certification" from an external qualified source to serve in the deeming capacity.

Response: We have been granted limited statutory authority regarding what specific requirements are deemable. We proposed modifications to our regulations to mirror our current statutory authority. To the extent the commenter is proposing that CMS consider ways of assessing an organization's compliance with fraud, waste, and abuse requirements that suggestion would be outside the scope of this proposal.

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))

In the October 2009 proposed rule, we proposed eliminating 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 require corrective action plans (CAPs) to be submitted for our approval prior to us issuing a notice of intent to terminate or nonrenew a contract. Instead, we proposed that the sponsoring organization be 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.

We also proposed amending the existing language at § 422.506(b)(3), § 422.510(c)(1), § 423.507(b)(3), and § 423.509(c)(1) which 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. Specifically, we proposed to afford sponsoring organizations with at least 30 calendar days to develop and implement a CAP, prior to issuing the notice of intent to terminate or nonrenew. CMS is adopting the proposed language into the final rule

with a few technical changes to § 422.506(b)(3)(i) and (ii), § 422.510(c)(1)(i) and (ii), § 423.507(b)(3)(i) and (ii), and § 423.509(c)(1)(i) & (ii). First, we are deleting the phrase “that formed the basis for the determination to non-renew the contract” from the proposed revised regulations governing non-renewals at § 422.506(b)(3)(i) and § 423.507(b)(3)(i) and deleting the phrase “that formed the basis for the determination to terminate the contract” from the proposed revised regulations governing terminations at § 422.510(c)(1)(i) and § 423.509(c)(1)(i). The reason for this revision is that, upon further consideration, we have concluded that this language is superfluous and has the potential to cause confusion concerning when CMS must provide notice and reasonable opportunity to correct deficiencies.

Next, we are modifying § 422.506(b)(3)(i), § 423.507(b)(3)(i), § 422.510(c)(1)(i), § 423.509(c)(1)(i) to state that CMS will provide the sponsoring organization a “reasonable opportunity” of “at least 30 calendar days” to develop and implement a corrective action plan. This modification made the provision at § 422.506(b)(3)(ii), § 423.507(b)(3)(ii), § 422.510(c)(1)(ii), and § 423.509(c)(1)(i) duplicative and unnecessary, therefore we are deleting that provision.

These revisions do not alter the meaning and purpose of the proposed revised regulations and are strictly editorial changes.

Comment: We received numerous comments regarding our proposal to modify the overall approach and timeframe sponsoring organizations are afforded for developing and implementing a CAP prior to CMS issuing a notice of intent to terminate or nonrenew. Although almost all commenters were supportive of CMS’ proposal to move to an outcome oriented approach for reviewing CAPs, some commenters believe that 30 days is not enough time for sponsoring organizations to develop and implement a CAP. Commenters provided several reasons to support this concern, including the fact that CAPs may involve complex and time consuming programming or modification of systems and that the proposed change could result in sponsoring organizations pursuing a more cursory or manual remediation rather than a fuller remediation. Other commenters recommended that rather than specifying a time period, CMS and sponsoring organizations should mutually agree on a time period that is

best for completing a CAP. A few commenters expressed that 30 days was more than enough time to correct deficiencies and that the regulations need to state more clearly that the corrective action should be completed within the same 30-day period.

Response: Our proposal specifically stated that the time period afforded sponsoring organizations would be “at least” 30 days, thereby proposing the minimum amount of time that CMS would afford a sponsoring organization to develop and implement a CAP. We believe our proposal is reasonable and accounts for those situations where we determine that longer periods of time are warranted to demonstrate correction (for example, when corrections must be made to electronic information systems). Our proposal does not intend to limit the development and implementation of a CAP to 30 days in all cases because we agree that there are some deficiencies of a complex or technical nature that may require additional time to rectify.

Comment: A few commenters requested that CMS clarify how it will determine if a sponsoring organization has attained compliance (for example, what are CMS’ expectations and what supporting documents would we require in such situations to demonstrate compliance).

Response: Our proposal to change to an outcome based approach is not making modifications in the current methodologies for assessing whether an entity is in (or out of) compliance with our requirements. For example, CMS currently conducts validation activities based on account management data and information, audit results, beneficiary complaints, sponsoring organization reporting requirements and performance data indicators to determine whether a sponsoring organization is in compliance with our requirements. We will continue to determine if the sponsoring organization is in compliance with our statutory, regulatory and program requirements by utilizing these kinds of monitoring and oversight measures. The proposed language is only clarifying that for non-renewal and termination actions, we will not be requiring the sponsoring organization to submit its corrective action plans for approval by us, but instead the sponsoring organization must submit proof that identified deficiencies have been corrected.

Comment: One commenter suggested that if CMS retains the authority to reject a CAP based on the process used to fix the deficiency, the sponsoring organization should be allowed to submit its CAP to CMS for approval,

and if not disapproved by CMS within a specified period, assume that the CAP is approved from a process perspective.

Response: The commenter has misunderstood our proposal. We are proposing to modify the current CAP process to be entirely outcome oriented and we will no longer be requiring sponsoring organizations to submit corrective action plans for approval (that is, the process for how the plan goes about correcting its deficiencies will not be approved or disapproved by CMS). Rather, the process will be independently developed and implemented by the sponsoring organization and our focus will be on determining whether the deficiencies/problems that created the need for the CAP have been corrected.

Comment: A commenter requested that CMS not apply the 30-day CAP timeframe to “routine or ad-hoc audits.”

Response: The procedures governing the corrective action plan process associated with routine or ad-hoc audits are not specified in regulation. To the extent, however, that we would initiate a termination or nonrenewal action against a sponsoring organization based on a routine or ad-hoc audit CAP, we would follow the procedures outlined in this regulation.

Comment: A commenter recommended that sponsoring organizations, which are currently under a CAP, be allowed to engage the services of an independent auditor to evaluate whether the sponsoring organization is in compliance with CMS’ requirements.

Response: Our proposed language was not intended to prevent a sponsoring organization from taking the initiative to use an independent auditor to help identify and correct underlying compliance deficiencies.

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

In the October 2009 proposed rule, we proposed two changes to the regulations to provide additional tools to assist us in making the determination to lift an intermediate sanction as stated in § 422.756(d)(3) and § 423.756(d)(3). First, we proposed providing CMS with the discretion to require a sponsoring organization, under an intermediate sanction, to hire an independent auditor to provide us with additional information that we will use to determine if the deficiencies upon which the sanction is based have actually been corrected and are not likely to recur. We also proposed an alternative proposal in which we would

grant sponsoring organizations the discretion to hire an independent auditor to evaluate the sponsoring organization's compliance with our requirements and 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. After considering the comments we received in response to this proposal, we are adopting the proposal without modification, which provides CMS with the discretion to require a sponsoring organization, under an intermediate sanction, to hire an independent auditor.

Second, we proposed changes to § 422.756(d)(3) and § 423.756(d)(3) to provide CMS with the discretion to require a sponsoring organization, subject to a marketing and enrollment sanction, to go through a test period during which the organization could market and accept enrollments for a limited time in order for us to determine if the sponsoring organization's deficiencies have been corrected and are not likely to recur. Additionally, we proposed to revise these provisions to provide that following the test period, if we determine the deficiencies that formed the basis for the sanction have not been corrected and 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, in these instances, would not have a right to a hearing to challenge our determination to keep the sanction in effect. We are finalizing this proposal without modification.

We also proposed deleting existing provisions at § 422.756(c) and § 423.756(c) because these provisions are duplicative of the list of sanctions at § 422.750(a) and § 423.750(a) and are unnecessary. In this final rule, we are adopting all of these proposals without further modification.

Comment: CMS received numerous comments regarding the engagement of an independent auditor by a sponsoring organization under sanction by CMS, with most commenters supporting the alternative proposal in which CMS may allow the sponsoring organization the discretion to hire an independent auditor. Commenters provided various rationales for their support of the alternative proposal, including the potential financial and operational burden to sponsoring organizations when required to engage an outside auditor; that sponsoring organizations may already have the internal resources available to provide the information to

CMS; and that absent standards, CMS could impose this requirement in an arbitrary and capricious manner. A commenter opposing both proposals because the commenter did not believe it was necessary for CMS to grant the sponsor the discretion to hire independent auditors, and that by allowing discretion to hire an independent auditor, a sponsoring organization that did not hire the auditor would then be viewed in a negative light. Finally, one commenter expressed concern with our alternative proposal that when an independent auditor was not required by CMS, but was retained by the sponsoring organization at their discretion, CMS would merit only "some weight" in the decisionmaking process to lift the sanction. Specially, the commenter recommended that the independent auditor's evaluation should have the same standard of weight regardless of whether the independent auditor was required or was discretionary.

Response: When a sponsoring organization has been sanctioned, the organization's deficiencies have risen to a serious and significant level. We believe that we should have the flexibility to require the sponsoring organization to hire an independent auditor for the benefit of both us and the sponsoring organization. To ensure that the use of the independent auditor will be beneficial for the sponsoring organization and to us, we intend to consider the sponsoring organization's ability to afford an independent auditor as well as the sponsoring organization's ability to demonstrate through its own resources that it has corrected its deficiencies and they are not likely to recur. To determine whether or not we would require an independent auditor, we would check to see if the sponsoring organization was on our financial watch list as well as on the financial watch list of any of the States or commonwealths in which the sponsoring organization was licensed. Also, whenever a sponsoring organization is under sanction, we engage in ongoing discussions with its senior leaders and management. If we were considering the use of an independent auditor, we would discuss this with the sponsoring organization and solicit their feedback in order to fully comprehend the financial makeup and stability of the organization.

As the proposed regulatory language reflected, this authority will not be exercised in all circumstances because we recognize that an independent auditor may not be needed or beneficial in all circumstances. For these reasons, we are maintaining the requirement in

the final rule that when a sponsoring organization has been sanctioned CMS may require that the sponsoring organization hire an independent auditor.

Comment: CMS received a number of comments requesting that CMS provide more clarification related to our use of the term independent auditor in our proposal, including providing a definition, minimum qualifications, and whether conflict of interest rules would apply. One commenter suggested that CMS provide a list of auditors for sponsoring organizations to choose from. Another commenter seemed to be concerned that an independent auditor is generally used in the context of a financial audit and referred to "Sarbanes Oxley" stating that it has fairly clear rules with regard to conflicts of interest. In that respect, commenters requested that CMS clarify what context it used the phrase "independent auditor."

Response: We intend that sponsoring organizations will choose the independent auditor. We will work with sanctioned organizations to determine if the independent auditor they are proposing is appropriate. Some basic examples, however, of standards that we will require for independent auditors are knowledge of the Part C and Part D programmatic requirements and experience evaluating an organization's performance in the areas specific to the deficiencies. To the extent that one commenter was referencing financial audits under the Sarbanes Oxley Act of 2002 (Pub. L. 107-204, 116 Stat. 745, enacted July 30, 2002), this proposal is not governed by the standards in Sarbanes Oxley. The type of audit contemplated by Sarbanes Oxley is a financial audit and not a program compliance audit. The audits proposed here would involve an independent evaluation of whether the sponsoring organization is in compliance with CMS requirements. We will evaluate whether or not there is a need to release more detailed information in the future through subregulatory guidance or other appropriate means.

Comment: Several commenters requested that CMS provide standards for when an independent auditor would be needed. Commenters wanted clarity on when an independent auditor would be required, what types of issues the auditor would be called to review, and the parameters under which an auditor would perform its work. One commenter requested that we limit the focus of the audit to the bases for the sanction.

Response: During the period of the sanction, we communicate regularly with the sponsoring organization and,

therefore, we intend to fully discuss with the sanctioned organization the basis for concluding an independent auditor is necessary prior to requiring the organization to retain the independent auditor. We intend to utilize the requirement in our proposal when we determine that an independent auditor would be beneficial, such as in situations where the deficiencies are highly technical in nature. Also, if the sanctioned organization is having difficulty demonstrating to us that its deficiencies have been corrected, an independent auditor can provide us with assurances that the deficiencies have in fact been corrected through a neutral third party evaluation. We intend to determine what areas the independent auditor should assess depending on the nature and extent of the deficiencies. We do not believe it is possible or appropriate to provide this information in regulation since each sanctioned organization may require a different assessment based on its particular deficiencies. With respect to the comment that the focus of the audit should be limited to the bases for the sanction, based on our experience, we believe the independent auditor would need the flexibility to broaden the assessment because new or related issues may arise in the period after the sanction is imposed that need to be evaluated in order to ensure that the deficiencies have been corrected and are not likely to recur.

Comment: Several commenters were concerned with our comparison of the independent auditor in this requirement to the Corporate Integrity Agreements (CIA) used by the HHS Office of Inspector General (OIG) because information found under the CIA is not publicly disclosed, and the commenters believe that the results should be publicly disclosed. Commenters also stated that in the case of nursing homes, experience has shown that CIAs have not been effective and that nursing homes have not improved as a result of CIAs.

Response: When a sponsoring organization is subjected to an intermediate sanction, this information, along with the bases for the sanction, is publicly disclosed through the CMS Web site. Additionally, the public subsequently is notified as to whether we have determined that these deficiencies have been corrected and are not likely to recur. We do not believe that there is any significant value in making the public aware of audit results related to an internal technical assessment of the correction of these deficiencies that may be relied on to make our ultimate determination.

However, to the extent these documents would be required under existing law to be disclosed we fully intend to comply with those requirements.

With regard to the commenters who were concerned about the overall effectiveness of using independent auditors to assist us in evaluating compliance, correcting the deficiencies is ultimately the responsibility of the sanctioned organization. Although, the independent auditor may consult with the sanctioned organization on the best way to fix its deficiencies, the main purpose of the independent auditor is to provide evidence and additional assurances which would assist us in making the determination that those deficiencies have been corrected. We intend that independent auditor results will be weighed with a host of other validation activities conducted by us and will not be the sole source of information concerning whether deficiencies have been corrected and are not likely to recur.

Comment: One commenter stated that the audit findings of an independent auditor should be subject to attorney-client privilege and that they would only be subject to release to CMS if the sponsoring organization waived the privilege.

Response: We disagree with the commenter that results of the independent auditor are protected by attorney-client privilege. The purpose of the independent auditor is to provide a neutral third party evidenced-based evaluation of whether a sanctioned organization is in compliance with CMS requirements. Attorney-client privilege is a legal concept which protects communications between an attorney and his or her client and keeps certain communications between the parties confidential. Independent audit findings are by no means necessarily subject to the attorney-client privilege and, in this case, the sole purpose of the audit being performed is to provide information to CMS.

Comment: One commenter stated that CMS' determination not to lift the sanction after the results of the independent audit should be appealable and such appeal is required by law.

Response: There is no statutory right to appeal a decision by CMS to keep a sanction in effect. Appeal rights are afforded at the time the sanction is imposed.

Comment: One commenter requested that we remove the language "not likely to recur" from the independent auditor requirement. The commenter stated that it was not general practice for an auditor to opine as to whether the deficiencies were not likely to recur.

Response: We did not propose and do not intend to require the independent auditor to opine as to whether the deficiencies are not likely to recur. The independent auditor will perform an assessment to determine if the sponsoring organization is in compliance with our requirements and we would use that evaluation, along with other information provided by the sponsoring organization, to make our determination as to whether the deficiencies that formed the basis for the sanction have been corrected and are not likely to recur. The independent auditors report is evidentiary and not dispositive as to whether the deficiencies have been corrected and are not likely to recur. We make that determination.

Comment: We also received a number of comments on the proposal that in instances where marketing or enrollment sanctions have been imposed, CMS may require a sponsoring organization to engage in a marketing or enrollment "test period" in order to assist CMS in making a determination as to whether the deficiencies have been corrected and are not likely to recur. Most commenters wanted more clarity regarding the parameters of the "test period," including any limitation on enrollment during the test period, the duration, when it would be required and the level of performance required during the test period.

Response: The details concerning implementing a test period will vary from organization to organization depending on the nature and extent of the deficiencies that formed the basis for the sanction and other factors such as the organization's size, complexity of operations, etc. We intend to work closely with any sanctioned organization prior to establishing a "test period" and the organization will receive specific notice of the standards the organization must meet to demonstrate that its deficiencies have been corrected during the test period.

Comment: Several commenters asserted that sanctioned organizations should be afforded appeal rights if, after the marketing and enrollment "test period," CMS determines to keep the sanction in effect.

Response: Under our proposed provision, the "test period" is a validation activity that will help us to determine that the deficiencies that formed the basis for the sanction have been corrected and are not likely to recur. For example, when we validate a sponsoring organization's compliance with appeals and grievances requirements, we may perform an audit to test those areas. If the audit

demonstrates that the sponsoring organization has not corrected its deficiencies or that they are likely to recur, the sanction will remain in effect and the sponsoring organization cannot appeal that determination. Appeal rights are afforded at the time the sanction is imposed.

Comment: Several commenters expressed concern that sponsoring organizations subject to a “test period” would be under heightened scrutiny and that CMS would have sole discretion to determine the point at which the sponsoring organization has corrected the basis for the sanction. One other commenter questioned the value of a “test period” as well as the independent auditor and seemed to equate these validation activities to a situation where the sponsoring organization has been issued a corrective action plan (CAP).

Response: We intend to use a “test period” as one of a host of validation activities and we intend to work closely with any sanctioned organization prior to imposing a “test period” to ensure the sponsoring organization receives specific notice of the standards it must meet to demonstrate that its deficiencies have been corrected and are not likely to recur. We fully intend to subject all sponsoring organizations placed under a sanction to heightened scrutiny both during the sanction period and for some period afterwards to ensure that the deficiencies that formed the basis for the sanction are corrected and are not likely to recur. The “test period” requirement simply provides organizations under marketing/enrollment sanctions the same opportunity other organizations would have to demonstrate compliance with our standards for releasing the organization from the sanction during an established enrollment test period. The provision is not applicable to an organization that has been asked to implement a CAP and has not had a marketing and enrollment sanction imposed. This provision is limited to sponsoring organizations subject to intermediate sanctions.

Comment: One commenter requested that CMS adopt alternative approaches for evaluating whether it is appropriate to lift a marketing and enrollment sanction imposed on a sponsoring organization when the deficiencies that led to the sanction are ones where CMS cannot appropriately evaluate the extent of remediation through a trial enrollment and marketing period.

Response: We fully intend to continue to explore other ways to effectively validate whether deficiencies have been corrected while a sponsoring organization is under sanction. The test

period proposal was intended to address the specific dilemma faced by CMS and the sponsoring organization when a sanctioned organization cannot market and enroll during the sanction period so as to demonstrate that the deficiencies have been addressed.

Comment: One commenter suggested that CMS specify that any decision not to lift an intermediate sanction at the end of such “test period” is a separate decision from, and shall not automatically result in, an action to terminate a contract.

Response: We do not intend to use the decision not to approve a sponsoring organization’s request to release the sanction, in and of itself, as a basis for reaching a determination to terminate a contract. Termination determinations must always meet our specific statutory and regulatory requirements.

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

In the October 2009 proposed rule, we proposed to delete the enumerated bases for termination contained at § 422.510(a)(5) through (12) and § 423.509(a)(5) through (11). We proposed to modify language at § 422.510(a) and § 423.509(a) to separate the language into two paragraphs with the first paragraph, (a)(1), listing the statutory bases for termination and the second paragraph, (a)(2), clarifying that a sponsoring organizations (i) 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).

Based on the comments we received on the proposed rule, we have decided not to finalize our proposal and as an alternative to slightly modify existing regulations. First, we are finalizing the proposed modified language in provisions § 422.510(a)(1)–(3) and § 422.509(a)(1)–(3) so that the regulatory text mirrors the statutory language. Second, we are finalizing proposed modified language for § 422.510(a)(4) and § 423.509(a)(4), which states that CMS may now terminate under this provision when Medicare, Medicaid, or other State or Federal health care programs are affected. Next we are finalizing our proposed deletion of existing § 422.510(a)(5) and § 423.509(a)(5) because we believe that the provision is a basis for expedited termination and therefore inappropriately located in this part. We have decided to retain the remaining

enumerated bases for termination that we previously proposed to delete at § 422.510(a)(6) through (12) and § 423.509(a)(6) through (11). We are, therefore, redesignating § 422.510(a)(6)–(12) and § 423.509(a)(6)–(11) as § 422.510(a)(5)–(11) and § 423.509(a)(5)–(10) respectively. Finally, we are adding the two new proposed bases, with modified language, to the existing enumerated list at § 422.510(a)(12) and § 423.509(a)(11) (failure to comply with regulatory requirements) and § 422.510(a)(13) and § 423.509(a)(12) (failure to comply with performance standards). The discussion of these revisions is set forth in more detail below.

Comment: A number of commenters expressed specific concerns about our proposed changes to § 422.510(a) and § 423.509(a), namely our proposal to remove the enumerated standards for termination and proposal to mirror the statutory language. Commenters stated that the proposed language is too broad and vague, gives CMS unprecedented discretion and authority and invites arbitrary or inconsistently applied determinations by CMS. One commenter suggested that CMS maintain the existing language.

Response: We disagree that the proposed changes to § 422.510(a)(1) through (3) and § 423.509(a)(1) through (3) provide CMS with unprecedented authority and discretion. The proposed language merely mirrors the authority provided to CMS through statute. We have, however, after considering all of the comments, decided to retain the existing provisions from § 422.510(a)(6) through (12) and § 423.509(a)(6) through (11) into the final rule. These examples of substantive bases are now redesignated as § 422.510(a)(5) through (11) and § 423.509(a)(5) through (10) respectively.

Comment: A number of commenters expressed concern with the proposed language at § 422.510(a)(12) and § 423.509(a)(11) (formerly § 422.510(a)(2)(i) and § 423.509(a)(2)(i)) which provided that CMS may determine that a basis exists to terminate a sponsoring organization’s contract if the sponsoring organization fails to comply with *any* regulatory requirement contained in parts 422 or 423. While one commenter strongly supported the proposed change, many commenters believed that the revision removed the “substantiality” or “materiality” tests explicit or inherent in each of the existing requirements, and in effect it would allow CMS to terminate on the basis of a single instance in which a particular requirement is not met.

Response: We have considered the comments and have decided to remove the word “any” from the proposal to avoid confusion and have modified the regulatory text in the final version of the regulation to reflect this change. Adherence to all our regulatory requirements is important and necessary, but we acknowledge that in making a decision to terminate a contract, we would take into account the nature and extent of the failure to meet our regulatory requirements and the materiality of the requirement as compared to other requirements.

Comment: A number of commenters also expressed concern about the proposed language at § 422.510(a)(13) and § 423.509(a)(12) (formerly § 422.510(a)(2)(ii) and § 423.509(a)(2)(ii)) supporting the use of outlier analysis to reach a termination decision. These commenters opposed this proposal and argued that it is inconsistent with law and unfair to equate outlier status to noncompliance. Another commenter stated that it was improper to make contract termination decisions based on a determination that a sponsoring organization is the lowest performer among a cohort when the organization may still be performing adequately. Some commenters stated that they needed more clarity on the specifics associated with the outlier standards and access to the data underlying these standards. Additionally, commenters asserted that the outlier standards are too vague of a standard to serve as a basis for contract terminations, particularly when CMS has not disclosed the relevant standards or methodology and organizations have not been notified in advance of these standards in order to be afforded an opportunity to improve. Two commenters recommended that CMS allow sponsoring organizations to appeal CMS findings as a result of outlier analysis.

Response: Outlier analysis is an oversight mechanism by which we can more effectively focus our limited resources in determining which sponsoring organizations to target for further compliance analysis and assessment. We do not intend to use this analysis in and of itself as a basis to terminate a contract. Therefore, we have decided to remove this outlier language from the final rule, to avoid misunderstandings and confusion among sponsoring organizations concerning the use of this data to take termination actions.

Comment: CMS proposed to modify language at § 422.510(a)(4) and § 423.509(a)(4) (formerly § 422.510(a)(2)(iii) and

§ 423.509(a)(2)(iii)) to revise the agency’s existing regulatory authority to allow CMS to terminate a sponsoring organization when there is credible evidence that shows that the sponsoring organization has committed or participated in false, fraudulent or abusive activities affecting the Medicare, Medicaid, or other State or Federal health care programs. Two commenters on this proposed provision, one in support and the other opposing the provision, stated that CMS should not terminate contracts in cases where the employees committing the fraudulent acts have no involvement with the administration of the Medicare lines of business offered by the sponsoring organization.

Response: Our proposal was not intended to indicate that we will terminate a contract in the case of employee fraudulent acts unrelated to Medicare, Medicaid, or other State or Federal health care programs.

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

In the October 2009 proposed rule, we proposed to modify the language at § 422.662(a) and § 423.651(a) stating that the sponsoring organization must file a request for a hearing in accordance with the requirements specified in the notice of the contract determination or intermediate sanction. This proposed change would ensure that the proper officials within CMS receive the request and are able to act upon it in a timely manner. 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.” As we stated in the preamble to the proposed rule, we believe 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.

We also proposed a conforming change at § 422.662(b) and § 423.651(b) which governs 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 proposed change was made 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 appeal processes).

Since we received no comment on these sections, these changes are adopted without modification in this final rule.

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

In the October 2009 proposed rule, we proposed to delete the references to “substantial compliance” as a standard of review at hearing and delete the existing regulations which provide for an “earliest of” test from § 422.660 and § 423.650. We also proposed to explicitly state that the preponderance of the evidence is the standard of proof that we believe applies during the appeal of a contract determination or intermediate sanction. We also proposed to delete the existing language contained at § 422.660(b) and § 423.650(b) and replace it with language that provides that 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. Additionally, we specified in our proposal that the applicable requirements are § 422.501 and § 422.502 for 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.

We proposed to modify § 422.660(c) and § 423.650(c), which specified 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 proposed a change from the July 15th deadline to September 1st.

Finally, we proposed to modify existing regulations at § 422.676(d) and § 423.658(d) governing the conduct of the hearing 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 are adopting all of the proposed changes as the final rule without further modification.

Comment: Several commenters opposed CMS’ removal of the “substantial compliance” standard

asserting that this standard was well established and well understood as opposed to the new language that CMS proposed, which these commenters stated was vague and unclear.

Response: We disagree that the “substantial compliance” standard is clear and easy to apply in making a determination. As explained in the preamble to the October 2009 proposed rule, the “substantial compliance” language has led to confusion among parties to the hearing, has been difficult for the Hearing Officer to apply, and does not reflect the nuances of the different legal standards provided in the Act for making contract determinations and imposing intermediate sanctions. Our proposal, which provided that the standard of review is whether CMS’ determination is inconsistent with the regulatory requirements for taking the underlying action (for example, application denial, non-renewal, termination or intermediation sanction) provides the requisite specificity to be applied by the hearing officer and the parties to these actions. We also believe the proposal properly focuses the hearing officer and all parties to the hearing on the correct standard, and the pertinent issue under review at the hearing.

Comment: Several commenters expressed concern that the proposed changes result in the sponsoring organizations bearing the burden of proof in appeal proceedings and one commenter added that CMS’ proposal is inconsistent with the general rule articulated by the Supreme Court that the party seeking to take action ordinarily bears the burden of persuasion and cited to *Schaffer v. West*, 546 U.S. 49 (2005).

Response: The commenters have misunderstood the scope of our proposals because we did not propose a change as to which party bears the burden of proof. Existing regulations explicitly state that the sponsoring organization bears the burden of proof. Also, we believe that the commenter is mistaken in its reading and interpretation of the ruling in *Shaffer v. West*. In that case, the Supreme Court held that the burden of proof in an administrative hearing is properly placed upon the party seeking relief (“[T]he burdens of pleading and proof with regard to most facts have been and should be assigned to the plaintiff who generally seeks to change the present state of affairs and who therefore naturally should be expected to bear the risk of failure of proof or persuasion.”) In our appeal proceedings, the party seeking relief is the sponsoring organization, thereby making it

appropriate for that party to bear the burden of proof. Thus, existing regulations which require that the sponsoring organization bear the burden of proof are consistent with the legal precedent cited by the commenter.

Comment: One commenter requested that CMS provide a definition for the “preponderance of the evidence standard.”

Response: The preponderance of the evidence standard is a well established and defined legal standard. To make a showing by the preponderance of the evidence, one must show that it is more likely than not that the fact that the claimant seeks to prove is true.

Comment: Some commenters opposed changing the notification date from July 15th to September 1st. Some commenters noted that notification by September 1 of a favorable determination would not leave a sponsor with sufficient time to prepare for the upcoming year given that sponsors are permitted to start marketing for the upcoming year on October 1. One commenter recommended moving the application deadline to March to allow for adequate preparation of the application and suggested that adequate preparation may reduce the number of appeals.

Response: In most cases, we do not believe a favorable determination issued by the CMS hearing officer will be rendered as late as September 1st. However, moving the notification date of the favorable determination from July 15th to September 1st affords applicants that receive a favorable decision the opportunity to be sponsors in the contract year for which they applied. In all instances, this regulatory change works to the benefit of sponsors.

We believe that sponsors are given adequate time and instruction to complete the application. We believe changing the application due date would not significantly impact the number of appeals.

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

In the October 2009 proposed rule, we proposed to delete the references to expedited terminations based on false, fraudulent or abusive activities and severe financial difficulties contained in the termination procedures at § 422.510(b)(2)(i), § 423.509(b)(2)(i), § 422.510(c)(2) and § 423.509(c)(2) and in the appeal procedures at § 422.644(c)(2), § 423.642(c)(2), § 422.664(b)(2) and § 423.652(b)(2). We proposed to modify these provisions instead to reflect the more general

statutory language concerning our ability to take an expedited termination when we determine that a delay in termination caused by adherence to the required procedures would pose an imminent and serious risk to the health of the individuals enrolled with the sponsoring organization. We are adopting our proposal to include this statutory language, and based on the comments we have decided to retain and amend the two existing bases for expedited termination currently located at § 422.510(a)(4) & (a)(5) and § 423.509(a)(4) & (a)(5).

Comment: We received several comments on our proposals. Commenters were concerned that our proposal was overly broad, lacked specificity and that there were no examples of situations where we would pursue an expedited termination. Additionally, a few commenters were concerned that a sponsoring organization might be subjected to an expedited termination for a single, isolated incidence of non-compliance and that sponsoring organizations would not be afforded the opportunity for a hearing before the termination took effect.

Response: After considering all of the comments we received, we have decided to retain the two existing examples for when CMS may pursue an expedited termination as well as incorporate the statutory language into the final rule.

The existing regulation references § 422.510(a)(5) and § 423.509(a)(5) as one example of a situation where CMS would pursue and expedited termination, but it is also listed as a basis for termination. In the proposed regulation, we proposed removing this instance as a basis for termination, thereby removing its associated reference in expedited termination. We believed that this language created some confusion because it intertwines a basis for termination (that is, failure to make services available) with the statutory standard for making an expedited termination. Based on the comments we received, however, we see that the reference to this basis provided sponsoring organizations with a clear example of the instances under which CMS may decide to take an expedited termination. In order to resolve this issue, we have decided to add the language from § 422.510(a)(5) and § 423.509(a)(5) to the regulatory provisions on expedited terminations in the final rule. We have decided to finalize our proposal to delete this language as a basis for termination because we maintain that the circumstances in this provision would

lead CMS to pursue an expedited termination.

The second example in the existing regulation references § 422.510(a)(4) and § 423.509(a)(4) which concerns situations where there is credible evidence that a sponsoring organization committed or participated in false, fraudulent or abusive activities affecting the Medicare, Medicaid, or other State or Federal health care programs, including the submission of false or fraudulent data. Based on the comments we received, this reference also provided sponsoring organizations with a clear example of the circumstances under which CMS may decide to take an expedited termination. Therefore, we have decided to retain the reference to § 422.510(a)(4) and § 423.509(a)(4) as a basis for expedited termination.

Finally, we are moving forward with our proposal to incorporate the statutory language in the revised regulations governing expedited termination, thereby permitting CMS to expedite a termination if we determine that a delay in termination caused by adherence to the required procedures would pose an imminent and serious risk to the health of the individuals enrolled with the sponsoring organization. We do not agree that our proposal to include the statutory language is overly broad or vague, and believe that by retaining the two existing examples, it provides sponsoring organizations with some guidance on the types of issues that might lead CMS to pursue an expedited termination while still allowing us the flexibility we need to ensure we can act quickly in situations where adherence with the standard termination procedures would pose an imminent and serious risk to the health of Medicare beneficiaries.

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

In the October 2009 proposed rule, we proposed adding new language to § 422.670(b) and § 423.655(b) to state that either the sponsoring organization or CMS may request that a hearing date be postponed by filing a written request no later than 5 calendar days prior to the scheduled hearing, and that when either the sponsoring organization or CMS requests an extension, the Hearing Officer must provide a one-time 15-calendar day postponement, and additional postponements may be granted at the discretion of the Hearing Officer. We also proposed revising the language in § 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 was made 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). We are adopting all the proposed changes into the final rule without further modification with the exception of the timeframes outlined in § 422.670(b) and § 423.655(b) as set forth below.

Comment: Several commenters questioned CMS' proposal to allow sponsoring organizations or CMS to request an extension for the hearing by filing a written request no later than 5 calendar days prior to the scheduled hearing. Most commenters believed that allowing requests for extensions until 5 days prior to the scheduled hearing would not allow enough time for sponsoring organizations to change travel arrangements and commenters proposed different timeframes they thought would be more suitable.

Response: We agree with the commenters concerns and have decided to extend the timeframe for requesting an extension to the hearing date from 5 calendar days to 10 calendar days prior to the scheduled hearing in our final rule.

Comment: One commenter raised concerns that there may be times when an automatic, 15-day extension may not be workable due to previous commitments on the part of the Hearing Officer or non-requesting party and suggested CMS add language to the requirement to allow for an alternate, mutually agreed upon hearing date if the Hearing Officer or the non-requesting party is not available on the hearing date that would otherwise result from postponement.

Response: We believe that the addition of such language is not necessary because current regulations at § 422.670(b)(1) and (2) and § 423.670(b)(1) and (2) already provide that the Hearing Officer has the authority on his or her own motion, to change the time and place for the hearing.

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

In the October 2009 proposed rule, we proposed to delete the formal discovery process contained in § 422.682 and § 423.661. In the December 5, 2007 **Federal Register** (72 FR 68700), we published a final rule with comment period that finalized our revisions to § 422.682 and § 423.661 to provide 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. We also proposed to amend § 422.682 and § 423.661 to require that witness lists and documents be identified and exchanged at least 5 calendar days prior to the scheduled hearing. We are adopting § 422.682 and § 423.661 without further modification into this final rule.

Comment: Several commenters opposed CMS' removal of the formal discovery process from regulations. Commenters specifically stated that deleting discovery is a violation of their due process rights, and would deny sponsors the only opportunity they have to obtain the full breadth of information they are entitled to for a fair hearing. One commenter stated that the discovery process is the appropriate forum for the sponsoring organization to learn of the criteria CMS used in reaching its decision and that sponsoring organizations have a statutory right under 5 U.S.C. 552 to this information.

Response: We disagree with the commenters who stated that the removal of discovery from regulations is a violation of their due process rights and a violation of their statutory right to obtain information in this manner. Our hearings are informal administrative proceedings and as the court held in *Lopez v. U.S.*, "[t]here is no general constitutional right to discovery in administrative proceedings" *Lopez v. U.S.*, 129 F.Supp.2d 1284 (2000). Also, we do not believe that finalizing our proposal to remove discovery will create unequal or prejudicial treatment that will lead to a violation of due process. Both CMS and sponsoring organizations will be equally limited to producing and receiving witness lists and documents that must be exchanged at least 5 calendar days before the hearing. Also, we do not believe that full discovery for sponsoring plans is required to receive the necessary information from us for adequate and proper preparation for the hearing. Prior to the hearing, we will have already provided sponsoring organizations the specific information relied upon by CMS in reaching the determination which they are appealing. In cases of contract terminations or intermediate sanctions, we will have previously provided the specific basis for the determination within the notice

of intent to terminate or impose intermediate sanctions. Therefore, we believe that a witness list and documents are sufficient to meet the evidentiary needs of the parties. Additionally, any prior decisions of hearing officers are public record, and therefore, obtainable by sponsoring organizations. Sponsors have numerous statutory rights under 5 U.S.C. 552 which govern the agency's disclosure of public information; agency rules, opinions, orders, records, and proceedings. The removal of the discovery process does not circumvent the rights provided to the public under 5 U.S.C. 552.

Comment: One commenter also requested that if CMS moves forward with the proposal to eliminate the formal discovery process that we revise our proposal to include a list of the specific documents to be shared and to indicate the action that will result when the required documents are not shared prior to the hearing.

Response: Appeal proceedings will vary dependent on what type of determination is being appealed and we cannot possibly specify which documents would be necessary in each and every type of case. Also, if documents are not shared prior to the hearing, it is within the discretion of the hearing officer to determine what the consequences of that action or inaction for the parties to the hearing.

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

In the October 2009 proposed rule, we proposed revisions to 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 revised 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 were made 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). We received no comment on this section, and are adopting these changes without modification.

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)

In the October 22, 2009 proposed rule, we proposed revising the regulations governing the reopening of an initial contract determination or decision of a Hearing Officer or the Administrator under Parts C and D 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). We noted that the term "initial determination" is not used elsewhere in Subpart N (Contract determinations and appeals). We received no comment on our proposals and are adopting these changes without modification.

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

In the October 22, 2009 proposed rule, we proposed prohibiting an MA organization or Part D sponsor, as a condition of the consent to a mutual termination, 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. Specifically, under Part D, we proposed modifying § 423.508 by adding paragraph (e), which states that as a condition of the consent to a mutual termination, CMS requires 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 proposed adding 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). We also proposed redesignating the current § 423.504(b)(6) to § 423.504(b)(7).

Similar modifications were proposed for the MA regulations. Specifically, we proposed modifications to § 422.508 by adding paragraph (c), which states that as a condition of the consent to a mutual termination, we 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 added 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).

In proposing these changes, we noted that 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. Under § 422.506(a)(4) and § 423.507(a)(3), if a sponsor voluntarily nonrenews a contract, we cannot enter into a contract with the organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS. The primary difference between a nonrenewal and a mutual termination is often timing. For a nonrenewal request to take effect at the end of the current contract year, it 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). However, 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. In the October 2009 proposed rule, we noted that this is particularly true if a request for a mutual contract termination occurs once plan information has become publicly available, marketed to beneficiaries, and beneficiaries have been given the opportunity to enroll. These late terminations create significant disruption for beneficiaries and for us. Similarly, even greater disruption results from mutual terminations requested to take effect during the course of a contract year.

In light of the disruptions that may occur, we proposed that a termination by mutual consent, which involves a termination by an MA organization or a Part D sponsor as well as by us, 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.

After considering the comments we received in response to these proposals, in this final rule, we are adopting our proposals without modification.

Comment: One commenter stated that it is important to inform beneficiaries immediately when—(1) their plan is not in compliance with CMS requirements; (2) sanctions have been implemented; or (3) a plan is prohibited from applying for new contracts or service area expansions for a 2-year period. By notifying beneficiaries immediately of these situations, they will be afforded more time to plan. Immediate notification will increase the likelihood that the information will not be lost in the extraordinary amount of information given during the open enrollment period. The commenter recommended that CMS strengthen compliance in general in order to hold plans accountable through CMS monitoring and oversight.

Response: Although mutual terminations are often requested when a contract is, or will soon be, out of compliance with CMS requirements, a mutual termination can occur even when there is no current or expected compliance violation. Our proposed revision to this portion of the regulation only addresses the period of time during which a mutually terminated sponsor would be precluded from applying for a new or expanded contracts. As a result, this comment addressing the issue of beneficiary notice concerning Part C and D plan performance is outside the scope of the proposed regulatory change.

Comment: One commenter stated that it did not support the proposal for a 2-year ban because market conditions can create the need for contract terminations and service area reductions. The commenter requested that CMS allow flexibility on market re-entry based on environmental conditions and appropriate negotiations with and approval by the agency.

Response: Terminations can cause beneficiary confusion and disruption. Additionally, if a sponsor responds to market conditions through the nonrenewal process, a 2-year application ban would apply. Accordingly, we believe it is reasonable and appropriate to apply the same 2-year application ban in situations when a sponsor terminates a plan after the nonrenewal deadline. We also note that, the proposed regulation changes preserve our authority to permit affected organizations to submit applications in less than 2 years when special consideration is warranted.

Comment: One commenter stated that it did not oppose the proposed changes, but requested that CMS clarify that the 2-year moratorium is based on a sponsoring organization terminating all of its MA or Part D contracts, not a subset of each line.

Response: The regulation as proposed would apply to a licensed legal entity that mutually terminated any of its MA or PDP contracts. A complete exit from either program by an organization is not required for CMS to invoke the 2-year application prohibition.

Comment: One commenter requested additional clarity regarding “nonrenewal” and “mutual termination.” The commenter urged CMS to be especially cautious about any presumption by CMS that termination may be due to some type of poor performance. The commenter stated that it is possible that after the first week in June a plan will determine that it is not feasible to continue with the contract. The commenter included the example of a State-initiated dramatic midyear reduction in payment for Medicaid services in a dually integrated product. The commenter also stated that the references in § 422.508 to § 422.510 seem to imply some type of failure to perform. The commenter supported providing adequate notice of terminations to beneficiaries, but suggested that a 60-day timeframe may be adequate for end-of-year terminations. The commenter indicated that the 2-year prohibition against applying for new contracts or services areas is reasonable given the language “absent circumstances warranting special consideration.” The commenter stated that an example of such a circumstance should include the situation of when a plan is trying to be responsive to state purchasing initiatives on behalf of dual eligibles.

Response: With this proposal, we were not addressing whether a sponsor is a poor performer. Rather, the proposal was intended to make the consequences to a sponsor of a mutual contract termination the same as that for a non-renewal. Without this change, a plan might opt for a mutual termination rather than the less disruptive non-renewal in order to avoid the 2-year ban. Additionally, the existing 2-year ban on non-renewing sponsors is not meant to address those sponsors’ performance, although it may help us to identify good business partners. The 2-year application ban, as it has been applied to non-renewing organizations and, once this proposed change is adopted by CMS, to mutually terminating organizations, is intended to ensure continuity in the Part C and D programs

by imposing longer-term consequences on sponsors that might otherwise make annual decisions to exit and re-enter the programs.

Comment: A commenter asked CMS to clarify that this change applies only to mid-year mutual terminations and not to a plan electing to non-renew with ample notice to CMS (such as at the time of bid submission or per non-renewal guidance).

Response: Consistent with § 422.506(a)(4) and § 423.507(a)(3), the 2-year ban already applies to sponsors electing to nonrenew. The proposed regulatory change is an effort to extend the application of that rule to the analogous situation of a mutual contract termination, regardless of the effective date of that termination.

Comment: Commenters stated that while they understood the importance of the change, they would encourage CMS to be flexible as there may be instances where an MAO will conduct the right level of due diligence on its providers, yet a provider may experience a disruption that causes the organization to withdraw. The commenters stated that there is significant merit in those instances of an MAO acting in the best interest of Medicare beneficiaries and not effectuating the new plan or contract.

Response: Regardless of the degree of due diligence performed prior to contracting, the sponsor assumes all risks associated with complying with an MA or PDP contract, including a 2-year ban on new contracting resulting from a mutual termination. Also, as indicated in the proposed rule, CMS will retain the authority to accept applications where special consideration is warranted.

Comment: A commenter asked how this provision would be applied if an acquisition or merger is pending.

Response: The acquiring sponsor should assume that it is acquiring all the Medicare contract assets and liabilities of the selling organization, including a 2-year ban on new applications.

Comment: A commenter stated that plans should be allowed to terminate prior to the start of the benefit year if an adequate network cannot be obtained. The commenter also stated that if the termination occurs after the start of open enrollment, CMS should wait 30 days and allow beneficiaries to make their own elections before assigning them to an alternate plan. Additionally, it was suggested that there should be a mechanism in place to make sure that a plan cannot use termination as a tool to shift beneficiaries into a higher cost plan offered by the terminating sponsor.

Response: This comment does not concern the proposed application of the 2-year ban on mutually terminated sponsors. We will not address the comment as it is outside the scope of the proposed change.

Comment: A commenter stated that there are a variety of circumstances, including but not limited to the loss of an adequate network that may be beyond the control of the plan but force it to withdraw a contract. Such withdrawal may be in the best interest of the beneficiaries. Therefore, overall plan performance should not be judged on this one factor. If a plan can remedy the issue for the following contract year it should be allowed to re-contract. The commenter suggests that this issue be looked at on a case-by-case basis.

Response: This provision does not address whether a sponsor is a poor performer. Rather, the provision is intended to make the consequences of a mutual contract termination the same as those for a nonrenewal. The 2-year ban on nonrenewing sponsors is not meant to address those sponsors' performance; rather, it is intended to ensure continuity in the Part C and D programs

by imposing longer-term consequences on sponsors that might otherwise make annual decisions to exit and re-enter the programs.

Comment: One commenter asked if CMS intends to apply this provision to all types of applications regardless of plan type or geographic location.

Response: In the context of voluntary nonrenewals, our policy has been to apply this prohibition based on plan type and service area (for example, non-renewal of a PFFS contract does not prohibit the same organization from applying immediately for an MA-HMO contract for the same service area). We anticipate applying the same policy to mutual terminations.

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 finalize Part D rules regarding timeframes and responsibility for making redeterminations. Under Part C, we finalize rules to—

- Authorize us to annually establish limits 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.

We also finalize Part C and D marketing requirements by 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 require 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.	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. § 423.466. § 423.800.
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.

TABLE 2—PROVISIONS TO STRENGTHEN BENEFICIARY PROTECTIONS—Continued

Provision	Part 422		Part 423	
	Subpart	Section	Subpart	Section
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

In the preamble to our October 22, 2009 proposed rule, we recognized 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 also stated our continuing concern about the inherent financial incentives independent agents and brokers have when selling Medicare products. For this reason, while not proposing any specific changes in the October 2009 proposed rule, we solicited comments suggesting ideas for effectively providing Medicare health plan and drug plan information and enrollment assistance that ensures beneficiaries select the plan that best meets their needs, including whether additional changes are needed in recently established requirements relating to plan sponsors’ use of agents and brokers. We specifically requested comments regarding the tools we currently use (for example, our print publications and our online resources) to assist beneficiaries with their health care decisions; whether State Health Insurance Assistance Programs (SHIPs) have the capacity to serve significantly more Medicare beneficiaries; and the effectiveness of limiting the use of independent agents and brokers by MA organizations and PDP sponsors to certain times of the year, specifically, the open enrollment period (OEP) and annual enrollment period (AEP), or to selected groups of beneficiaries.

Comment: Several commenters provided very specific suggestions for an enrollment broker demonstration. Comments we received on an enrollment broker demonstration included suggestions for guiding principles that should govern such a

demonstration as well as recommendations on specific features that should be included. Some commenters expressed the concern the proposed enrollment broker demonstration would prevent plans from continuing to use plan-employed agents. Other commenters recommended that independent agents and brokers be permitted to make referrals and receive a referral fee, with the enrollment broker merely assisting with actual enrollment. One commenter suggested that the demonstration initially focus on one State that already uses a third party enrollment assistance approach for Medicaid managed care plan enrollment as a pilot. The same commenter provided a very detailed plan for how the commenter believed an enrollment broker demonstration should work. Under this suggested plan, the enrollment broker would receive applications, record oral scope of appointment confirmations, conduct third-party enrollment verification calls, and conduct general marketing activities providing high-level, standardized general information on plan options. The enrollment brokers would refer beneficiaries with detailed questions or needing more tailored plan presentations to plan-employed agents. The commenter also expressed concerns about the enrollment broker demonstration, suggesting that coordination and communication between the enrollment broker, plans, and beneficiaries would be crucial to the success of the demonstration; the ability to assure the quality of information provided to beneficiaries would be important; and enrollment broker training would also be a critical component of the program. This commenter suggested that CMS solicit additional input from MA plans on operational and information issues

involved with effective communication, coordination, and training. The commenter also had concerns about the role an enrollment broker would play in the disenrollment process.

Response: We thank the commenters for this feedback and will consider it as we continue to improve our tools for assisting beneficiaries with their health care decisions and as we continue to assess the impact of our current rules regarding independent agents/brokers.

Comment: A number of commenters provided us with responses to our request for comments on the idea of limiting the use of agents and brokers to the AEP and OEP, or to selected groups of beneficiaries. The majority of these commenters expressed concerns that limiting the use of agents and brokers in this way could disadvantage age-ins, dual-eligibles, and those eligible for the low-income subsidy. They believe strongly that these limits would decrease the service and support that beneficiaries depend on to understand plan benefits and make enrollment decisions. They also indicated that CMS’ current support tools are not sufficient to replace the function that agents and brokers serve.

Commenters also indicated that limiting the use of agents and brokers to certain times of the year is not feasible given that plans use agents and brokers throughout the year and that current CMS oversight of agents and brokers is sufficient. Along these same lines, one commenter supported the view set forth in the proposed rule preamble that sufficient time has yet not passed to fully evaluate the impact of the new marketing requirements codified by CMS following enactment of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Several commenters suggested that limiting the use of agents and brokers to the AEP

and OEP or to select beneficiary groups would, in fact, result in increases of the marketing abuses we are trying to eliminate and would force good agents out of business, leaving behind agents only interested in short-term gains.

Several commenters provided alternatives to limiting the use of agents and brokers to the OEP and AEP or with selected groups. The suggested alternatives can be grouped into three categories—(1) Recommendations to strengthen current rules, processes, and oversight of agents and brokers; (2) Recommendations to require better collaboration among stakeholders; and (3) Recommendations that may require regulatory changes.

Recommendations for strengthening current rules, processes, and oversight of agents and brokers included—

- Strengthening agent and broker education/training;
- Creating a Medicare license and industry designation that all agents must have in order to sell Medicare products; standardizing agent compensation by geographic area;
- Creating and requiring the use of a “replacement/suitability” form that agents would use when moving a beneficiary to a new plan;
- Strengthening CMS surveillance efforts;
- Stabilizing CMS’ guidance in this area by limiting the frequency of future policy changes; and
- Tightening our current rules regarding the use of independent agents and brokers.

Commenters’ recommendations for requiring better collaboration with stakeholders included—

- Working with plans, advocates, and associations to develop alternatives;
- Creating a list of agents/brokers prohibited from selling Medicare plans that would be shared with all stakeholders;
- Providing more support to and coordination with the States; and
- Periodically publishing best practices.

Additional recommendations that may require regulatory or statutory changes included—

- Requiring plans to share information on agent misconduct and terminations;
- Creating uniform compensation rates for MA plans and PDPs;
- Requiring agents and brokers to register with the National Insurance Producer Registry (NIPR);
- Precluding agents from selling MA plans or PDPs or selling to LIS beneficiaries;
- Allowing a one-time “new enrollment payment”; and

- Renewal compensation for all subsequent moves (regardless of plan type change).

Commenters also recommended—

- Rescinding “lock-in”;
- Limiting agent/broker involvement in marketing, but not limiting their involvement to certain periods during the year;
- Shortening the AEP; and
- Eliminating the additional three month OEP for MA plans at the beginning of the year and applying the enrollment period uniformly to MA plans and PDPs.

A number of commenters also provided recommendations with respect to our question about whether and how to expand the role of SHIPs. Almost all of these commenters expressed concerns about SHIP funding, capacity, and capability. They expressed concern about—

- Inadequate funding;
- The fact that SHIPs’ reliance on volunteers limits their ability to fully replace the role of independent agents and brokers;
- The lack of capacity of existing SHIP networks to service entire States; and
- The lack of knowledge by SHIP volunteers about plans in every local market within a State.

Several commenters suggested that by limiting plan options and standardizing benefits, SHIP counselors would be better able to handle questions from beneficiaries about plan differences. Other commenters suggested that by strengthening SHIP networks, their capacity could also be expanded.

Response: While we did not propose any changes to our regulations governing plans’ use of independent agents and brokers to sell Medicare plans in our October 22, 2009 proposed rule, we appreciate the thoughtful ideas and recommendations commenters offered. We recognize the important role 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 still have concerns about the inherent financial incentives independent agents and broker have when selling Medicare products. We recently implemented regulations (§ 422.2274 and § 423.2274) intended to reduce agent and broker incentives to enroll beneficiaries in plans inappropriately. We continue to agree with the commenter that suggested it is still too soon at this time to fully evaluate whether these new rules have achieved MIPPA’s goal of creating incentives for agents and brokers to assist beneficiaries with

selecting plans based on their health care needs. As we continue to monitor and evaluate our marketing rules and oversight activities, we will evaluate the need for any future notice and comment rule making.

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

In the October 22, 2009 proposed rule, in implementing sections 1851(h) and 1860D–1(b)(1)(vi) of the Act, we proposed narrowing the definition of the term “marketing materials” at § 422.2260 and § 423.2260 to exclude a new proposed category of “current enrollee communications materials,” which we proposed defining to include either situational materials or beneficiary specific customized communications. We proposed this change in order to streamline the review and approval of beneficiary communication notices to current members.

Specifically, we proposed revising § 422.2260 and § 423.2260 to exclude from the definition of marketing materials communications targeted to current enrollees that are customized or limited to a subset of enrollees or a specific situation, or that involve claims processing or other operational issues. In the preamble to the proposed rule, we cited the following examples of the types of materials that would be excluded from our proposed revised definition of “marketing materials”: 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.

In addition, we proposed to revise § 422.2262 and § 423.2262 to specify that, while the current enrollee communications excepted from the definition of marketing materials would not be subject to the statutory requirement that they be submitted to CMS for review and approval prior to use, we retained the right to review such materials, and their use could be disapproved (or disapproved subject to modification) by CMS.

In this final rule, we adopt these provisions with some modification. For reasons discussed below, we have in this final rule revised paragraph § 422.2260(5) (vii) to retain materials about membership rules and procedures, which we are calling “membership activities” (for example, materials on rules involving nonpayment of premiums, confirmation of enrollment or disenrollment, or non-claim specific notification materials) in

the definition of marketing materials subject to CMS prior approval. In addition, we have added a new paragraph § 422.2260(6) to expressly exclude from the definition of marketing materials ad hoc customized or situational enrollee communications.

Comment: A number of commenters supported our proposal to modify the definition of the term “marketing materials” to distinguish materials used to market to new potential enrollees from current enrollee communication materials. However, these commenters raised an ambiguity in our proposed revision to the definition of marketing materials at § 422.2260(5)(vii) and § 423.2260(5)(vii). These commenters noted that, as written, the revised paragraph (5)(vii) merely defines “current enrollee communications materials” without making it clear that such materials are excluded from the revised definition of marketing materials.

Response: We agree that, as written, the proposed revisions to the definition of marketing materials did not make it sufficiently clear that we were excluding customized or situational current enrollee communications from the definition of marketing materials, and that certain materials directed at current members should still be included in the definition. Accordingly, as noted above, in response to these comments, we have revised paragraph § 422.2260(5) (vii) to retain materials about “membership activities” (such as, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or non-claim specific notification materials) in the definition of marketing materials. In addition, we have added a new paragraph § 422.2260(6) to specifically exclude from the definition of marketing ad hoc customized or situational enrollee communications from the definition of marketing materials.

Comment: Several commenters suggested that, in the absence of a clear definition of claims processing or operational issues, we should define the terms “situational” and “beneficiary specific” narrowly. Several commenters requested that we specify those situations where beneficiary communications would be considered current enrollee communications materials and be excluded from the proposed revision to the definition of marketing materials. These commenters also suggested that we allow operational letters that pertain to enrollment, disenrollment and appeals issues to be excluded from the definition of marketing materials. Some commenters suggested that we specify that any

materials excluded from the definition of marketing materials are not subject to the Medicare Marketing Guidelines’ requirements that plans include certain plan mailing statements on envelopes regarding the contents of the materials enclosed within. In addition, these commenters requested additional guidance regarding how we intend to operationalize the process for review and approval of situational enrollee communications that would, if the proposed provisions were finalized as proposed, be outside CMS’s current marketing review and approval processes.

Response: We disagree that it is necessary, and do not believe it would be appropriate, to attempt to specify in the regulations text an exhaustive listing of enrollee communications that are not considered marketing materials per our revised definition of the term “marketing.” Our intent is to define these exclusions from the definition of marketing materials narrowly to include communications that are either customized or intended for a subset of current enrollees and which deal with specific situations or cover member-specific claims processing or other operational issues. Our intent was not to exclude from the definition of marketing materials communications that are used more broadly or that convey information about plan benefit structures. As noted previously, in response to earlier comments and this comment, we have revised our proposed definition of current enrollee communications materials in the final rule to add a new § 422.2260(6) to better describe our intent in the proposed rule, and now refer to these materials as “ad hoc enrollee communications materials.” The final definition encompasses materials that are targeted to current enrollees; are customized or limited to a subset of enrollees; do not include information about the plan’s benefit structure; and apply to a specific situation or cover member-specific claims processing or other operational issues. We envision that ad hoc enrollee communications materials could include the following types of materials;

- Communications about a shortage of formulary drugs due to a manufacturer recall letter.
- Letters to communicate that a beneficiary is receiving a refund or is being billed for underpayments.
- Letters describing member-specific claims processing issues.

Although we mentioned the Part D EOB in the preamble to the October 2009 proposed rule as an example of a customized current enrollee communications material in the

preamble to our proposed rule, in light of the comments we received on the scope of the exemption from the marketing definition, we no longer believe that example was appropriate, particularly given the importance of our review of EOB templates. Thus, under this final rule, we will continue to require submission and approval of EOB templates through the CMS marketing review and approval process as part of the new definition of marketing materials, and distinguish this general, regularly issued notice from documents pertaining to the processing of an individual claim. We intend to provide further guidance on the types of marketing materials that would be considered ad hoc enrollee communications materials, as well as any alternate processes for their review and approval, in the Medicare Marketing Guidelines.

Comment: One commenter suggested that all prospective and current member materials be submitted to CMS as file and use materials so that there is a centralized and consistent place for beneficiary communication to be housed within CMS. This commenter suggested, as an alternative, that the plan develop internal processes to monitor materials for consistency with CMS requirements rather than filing those materials with CMS. We note that MA organizations and PDP sponsors already have the responsibility to ensure, from a monitoring and compliance perspective, that their marketing materials are complete, accurate, and consistent with marketing rules. A few commenters suggested that we require plans to submit a report on beneficiary communications and audit these communications periodically to ensure that plans are not engaging in inappropriate beneficiary marketing practices, and that we retain oversight responsibilities for these materials.

Response: As stated previously, we have revised the definition of “customized current enrollee communications materials” in this final rule such that it covers a narrow class of ad hoc, customized beneficiary communications materials. We will provide more information about alternative review and approval processes for customized current enrollee communications materials in the Medicare Marketing Guidelines. We note that we periodically audit marketing materials. We will also ensure that ad hoc enrollee communications materials meet all relevant requirements and are reviewed, approved, and used appropriately.

Comment: One commenter recommended that we extend our

current waivers of marketing review and approval requirements for employer group waiver plan marketing materials to employer group waiver plan enrollment materials. Some other commenters requested that our current regulations concerning review and approval of marketing materials be expanded to apply to third party entities, as these commenters believe third party entities tend to send inaccurate or incorrect information to beneficiaries.

Response: These comments address our exercise of employer group waiver authority, and accordingly are outside the scope of this rulemaking, and not addressed in this final rule.

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

In order to reduce variability of marketing materials and to ensure documents are more accurate and understandable to beneficiaries, we proposed, under the authority of sections 1851(h) and 1860D-1(b)(1)(vi) of the Act, to move toward greater standardization of the information provided in plan marketing materials. Specifically, we proposed revising § 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 noted that we will provide MAOs and PDP sponsors with standardized marketing materials through the annual Call Letter, Health Plan Management System (HPMS) memoranda, or other guidance documents. We believe this change will ensure beneficiaries receive more accurate and comparable information to make informed decisions about their health care options, as well as lead to increased efficiencies and greater consistency in our marketing material review protocols and processes. In this final rule, we adopt these provisions as proposed. For the upcoming 2011 plan year, we plan to update some of our current standardized documents later this spring through guidance, but we are unlikely to standardize new types of documents. For 2012 and future years, we will consider and explore standardizing additional forms and materials.

Comment: Several commenters strongly supported our proposed rule to require MAOs and PDP sponsors to use standardized language and formats in marketing materials in instances where we provide them. Other commenters supported this proposal but urged CMS

to use consumer research and testing to determine the terms and features consumers want and the best ways to disclose that information to assist beneficiaries with making informed decisions about their health care options.

Several commenters suggested we collaborate with the industry, advocates, and State agencies to develop standardized models, or convene a workgroup to explore ways of improving the wording of model materials. In addition, some of these commenters suggested, as an alternative, that we solicit document examples and suggestions from plans regarding the creation of standardized materials and establish from these examples best practices for model language, content, and format.

Response: Given the support for our proposed requirement, we are adopting it as set forth in the proposed rule. We agree with the commenters' recommendations that CMS should research and consumer test standardized model marketing materials, when practical, as well as engage in dialogue with the industry, advocates and State agencies as part of our efforts to standardize more marketing model materials. As we did when we reissued the standardized annual notice of change/evidence of coverage (ANOC/EOC) models for contract year 2010, we intend to continue to consumer test our marketing materials, as practical, to ensure that they accurately describe plan benefits and assist beneficiaries with making the best health care decisions for their particular needs. As part of the process of revising the standardizing ANOC/EOC models, we also conducted listening sessions with the industry to solicit input on improving standardized documents. We received a great deal of useful information as a result of those sessions, which we believe was critical to improving the consumer friendliness of those models. In addition, we will continue to provide opportunities for external stakeholders to comment on draft versions of model documents prior to finalizing them.

Comment: Many commenters requested clarification on whether, in developing standardized model marketing materials, we will continue to allow plans the flexibility to modify model documents to accurately convey specific or unique plan information. Many commenters argued that our existing models do not adequately capture the range of variation in plan types and benefits and that standardizing additional models could impede effective communications with

members and potentially lead to beneficiary confusion.

These commenters also expressed concern that without such flexibility and space for free form text, plans will be unable to adequately capture the nuances and unique features of the various plan types. Commenters specifically indicated that it was imperative for us to allow flexibility within standardized models for special needs plans (SNPs), cost plans, point-of-service (POS) plans and employer group plans. A few commenters requested the option to waive standardized language for SNPs, or to develop separate standardized documents for these plans if we do not provide sufficient flexibility within standardized models. A commenter suggested that CMS develop documents specifically for low-income subsidy (LIS) eligible beneficiaries and that we provide documents translated into non-English languages, as well as documents in Braille.

Response: We agree that standardized materials should be sufficiently tailored to the intended recipients to relay plan information as clearly as possible. Accordingly, we intend to continue to allow plans flexibility to accurately convey specific plan information. As with the current ANOC/EOC standardized models, we will permit plans to capture the unique features and nuances of their various plan types and plan benefits through variable text, as appropriate. Our requirement to use standardized models when we make them available does not change this practice; we are simply moving toward standardizing more marketing documents.

We will consider how best to provide information to LIS-eligible individuals as we standardize models. With regard to providing translated materials, our Medicare Marketing Guidelines currently require plans to provide translated and alternative format documents to beneficiaries. Specifically, plans are required to translate materials in service areas where at least ten percent of the population speaks a non-English language as its primary language. In addition, plans must make basic enrollee information available to individuals with disabilities (for example, visually impaired beneficiaries) and must ensure that information about their benefits is accessible and appropriate for Medicare beneficiaries who have disabilities.

To ensure that beneficiaries understand materials translated into a non-English language, we require that plans translating their marketing materials into other languages use

standardized language. For example, plans translating materials into Spanish or Cantonese should use a standard Spanish or Cantonese language resource (such as, “Real Academia Española” [Royal Spanish Academy], the most widely-recognized institution responsible for regulating the Spanish language).

Comment: Several commenters suggested we clearly identify the documents we intend to standardize, while two commenters suggested we limit the documents we intend to standardize. One commenter wanted clarification on what “when specified by CMS” means. In addition, many commenters urged us to release standardized documents to plans early in the year to allow plans sufficient time to disseminate plan information to beneficiaries.

Response: In addition to the ANOC/EOC, we indicated in the 2009 Call Letter that we intended to standardize the Part D explanation of benefits (EOB), pharmacy directory, provider directory, plan formulary, and transition notice. We are currently in the process of consumer testing and revising some of these models to include plain language.

With regard to the comment about what “when specified by CMS” means, as with the ANOC/EOC, CMS will specify which documents must be used without modification through guidance documents such as the annual Call Letter or HPMS memoranda. Finally, we are committed to releasing final standardized models as early as possible in the year in order to permit plans sufficient time to prepare and disseminate those documents to beneficiaries for the following contract year.

Comment: A commenter suggested that, as an alternative to our proposed requirement that plans use standardized documents as specified by CMS, we should allow for review of requested changes to standardized language similar to our review of hard copy change requests for the Summary of Benefits.

Response: We disagree with the commenter’s suggestion. As stated elsewhere in this preamble, we believe standardization leads to improvements in accuracy, comparability, and understandability, as well as increased efficiencies and greater consistency in our marketing material review protocols and processes. Permitting hard copy changes would undermine our efforts to reduce variability in marketing materials. In addition, we believe that we can address the commenter’s concerns by permitting plans to use variable text fields throughout

standardized documents so that they accurately reflect unique plan information.

Comment: One commenter understood and appreciated the need to standardize models but was concerned that requiring a standardized format limits options, may expand the length of current model documents, and could potentially drive up costs of printed materials.

Response: We believe the benefits of increased standardization outweigh the commenter’s concerns. The move toward standardizing more documents will reduce the variability and errors in marketing materials, and will ensure that standardized documents provide more accurate, understandable, and comparable information across plans, thereby helping beneficiaries to make the best possible health care decisions for their particular needs.

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

We proposed to amend the regulations at § 422.74(d)(1) and § 423.44(d)(1) regarding disenrollment for nonpayment of premiums to require a minimum grace period of 2 months before any involuntary disenrollment occurs, in order to 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. Furthermore, we proposed to codify existing subregulatory guidance regarding the beginning of the grace period for Part D. In this final rule, we adopt these provisions as proposed.

Comment: Several commenters supported our proposed regulatory revision to increase the length of the minimum grace period and further requested that CMS exempt beneficiaries from having to pay plan premiums if the organization fails to request payment of the premiums in a timely manner. Another commenter supported this change and further recommended that CMS also require plans to provide for exceptions in cases of financial hardship or other special circumstances.

Response: We appreciate the support for this proposal and are adopting it as proposed. Although we do not believe that it is appropriate to exempt beneficiaries from paying premiums for periods of coverage based on late notification, we strongly encourage plans to work with such individuals to implement payment plans where financial hardship could be involved. Also, we note that a change in policy

with respect to an individual’s eventual obligation to pay his or her premiums is not within the scope of this rulemaking.

Comment: Another commenter who supported the proposed regulatory revision further requested that CMS develop a method for beneficiaries to engage CMS in resolving premium payment disputes, such as whether individuals who qualify for the Part D low income subsidy or are enrolled in a state pharmaceutical assistance program (SPAP) owe plan premiums, in addition to disputes regarding individuals who experience problems with premium withhold from their Social Security benefits.

Response: Although there is no formal CMS administrative process for dealing with these issues, we do play an important role in resolving premium payment disputes through our existing casework procedures. CMS caseworkers often deal directly with individuals who have their premiums withheld from their SSA benefit payment, and we also work with plans to resolve both premium issues involving individuals or groups of enrollees, such as the LIS population in a plan. We also facilitate discussions between plans and SPAPs about such payment issues. We will continue to look at ways to better address these issues.

Comment: One commenter supported the change and recommended that the 2-month grace period begin the first of the month for which the enrollee is delinquent and not from the point of notification.

Response: Current regulations state that the grace period begins the first day of the month for which the premium is unpaid. Subregulatory guidance (§ 50.3.1 of Chapter 2 of the Medicare Managed Care Manual and § 40.3.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual) further clarifies that the premium is “unpaid” only after the member is notified of, or billed for, the actual premium amount due. We clarified that the grace period not begin prior to the member being notified of the delinquency was established to ensure that members have the full grace period in which to resolve the premium payment issue. We agree with the commenter that the grace period should begin the first day of the month for which the enrollee is delinquent, but only if the organization has previously requested payment of the premium and has provided the member an opportunity to pay. Accordingly, in this final rule, we are revising § 422.74(d)(1) and § 423.33(d)(1) to include the requirement that the grace period begin on the first day of the month for which the premium is unpaid or the first day

of the month following the date on which premium payment is requested, whichever is later.

Comment: Several commenters representing plans opposed the proposed change. One commenter contended that the change would not result in a reduction in disenrollments and requested that CMS instead maintain the minimum 1-month grace period and allow organizations to offer a longer grace period at their discretion. Another commenter cited the potential costs that may be incurred by organizations to make systems enhancements and to modify current administrative processes, policies, and procedures. Another commenter feared lengthening the minimum grace period from 1 month to 2 months would potentially expose the organization to increased financial liability.

Response: We believe that providing additional time for individuals to pay their premiums will assist a great number of individuals in meeting their financial obligations and avoid disenrollment. As discussed in the preamble to the October 22, 2009 proposed rule (74 FR 54657), under current rules, individuals may have less than a month to resolve payment delinquencies. Thus, we believe this proposal will provide a valuable beneficiary protection, particularly in view of the significant potential gap in coverage that could result from such a disenrollment, given that in many cases an individual may not be able to re-enroll until the following annual election period. It will also help to reduce the number of situations where individuals pay their premiums shortly after their disenrollments take effect but the plan has already submitted a disenrollment transaction.

Many organizations currently offer a grace period in excess of the one month minimum that is currently required. As such, the impact of the proposed change is limited to those organizations that have chosen to implement the minimum requirement. For these organizations, we believe any administrative costs that may result from changing from a one month to a two month grace period are fully justified by the benefits to be gained by both the organization and its members by providing a more reasonable time frame for all parties to resolve premium payment issues and avoid disenrollment. With respect to the financial liability issue, we also note that the proposed change would not affect an organization's ability to pursue collection of past due premium payments from current and former members.

Comment: One commenter requests that CMS change the requirement for issuing disenrollment notices, stating that a timeliness standard of 5 or 7 days would be more manageable than the current three business day requirement.

Response: The 3-day requirement referred to by the commenter is not for provision of the disenrollment notice; rather, it is the deadline for organizations to submit the ensuing disenrollment transaction to CMS. This timeframe was established to provide adequate time for data to be transmitted to CMS to ensure the timely processing of any necessary auto-enrollments for those individuals who receive the Part D low income subsidy. Therefore, we are not adopting this suggestion.

Comment: One commenter requested that CMS clarify that the grace period applies only to members for whom CMS makes payment to the organization.

Response: Our interpretation of this comment was that it was intended to address situations where a plan's enrollment records may not immediately match CMS records, and thus there is some question as to whether an individual is enrolled in the plan. Given that the plan has determined the beneficiary eligible for the plan, has notified the beneficiary of the enrollment, has submitted the enrollment to CMS and the discrepancy in the enrollment record is not caused by any action of the beneficiary but instead is an issue to be resolved between CMS and the plan, we believe it would be appropriate for the same grace period policies to apply to such a beneficiary as to a confirmed plan enrollee.

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

In our October 22, 2009 proposed rule, under the authority of sections 1852(b)(1)(A), 1856(b)(1), and 1857(e)(1) of the Act, we proposed to amend § 422.100(f)(3) by adding a new paragraph (f)(4) to specify that all local MA plans must establish a maximum out-of-pocket (MOOP) liability amount inclusive of all Medicare Parts A and B services, the amount of which would be set annually by CMS. We also noted that, under our proposal to require that a MOOP amount be established for local MA plans, the MOOP limit for local preferred provider organization (PPO) plans would be inclusive of all in-network and out-of-network beneficiary cost sharing. As discussed in the proposed rule, we believe that requiring the inclusion of such a limit in plan design is necessary in order not to discourage enrollment by individuals

who utilize higher than average levels of health care services (that is, in order for a plan not to be discriminatory in violation of section 1852(b)(1) of the Act).

In the preamble to our October 22, 2009 proposed rule, we generally described the process we have established to comprehensively review the proposed cost sharing of each plan benefit package and determine if MA plans' cost sharing designs—both in terms of aggregate expected out-of-pocket cost-sharing and particular cost-sharing amounts for certain health care services—discriminate against those beneficiaries with higher than average health care needs. We noted in the preamble to the proposed rule that we have annually established, through subregulatory guidance, a voluntary maximum out-of-pocket limit on Parts A and B services that, if adopted by an MA plan, would allow the plan greater cost sharing flexibility than it would otherwise receive absent the voluntary MOOP. We also noted that we have identified certain health care services 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) and described our process for conducting outlier analyses by which we consider the distribution of cost sharing levels submitted by MA organizations to identify levels in the upper end of the range for the purpose of reviewing whether cost sharing levels for submitted benefit designs are discriminatory. We believe these efforts have resulted in reduced discriminatory cost sharing and improved the transparency of plan design. For example, in contract year 2010, about 39.2 percent of all non-employer MA plans representing about 3 million MA enrollees adopted the voluntary MOOP limit on beneficiary cost sharing.

In the preamble to the proposed rule, we stated our intent to use a similar method for establishing a mandatory MOOP amount for Parts A and Part B services for all local MA plans as we used to establish the voluntary MOOP limit for contract year 2010. Therefore, the MOOP would be set by CMS at a certain percentile of fee-for-service (FFS) beneficiary out-of-pocket spending. We also noted that we set the voluntary MOOP limit at the 85th percentile of FFS spending for contract year 2010 but could set the limit at a different percentile or through a modified approach as determined by us in future years. We also proposed to continue to furnish information to MA organizations on our methodology and

the amounts for acceptable MOOP amounts on a timely basis through the annual Call Letter or Health Plan Management System (HPMS) memoranda. We solicited comments on this approach.

After considering the comments we received on this issue, we are finalizing § 422.100(f)(4) largely as proposed but, as discussed in greater detail below, are adding a new paragraph (f)(5) to address concerns raised by commenters about applying our proposed MOOP amount to PPO out-of-network services. Specifically, we are specifying in paragraph (f)(5) that the mandatory MOOP amount under paragraph (f)(4) would only apply to PPO network services, while a higher catastrophic maximum would apply to both in- and out-of-network liability. In setting a higher catastrophic maximum, we will take into consideration standard practices in commercial benefit design as well as protecting beneficiaries who use out-of-network providers.

Comment: Several commenters noted that a MOOP amount protects beneficiaries from catastrophic medical costs and supported our proposal. Another commenter noted that it was important that all Parts A and B services be included in the MOOP amount. Another commenter supported our proposal on the grounds that it will bring an element of standardization to the MA program.

A number of Medicare Advantage organizations (MAOs) expressed concern that Original Medicare does not have a MOOP and argued that it would therefore not be equitable to require one for MA plans. These commenters were also concerned that a mandatory MOOP would increase plans' costs and result in increased premiums for beneficiaries, particularly if the dollar limit is too low. Some commenters were also concerned that a mandatory MOOP amount would result in adverse selection, with "sicker" Medicare beneficiaries dropping out of Original Medicare and selecting MA plans. One commenter advocated that we continue our current process of allowing voluntary MOOP limits with a more stringent review for plans that do not adopt the voluntary MOOP limit.

Response: As discussed in the proposed rule, we believe that requiring the inclusion of a MOOP limit is an important step to ensure that individuals who utilize higher than average levels of health care services are not discouraged from enrolling in MA plans that do not have such a limit in place. Given that regional PPO plans are required by statute to have such a liability limit in place, and a substantial number of local plans have adopted one

voluntarily, we were concerned that high cost enrollees would be discouraged from enrolling in MA plans that did not include a MOOP limit. We believe that requiring a mandatory MOOP limit does not unduly disadvantage MA plans relative to original Medicare. We note that beneficiaries in original Medicare have the option of selecting between two Medigap policies, K and L, that afford them an annual cap on out-of-pocket expenses (currently at \$4,600). In addition, enrollees in the original Medicare program can select among other Medigap policies that limit their cost-sharing liability for Parts A and B services. As noted previously, a significant number of MA plans have already successfully designed benefit packages that include MOOP limits and have continued to effectively compete in the marketplace.

We agree, however, that retaining a voluntary MOOP amount that is lower than the mandatory maximum we have proposed would preserve current incentives for further reducing enrollee out-of-pocket liability. Therefore, in addition to establishing a mandatory MOOP amount, we also plan to continue our current policy of offering MA plans the option of establishing a lower voluntary MOOP amount in exchange for more flexibility in cost-sharing thresholds than available for plans that adopt the higher mandatory MOOP for contract year 2011. Under this approach, the voluntary MOOP amount would be set at an amount lower than the mandatory MOOP, and would therefore not disadvantage those MA plans that have adopted the voluntary MOOP in previous contract years. We would in effect establish two sets of Parts A and B service cost-sharing thresholds under this approach, one applicable to plans selecting the higher, mandatory MOOP amount, and the other applicable to those choosing the lower, voluntary MOOP. To incent plans to adopt the lower MOOP amount, we would allow plans greater cost sharing flexibility for Parts A and B services if they adopt the lower, voluntary MOOP. We plan to articulate this voluntary MOOP policy through subregulatory guidance such as the annual Call Letter or a similar document.

Comment: Several commenters were concerned that a mandatory MOOP amount should not be set so high as to discourage low income individuals from joining MA plans. Other commenters recommended that we ensure that the MOOP amount is low enough to benefit low income individuals. One commenter also expressed concern that

a MOOP limit may disadvantage smaller local plans compared to larger plans, potentially resulting in those smaller plans being priced out of the MA market. One commenter recommended that we use a fixed benchmark for the MOOP amount, rather than the 85th percentile of expected FFS spending cited in the preamble to our proposed rule, as the cut-off established for contract year 2010, which they believe would still be too high an amount for low income enrollees. Another commenter supported a cut-off at a higher percentile of FFS to ensure that plans do not have to increase their premiums or, alternatively, that the MOOP amount be set no lower than \$7,500 in order not to affect the sustainability of the MA program. Another commenter supported a mandatory MOOP amount, but argued that plans should be allowed to establish their own MOOP amounts.

Response: In establishing the mandatory MOOP amount, we will be cognizant of the balance we must strike between affording beneficiaries reasonable protection from high out-of-pocket expenses and our desire that the MA program remain viable for health plans and beneficiaries. We will carefully assess the impacts of the MOOPs we establish, annually adjusting the limit as necessary based on the previous year's experience, as well as other factors as appropriate, to ensure that this balance is maintained. As noted previously, we believe the approach of establishing a higher, mandatory MOOP amount and a lower, voluntary MOOP amount will allow us to better strike this balance.

Comment: A couple of commenters did not believe their systems would support tracking of out-of-pocket expenses relative to a mandatory MOOP limit, and that the imposition of one would therefore introduce a significant new administrative burden. One commenter argued that we should furnish additional funding to MA plans due to the costs of implementing a mandatory MOOP amount.

Response: We recognize that those plans that have not already voluntarily introduced a MOOP may need to invest resources in ensuring their systems are designed to implement this requirement. We believe, however, these costs need to be weighed against the benefits of ensuring that MA plan designs without a MOOP limit do not discourage enrollment by high cost individuals.

Comment: Several commenters requested clarification regarding the applicability of our proposed

requirement to establish a mandatory MOOP amount to MA plans.

Response: Because a statutory MOOP requirement is already in place with respect to regional PPO plans, we proposed applying the new mandatory MOOP requirement only to local MA plans in our proposed rule. While we now believe regional PPOs should be subject to the same requirements with respect to a MOOP as local MA plans, since our proposed rule did not give MA organizations offering regional PPOs an opportunity to comment on such a proposal, we will need to address this discrepancy in future notice-and-comment rulemaking. However, we note that regional PPOs will have the option of implementing any mandatory or voluntary MOOP amounts we establish for local MA plans.

Comment: A number of commenters recommended that we announce the mandatory MOOP amount, and the methodology we use to set it, as early as possible in the year preceding the contract year in which we will apply that amount (for example, in the Advance Notice of Methodological Changes). Another commenter recommended that this information be provided in our annual Call Letter.

Response: As specified in the preamble to the proposed rule, we intend 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 a similar guidance document.

Comment: Two commenters were concerned that the mandatory MOOP would apply to all in- and out-of-network PPO services, and contended that such an arrangement could lead to a reduction in the number of PPOs offered given the potential increase in plan costs that would result. One of these commenters believed including cost-sharing applicable to out-of-network plan covered services will undermine incentives to use preferred providers that are central to the design of a PPO.

Response: As stated in the proposed rule, we believe that some protection against out-of-pocket liability should apply to enrollee cost-sharing for both in- and out-of-network services covered by PPOs. However, we agree with the concerns of the commenter highlighting the effect a single MOOP applying to all services would have on incentives to use preferred providers. In addition, for reasons of beneficiary transparency and consistency, we believe that local PPOs should be subject to the same type of MOOP requirements as regional PPOs, which have a different MOOP for out-

of-network cost-sharing than that which applies to use of PPO in-network services. Therefore, we are revising § 422.100 by adding a new paragraph (5) that specifies that, in addition to the MOOP for Medicare Parts A and B services that all local MA plans will be subject to—which would apply only to the use of network providers—all local PPO plans must also establish a total catastrophic limit on beneficiary out-of-pocket expenditures for both in-network and out-of-network Parts A and B services consistent with the requirements applicable to regional PPOs at § 422.101(d)(3). This total catastrophic limit will be no greater than an annual limit set by CMS. In addition, we will also offer local PPO plans the option of implementing any voluntary MOOP amount CMS establishes for local MA plans.

Comment: One commenter requested clarification regarding whether all Medicare Parts A and B services would be included in the MOOP amount.

Response: As noted in the preamble to our proposed rule, cost-sharing for all Parts A and B services would be included in the MOOP amount. Such cost-sharing includes any plan deductibles applicable to Parts A and B services, but excludes monthly plan premiums.

Comment: A commenter argued that since States pay cost sharing for members of dual-eligible special needs plans (SNPs), there is no need to apply a MOOP to these plans. Another commenter contended that dual-eligible SNPs cannot charge their enrollees a premium as a practical matter, which would further disadvantage this plan type if they were required to implement our MOOP limit. Another commenter recommended that we provide guidance on how the MOOP will apply to SNP enrollees, particularly those in dual-eligible SNPs. This commenter was specifically interested in guidance regarding what States' obligation would be with respect to premiums and cost sharing, as well as the actual out-of-pocket liability for a dual-eligible SNP enrollee. Additionally, this commenter was concerned that dual-eligibles may experience an unnecessary reduction in supplemental benefits if our final requirement does not clearly distinguish what these individuals actually pay as out-of-pocket costs versus what Medicaid should pay.

Response: We disagree with comments recommending that SNPs be exempted from MOOP requirements. Dual-eligible individuals entitled to have their cost sharing paid by the State and enrolled in a SNP may experience midyear changes in their Medicaid

eligibility. In those cases, these individuals may be required to directly pay the plan cost sharing that otherwise would be the obligation of the State. Accordingly, we will not exempt SNPs from the requirement that they implement a MOOP amount as established annually by CMS.

Comment: Another commenter recommended exempting employer plans from our MOOP requirements because such a benefit design would be inconsistent with the benefits employer plans currently offer.

Response: We disagree with this commenter that such a regulatory exception is warranted. The same considerations involving discrimination against high cost enrollees could also apply in the employer plan context, particularly if the employer allows more than one plan option. In exceptional cases in which CMS agrees that a waiver of this rule would be in the interest of Medicare beneficiaries served by an employer group, CMS could consider waiving the regulations through the employer group waiver authority under section 1857(i) of the Act. Employer plans will therefore be subject to the regulatory MOOP requirement finalized in § 422.100(f)(4) that applies to all MA plans.

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

In our October 22, 2009 proposed rule, we proposed to amend our regulations on the general requirements related to Medicare Advantage (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.

For Part C plans, we proposed to annually review bid data to determine specific cost sharing levels for Medicare A and B services below which we would not consider there to be a discriminatory effect, and therefore may be approved in an MA benefit package. Specifically, we proposed amending § 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 us to be discriminatory.

Similarly, for Part D plans, we proposed to annually review bid data to determine acceptable cost sharing tiers for benefit packages offering non-defined standard prescription drug coverage. To this end, we proposed revising § 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 us to be discriminatory.

We also explained in the preamble to the proposed rule that we would furnish information to MA organizations and Part D sponsors on our methodology and the cost sharing thresholds for the following contract year based on the prior year's bids, and on a timely basis either through the annual Call Letter or Health Plan Management System (HPMS) memoranda. We solicited comments on this approach, including the extent to which we provided sufficient clarity on how we would determine whether cost-sharing levels are discriminatory.

After considering comments we received on this issue, we are adopting proposed § 422.100(f)(5) (which, in light of the new subparagraph (f)(5) discussed above, is recodified as subparagraph (f)(6)) and § 423.104(d)(2) with minor revisions made in response to comments discussed below that are intended to clarify that limits will only be established for those Parts A and B services specified by CMS. We note that section 3202 of the Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111-148) "Benefit Protection and Simplification" will apply to MA plans offered in 2011. Section 3202 of PPACA specifies that, unless a specified exception applies, the cost sharing charged by MA plans for chemotherapy administration services, renal dialysis services, and skilled nursing care may not exceed the cost sharing for those services under Parts A and B. Where these new limits apply, they will constitute an absolute limit on cost-sharing for the service in question by operation of statute, and we will not set limits under this final rule. After the publication of this rule, we will issue clarifying guidance concerning section 3202 and other provisions of PPACA that impact this regulation.

Comment: A number of commenters supported our proposed requirement to specify that cost sharing for Medicare A and B services may not exceed levels annually determined by us to be discriminatory. One of these commenters supported us in continuing our current approach to applying a discrimination test.

A number of commenters opposed our proposed requirement to establish individual Parts A and B service category cost-sharing thresholds, suggesting that individual service category thresholds would result in higher premiums. Other commenters believed that cost-sharing limits would present significant additional administrative costs for plans. A

number of commenters contended that individual service category thresholds would limit the availability of unique benefit designs and, consequently, limit beneficiary choice. One commenter argued that we should not limit plans' ability to use cost sharing as a tool to encourage beneficiary choice of cost effective and clinically appropriate services. Another commenter recommended that, rather than adopting cost-sharing thresholds, we should evaluate other options for identifying and preventing discriminatory benefit designs, such as evaluating the prevalence of utilization control mechanisms (for example, prior authorization) on services frequently used by patients with a particular high-cost conditions.

Response: We believe establishing individual service cost-sharing thresholds is necessary to ensure that beneficiaries who utilize higher than average levels of health care services will not be discouraged from enrolling in MA plans with cost-sharing in excess of thresholds set by CMS and that our proposal to set specific amounts in advance improves the transparency of, and comparability between, plan choices for beneficiaries.

We are therefore finalizing our proposal to allow us to annually set cost sharing thresholds for Medicare Parts A and B services.

In establishing service category cost-sharing thresholds, we will be cognizant of the balance we must strike between affording beneficiaries reasonable protection from high out-of-pocket expenses that could discourage enrollment and our desire that the MA program remain viable for health plans and beneficiaries. We will carefully assess the impacts of the cost-sharing thresholds we establish, annually adjusting the limits and the particular Parts A and B services that are subject to such limits as necessary based on the previous year's experience and other factors as needed, to ensure that this balance is maintained. As we have in previous years, we plan initially to establish cost-sharing thresholds for those Parts A and B services that we have, through a number of years of experience with plan benefit reviews, identified as particularly likely to have a discriminatory impact on sicker beneficiaries. Specifically, under our current cost sharing review process which has developed from our past experience in reviewing benefit packages we focus our review on 14 service categories we have identified a particularly likely to have discriminatory impact on "sicker" beneficiaries: inpatient catastrophic (90)

days, inpatient short stay (10 days), inpatient mental health (15 days), SNF (42) days, home health (37) days, physician mental health visits, renal dialysis (156) visits, Part B drugs, chemotherapy, radiation, DME, equipment, prosthetics, supplies and diabetes tests.

As discussed elsewhere in this preamble, in addition to establishing a mandatory maximum out-of-pocket (MOOP) limit on overall cost-sharing for Parts A and B services, we also plan to continue our current policy of offering MA organizations the option of adopting a lower voluntary MOOP with greater flexibility in Parts A and B cost sharing than available for MA plans that meet only the higher mandatory MOOP. Under this approach, the voluntary MOOP would be set at an amount lower than the mandatory MOOP and would therefore not disadvantage those MA plans that have adopted the voluntary MOOP in previous contract years. In implementing thresholds for discriminatory cost-sharing for individual services, we plan to establish two sets of Parts A and B service cost-sharing thresholds, one applicable to plans choosing the higher, mandatory MOOP, and the other applicable to those choosing the lower, voluntary MOOP. We plan to articulate the cost-sharing thresholds associated with the lower, voluntary MOOP through subregulatory guidance such as the annual Call Letter or similar guidance document.

In establishing cost-sharing thresholds, we will consider an MA organization's need to use cost-sharing as a tool for preventing overutilization of services. While we have not been provided evidence that this requirement would increase plans' administrative costs, we also note that MA organizations will be able to account for any increased administrative costs in their annual bids. Finally, with respect to the comment about reviewing prior authorization, we believe that establishing cost-sharing thresholds is a more efficient and effective method for eliminating discriminatory MA plan designs.

Comment: One commenter questioned our authority to impose individual service category thresholds, and urged us to withdraw our proposal.

Response: We disagree with this commenter. As discussed in the preamble to the October 22, 2009 proposed rule, our proposal relies upon the authority in section 1852(b)(1) to ensure that an MA plan would not substantially discourage enrollment by certain MA eligible individuals and our authority under section 1857(e)(1) of the

Act, under which we may add “necessary and appropriate” contract terms; and, with respect to MA plan cost sharing, the authority in section 1856(b)(1) of the Act, under which we may establish MA standards by regulation.

Comment: Some commenters sought clarification on how we will address cost sharing thresholds with regard to dual-eligible special needs plans (SNPs). These commenters specifically asked whether we would exempt dual-eligible SNPs from our proposed establishment of mandatory Parts A and B service thresholds, since States pay dual-eligibles’ cost sharing. These commenters argued that our proposed requirement could force dual-eligible and chronic care SNPs to charge a premium, thus making their plans unattractive to dual-eligibles and other low-income enrollees.

Response: We disagree with commenters recommending that dual or chronic care SNPs should be exempted from our service category cost-sharing thresholds. As long as a plan has at least some enrollees subject to all of a plan’s cost-sharing amount, those enrollees could still be discouraged from enrolling or continuing their enrollment in the plan given particularly high cost-sharing for specific services. Even those SNPs that exclusively serve dual-eligible enrollees entitled to have their cost sharing paid by the Medicaid program can include some individuals who lose their Medicaid status midyear and become subject to plan cost sharing which would no longer be paid by the Medicaid program. Plans should not establish excessive cost-sharing regardless of whether the State is responsible for beneficiaries’ cost-sharing. We are therefore not exempting SNPs from the mandatory MOOP and cost sharing limits that apply to other MA plans.

Comment: One commenter asked us to consider exempting employer plans from our cost-sharing threshold requirements, arguing that such a requirement would complicate their efforts to offer their current and retired employees parallel coverage.

Response: We disagree with this commenter. The nature of employer arrangements varies greatly. In some cases, an employer may offer more than one MA plan option, and one or more of those plans may still discourage enrollment by certain beneficiaries through their benefit design. Also, in the case of an employer plan, if a compelling reason exists for an exemption from the limits in this final rule, and if we determine an exemption would be in the best interests of

beneficiaries, employers could request a waiver of these limits under the employer waiver authority.

Comment: Some commenters recommended that we establish cost sharing thresholds for Parts A and B services as soon as possible prior to the bid submission deadline (for example, in the Call Letter or Advance Notice of Methodological Changes) and provide stakeholders with an opportunity to provide comments regarding the thresholds and the methodology used to arrive at those thresholds. Some commenters representing non-plan stakeholders also requested that we provide this information via means other than the HPMS, since only plans have access to HPMS and advocates and other non-plan entities would like to receive the information we share with plans via HPMS. Another commenter recommended that we permit MA organizations to resubmit a bid and benefit package if the initial bid is rejected due to a finding by CMS of discriminatory cost sharing.

Response: As stated in the preamble to the proposed rule, we intend to furnish information to MA organizations and Part D sponsors on our methodology and the cost sharing thresholds for the following contract year on a timely basis either through the annual Call Letter or similar guidance document. We will consider ways of disseminating this information through other means to ensure that all stakeholders have an opportunity to comment and note that we generally post draft Call Letters to the CMS Web site to ensure broad public availability. With regard to opportunities to resubmit bids and benefit packages, given that we expect to provide guidance regarding cost-sharing thresholds prior to bid submission, we do not anticipate the need to allow plans to resubmit bids or benefit packages if their submissions are inconsistent with published guidance. As part of our review of submitted bids and benefit packages, we may contact plans to give them the option of modifying their bids and benefit packages if we have made a determination that the proposed plan benefit package or cost sharing contains discriminatory amounts not outlined in published guidance.

Comment: One commenter recommends that cost-sharing limits, and the service categories to which they apply, remain stable from year-to-year.

Response: We intend to implement cost-sharing thresholds carefully to ensure the right balance of ensuring against discriminatory effects of high cost-sharing and continued viability of the MA program. While we believe

stability in the thresholds and the particular services to which those thresholds are applied is important, we also believe it is necessary to allow ourselves the flexibility to build on “lessons learned” each year, and to reevaluate both the thresholds and the Parts A and B service categories to which they apply, to account for any statutory changes in Original Medicare cost-sharing limits as well as other changes to the MA program, and refine our approach accordingly to maintain such a balance.

Comment: Some commenters believed that we were not clear in the proposed rule regarding whether we would set cost sharing thresholds for all Parts A and B service categories, or only for selected categories identified as potentially discriminatory. These commenters requested further clarification on our intended approach.

Response: As we have done in the context of benefits review in previous years, we intend to focus on service categories particularly likely to have a discriminatory impact on sicker beneficiaries. Initially, we will focus on the service categories we have targeted historically in our benefit review. We expect to refine our approach over time in order to achieve the right balance between plan choice and protection from high out-of-pocket costs. We intend to build on our experience, and potentially make modifications to the list of Parts A and B service categories to which we would apply cost-sharing thresholds.

Comment: A couple of commenters recommended that, in setting cost-sharing limits, CMS consider enrollees’ cost-sharing both before and after members reach any deductible that may apply.

Response: We will consider whether to take plan deductibles into account as part of our methodology to establish cost-sharing thresholds.

Comment: One commenter requested clarification on how we will establish cost sharing thresholds based on the previous year’s experience. One commenter urged that the thresholds not be adjusted based on current year data.

Response: As described in the preamble to our proposed rule, we intend to review the prior year’s bid data, as well as actuarial equivalency relative to Original Medicare, to identify cost sharing outliers and establish a reasonable threshold. With this information, and other factors we may identify as we gain experience in establishing these thresholds, we will annually set cost-sharing thresholds as described in this preamble. We do not

anticipate that these levels will need to be changed after bids have been submitted. However, as previously noted, we will conduct a review of submitted bids and we reserve the right to address discriminatory cost sharing or benefit design we identify in these post bid reviews by asking the plan to either modify or withdraw its bid to resolve discriminatory cost sharing.

Comment: One commenter recommended that service category thresholds be set at fixed dollar amounts.

Response: We understand that copayment amounts are more transparent and predictable for beneficiaries than coinsurance, and will attempt to establish thresholds as copayment amounts rather than coinsurance percentages where appropriate. Given the fact that original Medicare employs coinsurance percentages in its cost-sharing, there may be cases, in which we may limit the coinsurance percentage that can be imposed.

Comment: One commenter recommended that we not set a cost sharing maximum for routine services, such as physician visits and lab services, where there is limited financial liability, or for durable medical equipment (DME), where they argue that any particular cost-sharing maximum would invariably penalize one subset of enrollees. One commenter recommended that we establish thresholds on a per day, per stay, and per benefit period basis for SNF and inpatient services. Another commenter recommended that any threshold for Part B drugs apply to all Part B covered drugs.

Response: We disagree that physician visits and lab services should necessarily be exempt from cost-sharing maximums, though we currently do not contemplate imposing limits in such cases, and would only do so to the extent that we saw cost-sharing imposed that had a discriminatory effect. As stated previously, we initially will focus on those service categories we have historically identified as particularly likely to have a discriminatory impact on sicker beneficiaries and will refine our approach as needed and in line with our ultimate goal of eliminating discriminatory benefit designs. We welcome the feedback provided by other commenters with regard to DME, SNF and Part B drug copayments and will consider these recommendations as we finalize our methodology and thresholds.

Comment: Several commenters supported the proposal to review Part D plan bids to determine acceptable cost-

sharing tiers for benefit designs that deviate from the standard benefit package. One commenter indicated that this would bring a level of standardization to plans and make it easier for them to compare out-of-pocket expenses.

Response: We appreciate the comments.

Comment: Several commenters wanted to limit Part D cost sharing to a total maximum out-of-pocket amount.

Response: We do not believe that a regulatory overall liability limit for Part D would be practical or appropriate given the current design of Part D benefits (such as, the coverage gap). We also note that, under the Part D benefit, there is protection afforded to a beneficiary once they enter into the catastrophic phase of the benefit where there is nominal cost sharing.

Comment: One commenter wanted us to establish clear and definitive limits on cost sharing. Another commenter wanted us to consider the overall affordability of cost sharing that is imposed on non-low-income (LIS) Medicare beneficiaries. The commenter argues that this is particularly important when considering a plan design in which preferred formulary tiers do not include equally safe and effective drugs for the beneficiary's medical condition. Another commenter wanted us to take into account separate rules for cost contracts with HMOs under section 1876. Additionally, another commenter wanted clarification on how we will review plans with more than or fewer than a three tier benefit design. This commenter suggested that all tiers may not exceed levels determined by CMS to be discriminatory.

Response: We appreciate these comments. It is important to note that we review both formularies and benefit designs to ensure that a sponsor's prescription drug offering under Part D is not discriminatory. We have designed our yearly formulary reviews to ensure that all Part D plan formularies include a wide representation of drugs used to treat the Medicare population. As part of this review, we focus on identifying formularies with drug categories that may substantially discourage enrollment of certain beneficiaries, for example if the formulary places drugs in nonpreferred tiers without including commonly used therapeutically similar drugs in more preferred positions. As part of our yearly review of submitted benefit designs, we compare like plans to each other for the purpose of ensuring non-discriminatory cost-sharing.

Specifically, we perform an analysis of cost sharing at the tier level, to look for outliers. The outlier analysis considers

plan type (basic versus enhanced), tiering structure (for example, the number and type of tiers), and any differences among MA-PDs (including cost plans) and between MA-PDs and PDPs. When outliers are identified, we conduct negotiation calls with the relevant plan sponsors to ensure the cost sharing outliers are reduced prior to bid approval. We also require cost sharing levels for preferred tiers to be lower than cost sharing levels for nonpreferred tiers.

Comment: A commenter expressed concern that when coverage of a nonformulary drug is secured on appeal, the cost sharing under the nonpreferred tier can approximate, or even exceed, the negotiated price of the drug.

Response: The price charged to the beneficiary cannot exceed the negotiated price. The requirements related to qualified prescription drug coverage at § 423.104(g)(1) make clear that Part D sponsors are required to charge beneficiaries the lesser of a drug's negotiated price or applicable copayment amount.

Comment: Several commenters opposed setting cost sharing maximums, claiming that this will result in higher premiums for beneficiaries. One commenter asserted that CMS' proposal will limit the ability of Part D sponsors to design plans that provide choices for additional or richer benefits in other areas important to beneficiaries. For example, they argue that establishing maximum Part D brand cost-sharing levels will impact the ability to offer \$0 copayment for generic drugs; therefore, ultimately inhibiting the greater affordability and access. A commenter contended that our proposal fails to consider a plan design that is associated with a robust formulary. The commenter believes that such a plan should have the flexibility to impose higher member cost sharing, particularly for nonpreferred drugs, compared to a formulary that meets minimum requirements and, coupled with low premium which may be attractive to those with minimal drug utilization who seek protection from potential future changes in health status.

Response: In determining a maximum cost sharing amount for a tier above which we will view the plan's benefit design as discriminatory, we attempt to strike a balance between appropriate coverage under the benefit and the potential affect on the premium. As part of our benefit design review, and consistent with previous reviews, we consider all beneficiaries under the plan, and not just those beneficiaries expected to have limited utilization. Therefore, any actuarially-equivalent

cost sharing arrangement is reviewed, along with the rest of a plan's benefit design, to ensure that it does not discriminate against certain Part D eligible individuals. This sometimes results in a sponsor not being able to support higher member cost sharing amount under a robust formulary design for nonpreferred drugs or being able to support zero dollar generics. However, these cases are usually the exception since our review is designed to ensure the maximum utility of the benefit design for potential enrollees.

Comment: One commenter wanted CMS to prohibit the use of both copayment and coinsurance tiers under nonstandard Part D benefit designs.

Response: We disagree with the commenter and believe such a prohibition would unnecessarily limit plan design. Moreover, we believe that such a proposal is beyond the scope of this proposed rule, which addresses the authority of CMS to establish limits on cost sharing for purposes of determining whether or not such cost sharing is discriminatory. Our proposal did not address whether nonstandard benefit designs utilizing coinsurance are discriminatory.

Comment: One commenter wanted us to require that at least one drug within each therapeutic class be on each tier.

Response: We believe that such a proposal is beyond the scope of this proposed rule, which only addresses the authority of CMS to establish limits on cost sharing for purposes of determining whether or not such cost sharing is discriminatory. We also note that due to the varying number of drugs that may be available in a therapeutic class, this proposal may require many exceptions and be impractical to implement.

Comment: Several commenters expressed concern about our specialty tier policy. A few commenters want us to eliminate the exemption from tiering exceptions for specialty tiers. Another commenter asserted that drugs in the specialty tier are so expensive, an argument could be made that specialty tier coinsurance above 25 percent is excessive. Another commenter argues that the use of specialty tiers is a discriminatory practice that targets individuals who have medical conditions that necessitate use of expensive medications.

Response: We appreciate the commenters' concern in this area, which is one we will continue to study. Any revisions to the specialty tier policy will be done in future rulemaking. We note specifically that the commenters' request for us to eliminate the exemption from tiering exceptions for specialty tiers is outside of the scope of

this proposal. We also note that we have only allowed a higher coinsurance percentage greater than 25 percent for specialty tiers under alternative prescription drug coverage designs with decreased or no deductibles. Thus, overall, consistent with statutory and regulatory requirements, a basic alternative design must be actuarially equivalent to the defined standard benefit design.

Comment: One commenter wanted us to study the effects of high out-of-pocket costs, improve drug pricing disclosure, prohibit plans from changing the price of drugs, notify beneficiaries when a drug price is going to increase, ensure that Part D plan sponsors inform beneficiaries how to get medications free or at lower prices, and end discriminatory practice cost sharing.

Response: We appreciate the commenter's concerns over price fluctuations that may result in changes in cost sharing under a Part D plan benefit design that includes coinsurance and the effects that these changes may have on beneficiaries enrolled in these plans. However, several of these comments are outside of the scope of the proposed rule, which addresses our ability to establish threshold levels for cost sharing above which we would determine such cost sharing to be discriminatory. Moreover, we note that under section 1860D–11(i) of the Act, commonly known as the "Non-interference provision," we are prohibited from interfering in the negotiations among drug manufacturers, pharmacies, and sponsors of prescription drug plans (PDPs), and from requiring a particular formulary or price structure for the reimbursement of a covered Part D drug. Therefore, we do not have the authority to prohibit plans from changing the price of drugs.

Comment: Several commenters wanted information on discriminatory cost sharing made available through Call Letter and other public means, and want such information to be made available timely so that it can be taken into account prior to bidding.

Response: We appreciate the commenters' concern that we be as transparent and timely as possible with our guidance in this area. We will strive to make this information available as early as possible for sponsors to begin constructing their bids for the 2011 contract year.

Comment: One commenter stated that if a plan sponsor offers a plan design with zero co-payment amounts for certain mail order prescription drugs, it should be required to offer the same cost sharing at retail pharmacies.

Response: This comment is outside the scope of the proposed rule, which does not revise our level playing field policy between mail and retail drug offerings. We refer the commenter to section 50.2 of Chapter 5 of the Medicare Prescription Drug Benefit Manual at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/Chapter5.pdf> for our current policy in this area.

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

In our October 22, 2009 proposed rule, we stated that we have become increasingly concerned about the use of prior notification by PPO and PFFS plans as a condition for lower cost sharing. Program experience has demonstrated that such prior notification provisions are confusing to beneficiaries, misleading in terms of cost-sharing transparency, and in some instances, are 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 stated 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 determined 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 proposed 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. Specifically, we proposed 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 are adopting § 422.4(a)(1)(v) and (a)(3) without further modification in this final rule.

In our October 22, 2009 proposed rule, we also proposed to prohibit MSA plans from establishing prior notification rules. We believe that prior notification rules established by MSA

plans are also confusing to enrollees of those plans and have similar negative effects as those described above for PPO and PFFS plans. Accordingly, we proposed 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. We are also adopting § 422.4(a)(2) without further modification in this final rule.

Finally, the October 22, 2009 proposed rule discussed similar concerns about beneficiary confusion in connection with PPO plans that included a POS-like benefit. As we noted in the October 22, 2009 proposed rule and the Medicare Program entitled Establishment of the Medicare Advantage Program, published in the January 28, 2005 *Federal Register* (70 FR 4617 through 4619), we had stated that PPOs could 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. For the same reasons discussed above, we determined that this approach is confusing, and is subject to abuse as a prior authorization mechanism for non-network services. Therefore, in order to reduce the complexity of PPO plans' cost sharing designs and improve transparency for both enrollees and providers, we proposed in our October 22, 2009 proposed rule to prohibit PPO plans from offering such a POS-like benefit. Specifically, we proposed to revise the definition of POS in § 422.2 and § 422.105(b), (c), and (f) to indicate that 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. We are adopting § 422.105 without further modification in this final rule and revising § 422.2 as described below.

Comment: Several commenters supported our proposals to prohibit PPO plans (for out-of-network services), MSA plans, and PFFS plans from establishing prior notification rules and prohibit PPO plans from offering a POS-like benefit. Some of the commenters indicated that these practices are confusing and misleading and penalize members who are not able to give prior notification or who were unaware of the option. Some commenters also indicated that they found several plans

that charge exorbitant cost-sharing (up to 75 percent) for expensive items such as durable medical equipment when prior notification requirements have not been met. A number of commenters opposed our proposals to prohibit PPO plans (for out-of-network services), MSA plans, and PFFS plans from establishing prior notification rules and prohibit PPO plans from offering a POS-like benefit. Other commenters stated that these practices permit plans to alert the enrollee in advance of receiving a service that it may not be covered; reduce enrollees' cost sharing obligations when obtaining covered services from out-of-network providers; enable plans to better monitor and oversee members' use of out-of-network providers, thus allowing plans to assess and expand their provider networks; and identify those plan members who may qualify for plan disease management and case management programs. One commenter indicated that MA plan premiums likely would increase if this cost control technique were eliminated. Commenters opposed to CMS' proposals provided several recommendations for addressing our concerns about prior notification rules and POS-like benefits. Commenters' recommendations included retaining existing policies; enforcing the existing requirement (for example, requiring greater clarity in enrollee materials) to address concerns raised in the proposed rule; requiring PPO plans with POS-like benefit to better describe the cost-sharing amounts under each set of circumstances that may arise; requiring plans to more clearly describe the distinction between prior authorization and prior notification, and expressly identify those covered services subject to each process; and encouraging providers' outreach to plans to confirm prior authorization/notification provisions and members' cost sharing obligations.

Response: We agree with the commenters supporting our proposals to prohibit PPO plans (for out-of-network services), MSA plans, and PFFS plans from establishing prior notification rules and prohibit PPO plans from offering a POS-like benefit. As we stated in the October 2009 proposed rule, we believe 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. Also, the complexity of cost sharing designs using prior notification and POS-like benefits has made it more difficult for both enrollees and providers to understand

the enrollee's cost sharing obligation in advance of receiving services.

We acknowledge the concerns raised by commenters who opposed our proposals. However, we believe that most of these concerns can be addressed if the plan takes an active role to educate enrollees and providers about their 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. These MA plans should clearly explain the process for requesting a written advance determination in member materials and respond to requests from enrollees and providers on a timely basis. Plans may also encourage enrollees and providers to request advance coverage determinations prior to receiving costly services. These MA plans can also use requests for advance coverage determinations as a tool to identify enrollees who may qualify for disease management and case management programs or who require further care coordination. Plans can use the claims data submitted by non-network providers to expand their provider networks as well as identify those enrollees who would benefit from disease management and case management. We do not believe that prohibiting prior notification rules and POS-like benefits will lead to higher MA plan premiums. We believe that prohibiting PPO plans (for out-of-network services), MSA plans, and PFFS plans from creating prior notification rules and PPO plans from offering a POS-like benefit will reduce the complexity of these plans' cost-sharing designs and improve transparency for both enrollees and providers. Accordingly, we are adopting the proposals as set forth in the October 2009 proposed rule.

We are making a technical correction to the definition of point-of-service (POS) in § 422.2 in this final rule. We are deleting the word "additional" from the definition since it no longer applies to the definition of a POS benefit option.

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

In the October 22, 2009 rule, we proposed amending the length of the period for which individuals are re-deemed eligible for the full low income subsidy to conform § 423.773(c)(2), with guidance we issued in section 40.2.2 of Chapter 13 of the Medicare Prescription Drug Benefit Manual. As we noted in the October 2009 proposed rule, we review data from State Medicaid

Agencies and the Social Security Administration (SSA) every year to determine whether individuals currently deemed eligible for the subsidy should continue to be deemed (that is, “re-deemed”) eligible for the subsidy. These data, which are sent in July and August every year, allow us sufficient time to update individuals’ records in our systems, if necessary, and to make appropriate notifications if an individual is losing deemed status for the subsequent calendar year.

We also noted that when we review data in July and August, we also identify individuals who are newly eligible for Medicaid, a Medicare Savings Program, or SSI, and deem them eligible for LIS for the remainder of the current calendar year. In addition, we also re-deem 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 re-deeming process for them. Moreover, if we waited to re-deem these beneficiaries after the start of the next 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.

To address these issues, we proposed 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 have found that this policy promotes effective administration of the LIS benefit and decreases the administrative burden on CMS, the Social Security Agency, and State Medicaid agencies, as well as on subsidy eligible individuals. In this final rule, we adopt this provision as proposed.

Comment: Several commenters expressed support for our intent to put in regulation the minimum time periods for which beneficiaries are deemed eligible for the LIS.

Response: We appreciate this support for our intent to outline the minimum time periods of LIS eligibility.

Comment: One commenter urged us to consider making LIS deemed status permanent, or granting a 3-year period of presumptive eligibility. The commenter noted that while income and assets may fluctuate, most low-income Medicare beneficiaries are unlikely to

experience increases that are enough to affect their eligibility. The commenter also noted that making eligibility permanent would eliminate the need for redeterminations of eligibility, thus reducing administrative costs for the program and inconvenience and stress for beneficiaries.

Response: We understand the potential benefits to the LIS population of extending or making permanent their eligibility for the subsidy, and reducing the inconvenience and stress to beneficiaries is an ongoing goal of our administrative processes. Currently, approximately 95 percent of LIS-eligible beneficiaries are re-deemed for the following year prior to the end of the current calendar year, and half of those who are not initially re-deemed (that is, another 2.5 percent) are re-deemed within next 6 months. In addition to this, the number of beneficiaries who actually receive the annual Loss of Subsidy Letter, also known as the gray notice, has been decreasing over the last 4 years. This suggests that CMS and State efforts to improve the administrative process are working, and that individuals who continue to qualify for the low income subsidy are being identified appropriately, while the small proportion of individuals who may no longer qualify for the subsidy also are being identified. We believe that the approach being adopted here strikes a balance between making the re-deeming process as efficient as possible while still ensuring that beneficiaries receiving the subsidy are truly LIS-eligible. For these reasons, we are not adopting the suggested modifications.

Comment: A few commenters recommended that we require States to continue providing Medicaid coverage to a dual-eligible until the individual’s Part D enrollment actually takes effect.

Response: Section 1935(d) of the Act specifically precludes Federal medical assistance for Medicaid payments for prescription drugs for those Medicaid-eligible individuals who are also eligible for Part D, regardless of whether the person is enrolled in a Part D plan. Therefore, no modification to the regulations will be made.

Comment: One commenter requested additional regulatory changes to require improvements to the way we administer the LIS benefit, including improving the Web site, notices to encourage appropriate actions, and putting in place better “Best Available Evidence” policies and procedures to ensure that LIS status discrepancies are corrected.

Response: As noted previously, we continually consider ways to improve the administration of the LIS benefit and beneficiaries’ understanding of it. We

believe we have the authority to make the additional improvements the commenter suggested, as appropriate, without further modifying the regulation.

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

We proposed to codify in regulation the enrollment procedures that we use for LIS 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. Therefore, we proposed to include information on how we enroll all LIS-eligible individuals, including full benefit dual-eligible individuals, through the following changes:

- In § 423.34(a), we expanded 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 retained the definition of full benefit dual-eligible individual, and added a definition for “low-income subsidy eligible individual.” We have identified the need for a technical correction to the definition of “low-income subsidy eligible individual.” The proposed definition could be read to specify that the definition of full-benefit dual eligible—who are identified as a specific group of LIS eligibles—is that in § 423.722, which is limited to such individuals already enrolled in a Part D plan. However, the enrollment rules in § 423.34(b) applies to full-benefit dual eligibles not yet enrolled in a Part D plan. We made a technical correction to the regulation text to specify that the definition of full dual eligible individual is that in § 423.34.

- We amended the paragraph heading of § 423.34(c) to indicate that this paragraph describes the process we use to reassign LIS-eligible individuals during the annual coordinated election period. We indicate that the reassignment process applies to certain LIS eligible individuals (that is, not just full-benefit dual-eligible-individuals).

- We revised the paragraph heading of § 423.34(d) from “Automatic Enrollment Rules” to “Enrollment Rules.” We made this change to reflect the inclusion of full subsidy and other subsidy eligible groups in the 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 amended § 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 clarified that the paragraph heading and contents of this paragraph are limited to the effective date of enrollment for full benefit dual-eligible individuals. We also amended § 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 added a new paragraph to specify that the effective date for LIS 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.

In the proposed rule, we also acknowledged concern expressed by some commenters about auto-enrolling beneficiaries on a random basis. 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 noted that we are committed to taking appropriate steps to improve this process and welcomed comments related to all aspects of these procedures. In this final rule, we adopt these provisions as proposed.

Comment: Several commenters expressed support for expansion of auto-enrollment and reassignment to all individuals with LIS.

Response: We appreciate the support for this policy and are adopting the proposal without change.

Comment: Commenters urged us to shorten the time period for a plan enrollment so that it would take effect as of the date the person becomes subsidy eligible. The current time period can leave an individual who has applied and qualified for the subsidy with a gap of over 2 months between the time they express an interest in getting help with drug costs (via the application for the LIS) and the time they are

actually enrolled into a plan and receive that assistance. This timeframe may have made sense initially, since it was not clear that nondually eligible LIS recipients would have an ongoing SEP. Now that they have been extended that protection, there is less of a need to wait for their selection. Instead, the enrollment should happen quickly to ensure access to prescription drugs.

Response: Facilitated enrollment constitutes a passive enrollment process that requires advance notice of the opportunity to make an active election before the enrollment is effective. We have been unable to find a way to ensure that individuals who are facilitated at the end of the month can receive the required advance notice and have an opportunity to make an election on their own before that enrollment takes effect (though it is possible to do so for those at the beginning of the month). It is important to keep in mind that this population consists of individuals who have applied for LIS, are notified of their approved LIS eligibility, and informed via their LIS approval notice that they need to elect a plan in order to avail themselves of the subsidy. Thus, we believe they are likely to follow through on their previous actions and choose a plan on their own, leading to possible confusion if they receive a facilitated enrollment notice after they have already made an active election. Finally, we note that all individuals whose facilitated enrollment into a PDP has not yet taken effect may obtain coverage for immediate drug needs through the Limited Income NET demonstration.

We are committed to continue exploring ways of shortening the facilitated enrollment process without infringing on an individual’s ability to make a choice, or adding to the possibility of beneficiary confusion. However, it is important to note that proposed regulation text that we are now finalizing specifies that the enrollment effective date is “no later than” the first day of the second month” after we determine that they meet the necessary enrollment criteria. Therefore, although we are declining to amend the regulation as requested while we continue to address a number of operational issues that remain unresolved, the regulation language does provide the flexibility to shorten the timeframe if warranted and feasible.

Comment: One commenter noted that plans and beneficiaries would benefit from us specifying for both plans and beneficiaries any premium liability in instances when the beneficiary has a 25, 50, or 75 percent premium subsidy, in the process of conducting facilitated

enrollment. As part of this, the commenter suggested revising of the facilitated assignment letter to include that portion of premium for which the beneficiary is liable.

Response: When we notify plans of new facilitated enrollees, we do identify those beneficiaries who are partial versus full subsidy beneficiaries, both on the Transaction Reply Report confirming enrollments, as well as on the LIS History report. In addition, the individuals’ subsidy level is fully explained in the LIS approval letter from the Social Security Administration. However, we appreciate the suggestion for modifying the facilitated enrollment letter to reference a partial subsidy beneficiary’s premium liability, and will explore whether this is feasible. We believe the latter does not necessitate a regulation change since notification details are generally an operational issue, so we will not modify the regulation to reference this.

Comment: A few commenters requested that we require that plans notify dual-eligibles in advance of potential involuntary disenrollments. They noted that we conduct a special auto-enrollment early each month—

- To identify full benefit dual-eligibles who are disenrolled from their previous plan;
- Who have not chosen a new one; and

- Where there continues to be a risk of a coverage gap if the plan submits the disenrollment request to CMS after the special auto-enrollment occurs.

Response: Section 423.36(b) of the regulation and section 40.2 of Chapter 3 of the Medicare Prescription Drug Manual already require plans to provide advance notice of potential disenrollment, so there is no need for a regulation change to that effect. The special process we run each month to capture recently disenrolled individuals already represents a significant advance in our auto-enrollment procedures. However, we will continue to look at ways to modify auto-enrollment to more quickly place auto-enrolled beneficiaries in a new plan. Note that under any circumstances, full benefit dual-eligibles who are disenrolled will not encounter any coverage gap—instead their subsequent enrollment will be made retroactive to the date of the loss of coverage from the preceding plan.

Comment: One commenter suggested adding in § 423.34(f)(3) the phrase “unless the individual is not a full benefit dual-eligible as identified in § 423.34(g)” to the end of the sentence that comprises this subsection. The commenter believes this addition would

clarify that § 423.34(f)(3) does not apply to non-full benefit dual-eligibles who have LIS.

Response: Section 423.34(f), including subparagraph (f)(3), is already limited to full benefit dual-eligibles by virtue of the introductory regulation text before subparagraph (f)(1). Given this, we see no need to further specify that § 423.34(f)(3) does not apply to non-full benefit dual-eligibles, so we decline to amend the regulation as suggested by the commenter.

Comment: Several commenters suggested that we expand the PDPs to which it assigns or reassigns LIS beneficiaries to include enhanced benefit plans. One commenter further clarified that reassignments should include enhanced plans whose portion of the basic premium falls below the LIS benchmark, as this would be no more costly to the government and would give LIS beneficiaries the same options as available to other beneficiaries to enroll in enhanced benefit plans.

Response: While enhanced benefit plans may offer supplemental benefits, they always create a premium liability for the beneficiary, including those who are eligible for the 100 percent premium subsidy. This is because, by statute, the LIS does not cover the portion of the premium attributable to the enhanced benefit, even if the total premium is under benchmark, meaning that the beneficiary is liable for the enhanced portion of the premium. The statute clearly limits initial auto enrollments to plans where an individual has zero premium liability, and we have adopted the same policy approach for purposes of reassignments. Therefore, we decline to modify the regulation as requested. We note that LIS beneficiaries are always free to elect an enhanced benefit plan if they wish to access the enhanced benefits, but they would incur some premium liability.

Comment: Several commenters urged us to move away from random reassignment of LIS eligible individuals to a system of beneficiary-specific reassignment in which beneficiaries are matched with plans that include their current drugs and preferred pharmacy. They believe this would result in less disruption to beneficiaries, and increased adherence to currently-prescribed drug regimens, while potentially providing the LIS benefit at the lowest total cost to beneficiaries.

Response: We continue to explore alternatives to random reassignment that would minimize the potential for disruptions to continuity of care, and appreciate the commenters' support for a beneficiary-specific process. While we believe there is merit to beneficiary-

specific reassignment, we decline to amend the regulation to require it, given that § 423.34(c) currently provides CMS the discretion to implement such changes if our ongoing exploration of such an approach indicates that revisions to the current reassignment methodology are warranted.

Comment: A few commenters suggested that instead of reassigning LIS beneficiaries from plans whose premiums are going above the LIS benchmark, we should permit them to stay in the plan and be held harmless. They recommended a number of ways to do so, including giving affected beneficiaries a grace period of one year to remain in the plan, with no additional premium payment; letting the plan "absorb" any premium difference between the benchmark and the bid amount (up to \$2.00 per one commenter); or waiving the requirement that plans attempt to collect delinquent premiums.

Response: While we have discretion to determine which beneficiaries are subject to reassignment, we believe that section 1860D-13(a)(1)(F) of the Act, which requires uniform premiums, precludes us from adopting these recommendations (absent a demonstration such as the 2006-2008 "de minimis" demonstration, where premiums of "de minimis" amounts were waived). We note that we have already implemented a demonstration for the 2010 plan year that increased the LIS benchmark, which had the effect of substantially decreasing the number of beneficiaries who needed to be reassigned.

Comment: One commenter suggested that CMS should allow the plan (rather than CMS) to move the LIS members in to a zero-dollar premium plan offered by the same sponsoring organization.

Response: As outlined in section 30.1.5 of the PDP Eligibility, Enrollment, and Disenrollment Guidance, when we reassign a beneficiary, we first attempt to reassign to a PDP offered by the same organization. Only when that is not possible do we reassign to plans outside of the organization. Our experience has been that CMS-initiated actions are much easier to implement on a timely basis, and to monitor for accuracy and completion, than are actions that depend on sponsors to identify and submit enrollment transactions for the affected population. Therefore, we believe there is little or no benefit to delegating this responsibility to PDP Sponsors, and we decline to make the requested change.

Comment: One commenter urged us to let plans communicate sooner with

LIS enrollees they may lose to reassignment. The commenter suggested such communication be permitted earlier than is currently permitted in the reassignment process, to ensure affected beneficiaries understand their options.

Response: Plan sponsors are already permitted to communicate with current enrollees, subject to Part D marketing guidelines; the reassignment regulations under discussion here do not contain additional constraints on these rules, and we make every effort to involve sponsors in the reassignment communications process as early as possible. Thus, we believe there is no need for changes to the regulation to address this issue.

Comment: One commenter recommended that we include LIS recipients with partial premium subsidy as opposed to only full premium subsidy recipients in the annual reassignment process. The commenter noted that while it is true that recipients with partial premium subsidy will pay some premium no matter which plan they select, the amount they pay is lower if they are enrolled in a plan with the premium at or below the benchmark.

Response: We acknowledge that a partial subsidy beneficiary's premium would be somewhat lower in a zero-premium plan versus a plan with a premium over the benchmark, but in either case, these beneficiaries would still have to pay some portion of the premium. As always, our policies with respect to reassignment are intended to strike a fair balance between our dual goals of limiting beneficiary exposure to premium costs and also avoiding any potential negative impact on an individual's prescription drug coverage (such as changes to a pharmacy network or drug regimen). Since reassignment cannot eliminate the premium liability for such individuals under any circumstances, in this situation, we believe that potential for disruption to the prescription drug coverage outweighs the potential financial risks associated with paying a higher premium. Therefore, we do not believe that there is sufficient benefit to reassigning these beneficiaries, and we decline to adopt the commenter's suggested change to our existing approach.

Comment: A few commenters asked us to reconsider our decision not to include beneficiaries who elect their current plan ("choosers") in the reassignment process. Our reconsideration of this issue should begin with an evaluation of how choosers have been affected by the current process. In particular, the

Agency should identify the number of choosers who—

- Affirmatively switch plans every fall;
- Affirmatively switch plans during the year; and
- Are involuntarily disenrolled due to nonpayment of premium.

Response: We share the commenter's interest in this issue, and recently solicited input on whether we should reassign choosers who will face a premium liability of \$10.00 or more in the following year (*please see* page 84 of the Advance Notice of Methodological Changes for Calendar Year 2011 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2011 Call Letter, issued February 19, 2010). We will continue to assess choosers' experience in Part D plans above the benchmark, including the extent to which they subsequently elect another plan and the extent to which they experience problems with premium payments. As noted previously, the regulations do provide the flexibility to change the existing process should our reconsideration of our approach show it to be warranted.

Comment: Two commenters recommended that we send a notice to LIS choosers who have chosen to join or remain in plans in which they would incur a premium liability. The commenters suggested notifying them of their zero-premium options (including an analysis of drug utilization to determine most appropriate plan). The beneficiary would be permitted to respond to the mailing in an efficient manner (for example, via postcard, telephone call, or online) to indicate his or her choice.

Response: We continue to assess the experience of LIS choosers who face premium liability, and as noted above, have solicited input on whether we should reassign choosers who have a premium liability of \$10.00 or greater for the following year. We remain committed to reaching out to choosers whom we do not reassign to let them know about their options for zero premium prescription drug plans.

Comment: A few commenters urged us to require State Medicaid Agencies to increase the frequency of state submission of MMA data exchange files, which is the primary vehicle for notifying CMS of new dual-eligible beneficiaries. This would further minimize enrollment delays for new dual-eligibles.

Response: We believe this comment is outside the scope of this regulation, so we decline to amend the regulation in this manner. However, we continue to encourage states to submit these files

more frequently, and provide technical assistance on how to do so.

Comment: One commenter urged us to ensure that dual beneficiaries receive clearer information about all the options available to them, including information about Medicare Special Needs Plans that can provide their Part D benefits.

The commenter was especially concerned about the new Limited Income NET demonstration, which will automatically enroll LIS-eligible individuals who fail to elect a plan and are in immediate need of drugs in one Part D plan. This could create obstacles to seamless conversion from a Medicaid-only managed care plan to a Medicare Special Needs Plan offered by the same organization. The commenter encouraged us to establish more effective procedures to find and transition new duals into their Medicare benefits, especially those who are becoming Medicare-eligible because they are reaching the end of their 24-month disability waiting period.

Response: We appreciate the commenter's concern about ensuring dual-eligible beneficiaries receive information about all their options, and the need for ensuring a smooth transition for these beneficiaries between Medicaid and Medicare drug coverage. We have taken several steps to do so, and believe the Limited Income NET demonstration is an important step in further improving that transition.

With respect to the concerns about the Limited Income NET demonstration, we note that the Limited Income NET process only involves auto enrollment to a single Part D plan for a short, retroactive period. For all prospective periods, the long-standing process of random enrollment among all PDPs with a premium at or below the LIS benchmark would continue to apply. Further, we do not believe the Limited Income NET demonstration specifically, or auto enrollment generally, creates obstacles to seamless conversion. In both cases, our processes are designed to ensure that new dual-eligibles have access to Medicare drug coverage on the first day of their eligibility for it.

However, both those processes are also designed to ensure that any beneficiary election will trump a CMS-generated auto enrollment.

Comment: One commenter expressed support for the Limited Income NET demonstration program, but raised other concerns that the commenter believes the demonstration will not address: enrollment delays, LIS recipients in non-benchmark plans, and the need for accurate, LIS-specific information in plan mailings.

Response: We appreciate the support for the Limited Income NET program, and will continue to work on improving other areas of the program referenced by the commenter.

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

In the October 22, 2009 rule, we proposed to expand the SEP described in § 423.38(c)(4), which currently applies to full benefit dual-eligible individuals, to all LIS-eligible individuals. This proposed change is consistent with our authority in section 1860D-1(b)(3)(C) of the Act and will 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. In this final rule, we adopt the provision as proposed.

Comment: Several commenters expressed support for putting the continuous Special Enrollment Period (SEP) for non-full benefit dual-eligible beneficiaries that is currently in operational guidance into regulation.

Response: We appreciate the comments that support placing the SEP for non-full benefit dual-eligibles into the regulation.

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

In the October 22, 2009 proposed rule, under the authority of section 1860D-11(d)(2)(B) of the Act, we proposed to codify in regulation certain plan transition policies at § 423.120(b)(3) previously established through subregulatory guidance. We specifically proposed to codify in regulation 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.

We also proposed, consistent with our current guidance, that a Part D sponsor's transition process be applicable to nonformulary 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.
- Additionally, consistent with our current guidance, we proposed to codify the timeframes for the transition process

and the days' supply limit for a transition fill of an enrollee's medication. Specifically, we proposed to codify the transition process timeframe to apply during the first 90 days of coverage under a new plan.

In addition, noting that our existing guidance directs Part D sponsors to provide a temporary supply we proposed that Part D plan sponsors be required to ensure that the one-time temporary supply of nonformulary Part D drugs requested during the first 90 days of coverage in an outpatient setting 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 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. For these reasons, we proposed to require sponsors to honor multiple fills of nonformulary Part D drugs, as necessary during the entire length of the 90-day transition period. Further, we proposed requiring 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 proposing to codify the preceding requirements, we also clarified our expectations of sponsors with respect to providing transition notices. Consistent with our guidance that specifies that Part D sponsors send a written notice, via U.S. First Class mail, to each enrollee who receives a transition fill, we proposed to codify the guidance that directs sponsors to send this notice to each affected enrollee within 3 business days of the temporary fill. In addition to this codification, we also proposed requiring 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. All of these proposals were addressed by adding paragraphs (i) to (v) to our general transition policy requirement at § 423.120(b)(3). We are adopting paragraphs (i), (ii), and (v) as proposed without further modification. As explained below, we are modifying proposed paragraph (iii) by clarifying the existing language to state that the temporary supply of nonformulary 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 93 days in 31 day supply increments, with refills provided, if needed, unless a lesser amount is actually prescribed by the physician, and paragraph (iv) by clarifying that transition notices must be sent to beneficiaries within 3 business days after adjudication of a temporary fill.

Comment: A number of commenters supported our proposal of requiring an extended transition supply be given to enrollees residing in a LTC facilities. However, commenters requested that CMS provide the same protections to individuals requiring LTC in community-based settings as provided to those in institutions.

Response: While we appreciate that there are community-based enrollees who have nursing facility level of care and may experience access to multiple pharmacies, we are not persuaded that we should extend the LTC extended transition requirement to such individuals. We believe that residents of LTC institutions are more limited in access to prescribing physicians hired by LTC facilities due to a limited visitation schedule and more likely to require extended transition timeframes in order for the physician to work with the facility and LTC pharmacies on transitioning residents to formulary products. We believe that community-based enrollees, in contrast, are less limited in their access to prescribing physicians and do not require an extended transition period to work with their physicians to successfully transition to a formulary product.

Comment: Several commenters disagreed with the proposed timeframe in which to send out the transition notice of 3 business-days and recommended 3 calendar days. The commenters argue that a requirement of 3 calendar days is clearer and easier to enforce, particularly during holiday periods, when holidays delaying U.S. mail combined with the normal delays in mail delivery can severely cut into the time a beneficiary needs to try a

different drug and request a formulary exception.

Response: We disagree with these commenters that the proposed timeframe be changed to 3 calendar days, which includes weekends and holidays when standard businesses are closed. We do not believe that a calendar day timeframe will allow sponsors an acceptable period in which to mail out a transition notice. Rather, we believe that the 3 business day turnaround time for notice to be sent is consistent with current transition policy and it permits a beneficiary sufficient time to work with his/her prescriber to change to a therapeutically equivalent drug on a plan's formulary or begin the exceptions process.

Comment: Several commenters supported the proposed requirement that sponsors notify the prescriber when a transition fill has been made. One commenter stated that the proposal is a positive that allows consistency across the MA population and it provides protection of certain vulnerable populations. Many commenters requested that we develop a standardized transition format for notices and explanations to be provided to plans. Another commenter requested our review notices that sponsors provide to ensure that beneficiaries are not unknowingly being steered to mail order pharmacies.

Response: We appreciate the comments. We note that we have developed a model transition notice for plans to send beneficiaries and are considering for the future whether or not to make that model standardized. In addition, we have prepared model notices for sponsors to ensure that beneficiaries are not unknowingly being transferred to mail order pharmacies. Model transition notices may be found at *Part D Marketing Model Materials*.

Comment: Many commenters opposed the requirement to send the transition notice within 3 business days of the temporary fill being dispensed. These commenters requested changing the proposal to notice being sent within 3 business days after a temporary fill is processed. The commenters argue that this is consistent with the current language in Section 30.4.10 of Chapter 7 of the Prescription Drug Benefit Manual, where the phrase "within 3 business days of the temporary fill" has been understood by the industry to refer to the date the temporary fill is processed, since it is only when the claim is processed that a plan learns about it and can act on it.

Response: We agree and note that industry practice standards have interpreted the language to mean within

3 business days of a temporary fill being processed. Therefore, we are revising the language of § 423.120(b)(3)(iv) to read “within 3 business days of adjudication of a temporary fill.”

Comment: Some commenters expressed concerns with our proposal that Part D plan sponsors make reasonable efforts to notify the prescriber of the transition fill, with some commenters recommending that we make the prescriber notice requirement optional so that plans may exercise discretion to determine whether it is warranted. Another commenter stated that for the notification to be successful their master DEA file would need constant updating and that the requirement does not take into account emergency room or urgent care physicians covered by a blanket DEA number from the hospital. Another commenter suggested we should dialogue with the industry to review operational challenges to the prescriber notification. Yet another commenter suggested that we not implement the requirement unless we provides plan sponsors with access to databases with complete and accurate physician contact information cross-referenced with physician identifiers.

Response: We disagree with the commenters' request to make the prescriber notice optional and leave it to the plan's discretion whether such notification is warranted. The prescriber notification is a means of further strengthening beneficiary protections when dealing with formulary changes or utilization management protocols for necessary medications because the prescriber is in the best position to advise the beneficiary on the benefits or risks of switching to a different medication. Prescriber notification is an additional step to ensure a beneficiary is receiving optimal medication therapy outcomes with little to no delay in their drug regimen. As a result of this provision, sponsors and network pharmacies will need to ensure that they update their databases on a more consistent basis. We intend to provide additional guidance on what constitutes “reasonable notification efforts” in the future, but we do not envision providing plans with a comprehensive database of physician contact information as this is not information that we keep track of, and therefore it is not feasible for plans to rely on us to completely and accurately maintain such a database.

Comment: Several commenters stated that notification via U.S. mail occurs after the fact and suggests an alternative of beneficiary notification at the site of service.

Response: We continue to work with the industry to work on automated methods whereby beneficiaries are notified at point of sale that a drug dispensed is non-formulary. Until such time as these notifications are automated, plan sponsors must send written notice of transition fills through the U.S. mail.

Comment: One commenter requested CMS to define “other coverage” related to the requirement to provide a transition period for “newly eligible Medicare enrollees from other coverage” questioning whether this means that newly eligible Medicare enrollees who do not have “other coverage” should not qualify for a transition period. The commenter requests that we clarify that “newly eligible Medicare enrollee” would not include anyone who had been eligible for Medicare as a result of a disabling condition and moves to being eligible for Medicare as a result of reaching the specified age (such as, 65).

Response: We agree and clarify that “newly eligible Medicare enrollee” would include anyone who had been eligible for Medicare as a result of a disabling condition and moves to being eligible for Medicare as a result of reaching the specified age (such as, 65), including enrollees who do not have “other coverage” but who may be paying out of pocket for drugs they are currently taking.

Comment: One commenter supported the transition proposal but requests that CMS further revise § 423.120(b)(3) to standardize the amount of the temporary supplies that PDP sponsors are required to provide in the LTC setting. Some PDP sponsors have interpreted this element of CMS' transition policy that temporary supplies “may be for up to” 31 days to enable them to authorize fills of less than 31 days, even when physicians have prescribed a 31-day fill. The commenter recommends that we revise its proposed regulation to require PDP sponsors to provide transition supplies of at least 31 days unless a lesser amount is actually prescribed by the physician.

Response: We agree and are clarifying the existing language to state that the temporary supply of nonformulary 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 a lesser amount is actually prescribed by the physician. We believe this clarification is necessary to protect beneficiaries residing in LTC facilities from unnecessary delays in obtaining

the full amount of a temporary fill or from uneven interpretation among plan sponsors.

Comment: Many commenters suggested that we articulate in regulation the extension of transition fills through the completion of any requested exception, even if that process takes longer than 30 days. Moreover, commenters suggested that we also require a transition fill whenever a member encounters formulary difficulties obtaining current prescriptions. A few commenters urged us to codify in regulation the requirement that Part D plans cover an emergency supply of nonformulary drugs outside of the initial 90-day transition period. One commenter suggested that the regulations should be strengthened to provide that without evidence of timely written notice to the affected enrollee, the enrollee should be entitled to continue to receive the relevant medication(s). Other commenters requested we codify current guidance encouraging Part D sponsors to incorporate processes in their transition plans that allow for transition supplies to be provided to current enrollees with level of care changes.

Response: We note that current policy directs Part D sponsors to provide for a transition extension on a case-by-case basis when enrollees have not been successfully transitioned to the sponsor's formulary requirements. We do not believe that it is appropriate to codify this “case-by-case” directive into the existing rule. Our guidance already addresses that sponsors need to review an enrollee's request for an extension and the circumstances requiring such a request on an individual basis.

We also disagree with the comments that the regulation should be strengthened to provide that without evidence of timely written notice, the enrollee should be entitled to continue to receive the relevant medication(s). We believe that this situation would be more appropriately be handled through the complaint process given the level of scrutiny that would be required to verify whether evidence exists that notice was provided to the enrollee by the plan sponsor.

We also disagree with the comment requesting that we codify into regulation at this time our current guidance encouraging transition supplies to be provided to current enrollees with level of care changes. As we have not encountered large number of complaints, we will continue to examine this issue. If we decide to mandate transition in this area, we will do so through future rulemaking.

Finally, we will consider codifying our emergency supply policy for LTC enrollees in future rulemaking.

Comment: Some commenters urged us to adopt the GAO recommendation to make the ANOC sent prior to each open season more individualized and thus more valuable to plan enrollees.

Response: We appreciate commenters recommending a more individualized ANOC being sent out prior to each open season. We believe that this is outside the scope of this proposal, which is to strengthen beneficiary protections during the transition process.

12. Part D Sponsor Responsibility for Retroactive Claims Adjustment Reimbursements and Recoveries Under Part D (§ 423.464, § 423.466, and § 423.800)

In the October 22, 2009 proposed rule, under the authority of sections 1860D–23 and 1860D–24 of the Act, we proposed that sponsors make retroactive claim adjustments and take other payer contributions into account as part of the coordination of benefits. In making these proposed changes, we noted that some beneficiary changes (such as LIS status changes or midyear Part D enrollment changes), LTC pharmacy billing practices for dual-eligible beneficiaries, and the presence of secondary, tertiary, and even quarternary payers have 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 that plan sponsors would be required to make such reimbursements under § 423.800(c), we did not believe our current regulations addressed the other entities that may sometimes need to be taken into account in reimbursement or recovery transactions. Moreover, we noted 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, Part D sponsors sometimes struggle with how to manage these retroactive adjustments and those sponsors that are refunding overpayments or seeking underpayment recovery are each doing it differently.

We also noted in the October 22, 2009 proposed rule that, since our 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 rebilling, we have issued general guidance to direct sponsor coordination of benefit activities. As part of our implementation guidance on the automated process for the transfer of TrOOP-related data, we established a 45-day maximum time limit for the sponsor to take adjustment action, make a refund, and initiate recovery. We established this time limit after an informal survey and discussions with Part D sponsors and their processors.

We noted in the October 22, 2009 proposed rule (74 FR 54663) that many of the post-adjudication adjustments, such as those that are due to enrollment changes, are changes that affect beneficiary cost sharing, premiums and 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 a 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 on the beneficiary’s behalf because it ensures that these amounts are resolved timely.

For these reasons, we proposed at § 423.464 and § 423.466 to codify our previous policy guidance by proposing that sponsors must make retroactive claim adjustments and take other payer contributions into account as part of the coordination of benefits. Further, we proposed adding 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.

As part of making these proposed changes, we noted that, 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. However, we acknowledged that with the volatility of LIS data and Part D enrollments creating a significant volume of retroactive adjustments, Part D sponsors are facing more claims adjustments than current

pharmacy claim reversal and rebilling approaches can adequately address.

In addition, we acknowledged issues regarding proprietary pricing information and the chilling effect that disclosure of this information might have upon the ability of pharmacies to negotiate with payors. 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 then reported in the (Nx) 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, such a procedure would be generally impractical after the industry standard 30-day window because many supplemental payers will not accept the late claim.

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 would both enable reprocessing and address pharmacies’ concerns about revealing their proprietary pricing. However, as we noted in the proposed rule (74 FR 54663), 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.

Therefore, 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. We solicited 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 outweigh the benefits.

Our specific proposals to modify § 423.464 included the following changes:

- 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, overpayment reimbursements and overpayment recoveries; and

- Adding a new 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 underpayments, as well as to account for payments made, and for amounts being held for payment, by other individuals or entities. The new paragraph would also specify that Part D sponsors must have systems to track and report adjustment transactions and to demonstrate that—

(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 LIS eligible individuals have been processed in accordance with the requirements in § 423.800(c), and

(3) Recoveries of erroneous payments for enrollees have been sought as specified in § 423.464(f)(4).

Except as otherwise provided below, after considering the comments received in response to the proposed rule, this final rule adopts the proposed changes to the retroactive claims adjustment reimbursement and recovery provisions in § 423.464 and § 423.466.

Comment: Multiple commenters agreed that the costs of achieving precision in retroactive COB transactions outweigh the benefits of creating specialized electronic transactions for calculating payer-to-payer claims adjustments. A number of these commenters offered recommendations to CMS in response to our request for alternative approaches to improving post-adjudication coordination of benefits, including establishing a process to notify supplemental payers when an Nx transaction was not generated and the Part D sponsor is making a retroactive adjustment to the primary amount paid.

Response: We appreciate the commenters' concurrence with our assessment that the costs to create a specialized transaction for retroactive claims adjustments outweigh the benefits and their recommendations for improving post-point-of-sale adjudication coordination of benefits. Until such time as any cost effective

alternative approaches are identified, we will not require the development of payer-to-payer coordination of benefit transactions for retroactive claims adjustments. Instead, we will work with the industry to develop work-around solutions, such as imputing amounts to be reimbursed based on best available information, and will take the commenters' recommended approaches into consideration during that effort.

In the interim, the existing coordination of benefit requirements require sponsors to coordinate not only with beneficiaries, but also with SPAPs, other plans or programs providing prescription drug coverage and beneficiaries and other individuals or entities that have made payment on the beneficiaries' behalf. These requirements include coordination of benefits at point-of-sale, as well as retroactive claims adjustments necessitated by not only beneficiary changes, such as retroactive LIS eligibility determinations, LIS status changes or mid-year Part D enrollment changes, but also other payer changes, beneficiary submission of paper claims, etc. In addition, as discussed elsewhere in this rule, sponsors must have systems to track and report adjustment transactions and to process adjustments and issue refunds or recovery notices within 45 days of the sponsor's receipt of information necessitating a retroactive claims adjustment.

As specified in subregulatory guidance in the Medicare Prescription Drug Benefit Manual chapters on Coordination of Benefits and Premium and Cost-Sharing Subsidies for Low-Income Individuals, Part D sponsors should also: work with other providers of prescription drug coverage to resolve payment issues; have a process in place to handle 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 where the total payment to the pharmacy changes. Coordination of benefits guidance also includes the need to transfer TrOOP and gross covered drug cost balances to the new plan whenever a beneficiary transfers enrollment between Part D sponsors during the coverage year. As discussed elsewhere in this final rule, sponsors have a 45-day maximum time limit from receipt of changes in the reported transfer data to make an adjustment and issue a refund or initiate recovery.

Comment: One commenter suggested that CMS establish an exception that

would permit a Part D sponsor to refund the beneficiary directly without accounting for other payers if the net claims adjustment is \$10 or less and there is no N transaction reporting another payer amount paid on the claim.

Response: We disagree with this suggestion. Although individual claims adjustments may not exceed the suggested threshold, cumulative amounts due to other payers (such as SPAPs) could be substantial. Additionally, the other payers would be unaware that a claim had been retroactively adjusted and that a refund was issued to the beneficiary. As a result, the other payers would not know to seek recovery from the beneficiary. Therefore, we continue to believe that sponsors must comply with the coordination of benefits requirements without regard to the monetary amount of the adjustment.

Comment: One commenter asked that we clarify in § 423.464 that *pharmacies holding copayments are exempt from the coordination of benefits requirements since they do not meet the definition of a plan or program providing prescription drug coverage.* The commenter noted that this clarification will ensure that pharmacies recognize they are not a provider of prescription drug coverage, and are only entitled to reimbursement if the member should receive reimbursement and the pharmacy has attested that it is holding the member's cost-sharing amounts due and has not billed the member. Several other commenters requested that specific language be added to the regulations at either § 423.800(c), or § 423.464(g) and § 423.466(a), to clarify that the requirements, including the 45-day time period for issuing refunds or initiating recoveries due to retroactive adjustments, apply not only when a supplemental payer is involved, but also when a pharmacy is owed for cost-sharing initially withheld by the sponsor for LIS beneficiary claims.

Response: We agree that pharmacies are not providers of prescription drug coverage and, therefore, are not covered under § 423.464(g). However, it was our intention to apply the 45-day time limit to all retroactive adjustment regardless of whether a pharmacy alone, a pharmacy and the beneficiary, or a pharmacy, the beneficiary and another payer are involved. As a result, we are finalizing § 423.464(g) as proposed. In response to the concerns raised by the commenters regarding the application of the 45-day timeframe to pharmacies, in this final rule we are also amending § 423.800 to add a new paragraph (e) to make it clear that the 45-day timeframe

applies to adjustments involving pharmacies and beneficiaries, including LTC pharmacies holding cost-sharing amounts due. Generally, sponsors will reimburse the beneficiary for adjustments made to retail claims, but for full benefit dual-eligible individuals, in the absence of other information indicating the cost-sharing has been waived, the sponsor will reimburse the LTC pharmacy.

Comment: Several commenters argued that the 45-day time period for issuing reimbursement or initiating recovery should be changed to 90 days because of the various research and coordination issues that may need to be resolved with other stakeholders in the industry.

Response: We disagree with these commenters. We believe a 45-day period is more than sufficient to resolve any coordination of benefits issues and refund overpayments or institute recovery of underpayments resulting from the retroactive claims adjustments. As we stated in the proposed rule, we considered a 90-day time limit, but concluded that this longer timeframe was not in the best interests of beneficiaries because it would delay the payment of refunds and notification of the need for payment recovery.

Moreover, we noted that as part of the automated transfer of TrOOP-related data, we established a 45-day maximum time limit for sponsors to take adjustment action, make a refund and initiate recovery. We further explained that we established this time limit after an informal survey and discussions with Part D sponsors and their processors. For these reasons, we continue to believe that a 45-day time limit represents a reasonable compromise. Therefore, we are finalizing the requirement as proposed.

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

In the October 22, 2009 proposed rule (74 FR 54664), we proposed to revise § 423.466 by adding a new paragraph (b) that would establish a 3-year time limit on Part D coordination of benefits. In making this proposed change, we noted that 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 only directs 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. The COB chapter also directs sponsors, in

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

We also noted the benefits to be derived from this proposed change. In addition to limiting sponsors' financial liability, a specified 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 within that time frame. Moreover, we would benefit from a COB time limit because it would enable us to conduct reopening efficiently and on a predictable schedule.

In considering whether to establish 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 noted that the Medicare FFS time limit for filing claims, as specified in § 424.44, is 15 to 27 months depending on the date that the item or service was furnished and that under certain circumstances these time limits may be extended an additional 6 months. We also noted that the Deficit Reduction Act of 2005 (Pub. L. 109-171) (DRA) amended section 1902(a)(25) of the Act, to provide for a 3-year time limit for States to seek recovery of Medicaid claims payments when the State is not the primary payer. Although this DRA provision does not address SPAPs and, therefore, does not impose a time limit on the requirement for Part D sponsors to coordinate benefits with SPAPs, it does establish the time limit for State Medicaid programs to recover from Part D plans.

Having considered these filing limit precedents, we proposed 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 (non-network) entities paying, or holding amounts for payment, on the beneficiaries' behalf. Specifically, we proposed 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. Part D sponsors would be required to coordinate benefits with SPAPs, other entities providing prescription drug coverage, and other (non-network) payers for a period not to exceed 3 years from the date on which the prescription for the covered Part D drug was filled. Adding this provision to the regulation would 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.

As noted in our response to the comments below, after considering the comments received in response to this proposal, we continue to believe a 3-year time limit on Part D coordination of benefits is reasonable, and in this final rule, we are adopting the provision as proposed.

Comment: Two commenters expressed support for the establishment of a clear timeframe for coordination of benefits, and two others expressed agreement with the proposed 3-year time limit. A number of other commenters suggested alternative time limits of 2 years, 18 months or 1 year. The rationale cited by commenters for a shorter time period was that it would more closely align the COB time limit with the regulatory deadline for submission of Part D cost data, thereby reducing the number of payment reconciliation reopenings and curtailing the costs associated with maintaining open claims databases.

Response: We disagree that we should shorten the proposed coordination of benefits time limit. Other payers need time to seek reimbursement and sponsors need a clear limit in order to resolve claims for which they are responsible. We believe that a 3-year limit would permit CMS to address both needs. A timeframe that aligned with the regulatory deadline for submission of PDE data would allow only 6 months for submission of claims incurred late in the coverage year, a timeframe that we believe Part D experience to-date has demonstrated would not allow sufficient time for claim identification and subrogation. As we noted in the proposed rule, the 3-year limit is also aligned with the DRA timeframe, providing a uniform period for coordination of benefits for all payers, rather than creating different timeframes based on payer type (for example, SPAPs or other entities providing prescription drug coverage). This alignment will, in our view, ease administration for all parties.

Therefore, in the final rule, we adopt the requirement for Part D sponsors to coordinate benefits with SPAPs, other entities providing prescription drug coverage, and other (non-network) 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 the effective date of this final rule, the timeframe for coordination will have ended for claims for prescriptions filled any time in 2006, as well as for prescriptions filled in the early months of 2007. For example, a Part D sponsor would be responsible for coordinating benefits on a claim for a covered Part D drug filled on March 3, 2008 until March 3, 2011.

It is important to note that this final rule establishes a time limit for Part D sponsor liability for coordination of benefits with other payers and does not affect the timeframes for Part D sponsors to pursue Medicare secondary payer (MSP) claims and to recover amounts paid by the sponsor as primary when an MSP payer is identified. Such timeframes are separately identified in 42 CFR part 411.

Comment: One commenter stated the application of the DRA's health claim reimbursement rules and standards to prescription drugs is inequitable, because Part D claims processing, unlike health claims processing, is predominantly real-time. As a result, a 3-year submission window is not necessary.

Response: We disagree. Although no interpretive guidance has been issued on this provision, the plain reading of section 1902(a)(25)(J) of the Act encompasses all Medicaid claims, including claims for prescription drugs. As a result, we believe the application of this standard for Part D is appropriate.

Comment: One commenter recommended that CMS impose time limits for the payment of COB claims once filed with the Part D sponsor.

Response: This suggestion is outside the scope of the proposed rule. We can consider whether such a time limit is warranted and address the issue as appropriate in future rulemaking. However, we note that once a COB claim has been submitted, we expect Part D sponsors will make good faith efforts to promptly coordinate benefits with the submitter of the claim, whether an SPAP, another entity providing prescription drug coverage, a beneficiary or someone acting on his or her behalf, or another payer. Any payer that does not believe a Part D sponsor is making good faith efforts to coordinate claims on a timely basis should report the complaint to CMS.

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

Under the authority of section 1860D-4(b)(2)(A) of the Act, we proposed to revise our regulations at § 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.

As we noted in the October 22, 2009 proposed rule (74 FR 54665), 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 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, billing information on the NCPDP "Pharmacy ID Card Standard", which is the standard for identification cards for the Part D program, must be used by the pharmacies filling the beneficiaries' prescriptions to submit claims to the Part D sponsor (or its intermediary).

We noted that CMS guidance set forth in the Coordination of Benefits Chapter of the Prescription Drug Plan Manual (in section 50.4 entitled, "Processing Claims and Tracking TrOOP"), instructs plan sponsors to process all claims online real-time. 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. This guidance states further 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 proposed to revise § 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 proposed to codify this guidance in regulation 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. In addition, online, real-time processing 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.

We also proposed to add a new paragraph (c)(2) to § 423.120 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 noted that we would 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 noted further that 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.

Finally, noting 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, we also proposed 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 solicited comments on the operational issues and timelines that would be involved in making these proposed technical changes to claims processing systems.

After reviewing the comments received in response to these proposals, we are adopting these provisions with some modification. Specifically, we revised § 423.120(c)(4) to specify that effective on January 1, 2012 sponsors assign and exclusively use unique Part D identifiers. Exclusive use of these

identifiers requires that claims will only be paid if these specific numbers are submitted in the claims transaction.

Comment: Many commenters concurred with our proposal that Part D sponsors mandate that pharmacies electronically submit all claims to the Part D sponsor or intermediary unless the beneficiary expressly requests otherwise. Several commenters offered recommendations related to implementation of this new requirement, including that CMS modify standard beneficiary communications (such as the EOB) to include language that helps the beneficiary understand that they should review their EOBs to confirm that all of their claims are being submitted and, permit either home infusion providers to attest to the plan, or the plan to validate on audit, the beneficiary's claims submission election, since it is impractical for small home infusion providers to bill electronically.

Response: We appreciate the support expressed for the proposed new provision and the commenters' recommendations. However, we believe the clarifications associated with the recommendations, since these are related to implementation, are better addressed in subregulatory guidance. As we develop our implementation guidance, we expect to consider the clarifications and to continue to seek input from the industry and NCPDP.

Comment: One commenter asked how the requirement that pharmacies electronically submit all claims to Part D unless the beneficiary expressly requests otherwise would be enforced if members do not show their ID card.

Response: The requirement applies to pharmacies and not the beneficiary. Therefore, we will undertake no enforcement action against the beneficiary if the claim is not submitted to the Part D sponsor. However, even if the member does not show his or her ID card, pharmacies will be able to identify Part D claims based on the unique RxBIN/PCN identifiers already in the pharmacy system or in the response to an eligibility query from the TrOOP Facilitator, and will generally be expected to submit claims whenever such data are on file.

Comment: One commenter urged us to allow 6 months for plan sponsors to implement the required network pharmacy contract change and noted that sponsor experience suggests that contract language alone will not ensure pharmacy compliance.

Response: We agree that this provision will require time for Part D sponsors to implement. Therefore, we will implement the requirement

effective January 1, 2011. We likewise agree that contract language alone may not guarantee pharmacy compliance, but we expect other contract provisions will address the procedures the Part D sponsor will follow in the event a pharmacy fails to comply with this requirement.

Comment: One commenter requested that CMS clarify that notifying beneficiaries or discussing their options does not constitute "solicit[ation]" as mentioned in the preamble, that our lower cash price policy is still in place, and that any voluntary request to waive claim submission to the plan survives the entire life of the prescription and there would be no need to expect the beneficiary to make a request each time they refill that prescription.

Response: We agree with the commenter that discussing options per se does not constitute solicitation or steering. However, this must be a bona-fide discussion of options initiated by the beneficiary; that is, the discussion should not be initiated by the pharmacy with the intent to encourage the beneficiary to request his or her claims not be submitted to Part D in order for the pharmacy to avoid transactions fees. With regard to our lower cash price policy, we have not altered this policy. Finally, we intend to confirm in subregulatory guidance that any voluntary request to waive claim submission to the plan survives the entire life of the prescription and there would be no need to expect the beneficiary to make a request each time the prescription is refilled.

Comment: One commenter encouraged us to ensure that Part D sponsors' contracts with network pharmacies charge the beneficiary and the plan sponsor the lesser of the usual and customary price (U&C) or contracted rate without regard to special programs offered by the pharmacy.

Response: We believe that this comment is outside the scope of this proposal, which would only require that pharmacies submit all claims to Part D sponsors, unless the beneficiary requests otherwise. When a pharmacy's U&C prices are lower than the plan's negotiated price, we agree it is in the best interests of beneficiaries and taxpayers for the pharmacy to extend those U&C prices to Part D enrollees. However, because we do not directly regulate pharmacies, we have no authority to require them to do so.

Comment: Several commenters agreed with our proposed requirement related to unique payer/processor and enrollee identification, with several commenters suggesting that implementation be no sooner than January 1, 2011 or January

1, 2012 and not mid-plan year. One commenter stated that we should accommodate the continued use of unique identifiers already established by Part D sponsors, without regard to length or combination of characters. Other commenters were opposed to the requirement for Part D sponsors to create, and exclusively use, an RxBIN or an Rx BIN/PCN combination for Part D enrollees as well as to assign an Rx identifier to a Part D enrollee, because of the costs associated with implementation and potential disruption for pharmacies and beneficiaries. One commenter stated that CMS should emphasize that the RxBIN and RxPCN numbers should be assigned and differentiated at the sponsor level, and another commenter specifically requested clarification of the reference to "individual" Part D beneficiaries.

Response: We appreciate the general support for this provision and agree with the suggestions related to the timing of implementation, particularly in light of industry wide programming for HIPAA version D.0 conversion. Thus, the effective date for the requirement for a unique RxBIN or RxBIN/RxPCN combination and a unique Part D Rx identifier for each individual Part D member will be January 1, 2012. We believe this date will provide sufficient time for sponsors to implement necessary systems changes. Currently established unique identifiers may continue to be used. With regard to the level of assignment of the unique RxBIN or RX BIN/RxPCN combination, the appropriate level of assignment is at the Part D sponsor's parent organization rather than at the contract.

The assignment and exclusive use of these unique Part D Rx identifiers have a number of advantages for Part D. The primary advantage is the use of these identifiers enables pharmacies to recognize Part D beneficiaries, which is possible only with the level of identification supported by unique identifiers. Distinguishing Part D enrollees from the commercial insured permits the pharmacy to comply with any Part D-specific processing requirements, such as the requirement to submit claims electronically to the Part D sponsor or its intermediary, on behalf of the beneficiary unless the beneficiary makes an explicit request to do otherwise.

Other advantages to the use of unique Part D identifiers relate to the coordination of benefits. Currently, the TrOOP Facilitator and other switches that relay electronic pharmacy claims are unable to accurately determine whether an initial claim was paid by

Part D. As a result, the TrOOP facilitation process receives and processes coordination of benefits claims transactions even when the initial claims were not paid by Part D. This results in added processing costs for us and added workload for Part D sponsors receiving N transactions that cannot be matched to an initial claim because no Part D payment was made. Unique Part D Rx identifiers permit Part D claims to be processed independently and easily segregated for reporting and other purposes.

Comment: One commenter noted that the proposed requirements may have to be modified to conform to the new privacy provisions included in the Health Information Technology for Economic and Clinical Health (HITECH) Act that allow an individual to request that a covered entity restrict the disclosure of his or her protected health information.

Response: Our proposal would require Part D sponsors to require their network pharmacies to submit claims electronically to the Part D sponsor or its intermediary on behalf of the beneficiary "whenever feasible." Federal regulations implementing the privacy provisions of the HITECH Act have not yet been published. Upon publication of those regulations, we will review the provisions to determine if modifications of this requirement are necessary.

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

We proposed 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, consistent with the time frame provided under the MA visitor/traveler policy, the nature of the Part D benefit and the strong likelihood that a PDP enrollee can access the full range of PDP benefits while temporarily out of the service area. In this final rule, we adopt this provision as proposed.

Comment: Most commenters supported our proposal. One commenter opposed the proposed change and preferred that we either make no change or revise the PDP rules to permit the offering of a visitor/traveler benefit, similar to the policy applicable to MA organizations.

Response: Although the permissibility of visitor/traveler benefits under the Part D program is not strictly within the scope of this proposed rule, we recognize that these types of policies serve an important function in the MA program. However, for the Part D program we believe that delivery of the drug benefit is much more easily accomplished through out-of-area access

rather than a visitor/traveler benefit, given the national pharmacy networks that are generally involved in providing enrollees with their prescription drugs. Thus, we continue to believe, as did most commenters, that this population is better served by extending plans' flexibility to deliver services on an out-of-area basis, rather than by requiring the establishment and approval of formal visitor/traveler policies whenever an enrollee is out of the service area for more than 6 months.

Comment: One commenter wanted us to further codify that PDP enrollees temporarily absent from the plan service area and residing in a LTC facility be disenrolled after an absence of 6 months.

Response: We disagree with the commenter that an individual residing in a LTC facility while temporarily absent from the plan service area should be considered to have a permanent residence outside the plan service area and disenrolled on an involuntary basis due to his or her out-of-area status. Current subregulatory guidance (§ 50.2.1 of Chapter 2 of the Medicare Managed Care Manual and § 40.2.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual) instructs PDP sponsors to determine whether an enrollee's out-of-area status is temporary or permanent, such that involuntary disenrollment would occur prior to the expiration of the 6-month period only if it is confirmed that the enrollee has permanently relocated outside the plan service area. Under our proposed revision, PDP sponsors would effectuate an involuntary disenrollment upon confirmation of an enrollee's permanent residence outside the plan service area or expiration of a 12-month period, whichever occurs first. We believe this addresses the concern raised by the commenter with respect to ensuring a beneficiary's continued access to the Medicare prescription drug benefit while residing in an out-of-area long term care facility. Accordingly, we are adopting without change the revision as set forth in the proposed rule.

Comment: One commenter requested that we not extend the period of permissible temporary out-of-area residence for individuals enrolled in MA-PD plans.

Response: Since our proposed revision applies only to stand-alone PDP plans, we believe that this clarification is not necessary. The current 6-month rule for MA plans under § 422.74(d)(4)(B)(ii) will remain in effect.

16. Prohibition of Midyear Mass Enrollment Changes by SPAPS Under Part D (§ 423.464(e))

Consistent with the authority of sections 1860D-23(a)(1) and (b) of the Act, we proposed to add a requirement to § 423.464(e) to prohibit midyear mass enrollment changes by SPAPs. In making this proposed change we noted that most SPAPs perform 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 also stated our belief that mass re-enrollment into a new plan midyear 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. In this final rule, we adopt these provisions as proposed.

Comment: A few commenters were concerned that SPAPs may need to change Part D enrollment midyear for their SPAP enrollees because the SPAP determines that its members are not being adequately served by the Part D plan (for example, the plan does not adequately cover the drugs needed by the individual SPAP member), or the Part D plan fails in its obligation to coordinate benefits with the SPAP. One commenter in particular suggested we change the regulation text to indicate that SPAPs not "routinely" engage in midyear plan or non-calendar year plan enrollment changes, but allow nonroutine mass re-enrollment when an SPAP has determined that such enrollment changes would better serve the needs of its members and has provided CMS with the appropriate prior notification.

Response: We disagree with the commenters that SPAPs should be allowed to mass re-enroll its members during the calendar year, even when it is nonroutine. There are currently two actions the SPAP can take when it finds that its members are not being adequately served by a Part D plan. First, if an individual SPAP member is not being adequately served by the Part D plan (for example, the SPAP member's drugs are not covered or

pharmacy access is impeded under the plan), the SPAP may, using its authorized representative status, re-enroll that individual into another Part D plan. This one-time special enrollment period for individual SPAP members is allowed and further discussed in our current enrollment guidance (Chapter 3 of the Medicare Prescription Drug Benefit Program Manual). If an SPAP finds that the Part D plan is not serving its members because the Part D sponsor is in violation of Federal statute or regulation, the SPAP should contact us to report the plan's violation(s). We will then take the appropriate action in accordance with its compliance rules. Actions by CMS may include developing a corrective action plan with the Part D sponsor, suspending enrollment into the Part D sponsor's plan, or, if necessary, termination of the Part D sponsor's contract. We believe that both of these actions will adequately address problematic plans and that an exception for nonroutine mass midyear enrollments will not be necessary.

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

In the October 22, 2009 proposed rule, under the authority of sections 1857(a) and (c) and 1860D-12(b)(1) and (b)(3)(B) of the Act, we proposed revisions to the nonrenewal beneficiary notification requirements at § 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 noted that the existing regulations required notification 60 days prior to the effective date of the nonrenewal for both enrollees and the general public. 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. We also noted that when we previously 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 proposed at § 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 back to at least 90 days.

We also proposed removing the requirement for nonrenewing plans (in voluntary nonrenewal situations) and for us (in CMS-initiated nonrenewal situations) to provide notice of the nonrenewal to the general public by publishing a notice in one or more newspapers of general circulation. This change was 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, nonrenewal information is now easily available to the general public through Internet Web sites maintained by us (for example, <http://www.Medicarsuchasov>), a resource not available to the public when the newspaper notice requirement was first adopted. We believe that this information, in conjunction with the requirement to provide personalized nonrenewal information to plan enrollees is sufficient to ensure adequate notice of the plan's nonrenewal. Therefore, we proposed 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.

Comment: One commenter stated that in order to improve the member experience and make the requirements consistent, the "90 day prior to the effective date of nonrenewal" notification deadline should only apply to enrollees whose coverage is being terminated, and not to enrollees that are being mapped to another plan (such as Consolidated Renewal or Renewal Plan with SAR/Modified ANOC scenarios) because they are not losing coverage.

Response: The change to the nonrenewal regulation only applies to beneficiaries who are losing coverage for the upcoming benefit year. It does not, as the commenter suggests, apply to beneficiaries who are involved in a plan consolidation, as their coverage will continue without interruption in the upcoming benefit year.

Comment: Many commenters support the change in the notice requirement from 60 to 90 days. Commenters agreed that beneficiaries should be given more time to choose a new Medicare plan prior to the start of the new benefit year.

Response: CMS appreciates these comments.

Comment: Many commenters agreed that the publication of a nonrenewal notice in newspapers is no longer an effective means of communication, and support removing this requirement for nonrenewing plans.

Response: CMS appreciates these comments.

Comment: Several commenters stressed the importance of CMS issuing its model nonrenewal notice in time for plans to meet the 90 day requirement.

Response: CMS agrees with these comments and plans to issue the model notice during the summer of each year, as it has in the past, to ensure that plans have enough time to fulfill this requirement.

Comment: One commenter asked if the 90-day period runs from the start of open enrollment.

Response: The regulation clearly indicates that the notice must be sent "at least 90 calendar days before the date on which the nonrenewal is effective."

Comment: One commenter suggested that the CMS approved nonrenewal letter which provides information about sources for help in comparing Medicare plans is a good means to provide information in the case of mutual terminations.

Response: We believe that the topic of notices for plans that are undergoing a mutual termination is outside of the scope of this proposed regulatory change. We note, however, that § 423.508 of the regulation requires that when a contract is terminated by mutual consent, the Part D plan sponsor must notify its Medicare enrollees of the termination "within timeframes specified by CMS."

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, in the October 22, 2009 proposed rule, we suggested changing the requirement for PDP sponsors and MA organizations to provide written notification of the alternative Medicare plans available to replace the nonrenewing plan. We proposed changing the existing requirement to permit 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 is 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. We noted that 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 proposed 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. As discussed above, in either case, a personalized, CMS-approved beneficiary notice regarding the nonrenewal must still be sent to each beneficiary.

After reviewing the comments received in response to these proposals, we adopt the proposed changes into this final rule with some modification. Specifically, we revised the regulation at § 423.507 to require that both Part C and Part D organizations inform beneficiaries of all MA and PDP available options. We also revised the regulation at § 422.506(a)(2)(ii)(A) to require that Part C organizations inform beneficiaries of all MA, MA-PD, and PDP options.

Comment: One commenter suggested that instead of providing alternative plan information in the nonrenewal letter, organizations should have the voluntary option of calling beneficiaries. Additionally, the commenter believed that organizations should provide a letter that contains language that directs impacted members to the Medicare Web site for the most current Medicare plan information available in their service area.

Response: The requirement to list alternative plans is independent of the requirement to provide a personalized beneficiary notice. The required personalized beneficiary notice already contains information about using the Medicare Web site to obtain information about available plans. We disagree with the commenter's recommendation that organizations should not be required to provide alternative plan information and that the phone calls to notify beneficiaries be voluntary. Some beneficiaries may not be comfortable with, or do not have access to the Internet. Therefore, we believe it is in the best interest of the beneficiaries to be provided with either a written list of alternative plans or to receive a phone call informing them of whom to contact to learn about their enrollment options.

Comment: Several commenters supported the proposed change that provides nonrenewing plans with the

option to choose to give advance information to enrollees about alternative Medicare plan options in writing or to make outbound calls to all affected enrollees to ensure beneficiaries know whom to contact to learn about their enrollment options. It was stated that this approach also provides plan sponsors with the flexibility to vary the outreach methods used in order to accommodate different segments of their membership on a timely basis.

Response: We appreciate the commenters support of our proposed changes.

Comment: One commenter suggested that in the event of a nonrenewing MA plan, CMS should require that the written notification include Original Medicare and stand-alone PDPs among the alternative options available to the affected beneficiary. (Under the proposed rule change, the MAO would only be required to "provide a CMS-approved written description of alternative MA plan options available for obtaining qualified Medicare services within the beneficiaries' region.") Should the information be communicated via telephone by the MAO, then the person responsible for informing the beneficiary of his or her enrollment options should similarly be required to tell the beneficiary about Original Medicare and stand-alone PDPs in addition to other relevant plan options.

Response: The list of available options is accompanied by the required personalized beneficiary nonrenewal notice that provides information about the beneficiary's various options including, when applicable, Original Medicare. We do agree with the commenter's suggestion to include additional alternative available Medicare plans; and therefore, have revised the regulation to require that both Part C and Part D organizations inform beneficiaries of both MA and PDP available options.

Comment: Several commenters requested that the notification requirements mandate different personalized notices with more specialized information for different populations, particularly dual eligible and SNP beneficiaries.

Response: We believe this comment is outside of the scope of the proposed regulatory changes because these changes did not address the information required within the personalized beneficiary notification. Rather, the proposed changes only discussed the list of alternative plans that must be provided with the personalized notice.

Comment: Multiple commenters raised strenuous objections to the

change that allows plan sponsors and organizations to place outbound calls to enrollees in plans that they are terminating to tell them who to call to learn about enrollment options. Commenters believed that allowing telephone calls invites the possibility of marketing abuses. Specifically, the commenters stated that this change "creates a major marketing loophole, and allows plans to steer enrollees to other plans offered by the same sponsors and organizations, regardless of whether those plans are best for them." The commenters believed that beneficiaries need to be provided with all of the information about alternative plans, and all other options including returning to traditional Medicare. They stated that the information should be provided by CMS or by a neutral, trained counselor. In addition, they believed once plans have been told that their contracts will not be renewed, there is no incentive for the plans to act appropriately and according to Medicare marketing guidelines when interacting with beneficiaries. Commenters suggested that the proposed regulation authorizing calls to beneficiaries should be clarified to include strict plan communication restrictions that properly protect beneficiaries who are especially vulnerable as a result of plan terminations. Furthermore, CMS should make clear that any sponsor that markets plans when notifying beneficiaries of plan terminations will be considered to be violating Medicare marketing rules.

Response: We do ensure that beneficiaries are informed of all of their options by requiring all nonrenewing plans to provide a personalized beneficiary notice which is separate from the plan's requirement to provide a list of alternative plans or make outbound call to inform beneficiaries of whom to contact to learn about their enrollment options. The required personalized notice includes information about all of the beneficiaries' choices and provides contact information for CMS and SHIP offices so that beneficiaries can contact "neutral" parties to obtain additional information about enrollment options. CMS does not believe that plans should be prohibited from contacting beneficiaries by phone, especially in light of the fact that plans regularly speak to beneficiaries by phone as part of the normal course of administering Medicare benefits. Furthermore, we believe that phone calls can provide beneficial individualized beneficiary service. Additionally, CMS will issue

guidance that instructs plans to submit all nonrenewal related scripts for CMS approval so that plans are providing appropriate and accurate information about the beneficiary's plan choices.

Comment: One commenter stated that when plans map beneficiaries to an alternative plan offered by the sponsor rather than nonrenewing, the beneficiaries are not afforded nonrenewal rights that include a special election period and the personalized beneficiary nonrenewal notice. The commenter believed that the rights of members should be the same, and they should all default to Original Medicare with the option of enrolling in a PDP.

Response: This comment concerns Part C and D enrollment policy and is outside the scope of the proposed regulatory changes related to beneficiary notification included in the proposed rule. CMS will consider this comment when we prepare the annual nonrenewal guidance.

Comment: Several commenters proposed allowing plans to provide the alternative list of plans available via electronic format for beneficiaries who have chosen to "opt-in" to receiving communications by electronic means.

Response: We believe that for the purposes of ensuring consistency in the application of the notification requirements, the list of alternative plans should be provided only in hard copy at this time. Also, CMS believes that beneficiaries' access to and use of on-line resources is not yet widespread enough to justify the adoption of regulations that allow for notification exclusively (even on an opt-in basis) through electronic communication. Should Medicare beneficiaries' Internet use patterns change in the coming years, CMS may make appropriate revisions to this policy.

Comment: One commenter asked what number of attempts would be required of sponsors that elect the option to make calls to beneficiaries.

Response: We believe that it is appropriate to address this question through the issuance of nonrenewal or marketing sub-regulatory guidance which provides more flexibility for changes than the rulemaking process.

Comment: One commenter asked what to do if the list of alternative plans that is sent in the mail to the beneficiary is returned.

Response: We believe that the standard practices organizations have presently adopted for handling beneficiary mail that is returned should be applied by the nonrenewing sponsor in such instances.

Comment: One commenter stated that the rules for consolidation that map

beneficiaries to another plan for the following benefit year results in disparate treatment of beneficiaries. For example, if one Plan Benefit Package (PBP) is entirely mapped into another PBP (so only one PBP continues in the upcoming year), all members in both original PBPs receive a standard Annual Notice of Change (ANOC). However, if some counties are mapped into another PBP but others remain (so both PBPs exist in both the current and upcoming years), members in the mapped counties receive a modified ANOC. The commenter stated that from the member standpoint, it doesn't matter which situation they are in, in either case they are mapped into a new plan. This disparate treatment of members in similar situations can lead to confusion among members and creates difficulties for customer service staff attempting to explain the contents of ANOC packets.

Response: This comment is outside of the scope of the proposed regulatory change.

Comment: One commenter stated that CMS must issue alternative plan information far enough in advance for plans to meet the requirement to include alternative plan information in the beneficiary specific letters that are due on October 1.

Response: We have an HPMS module that provides plan option information to nonrenewing sponsors. We acknowledge that we cannot hold sponsors accountable for meeting the October 1 deadline unless we provide timely plan option information through HPMS to the sponsors, and CMS intends to make every effort to ensure that sponsors receive this information in a timely manner.

Comment: One commenter proposed that if a plan chooses to call beneficiaries instead of sending a list, the plan should be obligated to document that the beneficiary was reached and that a message left on an answering machine is not sufficient.

Response: We believe that the issue of call documentation is better addressed through the issuance of nonrenewal guidance which provides more flexibility for changes than the rulemaking process.

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

In the October 22, 2009 proposed rule, we proposed to reconcile a discrepancy with respect to notice of completely favorable expedited redeterminations by adding new paragraph (d)(2) to § 423.590. The proposed change would 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. As noted in the preamble to the proposed rule, the change is consistent with the requirements in § 422.590(d)(3) of the MA regulations.

We also proposed in § 423.590(d)(2) to allow Part D plan sponsors to make the initial notice of an adverse expedited redetermination orally, so long as a written confirmation of the decision is mailed to the enrollee within 3 calendar days of the oral notice. In addition, we proposed to revise paragraph (g) by adding cross references to paragraphs § 423.590(d)(1) and (d)(2) in order to apply the written notice requirements in paragraph (g) to adverse expedited redetermination decisions. As noted in the preamble to the proposed rule, we believe adding these two notice requirements to the Part D expedited redetermination process is in the enrollee's best interests given the expedited status of these requests, and is consistent with our subregulatory guidance and the process for notifying enrollees of adverse expedited coverage determination decisions in § 423.572(b).

Similarly, we proposed adding § 423.590(h) to establish the form and content requirements for fully favorable redetermination decisions, and proposed making those notice requirements applicable to redeterminations issued under paragraph (a)(1). We also proposed to reference paragraphs (d)(1) and (d)(2) in paragraph (h), so that the form and notice requirements in paragraph (h) would also apply to fully favorable expedited redetermination decisions. As we noted in the proposed rule, incorporating these Part D standard redetermination notice requirements will provide an important beneficiary protection by ensuring continuity of care for Medicare beneficiaries who are obtaining refills of prescription drugs under Part D, and doing so does not conflict with the related MA provisions. After considering the comments received in response to these proposals, we adopt these provisions without modification in this final rule.

Comment: We received a number of comments supporting the proposal allowing Part D plan sponsors to make the initial notice of a fully 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. However, one commenter suggested revising the 3

calendar day requirement to 3 business days.

Response: We appreciate the comments we received in support of this provision. With respect to the comment recommending that we revise the calendar day requirement to business days, we have consistently used the calendar-day timeframe for all Medicare appeals processes, and we do not believe there is a compelling reason to depart from that standard for written notice of favorable decisions. We note that plan sponsors are required to mail (not deliver) the notice within 3 calendar days.

Comment: We also received many comments favoring our proposal giving Part D plan sponsors the option of making the initial notice of an adverse expedited reconsideration orally and then following up with written confirmation of the decision. Commenters also supported applying the written notice requirements in paragraph (g) to adverse expedited redetermination decisions. However, a number of commenters expressed concern about starting the 60-day timeframe for requesting an appeal on the date an enrollee receives oral notice of an adverse decision. The commenters noted that it may be very difficult for an enrollee to keep track of the deadline for filing an appeal if the 60-day timeframe begins on the date they receive oral notice of a plan's decision. The commenters suggested starting the 60-day timeframe on the date printed on the written denial notice.

Response: We agree and believe the 60-day timeframe for requesting an appeal of an adverse decision should begin on the date printed on the written denial notice. However, we believe the appropriate place to make this clarification is in our subregulatory guidance. Therefore, we will make this clarification in Chapter 18 of the Prescription Drug Benefit Manual.

Comment: A commenter requested that CMS develop a model letter for fully favorable redetermination decisions and written redetermination decisions that follow oral notice under § 423.590.

Response: We agree that it would be helpful to provide plan sponsors with either model language or standardized notices for use in issuing fully favorable redetermination decisions and written redetermination decisions that follow oral notice, and will explore the feasibility of implementing these options. Any notice(s) we develop will be published in Chapter 18 of the Medicare Prescription Drug Benefit Manual.

Comment: Numerous commenters supported the proposal requiring plan sponsors to include specific information (such as, the conditions of approval) in favorable decision notices. However, one commenter opposed the proposed requirement and suggested instead that we allow plan sponsors to provide the approval conditions on request.

Response: Currently, plan sponsors must provide the conditions of approval to enrollees upon request. Thus, the commenter's suggestion would not address the issue we were trying to resolve in the proposed rule. As noted in the preamble to the proposed rule, we believe it is important to include the conditions of approval in favorable notices to help ensure continuity of care for Medicare beneficiaries who receive prescription drugs under Part D. Prescription drugs are often provided to beneficiaries on a recurring basis. Therefore, it is important for an enrollee to know the conditions of the approval (such as, duration, limitations, and coverage rules for refills) before a refill is needed, so that, if necessary, the enrollee can work with his or her prescriber to secure prior approval for additional refills, obtain an exception, or switch to an appropriate alternative prescription.

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

We proposed specific language related to oral requests for organization determinations, except for payment-related requests. As we noted in the October 22, 2009 proposed rule, 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 that would allow enrollees to request standard organization determinations both orally and in writing. Therefore, we added specific language in § 422.568 to allow oral requests for organization determinations, except where the request is for payment.

Comment: Although one commenter opposed allowing oral requests because of concerns about proving that a request was made, we received several comments in support of our proposed revision. Many of those who supported our proposal also suggested that we require plans to develop a confirmation and tracking system for oral requests.

Response: For several years, we have, without difficulty, allowed enrollees and physicians to orally request expedited organization determinations. Thus, we believe allowing enrollees to also request standard organization determinations orally will not pose any issues regarding tracking such requests. Currently, Chapter 13 of the Medicare Managed Care Manual (section 50.2) instructs plans to maintain a process for tracking expedited organization determinations, and we agree with the commenters' recommendation to place a similar requirement on plans regarding oral requests for standard organization determinations. Accordingly, we are revising § 422.568 as proposed without change. We will also add this requirement to Chapter 13 of the Medicare Managed Care Manual to ensure compliance.

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

We proposed to remove the language from § 422.566(b)(4) and § 422.568(c) that an enrollee must disagree with the plan's discontinuation or reduction of a service for the plan's decision to be considered an organization determination. 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 decision 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), a plan must give an 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). We indicated that we no longer believe that it is necessary to require an enrollee's "belief" that the services in question are medically necessary in order to consider these reductions or discontinuations to be organization determinations, nor did we believe that it is appropriate to condition the delivery of a notice on an enrollee's "disagreement" with the discontinuation or reduction of an ongoing course of treatment. Therefore, we proposed to change this language 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.” We noted that § 422.620 through § 422.626 already provide enrollees who are receiving care in an inpatient hospital, skilled nursing facility, home health, or comprehensive outpatient rehabilitation facility (CORF) setting with the right to receive a notice and expedited review of service terminations for ongoing courses of treatment in these settings. Thus, our intention was to ensure that enrollees who are receiving previously authorized ongoing courses of treatment outside the settings covered by § 422.620 through § 422.626 would automatically receive notice and appeal rights if such services were terminated, and enrollees in all settings would automatically receive notice and appeal rights if the level of care or amount of such services was reduced.

Comment: Most commenters supported our proposed revisions. However, a few commenters requested further clarification about whether and how this revision altered plan or provider notice requirements. One of these commenters also requested clarification that the changes proposed would not create a new requirement for plans to notify enrollees each time a participating provider discontinues treatment under § 422.566 and 422.568. This commenter noted that the clauses proposed for deletion were originally added as part of the notice and comment process when the requirements for an enrollee’s expression of dissatisfaction were first adopted.

Response: As we note previously, § 422.620 through § 422.626 automatically trigger the requirement for plans and providers to give a notice with appeal rights whenever enrollees experience service terminations while they are receiving care in the inpatient hospital, skilled nursing facility, home health, or CORF settings. Conversely, § 422.566 and § 422.568 currently require an enrollee to express dissatisfaction about a termination or reduction of services in order to receive notice and appeal rights. Therefore, our goal in no longer requiring an enrollee’s disagreement was to ensure that plans would be required to provide notices whenever they discontinued or reduced a previously authorized ongoing course of treatment, regardless of the setting. However, as we considered these comments, we recognized that some additional restructuring of the provision would be needed to ensure a clear and consistent understanding of the policy.

Enrollees who are receiving care in settings governed by § 422.620 through

§ 422.626 receive notices with appeal rights only when services are being terminated. However, enrollees do not automatically receive notices when previously authorized ongoing courses of treatment are reduced in these settings. Consistent with our proposal, we are establishing the policy to require notice and appeal rights, in all settings, for previously authorized ongoing courses of treatment that either end or are reduced prematurely. We note that the phrase “previously authorized ongoing course of treatment” means a series of services or treatments that have been approved in writing (such as through a plan of care). Accordingly, a reduction in the level of care of a previously authorized ongoing course of treatment may include a change in the mix or range of services/sessions, a decrease in the intensity of the care, or a reduction in the amount of services/sessions provided relative to the original authorization.

Unlike the provider settings under § 422.620 through § 422.626, when a course of treatment ends in other settings under § 422.568(c), it will not result in automatic notice and appeal rights if the enrollee received all of the services as planned in the original authorization. In these cases, if an enrollee believes that those services should continue, he or she must request a new organization determination from the health plan. Accordingly, we are finalizing § 422.566(b)(4) and § 422.568(c) to include the revisions noted previously.

22. Representatives (§ 422.561, § 422.566, § 422.574, and § 422.624)

We proposed to amend § 422.561 to clarify that a representative may act on an enrollee’s behalf with respect to the grievance process. As we explained in the preamble to the October 22, 2009 proposed rule, for various reasons, enrollees may choose or need to have someone represent them 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, unlike the corresponding Part D regulation, existing § 422.561 does not explicitly permit representatives to file grievances on behalf of an enrollee. In order to rectify this and be consistent with the Part D definition of representative at § 423.560, we proposed to amend the definition of representative under § 422.561. Similarly, we proposed to remove the term “authorized” before “representative” in § 422.574 and § 422.624, so that the definition is consistent throughout subpart M.

Comment: Several commenters supported removing the word “authorized” before “representative” in order to be consistent with the definition of the term “representative” and less limiting in the application of the term. However, a perceptive commenter noted that we overlooked making this revision in two places under § 422.566(c).

Response: We intended to make this change throughout all of subpart M, and as such, will finalize § 422.566(c) in the final rule to include these additional revisions.

Comment: A few commenters requested that we restructure all of subpart M of part 422 so that the general provisions section (§ 422.562) includes provisions about enrollee rights and MA provider notice responsibilities for services rendered by skilled nursing facilities (SNFs), home health agencies, (HHAs), and comprehensive outpatient rehabilitation facilities (CORFs) and services provided in the inpatient hospital setting. These commenters also recommended creating new sections to describe provider notice requirements for all settings and the notice requirements and appeal rights specifically related to Part B services. This restructuring, the commenters suggested, would provide a more thorough overview of beneficiary rights under subpart M, and place the notice and appeal language in a more appropriate place in the regulatory scheme.

Response: This comment is beyond the scope of the proposed rule. However, we note that subpart M, like subpart I of part 405 and subpart M of Part 423, describes the various levels of the MA appeals process, including the associated beneficiary rights and provider notice requirements, in the order in which they occur. We believe this structuring of the appeals provisions makes it easier to follow the process. We do not agree with the suggestion that the current order of the regulatory provisions prevents enrollees from appealing adverse decisions about Part B (or any other Medicare) services and believe that restructuring subpart M as recommended, would not result in additional notice or appeal rights for enrollees. Finally, to make certain that beneficiaries understand the MA appeals process and their rights under this process, we ensure that beneficiary materials and notices, such as the Evidence of Coverage and Notice of Medicare Noncoverage are comprehensive, clear, and easy for enrollees to understand.

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

In the October 2009 proposed rule, we proposed adding new provisions (§ 422.111(g) and § 423.128(f)) to the existing regulations that govern the information that must be disclosed to enrollees and potential enrollees. Specifically, we proposed to add that CMS 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. While a number of commenters opposed this proposal, an equal number of commenters supported it. The latter noted that they support the goals of this proposal to provide beneficiaries with the information they need to assess the quality of care they are receiving and to make sponsoring organizations accountable for their performance deficiencies, which should improve compliance with the rules and requirements of the Medicare program. We also solicited comments 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 the 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).

We are finalizing the proposed changes to § 422.111(g) and § 423.128(f) with a modification to § 422.111(g) discussed in detail below.

Comment: A number of commenters were concerned that we have not provided enough detail about the proposal, including what compliance and performance deficiencies would rise to a level to trigger the disclosure requirement, as well as the types, format and timing of these disclosures. These commenters were concerned that the proposed regulations allow CMS too much discretion, could be inconsistently applied and may lead to unnecessary confusion and alarm for beneficiaries. Also, commenters stated that the existing performance ratings, through the Medicare Web site, currently provide adequate disclosure to beneficiaries.

Response: As we clarified in the proposal, our intent is to invoke this disclosure authority when we become aware that a sponsoring organization has serious compliance or performance

deficiencies such as those that may lead to an intermediate sanction or require immediate correction and where we believe beneficiaries should be specifically notified. One example of a situation where enrollees should be notified of performance or compliance deficiencies would be when a sponsoring organization fails to provide beneficiaries with the proper premium notices to collect premium amounts in arrears. Another example would be if a sponsoring organization failed to provide access to services and we instructed the sponsor to contact enrollees regarding this issue and assist them with obtaining needed services or medications. In each of these situations we would require a sponsoring organization to disclose the deficiency to its enrollees and take affirmative steps to alleviate any problems for enrollees, such as providing enrollees with options to fix the issue.

The performance ratings routinely available to beneficiaries, while equally important for the promotion of transparency and informed choice, generally will not include information about the type of performance deficiencies that will be the subject of these disclosure requirements. Also, we intend to use the normal account management oversight processes to review and approve any disclosures before they are made to beneficiaries to ensure that information disclosed is clear, and unambiguous and to lessen the potential for confusion, alarm or other potential negative impacts on beneficiaries.

Comment: Several commenters raised concerns that this requirement would be administratively and financially burdensome on some sponsoring organizations either because these disclosures could lead to a significant increase in grievances and expenditures responding to beneficiary concerns over the disclosures or could unnecessarily alarm beneficiaries and lead to requests for disenrollment. These commenters also were concerned about the utility of these kinds of disclosures based on their experience that Medicare beneficiaries rarely request information about compliance and performance and have demonstrated no interest in information about sanctions taken by CMS.

Response: As we stated in our October 22, 2009 proposed rule, the primary purpose of this requirement is to promote transparency and informed choice especially in those situations where we believe beneficiaries need or should have access to this information. We intend to exercise our authority judiciously in those situations where we believe that the information being

required to be disclosed will have a positive effect on transparency and informed choice. Similarly, we intend to use our normal account management oversight processes of review and approval of materials disclosed to beneficiaries to lessen the prospect for beneficiary confusion or concern which could lead to unnecessary grievances and requests for disenrollment. Finally, we believe that beneficiaries would be interested in receiving information about serious or significant compliance or performance deficiencies which potentially could affect them.

Comment: Several commenters provided suggestions concerning how we should make this information available to enrollees. One commenter stated that we should require that sponsoring organizations make information available upon request or on the Medicare Web site and another commenter requested that we consider alternative means of supplementing existing performance information available to beneficiaries through the CMS Web site.

Response: We do not agree with the suggestion that sponsoring organizations should only make such information available upon request or on the Medicare Web site. We intend to require that enrollees receive this information from sponsoring organizations in those circumstances where we believe beneficiaries must be affirmatively made aware of these deficiencies. Providing information upon request or merely posting on a Web site which enrollees may or may not access does not promote the degree of transparency and accountability by sponsoring organizations, for their deficiencies, that was contemplated by our proposal. Also, not all beneficiaries have access to the Medicare Web site and we believe beneficiaries may not be aware that they can request this information.

Comment: One other commenter suggested that sponsoring organizations should not be required to disclose deficiencies that occurred in the past because those issues may have been corrected and are not relevant to the current status of the plan.

Response: We intend to conduct our oversight responsibilities in a manner such that the kinds of compliance and performance deficiencies contemplated by these disclosures come to our attention as quickly as possible and are similarly disclosed to enrollees in a timely manner. However, it is not always possible for us to be aware of situations contemporaneous with their occurrence. We intend to take into account whether the deficiencies have been corrected and the utility of making

such disclosures to beneficiaries in these instances when making a decision as to whether disclosure will be required.

Comment: A number of commenters expressed concern with the timing of these required disclosures and the related issue of whether beneficiaries may elect other options once they receive one of these disclosures. Several commenters requested that disclosure be imposed only in those circumstances where a beneficiary would be afforded the opportunity to elect another plan option, some requested that disclosure of performance deficiencies be immediate so that beneficiaries would have more time to plan their health care decisions and several commenters believe that disclosures throughout the plan year would decrease the likelihood that information would get lost during the annual coordinated election period (AEP) or open enrollment period (OEP).

Response: We agree with the commenters who recommended that disclosure of these compliance and performance deficiencies be made as expeditiously as possible to beneficiaries and therefore we also agree that these disclosures may be required throughout the plan year. Also, with respect to the comments relating to allowing beneficiaries to elect other options, based on the nature and extent of the deficiencies that necessitated the disclosure, we intend to exercise our authority to grant a special election period for beneficiaries affected by the plan's compliance or performance deficiencies as permitted in § 422.64 and § 423.38. Our intention is to provide actionable information to beneficiaries. In some cases, the appropriate action may be to afford beneficiaries an opportunity to elect another plan option. In other cases, it may be sufficient to require plans to disclose the deficiency to its enrollees and provide enrollees with options to fix the issue.

Comment: We received one comment that questioned CMS' authority to require a sponsoring organization to disclose to its beneficiaries its compliance or performance deficiencies. The commenter provided no specifics for the assertion and merely stated that they have expressed to us on numerous occasions the "well-founded legal and policy objections" to self-disclosure.

Response: We currently have both statutory authority pursuant to sections 1851(d) and 1860D-1(c) of the Act and existing regulatory authority under § 422.111(f)(8)(v) and § 423.128(c)(1)(vii) to require sponsoring organizations to disclose information to its enrollees to help them make informed choices about

their healthcare. We note that the commenter did not provide a further description or citation to the "well founded legal and policy objectives" that they stated had been previously submitted to us. To the extent that the commenter is referring to a prior proposal related to the mandatory self-disclosure of fraud, waste, and abuse issues, the disclosures that are the subject of these proposals are entirely distinguishable and this proposal is completely unrelated to any past proposals involving the mandatory self-disclosure of fraud, waste, and abuse issues. The current provision, for which there is explicit statutory authority, involves disclosures of compliance and performance deficiencies that we are already aware of and has determined involve an issue that enrollees should be notified of expeditiously. However, we are modifying the language in § 422.111(g) to replace the term "self-disclosure" with "disclosure" to avoid any confusion.

Comment: One commenter questioned how CMS intends for sponsoring organizations to disclose to their enrollees that they have resolved the disclosed compliance/performance issues after the required disclosure is made.

Response: We recognize that sponsoring organizations will want to correct any underlying compliance or performance deficiencies that led to these kinds of disclosures quickly. Our proposal was specifically intended to utilize transparency to incentivize and promote sponsoring organizations' compliance with CMS requirements. As with the required disclosure notice, we intend to use the normal account management oversight processes to review and approve any notices that sponsoring organizations wish to provide to enrollees concerning a correction of the underlying compliance or performance deficiencies that led to the disclosure.

Comment: One commenter requested that we issue a written warning to sponsoring organizations before sending the actual notice requiring disclosure.

Response: We do not believe issuing a written warning to sponsoring organizations prior to requiring disclosure furthers any particular compliance or oversight objectives and additionally may not always be feasible, especially if the deficiency has just occurred and beneficiaries need to be notified immediately. We retain the discretion to issue a compliance action (including a written warning), separate and apart from the requirement to have sponsoring organization's disclose deficiencies to enrollees, based on the

underlying associated compliance or performance deficiency. Therefore we are not incorporating this commenter's suggestion.

Comment: One commenter expressed concern that sponsoring organizations do not have the opportunity to challenge or appeal the application of this requirement.

Response: These disclosure provisions merely require sponsoring organizations to provide beneficiaries with access to information. There is no statutory or regulatory right to challenge or appeal a CMS requirement to disclose information to enrollees. However, to the extent we take a contract or enforcement action (for example, an intermediate sanction or a civil money penalty) against the sponsoring organization for an associated underlying compliance or performance deficiency, the sponsoring organization would be afforded any appeal rights associated with the action taken.

Comment: One commenter was concerned that sponsoring organizations would not comply with the requirement.

Response: We have established mechanisms for ensuring compliance and fully intend to enforce these requirements and to take appropriate corrective and enforcement action should sponsoring organizations fail to comply with this requirement.

Comment: One commenter recommended that defined timeframes be issued in which CMS should respond to a beneficiary's inquiry related to the disclosure of a plan's performance or compliance deficiencies.

Response: We have established mechanisms for ensuring we respond to all beneficiary inquiries and these established mechanisms would apply equally to any inquiries received from beneficiaries concerning these kinds of disclosures.

Comment: One commenter suggested that we make public the information on its Web site in a manner that is more detailed and easier to find.

Response: Our proposal was not intended to solicit comments about the information on our Web site and therefore we are not specifically addressing this comment.

Comment: One commenter requested that we modify the plan ratings for special needs plans (SNPs) because they do not accurately measure plan performance.

Response: Our proposal was not intended to address the methodology for plan ratings and therefore we are not specifically addressing this comment.

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

We proposed to amend the definition of an MA plan “service area” at § 422.2 to exclude facilities in which individuals are incarcerated, consistent with the definition of service area for a Part D plan and in light of the fact that incarcerated beneficiaries are unlikely to have access to MA plan services, as required under § 422.112. We received several comments on this provision, all of which supported our proposal. We appreciate the support for the changes and are finalizing the proposed revision

to the definition of MA plan “service area” without modification.

C. Changes To Provide Plan Offerings With Meaningful Differences

This section addresses proposals in our October 22, 2009 proposed rule that were designed to promote plan offerings with meaningful differences, and ensure plan viability. We discuss below proposed revisions that would help ensure that plans offered by the same organization in the same area have meaningful differences from each other, provide for a transition to the applicability of such rules when an existing organization is acquired by or

merged with another organization, and provide that plans that have failed to attract enrollees over a period of time without justification may be non-renewed. We believe that these revisions will help us accomplish the balance we wish to strike between encouraging robust competition and providing health plan and PDP choices to beneficiaries that do not create confusion for beneficiaries because there are meaningful differences in benefit packages among the plans offered. We discuss these provisions in connection with comments we received in response to the proposals outlined in Table 3.

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. Meaningful Differences in Bid Submissions and Bid Review (§ 422.254, § 423.265; § 422.256, and § 423.272)

Under our authority in 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 that CMS finds “necessary and appropriate” and with respect to Part D, our authority under section 1860D–11(d)(2)(B) of the Act to propose regulations imposing “reasonable minimum standards” for Part D sponsors, our October 22, 2009 proposed rule proposed changes to our regulations to ensure that plan offerings by MA organizations and Part D sponsors represent meaningful differences to beneficiaries with respect to benefit packages and plan cost structures. Specifically, we proposed to revise § 422.256(b)(4)(i) and § 423.272(b)(3)(i) to specify that we would only approve a bid submitted by an MA organization or Part D sponsor if its plan benefit package or plan cost structures were substantially different from those of other plans offered by the organization or sponsor in the area with respect to key plan characteristics such as premiums, cost-sharing, formulary structure, or benefits offered. We also proposed to make related changes to § 422.254(a)(5) and § 423.265(b)(3)(i) to require that MA organizations and Part D sponsors must ensure that multiple bids submitted for plans in the same

area are submitted only if the plans meet the foregoing test of being substantially different from each other.

After reviewing the comments we are finalizing our proposals with the technical changes to § 422.254(a)(4), § 423.265(b)(2), § 422.256(b)(4)(i) and § 423.272(b)(3)(i), explained below.

Comment: Most commenters supported our proposal to require meaningful differences in bids but asked for greater specificity about how the new rules would apply. Several commenters requested that CMS identify the specific thresholds and criteria to be used in determining that meaningful differences between plans exist, and several others requested that CMS annually publish the standards early in the year preceding the contract year to which the thresholds and criteria apply. A few commenters requested that criteria for meaningful differences be published annually and be subject to public comment. One commenter requested that CMS include public notice of areas with limited plans.

Response: We agree with the commenters that it is important to provide more information and greater specificity concerning standards that we will use in assessing meaningful differences, and agree that MA organizations and Part D sponsors should have this information early in the year preceding the contract year to which the standards would apply in

order to assist them in developing their plan offerings for the contract year. However, we also believe it is important to retain flexibility when considering meaningful differences. Therefore, as specified in our October 2009 proposed rule, our final regulations at § 422.256(b)(4) and § 423.272(b)(3) continue to include the general substantive standard we will use when assessing plan bids, with the expectation that greater specificity in how this standard will be applied will be provided, with an opportunity for comment on our more detailed criteria, through guidance such as our annual call letter. We do not agree that it is necessary to provide a separate public notice of areas with limited plan choices, as the number of choices available in an area is already provided to beneficiaries in that area in the Medicare & You Handbook, and on the Medicare Web site.

Comment: One commenter opposed the proposed changes and recommended that CMS reevaluate its policy on differences that are meaningful to beneficiaries, which the commenter believed was based purely on actuarial policies. The commenter argued that CMS’ policy could be considered discriminatory because geography would be a factor in whether multiple plans had to be different from each other.

Response: We believe our proposed policies would require differences in criteria that beneficiaries, not actuaries, would find meaningful, while still providing MA organizations and Part D sponsors with flexibility in offering different plan options. We disagree with the commenter who believes that considering the geographical region of a plan could be considered discriminatory, since the beneficiary confusion issue we are addressing in this rule only applies when duplicative plans are offered by the same organization in the same area. Moreover, we believe that greater scrutiny of differences between an organization's plan offerings in an area where more plans are offered is justified in that the higher the total number of plans offered in an area, the greater is the potential for beneficiaries to be confused and overwhelmed.

Comment: Several commenters had specific questions, concerns, or suggestions about how to best assess meaningful differences. Several commenters wrote that CMS should not place so much focus on Part D formularies as a means of determining meaningful differences. In connection with this issue, several commenters believed that focus on the plan formulary could lead to sponsors offering at least one plan with a "bare bones" formulary. Such "baseline" or "benchmark" plans could harm LIS enrollees, as such enrollees would likely be disproportionately enrolled in such plans and are least able to navigate barriers such as utilization management restrictions. Concerning other specific issues, a commenter wrote that MA-PD plans offered by the same organization should be assessed for meaningful differences based on the health care benefits offered by each plan and not the Part D benefits of each, as standardization of the Part D benefit is generally helpful for beneficiaries.

Response: With respect to focusing on plan formularies as a criterion for assessing meaningful differences in Part D plans, we note that while we believe differences in formularies to be a fundamental area for assessing plan differences, this was not the only element of Part D plan offerings we proposed to assess. Indeed, we proposed to look at premiums and cost-sharing, as well. With respect to the concerns that focusing on the formulary could lead to "bare bones" plans in which LIS beneficiaries could be disproportionately enrolled, the Part D program requirements clearly specify the minimum requirements for basic prescription drug coverage, and plans' formularies are reviewed and approved

only if they are determined to provide adequate access consistent with those requirements. As explained in 30.2.7 of Chapter 6 of the Medicare Prescription Drug Manual (*see* http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage), we review submitted drug lists to ensure that they are consistent with best practice formularies currently in widespread use today. Our goal is to ensure that all Part D formularies are sufficiently broad in scope so as to contain the drugs most commonly used to treat the conditions faced by Medicare beneficiaries. Nothing in our proposed regulations would permit a sponsor to offer anything less than the current standard for the basic Part D benefit.

Comment: A commenter asked if five SNP plans offered by the same MA organization would be considered meaningfully different, even if the formulary offered by each resulted in similar out-of-pocket costs, simply because the plans offered were SNPs. Another commenter cautioned that coverage in the gap may be little different than no coverage in the gap if such coverage consists solely of generic drugs. The commenter suggested that a plan's initial coverage limit is a better indicator of meaningful differences between plans. A commenter noted that his studies indicate that enhanced Part D benefits are increasingly meaningless, and that genuine coverage in the gap is the primary indicator between enhanced and standard plans, given that cost-sharing and premiums are often no different between enhanced and basic prescription drug coverage. According to this commenter, his studies show that gap coverage is also often not meaningfully different because such coverage is: (1) Almost always accomplished through generic drugs; (2) many generic drugs are not normally covered by plans claiming to offer such coverage; and (3) copayment amounts in the gap are higher than copayments before reaching the initial coverage limit. The commenter suggested that a plan should be required to cover all formulary drugs in the gap if the plan wants to offer gap coverage and, if this is not feasible, plans offering gap coverage for generics should be required to offer the same coverage in the gap for generics that they offer in the initial coverage period. Another commenter wrote that its experience was that utilization of generic drugs is one of the best ways that a member can delay onset of the coverage gap.

Response: With respect to the comment on multiple SNPs offered by

the same organization, we would not consider five SNPs offered by the same organization to be meaningfully different simply because the plans offered are SNPs. As is also the case in our provision to non-renew low enrollment plans, we believe that SNPs may warrant special attention when assessing meaningful differences because of such factors as the enrollee population served and differences in benefits (Medicare and Medicaid in the case of dual-eligible SNPs). However, we do not believe that such plans should receive exemptions from either the requirements concerning low enrollment or meaningfully different plans simply because they are SNPs.

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 from taking advantage of the system "through product design."¹ Gold continues by identifying the sheer array of plan types with their different characteristics, such as access to services or cost structures, as confusing to beneficiaries to the point that they may not choose the plan that is best for them in terms of costs or benefits. 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."² In another study of Part D plan offerings, published in a 2009 paper by Jason T. Abaluck and Jonathan Gruber, the authors determine that "elders place much more weight on plan premiums than they do on the expected out of pocket costs that they will incur under the plan" and that

¹ Gold, Marsha. Strategies for Simplifying the Medicare Advantage Market. Publication prepared for the Kaiser Family Foundation. July, 2009.

² Rice, T. Reducing the Number of Drug Plans for Seniors: A Proposal and Analysis of three Case Studies. Presentation at Academy Health Annual Research Meeting: Washington, DC. June 9, 2008.

“they substantially under-value variance reducing aspects of alternative plans,” confirming that the array of Part D plan offerings can often lead to inconsistent choices among seniors with respect to determining costs, and plan features most beneficial to them.³

We agree with the commenter who wrote that coverage in the gap may not always be meaningfully different if such coverage consists solely of a subset of formulary generic drugs but we disagree that an enhanced alternative plan should be required to cover all formulary drugs in the gap if the plan wishes to claim to offer gap coverage. Rather, we believe that a meaningful difference with respect to an enhanced plan must be represented by a significant increase in benefits over basic coverage. Similarly, if two enhanced plans are offered by the same sponsor in a service area, a meaningful difference among those two plan offerings must be represented by a significant difference in benefits offered.

Comment: One commenter recommended that we permit an MA organization to offer three plans of each plan type in a service area, while another wrote that CMS should not arbitrarily limit the number of plans offered by an MA organization in a service area.

Response: Although permitting an MA organization to offer three plans of each plan type may be reasonable in some circumstances, we do not agree with the commenter that this should necessarily be the case. To the extent that the three plans have meaningful differences from each other that avoid beneficiary confusion, we believe that three plans of the same type (for example, coordinated care plan) would be permissible. Because the number of plans of the same type that would be permitted under this rule would depend on the plan design, and on ensuring that beneficiaries are not confused, we disagree with the commenter that we are imposing an “arbitrary” limit on plan offerings.

Comment: A commenter suggested that CMS require all health care plans to have at least one basic, standardized plan that would be transparent and understandable to beneficiaries no matter where or by which organization the plan was offered.

Response: We do not agree with the commenter that all MAOs offer at least one standardized plan no matter where

or by which organization the plan is offered. While it is important to ensure that plan options are meaningfully different, we also believe MAOs should have the flexibility to craft distinct plan options for beneficiaries.

Comment: One commenter implied that CMS was not aware that plan benefit designs with low or no premiums and higher cost-sharing may be attractive to some beneficiaries, and plans with no deductibles and higher premium attractive to others and, as a result, both structures should remain a viable choice in the marketplace. A commenter urged CMS to look at an organization or sponsor’s plans “holistically” when assessing meaningful differences. Another commenter cautioned that while establishing meaningful differences among plans offered by an MAO or sponsor is important, CMS must watch for complexities in plans’ cost-sharing structures, as these various structures make it far more difficult for beneficiaries to evaluate differences between or among benefit packages.

Response: Contrary to the commenter’s suggestion, we are well aware that some beneficiaries prefer plan benefit designs with low or no premiums and higher cost-sharing while others may prefer high deductible/high premium plans, and we have no intention of prohibiting these as “a viable choice” for beneficiaries. To the contrary, our requirement that plans have meaningful differences from one another is designed to promote such differences in plan design. CMS’ concern is with MAOs and Part D sponsors that offer several plans in the same service area that have few distinctions, not with plans with benefit or cost structures which are clearly quite different.

Comment: A commenter requested that we consider premiums, the provision of health and wellness programs, and dental or vision coverage in our assessment of meaningful differences between MA plans. Another commenter took exception to our example in the proposed rule that an HMO with a point of service (POS) option and local PPO can sometimes be similar, that is, may not be meaningfully different, and wrote that local PPOs are, in fact, different by virtue of offering out-of-network coverage. Another commenter agreed that HMOs with a POS option are largely indistinguishable from local PPO plans.

Response: The focus of our review for meaningful differences is primarily on cost differentials between plans for Parts A and B services, the presence of a Part D benefit, the ways beneficiaries access

services (that is, through a network, as in an HMO or in a non-network context such as a PPO) and overall plan costs. The addition of individual supplemental benefits may not trigger the annual thresholds we have used to establish significant differences in overall plan costs among an MA organization’s plan offerings in a service area. That said, our recent experience in reviewing plan benefit packages suggests that the addition of some supplemental benefits can result in significant differences in out-of-pocket costs. Therefore, it is possible that an individual supplemental benefit or group of supplemental benefits could result in plans being meaningfully different from one another. With respect to the comments concerning our example that PPOs and HMOs with a POS option could be considered similar if offered by the same MAO even though they technically are different plan types, we cited this example to illustrate that even though these are different plan types it is possible that such plans, if offered by the same MAO, could be considered similar under some circumstances. For example, if access to care in-network, and coverage of services out-of-network is essentially the same in both plans, and there are no other significant differences between the two in benefits or costs, there would not be “meaningful” differences between the two plans.

Comment: A commenter cautioned that CMS should be aware that an MA organization offering several dual SNP plans might have several similar benefit packages for Medicare benefits, but the same plans could have quite different Medicaid benefits. Another commenter supported our intention, as expressed in the proposed rule, to permit multiple plan filings by the same MA organization in certain circumstances and wrote that CMS should formally recognize the “Medicaid agency’s purchasing strategy” in any assessment of meaningful differences among dual eligible SNP plans.

Response: We do not consider differences in Medicaid benefits among dual eligible SNPs offered by the same MA organization as significant differences for purpose of our review, since we are reviewing differences in MA plan offerings, not Medicaid benefits. We would consider Medicare premiums (as part of a plan’s cost structure) as part of its review of bids. In short, as an earlier commenter urged, CMS intends to look “holistically” at an organization or plan sponsor’s offering in a service area when determining whether or not an organization’s or

³ Abaluck, Jason T, and Jonathan Gruber. Choice Inconsistencies among the Elderly: Evidence from Plan Choice in the Medicare Part D Program. NBER Working Paper Series. Working paper 14759. February, 2009. <http://www.nber.org/papers/w14759>.

sponsor's offerings are meaningfully different.

Comment: A commenter wrote that CMS should ensure that CMS' policies do not inadvertently remove meaningful choices in areas where choices may be comparatively limited (*Barrow County, Alaska v. Dade County, Florida*, for example). Another commenter wrote that CMS should consider limiting an organization's or sponsor's plan offerings in a geographic area similar to the Federal Employee Health Benefits Program or plans offered by some other employers.

Response: We do not intend to prevent plan choice in rural areas through implementation of the requirement for meaningfully different plans. The intent of the provisions is to ensure genuine choices for beneficiaries as well as transparency in plan offerings so that beneficiaries can make informed decisions about their health care plan choices. For this reason, we do not agree with the commenter who suggests that we limit an organization/sponsor's plan offerings in a geographical area to an arbitrary number of plans, since this could actually limit additional meaningful choices.

Comment: Two commenters cited discrepancies in the preamble and regulations text for Parts C and D concerning bid submissions (§ 422.254(a)(4) and § 423.265(b)(2)) and asked that we ensure the final regulations text reflects the language of the preamble by specifying that meaningful differences include differences in "cost-sharing or benefits offered, (MA regulations)" and "premiums, cost-sharing, formulary structure, or benefits offered" (Part D regulations) instead of the proposed regulations text for these sections, which was more general "benefit packages and plan costs" (MA regulations), "beneficiary out-of-pocket costs, and formulary structures" (Part D regulations). In addition the commenters asked that the list of meaningfully different elements cited in the bid submission and review sections be connected with the coordinating conjunction "or" instead of "and." One of the commenters recommended that the bid review sections for both the Part C and D regulations at § 422.256(b)(4)(i) and § 423.272(b)(3)(i) cross reference the criteria for meaningful differences in the bid submission sections for both programs (§ 422.254(a)(4) and § 423.265(b)(2)).

Response: We agree with the comments suggesting that the regulations text for the bid submission and review sections specifying the criteria we will use in assessing if an

MA organization's or Part D sponsor's bids are meaningfully different should be connected with "or" instead of the coordinating conjunction "and." As a result, we are revising our regulations at § 422.254(a)(4), § 422.256(b)(4)(i), § 423.265(b)(2), and § 423.272(b)(3) to state that an [MA or Part D] organization's bids must reflect differences in "benefit packages or plan costs." We also are making conforming changes to § 422.256(b)(4)(ii) and § 423.272(b)(3)(ii) which concern acquisitions and mergers, as these sections use similar language. However, we disagree with the commenter who urged that the preamble language referencing "plan characteristics such as premiums or cost-sharing" (MA program) or "premiums, cost-sharing, formulary structure," (Part D program) should be reflected in the regulations text. Although these are certainly elements that may result in meaningfully different plans, we believe the current language captures these elements while providing the necessary flexibility to view plans "holistically."

In addition, the commenter correctly points out that in order to make the Part C and D regulations consistent, § 422.256(b)(4)(i), which concerns MA bid reviews, should cross reference § 422.254(b)(4), which concerns submission of MA bids.

With the exception of the revisions noted previously, we are finalizing the provisions as proposed.

2. Transition Period in Cases of Mergers and Acquisitions (§ 422.256, § 423.272)

In connection with our proposal to ensure that plan offerings represent meaningful differences, we proposed to add § 422.256(b)(4)(i) and § 423.272(b)(3)(ii) to provide MA organizations and Part D sponsors involved in mergers or acquisitions a 2-year transition period from the merger or acquisition to ensure that plans offered by the MA organization or Part D sponsor are significantly different from each other. After a transition period of 2 years, we would only approve a bid submitted by an MA organization or Part D sponsor, or a parent organization to that entity, if the benefits or plan cost structure represented by that bid were substantially different from any other bid submitted by the same MA organization or Part D sponsor (or parent organization of that entity). We requested comments regarding the adequacy of our proposed transition period length of 2 years in both the MA and Part D contexts, particularly since we had previously, as articulated in the 2008 Call Letter for Medicare health

plans and PDPs, that PDP sponsors affected by mergers or acquisitions would be afforded a 3-year transition period. After reviewing the comments received in response to this proposal, we are finalizing the proposed provisions without modification.

Comment: Several commenters agreed with our proposal to require organizations and sponsors acquiring or merging with existing entities to offer plans with meaningful differences within two years of the merger or acquisition. One of the commenters wrote that 2 years was "more than adequate" for affected organizations and sponsors to offer meaningfully different plans. Another wrote that while 2 years was sufficient, CMS should consider notifying beneficiaries 1 year in advance of a plan's non-renewal so that they have clear notice of any changes.

Several commenters disagreed with the proposal to permit 2 years for transition, recommending, instead, that CMS maintain the current 3-year requirement articulated in the 2008 Call Letter. A few commenters believed that the language in the proposed rule could be interpreted to permit as little as one bidding cycle/bidding year between an acquisition or merger and the offering of meaningfully different plans. One commenter said that a 2-year transition period would be disruptive to beneficiaries and would not permit plans to develop adequate benefit packages. This commenter requested that CMS permit a 3-year transition period. Another commenter contended that organizations/sponsors need 3 years after a merger or acquisition in order to adapt their benefit packages to comply with the meaningful differences rule, and to implement a robust communications plan for implementing required changes.

Another commenter argued that CMS should not state that the transition period will be "as determined by CMS," but rather specify how the transition period will be measured. The same commenter wrote that if CMS does finalize the proposed requirement, we should not apply it to any acquisition prior to issuance of the rule, as the organization would have already taken action based on transition-related guidance in the 2008 and 2009 call letters.

Response: As stated in the preamble to the proposed rule, based on our experience, we believe that our proposed timeline for transitions provides ample time for organizations and sponsors to ensure that benefit packages are sufficiently different and to notify enrollees of any changes. Because the transition period actually applies for

the two contract years following the year of the acquisition or merger, that is, if a merger takes place in 2010, the MAO or sponsor would have until 2013 to offer meaningfully different plans, we believe this period is disruptive neither to plans nor to beneficiaries, and thus disagree with the commenter who asserted that a 3-year transition was needed to allow MA organizations and Part D plan sponsors to adapt their benefit structures and communicate to beneficiaries about the changes being made.

We clarify that only organizations or sponsors that merge or are acquired after the effective date of this final rule will be subject to the requirement at § 422.256(b)(4)(ii) and § 423.272(b)(3)(ii) that their offerings are meaningfully different after a 2-year transition period. In the case of plans offered by organizations or sponsors that merge or acquire other plans prior to the effective date of this regulation, the previously articulated 3-year transition period would apply.

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

As part of our process to streamline and simplify the plan selection process for beneficiaries, and ensure that beneficiaries are only offered plans with long-term viability, we proposed in § 422.506(b)(1)(iv) and § 423.507(b)(1)(iii) to include, as a specific ground for non-renewal of a contract, a finding that a Part C or Part D plan has failed to attract a significant number of enrollees over a sustained period of time. We justified this requirement on the grounds that, as a general matter, continuing such a low enrollment plan was not consistent with effective and efficient administration of the Medicare program for purposes of section 1857(c)(2)(B) of the Act (incorporated for Part D under section 1860D–12(b)(3)(B) of the Act), which provides authority to terminate a contract under such circumstances. In the preamble to the proposed rule, we acknowledged that there may be instances in which low enrollment over a sustained period of time is a function of the type of beneficiaries served, geographic location, or other circumstances, and that we would consider continuing to renew a low enrollment plan in such situations including, but not limited to, chronic care SNPs offering health care services especially tailored to this category of beneficiaries and not available elsewhere or employer group health plans offering benefits augmenting those of an MA plan to employees of a small business. We further stated that, if a

case could 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 non-renew that plan. Similarly, we also stated that the threshold for low enrollment could fluctuate, although we noted that we used a threshold of 100 enrollees for purposes of reducing the number of low enrollment plans for contract year 2010. Therefore, we did not propose to revise our regulations to specify a specific threshold. We solicited comments on this approach and whether we had provided sufficient clarity on how we would determine whether a low-enrollment plan would be non-renewed.

Comment: Several commenters supported the proposal to non-renew low enrollment plans, but recommended that the threshold and guidelines we would use to apply this requirement (including such factors as the number of plans in a market, plan enrollment, and the number of years of operation with low enrollment numbers) be clear and transparent, and that they be made available publicly early in the year preceding the contract year to which they will apply. One commenter wrote that CMS should convene a working group prior to enacting our proposed policy to non-renew low enrollment plans. Another commenter wrote that CMS should consider low enrollment to be in the 250 to 500 enrollee range rather than 100 enrollees (the number used in our efforts to reduce low-enrollment plans for contract year 2010, as detailed in the preamble to our proposed rule). Another recommended a low enrollment threshold of 1000 enrollees because it believes that plans serving fewer than 1000 people in a service area would be unable to offer negotiated savings, quality managed care, or popular plan features. A commenter asked CMS to clarify what is meant by “a small number of enrollees over a period of time.”

Response: We agree that guidelines concerning minimum enrollment thresholds and criteria should be published annually and as early as possible in the year preceding the contract year to which they will apply. While we disagree that we should specify thresholds in regulations, we intend to provide opportunities for the public to review and comment on our proposed thresholds and criteria for assessing low enrollment for the following contract year (for example, through our annual call letter). We

recognize that we must be flexible in assessing minimum enrollment to ensure that plans with legitimate reasons for low enrollments, such as lack of other health care plan options, specialized plan offering (such as, a chronic care SNP), or recent establishment of the plan, may continue to operate and that beneficiaries who might not otherwise have access to health care options offered by a low-enrollment plan will continue to have such access. Because we intend to provide for public input annually on our implementation guidance and will consider the suggestions for specific threshold amounts submitted by the commenters in that context, we do not believe the suggested “workgroup” to be necessary. With respect to the question of what constitutes “a small number of enrollees” over a period of time, the process described above may also be used to determine the number of enrollees that would trigger application of this regulation, as well as the period of time for which the small number would have to be sustained.

Comment: Another commenter recommended that CMS make clear that the length of time a plan has had low enrollment will be a primary factor in determining whether a plan is non-renewed, and that we should modify our regulations language to explicitly provide for “waivers” of the proposed requirement at § 422.506(b)(1)(iv) (§ 423.507(b)(1)(iii) for Part D plans) when special circumstances such as the type of beneficiaries served, geographic location, and absence of the plan would significantly limit beneficiary health care options in a service area.

Response: The length of time in which a plan has had low enrollment is only one of the factors that we will consider in determining whether it is consistent with effective and efficient administration of the Part C or Part D benefit. We will also consider the type of benefits being offered under the plan and the nature of the enrollment in the plan. As stated above, we recognize that we must be flexible in applying any minimum enrollment requirement to ensure that plans with legitimate reasons for low enrollments, such as lack of other health care plan options, specialized plan offering or recent establishment of the plan, may continue to operate. This flexibility will ensure that beneficiaries who might not otherwise have access to health care options offered by a low-enrollment plan will continue to have such access. Because we intend to apply this requirement in a flexible manner that considers the particular circumstances of each low enrollment plan, we do not

believe it is necessary to modify the proposed regulations at § 422.506(b)(1)(iv) and § 423.507(b)(1)(iii) to provide explicitly for “waivers” of this requirement.

Comment: A commenter recommended that non-renewed plans be permitted to passively enroll affected enrollees into another plan offered by the MA organization or Part D sponsor.

Response: With respect to the recommendation to provide for passive enrollment of beneficiaries in a non-renewed plan into another plan offered by that organization, we believe this is appropriate only in limited circumstances when a compelling case can be made that such passive enrollment is in beneficiaries’ best interests. In making such determinations, we take into consideration criteria such as benefits, cost sharing, the provider network, and premiums to ensure a comparable plan offering. In all other cases, we believe it is most appropriate to leave enrollment decisions to beneficiaries, who will have an opportunity during the annual coordinated election period to select another MA plan or Part D plan offered by the MA organization or Part D sponsor offering the plan being terminated. If a plan is terminated or nonrenewed, the affected organization or sponsor must follow all beneficiary and CMS advance notification requirements as specified in §§ 422.506, 422.508, 422.510, and 422.512 (MA program regulations), §§ 423.507, 423.508, 423.509, and 423.510 (Part D program regulations) and related guidance for both programs. In addition, passive enrollment initiated by an organization or sponsor in the absence of CMS approval is not among the transactions permitted by us in our annual renewal/non-renewal guidance. Because of these requirements and policies, an MA organization or Part D sponsor wishing to enroll members from the terminating or non-renewing plan into another of their plans could not do this without prior CMS review and consent. If we were to determine that such a transaction was in beneficiaries’ best interests, we would, as is our practice, facilitate and closely monitor the process. We note as well that beneficiaries in terminated or non-renewed plans have guaranteed issue Medigap rights, access to information about other available health care options, and other information that will assist them in finding plans most suited to their needs.

Comment: Several commenters supported our proposal but asked that we make exceptions for SNPs. One commenter requesting the SNP

exception wrote that “status as a SNP should be prima facie evidence that low enrollment is justified.” A few of these commenters specifically requested that such exceptions be codified in the final regulations text. One commenter requested an exception be made for employer group plans. One commenter requested an exception for MA-only plans, stating that enrollees who get their prescription drugs through some means other than an MA–PD should still have the option of remaining in an MA-only plan, and another commenter requested that “national” plans be exempted from these requirements.

Response: While we will consider exceptions on a case-by-case basis to any low-enrollment thresholds we establish, we do not believe it is necessary to exempt any specific plan type a priority. As we stated in the preamble to the proposed rule, there may be reasons for exceptions based on plan type, geography, or special health conditions of enrollees served that warrant a waiver of the requirements. However, a specific plan type, for example, a SNP or employer group plan, will not automatically be exempt from the minimum enrollment standard for renewal due to plan type alone. While sustained low enrollment may well be justified in the case of certain SNPs serving individuals with a relatively rare condition, a SNP serving an individual with a more common disease such as diabetes, or serving dual eligibles, should be able to attract enrollees. Similarly, we do not believe there is justification for exempting MA-only plans or “national” plans from the requirements unless there are other reasons to exempt them (for example, lack of other health care plan options, the specialized nature of the plan, or the recent establishment of the plan).

4. Medicare Options Compare and Medicare Prescription Drug Plan Finder

In the proposed rule we asked for comments on ways to improve the web tools, Medicare Options Compare (MOC), and the Medicare Prescription Drug Plan Finder (MDPF). We summarize and respond to these comments below.

Comment: One commenter requested that CMS add a function to limit the information that can be seen in the MOC so that users of the tool can focus on information they need most.

Response: The 2011 contract year update will include functions that expand and collapse which will help users of the MOC better focus on specific information.

Comment: Another commenter asked that the MOC contain direct links to the

plan(s) discussed, not just the organization’s Web site as is now often the case.

Response: We are not making the suggested change at this time as we believe that MOC already includes sufficient information to contact plans.

Comment: Another commenter requested that the tool clearly indicate what is meant by an “enhanced plan,” even if this is just a general description in the tool of the typical features of an enhanced plan.

Response: We do not believe that revisions are necessary as information on enhanced plans is currently available in the glossary and at <http://www.medicare.gov/medicarereform/howtoread.asp>.

Comment: A commenter requested that CMS add back the search function in MPDPF notifying the user of the number of drugs covered by a particular plan. The same commenter requested that information be included about when a plan last updated its drug pricing information and that the tool includes information about coverage of drugs traditionally covered under Part B, for example, infused and injectable drugs for MA–PD plans.

Response: Currently the drugs an individual beneficiary takes may be entered and displayed to determine coverage, but the MPDPF does not permit display a list of all the drugs a plan covers as this would take a very long time for the tool to display. CMS reviews drug pricing on a regular basis and the data is updated monthly to reflect any changes. We believe the compare function best permits users to tailor their searches for the specific drugs in the specific forms that they need.

Comment: Another commenter wrote that the MOC is relatively thorough but inconsistent in that some plans in the tool do not include information about health care costs and that saved searches often yield different results when retrieved later. The commenter recommended that the tool be refined to allow the user to move easily back and forth between information for MA and Part D plans, that the conditions required for enrollment in a chronic care SNP be specified, and that the function concerning costs for tiers of drugs is “incredibly unfriendly and confusing.”

Response: We are considering how best to streamline and make the use of these comparative functions easier.

D. Changes To Improve Payment Rules and Processes

This section addresses three payment issues under Part C. 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	Subpart F	§ 422.2	N/A	N/A.
Dispute and Appeals Process	Subpart G	§ 422.311
Payments to Medicare Advantage Organizations-Actuarial Valuation	Subpart F	§ 422.254	N/A	N/A.
Determination of Acceptable Administrative Costs by HMO/CMP 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. Definitions Related to Risk Adjustment Data Validation Appeals (§ 422.2) and Addition of Medicare Advantage Organization Risk Adjustment Data Validation—Dispute and Appeal Procedures (§ 422.311)

In the October 22, 2009 proposed rule, we proposed regulations establishing an appeals process to be used by MA organizations to appeal the error calculation resulting from Risk Adjustment Data Validation (RADV) audits. As explained in the preamble of that proposed rule, under RADV audits and medical records are reviewed to determine whether they support diagnosis codes (known as Hierarchical Condition Codes, or HCCs) submitted to us under the MA risk adjustment methodology. Under this methodology, certain diagnosis codes are considered to signify higher costs for the enrollee, and therefore, we pay a higher amount to the MA organization for an enrollee to reflect these higher costs. If, in fact, a diagnosis code was not justified by the enrollee’s medical condition, the higher payment amount associated with that diagnosis code would have been an overpayment. Under the RADV audit process we plan to recover the overpayments identified during the RADV audit. The appeals process we proposed in the October 22, 2009 proposed rule was intended to provide a mechanism for MA organizations to appeal the error calculation associated with the overpayments identified under RADV audits. We invited and received a large number of comments from health plans, managed care industry trade associations, and other interested parties regarding not only the proposed appeals process, but on the RADV audit process and underlying MA payment policy producing the overpayment findings and our definitions proposed at § 422.2. Since neither the statute nor existing MA program regulations

currently specify a process for appealing overpayments resulting from RADV audits, the appeals process we proposed was based on our authority to establish MA program standards by regulation at section 1856(b)(1) of the Act. Specifically, we proposed adding a new § 422.311 to part 422, subpart G, to specify RADV dispute and appeal rights for MA organizations. We proposed regulatory provisions allowing MA organizations that undergo RADV audit(s) to—(1) submit physician and other practitioner signed attestations relating to physician and other outpatient medical records that had a missing signature, or credentials that resulted in a payment error finding; (2) dispute certain other types of medical record review-related findings 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, we noted that MA organizations would be able to reduce their RADV payment error and thereby, reduce their overall estimated MA payment error. Therefore, we proposed the following provisions under part 422:

- To revise § 422.2 to add definitions of six terms that pertain to RADV activities, and thus to our proposals for implementing a RADV dispute and appeal processes.
- A new § 422.311 describing procedures that we would implement to afford MA organizations facing a potential overpayment determination resulting from RADV audits the opportunity to have certain potential RADV payment errors addressed in advance of RADV-audit-related payment error determinations, and to have other types of confirmed payment errors overturned. At § 422.311(a) and (b), we summarized the RADV audit procedures. Beginning with § 422.311(c), we proposed implementing

a three-pronged RADV dispute and appeal procedure that MA organizations could employ to reduce their RADV payment error rate, including—

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

We noted that 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 signatures 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 only for health services that were provided by certain physician specialties. Therefore, RADV audit procedures require that, in addition to finding diagnosis information that would support the HCCs submitted by the MA organization for risk adjustment purposes, physician signatures, and appropriate credentials must be present on medical records. Medical records with missing signatures or credentials are scored as errors under RADV audit procedures. We estimated 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 from those records. Moreover, 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 would otherwise originate from medical record signature, or credential-related discrepancies.

Therefore, in proposed § 422.311(c)(1), we proposed to implement a process that would allow MA organizations to voluntarily submit CMS attestations (that is, attestations developed and pre-populated by CMS). These attestations would be signed by physicians/practitioners who would attest responsibility for providing and documenting the health services in the physician and outpatient medical record(s) that were submitted for RADV audit. We specified at proposed § 422.311(c)(1)(ii) and (iii) that MA organizations would be eligible to use attestations to address signature or credential-related discrepancies only from physician or outpatient medical records; attestations would not be allowed to address signature or credential-related discrepancies found on 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. Attestations would not be acceptable to address any issues outside of the RADV-audit process.

At proposed § 422.311(c)(1)(C)(iv), we indicated that we would prospectively notify MA organizations that if the “one best” medical record used to validate an audited HCC were 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 described the proposed process that we would jointly undertake to review attestations submitted for our review at proposed § 422.311(c)(1)(iv) and (v), noting the following:

- Only CMS-generated attestations that meet certain requirements described at § 422.311(c)(1) and (d) would be eligible for consideration. Failure to meet these requirements would result in us not reviewing or accepting submitted attestations.
- CMS attestations that have been altered or amended (for example, striking out prepopulated words and replacing them with hand-written replacement words) without instruction or written concurrence from us would not be accepted.
- Attestations would need to accompany the medical record at the same time that the medical record was submitted to us for RADV audit. MA organizations would not be permitted to

submit attestations before or after submission of their RADV medical records.

- Attestations would need to originate from the physician/practitioner whose medical record accompanies and corresponds to the attestation. We would not accept attestations or medical records from any party other than the MA organization.
- Organizations would not be permitted to submit attestations during the documentation dispute or RADV reconsideration processes described at § 422.311(c)(2) and § 422.311(c)(3).

At proposed § 422.311(c)(1)(iv), we described 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 not be eligible for further appeal.

We further proposed affording MA organizations the option of disputing other nonsignature or credential-types of RADV-related medical record diagnosis coding discrepancies via a proposed documentation dispute process that we described in new paragraph § 422.311(c)(2). Under our proposal, in order to be eligible for documentation dispute, MA organizations would need to submit their “one best” medical record in accordance with RADV medical record submission deadlines established by us during the RADV medical record request process.

At proposed § 422.311(c)(2)(a), we specified the types of RADV-related errors that would be eligible for the proposed documentation dispute process. The documentation dispute process would apply only to the errors that arise out of operational processing of medical records selected for RADV audits and submitted to us 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 a RADV audit.

At § 422.311(c)(2)(ii), we proposed 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 would not be eligible for documentation dispute. At proposed § 422.311(c)(2)(iii) and (iv), we indicated 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 would undertake to notify MA organizations of the results of documentation dispute reviews. As described at proposed § 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.

Proposed § 422.311(c)(3) would establish an appeals process under which RADV payment error calculations would 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 would afford MA organizations the opportunity to dispute aspects of our medical record review process, the proposed RADV payment error calculation appeal process was 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 proposed 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.

Given the complexity of RADV audits in general, and the calculation of RADV-related error rates in particular, we stated our belief that it was prudent to afford appellant MA organizations multiple-layers of RADV-related payment error appeal.

At proposed § 422.311(c)(3)(ii), we also specified that MA organizations would not, under the proposed RADV payment error calculation appeal process, be permitted to appeal medical record review errors, nor would MA organizations be permitted to seek formal appeal of physician or practitioner signature or credential-related review errors. We believed that medical record review-related issues would be addressed as a result of the rigorous medical record review process, and the attestation and documentation dispute processes described earlier in the proposed regulation. In accordance with our proposed regulation at § 422.311(c)(3)(i), the RADV payment error calculation appeals process would only apply to errors identified in the RADV payment error calculation. MA organizations would not be permitted to

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 would need to adhere to established RADV audit requirements, including the submission of medical records in the manner and by the deadlines specified by CMS.

Furthermore, we noted that MA organizations would not be permitted to appeal our RADV payment error calculation methodology. Our justification for excluding methodological appeals was two-fold. First, we said the methodology that we planned to employ to calculate RADV payment errors was methodologically sound and academically defensible. We stated that we intended 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 would be given an opportunity to provide comment to us under our annual notice of RADV audit methodology. Second, in addition to providing an annual notice of RADV audit methodology, we stated that we would provide an expanded explanation of methodology as part of each RDV audit report that we send to MA organizations that undergo RADV audit. Included in this expanded explanation of methodology would be RADV payment error calculation factors unique to each audited MA organization that would enable the MA organization to independently calculate its own RADV payment error.

At proposed § 422.311(c)(3)(iii) and (v), we specified that MA organizations would be notified of their RADV payment error calculation appeal rights at the time we issue a RADV audit report to that organization. MA organizations would have 30 calendar days from the date of this notice to submit a written request for reconsideration of its RADV payment error calculation. A request for reconsideration would need to 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 would need to include additional documentary evidence that the MA organization considers material to the reconsideration, though MA

organizations would be 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 proposed § 422.311(c)(3)(iv), we further specified that the MA organization would bear the burden of proof to demonstrate that our RADV payment error calculation was clearly incorrect.

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

At proposed § 422.311(c)(3)(v) and (vi), we described 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 would review our RADV payment error calculation and any written evidence submitted by the MA organization that pertains to CMS' RADV payment error calculation, recalculate the payment error utilizing our RADV payment error calculation methodology (as specified in our standard operating procedures), and render a determination whether the RADV payment error calculation was accurate. This CMS official or CMS contractor not otherwise involved in RADV error-rate calculation activity would recalculate and arrive at an independent RADV payment error. Whether the official or contractor agreed with our payment error calculation, or overturned the calculation and established a new RADV payment error, this party's RADV payment error calculation determination would be issued to a CMS reconsideration official. The CMS reconsideration official would review their analysis and make 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 recommended overturning CMS' RADV payment error calculation and the reviewing CMS reconsideration official agreed with the newly calculated RADV payment error, we would issue a reconsideration decision which informed 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 upheld the

decision of the CMS official or contractor to sustain our initial RADV payment error calculation, the reconsideration official similarly would notify the appellant MA organization of its determination. In either instance, the decision of the reconsideration official would be final and binding, unless a request for hearing was filed by CMS or the appellant MA organization.

At proposed § 422.311(c)(4), we clarified that if CMS or an MA organization were dissatisfied with the decision of the CMS reconsideration official described at § 422.311(c)(3), CMS or the MA organization would be permitted to request a second-level RADV payment error calculation appeal, which is a hearing on the RADV payment error calculation determination. CMS or MA organization choosing to pursue a hearing would be required to file a request for hearing within 30 calendar days of the date the MA organization received the written RADV payment error calculation reconsideration decision, as described at proposed § 422.311(c)(3)(vi).

We noted that CMS or MA organizations requesting a hearing would need to do so in writing, including a copy of the CMS reconsideration official's decision to either uphold or overturn the initial RADV payment error calculation, and specify the findings or issues in that reconsideration decision that they disagreed with and why they disagreed with them. The hearing would 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 would be held on the record, unless the parties requested, subject to the Hearing Officer's discretion, a live or telephonic hearing. The Hearing Officer would also be permitted to schedule a live or telephonic hearing upon their own motion. The CMS Hearing Officer would be limited to a review of the record that was used for the initial RADV payment error calculation and the reconsidered RADV payment error calculation.

Additionally, we noted that the Hearing Officer would have full power to make rules and establish procedures, consistent with the law, regulations, and CMS rulings. These powers would include the authority to take appropriate action in response to failure of an organization to comply with such procedures.

At proposed § 422.311(c)(4)(iv), we also indicated that the CMS Hearing Officer would review and decide

whether the reconsideration official's decision was correct and to notify CMS and the MA organization in writing of his/her decision, explaining the basis for the decision, which would be final and binding, unless the decision was reversed or modified by the CMS Administrator in accordance with § 422.311(c)(5).

We explained that the third level of RADV payment error calculation appeal that MA organizations can request would be discretionary review by the CMS Administrator. We described this proposed process at § 422.311(c)(5). At this level of appeal, CMS or the MA organization would be permitted to 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 calendar days of receipt of the CMS Hearing Officer's determination. If the Administrator agreed to review the case, the Administrator would review the Hearing Officer's decision as well as any other information included in the record of the Hearing Officer's decision and would determine whether to uphold, reverse, or modify the CMS Hearing Officer's decision. The Administrator's determination would be final and binding.

We also noted that, based on our experience with appeals of MA and Medicare Part D program contract determinations, we have determined that it would be necessary for us to establish a "compliance date" to use as a reference point in issuing a ruling regarding RADV audit findings. Therefore, we proposed at § 422.311(b)(2), to require 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 would need to submit medical records to us. We stated we would inform an MA organization in writing regarding selection for RADV audit, including the due date for submission of medical records.

We invited and received a large number of comments from health plans, managed care industry trade associations, and other interested parties regarding not only the proposed appeals process described in proposed § 422.311—but also the RADV audit process and underlying Medicare Advantage payment policy. These comments have resulted in changes to our above-described proposals as discussed below.

While many comments that we received relate to the underlying RADV audit process and risk adjustment methodology and may not directly address the RADV appeals process specifically, we are responding to these comments, because they appear to be relevant to the RADV appeals process that we had proposed in our Notice of Proposed Rulemaking. Certain comments were outside the scope of our proposed rule and we have not included responses to those comments.

Comment: A comment alleged that it was premature for CMS to propose rules related to the RADV appeals process because the commenter stated that the Administrative Procedure Act (APA) required that the underlying RADV audit process giving rise to the overpayments that would be appealed under our proposed regulations be subjected to notice and comment rulemaking.

Response: We disagree and believe that the RADV audit process does not establish any substantive rules within the meaning of the APA or section 1871 of the Act, but rather is a means for ensuring that payments made to MA organizations comply with substantive rules governing MA payments that are set forth in the statute, and in regulations that have been subjected to notice and comment procedures. Regulations specifying that payment amounts are subject to audit (for example, § 422.504(d)(1)(i)) have been subjected to notice and comment procedures, and provide ample notice of the fact that we have the right (and, indeed, the duty) to ensure that MA payment amounts are accurate. See also, § 422.310(e), which states that MA organizations and their providers and practitioners will be required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS, and that there may be penalties for submission of inaccurate data.

Indeed, we would point out that throughout the Medicare program, and government programs generally, audit policies and procedures intended to ensure or verify payment accuracy assist in the enforcement of rules, and are not themselves substantive rules subject to APA notice and comment procedures. Therefore, to the extent we are providing a RADV appeals process, we are providing an opportunity that does not currently exist for MA organizations to appeal audit findings that they would otherwise not have been permitted to question.

Comment: Some commenters stated that CMS did not follow proper procedures and stated that procedures

set forth in our proposed regulations, such as our "one best medical record" and other documentation requirements, established a substantive legal standard governing the payment to MA organizations, and therefore, they had to be included in the annual notice of changes to payment methods required under section 1853(b)(2) of the Act, which requires that MA organizations be afforded an opportunity to comment on changes in the methodology for determining MA payments.

Response: We disagree. The requirement in section 1853(b)(2) of the Act to provide an advance notice of methodological changes to MA organizations of proposed changes to the methodology and assumptions used to compute annual MA capitation rates pertains to the methodology for determining the proper amount of payment. All substantive changes to the risk adjustment methodology at issue in the RADV audit process have been described in the annual advance notice. The RADV audit process and appeals procedures proposed in the October 22, 2009 proposed rule do not make any substantive changes in the methodology for determining MA payment amounts. Rather, they are designed to ensure that this payment methodology has been applied correctly, and the MA organization has received the amount to which it was entitled under this methodology. The risk adjustment methodology provides that a specific amount be paid if an enrollee has a particular condition. The RADV audits and appeals process are designed to ensure that the enrollee in fact has that condition, and that the MA organization is thus entitled to the amount that has been paid for that condition. The fact that audits might determine that an MA organization was not, in fact, paid correctly, is not a change in methodology or assumptions related to how the payment amount is to be determined and therefore is not subject to the advance notice requirements under section 1853(b)(2) of the Act. Nonetheless, in our October 22, 2009 proposed rule, we proposed to provide notice of RADV audit methodology to the public, as well as a summary of RADV methodology issues for each audited MA organization at the time we issue our audit finding pursuant to an actual RADV audit. We offered to provide details of our RADV audit methodology in an attempt to provide additional transparency related to the process. We anticipate providing additional notice of RADV audit methodology to the public by publishing the methodology in some

type of Medicare program document—most likely in a Medicare manual later this year (2010).

Comment: A commenter stated that CMS was not complying with requirements in section 1871(a)(2) of the Act, which states that “No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, * * * shall take effect unless it is promulgated by the Secretary by regulation* * *”

Response: As discussed previously, the RADV audit process, and the appeals procedures addressed in this rulemaking, do not “establish” or “change” any “substantive legal standard governing * * * payment.” To the contrary, they are designed to ensure that the substantive legal standards for payment set forth in the statute and regulations are correctly applied. The substantive rules governing the amount of payment to which the MA organization is entitled are unchanged as governed by statute and implementing regulations.

Comment: A commenter urged that CMS suspend RADV audits until such time as CMS subjects the rules to notice and comment rulemaking.

Response: As discussed previously, we do not believe subjecting the RADV audit process to rulemaking is required or appropriate, there would be no basis for suspending the audit process.

Comment: One commenter noted that when the risk adjustment system was initially established, the Secretary was required to submit a report to Congress in accordance with section 1853(a)(3)(A) of the Act that documented the proposed method of risk adjustment of MA payment rates, and that included an evaluation of the method by an outside, independent actuary of the actuarial soundness of the proposal. The commenter believed that such an evaluation was required in the case of the RADV audit process.

Response: We disagree that RADV audits impact the risk adjustment system in any manner. As indicated earlier, RADV audits are solely to verify that the risk adjustment methodology is being correctly applied.

We also received a large number of comments from MA organizations, managed care trade associations and a law firm regarding RADV methodological-related issues. While some comments were not relevant to the rules that CMS proposed regarding the RADV appeals process, there were a number of comments that we believe

should be addressed, and as such, we do so as follows.

Comment: Many commenters recommended that CMS independently test and validate its RADV methodology before CMS implements it. The commenters indicated that CMS failed to provide any record of submitting its methodologies to an academic review and that if CMS has done so, we should have included such studies with the proposed rule so that interested parties could review and comment on any of these academic studies. The commenters recommended that CMS provide a process that permits thorough review and comment by plans of RADV audit methodology issues before undertaking further RADV audits. Several commenters further recommended that all methodological issues pertaining to RADV audits be appealable.

Response: Previously in this preamble we indicate that the process of independently reviewing medical records to validate risk adjustment data submitted by MA organizations for payment purposes has been established and operational for more than 10 years. Over the course of this timeframe, we have been advised on the RADV process by statisticians, senior analysts, expert medical record coders, physicians, managed care professionals, and other health care providers. From a medical record coding perspective, we have secured expert direction from Peer Review Organizations (PROs) (in the past) and Quality Improvement Organizations (QIOs) (currently) by incorporating them into the RADV team. From an analytic design and implementation perspective, we have in the past and continue to employ senior level expert analysts from different academic fields as independent contributors to the RADV operations team to review and validate the accuracy of the findings across the RADV process, including peer review of statistical sampling and payment error calculation methodologies. The independent expert analysis and review is similar to that conducted in an academic setting in that the participating parties are credentialed in a specific field of study, such as statistics, and possess substantial years of expertise conducting similar processes and analyses. The independent methodology review processes also involve the use of internal controls, and tests for consistency and accuracy. RADV procedures are subject to the evaluation requirements of the CMS Annual Financial Audit.

In addition, the RADV methodology that we employ in the process of reporting a component of the national Part C payment error is similar to the methodological approach that we employ in conducting contract-specific RADV audits and error calculations. This methodology has been reviewed and approved by officials at the HHS.

This notwithstanding, in considering the commenters’ questions, where necessary, we will incorporate additional independent third party review for purposes of validating RADV error-calculation methodology. As indicated in our proposed rule and cited elsewhere in the preamble to this final rule, we intend to publish its RADV methodology in some type of public document—most likely, a Medicare Manual, so that the public can review and provide comment as it deems necessary. Finally, to ensure that audited organizations understand how their RADV error rate was calculated, as indicated in our proposed rule, we further intend to describe our RADV methodology in each audited organization’s RADV audit report.

Given these efforts to ensure that the RADV process is transparent to audited MA organizations and the public, and that the methodology used under that process is reasonable, consistent, and accurate, we do not believe any further action is required.

Comment: Several commenters argued that CMS should include Medicare plan enrollees for whom no diagnosis code was submitted under the risk adjustment methodology as part of its RADV error testing samples. These commenters also recommended that CMS include “under-coding” findings in the audit error estimates in order to more accurately account for members’ health status.

Response: Our RADV audit policy does account for both underpayments and overpayments. The RADV process addresses under-coding through the application of rules for crediting a sampled enrollee with additional HCCs that are identified incidentally, during medical record review. We emphasize that these “additional” diagnoses were not originally submitted for payment for enrollees selected in the sample, and yet we provide audited organizations credit through our RADV medical record review process.

However, we have not and do not expect to sample enrollees for whom no HCCs were submitted. This is because the RADV is an audit process that is intended to validate the HCCs that were submitted by MA organizations in order to determine whether the additional payment amounts associated with these

diagnosis codes were properly made. Under our separate Risk Adjustment Data Submission Process, the data submission period for any given payment year is lengthy and extends beyond the actual payment year, providing a substantial amount of time for organizations to submit and/or correct enrollee HCC risk adjustment data for any given payment year—to reflect of enrollee health status. This is sufficient time for plans to submit data on all their enrollees, including those with no HCCs. The RADV audit process is not intended to serve as a de facto mechanism for extending the HCC data submission deadlines under which MA organizations operate.

We received a number of comments from MA organizations and a law firm regarding the financial impact of RADV audits. While these comments did not pertain directly to our proposed RADV appeals procedures, some comments nevertheless indirectly impact the RADV appeals rules. Therefore, we respond to several of these comments here.

Comment: Several commenters suggested that CMS's proposed methodology to calculate and apply error rates and payment adjustments across contract years after payments were made undermines the actuarially-based risk assumptions inherent in Plans' bid submissions.

Response: Regarding the assertion that RADV audits undermine the Part C bidding process, beginning with the introduction of the HCC risk adjustment model for CY 2004, we have published clear guidelines to be followed by MA organizations in the collection and support of diagnosis codes underlying risk scores for plan enrollees. In their preparation of a MA bid, certifying actuaries are expected to ensure that the underlying data are reasonable and appropriate for the circumstance, including the base year risk scores. If the ultimate risk scores for a plan's population are lower than initially forecast by the certifying actuary, then the plan is likely to experience lower than expected margin. Conversely, if the ultimate risk scores for a plan's population are higher than initially forecast by the certifying actuary, then the plan is likely to experience greater than expected margin. These results illustrate the nature of health plan capitation and the risk borne by MA organizations.

Comment: Commenters stated that the establishment of an audit methodology that involves retrospective contract-level payment adjustments creates the potential for unpredictable retroactive liability that MA organizations could

not have considered in developing bids for affected prior years. Commenters suggested that CMS' sampling methodology undercuts the mandate in section 1854(b)(6)(B)(iv) of the Act that MA organizations' rates reflect the revenue needs of the organization. The commenters assert that MA organizations did not develop bid submissions for calendar years 2006 through 2009 with an expectation that CMS would implement contract-wide payment adjustments based on provider documentation issues outside of the MA organizations' control. As a result, if payments effectively are reduced retroactively as the result of RADV audits, the bid submissions (and resulting payments) arguably would not adequately reflect Plans' risks, and MA organizations may be forced to dip into their reserves to repay dollars that were not anticipated to be at risk.

Response: We disagree. If plan bids are developed based on faulty data, such as inappropriate claim costs or risk score data, there is a greater likelihood of error in the bid projection. There are many factors that influence the accuracy of bid projection, and data quality is just one such factor. There is no legal authority to change a bid amount after it has been accepted regardless if additional information suggests that the bid is too high or too low.

In general, it is our belief that health plans are confusing actuarial equivalence in payment amount—which demographic adjustments, risk adjustment methodology, and coding intensity adjustment are all designed to achieve—with differences in the way costs are documented. Because MA organizations are paid on a capitation basis, costs are not covered for a specific service provided. Rather, they are based on the actuarial value of such costs. The risk adjustment methodology uses diagnosis codes as a proxy for higher costs associated with a particular diagnosis. Because, under original Medicare, costs of specific services received are reimbursed, the diagnoses leading to such costs being incurred have a different relevance under original Medicare than they do under the Medicare Part C payment system. The risk adjustment methodology and RADV audit process that we employ to ensure accuracy under Medicare Part C actually further actuarial equivalence, rather than conflicting with it. The differences between MA and original Medicare are simply attributable to differences in how payment is made. It is these differences that necessitate the actuarial equivalence standard in the first place.

Comment: Several commenters questioned whether CMS's RADV

medical record review coders have the qualifications and experience necessary to code RADV-related medical records. Commenters specifically questioned whether RADV coders were equipped to code accurately in situations in which clinical training may be required in order to recognize all extractable ICD-9 codes. They inquired into the certification and coding experience qualifications for the RADV coders.

Response: The coders that CMS uses to review RADV medical records are fully qualified to code RADV-related medical records. All coders are professionally certified for example, Certified Professional Coder (CPC), Certified Coding Specialist (CCS), Registered Health Information Administrator, (RHIA) and Registered Health Information Technician (RHIT), and must have prior experience coding medical records. Coders have access to physician consultation as needed. Coders also have access to our Independent Coding Consultant—a coding expert with more than 10 years of professional coding experience, which we require to be RHIA, coding certified and to have at least 5 years of experience in RADV-specific coding.

Comment: Several commenters objected to what they contend is a burden that RADV audits impose upon the physicians and physician practices who must produce medical records necessary to conduct audits. These commenters recommended that CMS take into account the potential impacts of more aggressive program integrity efforts on the medical practices that provide care to MA plan enrollees. Outside of the proposed rule, we have also received letters arguing that the burden associated with RADV audits is not limited to the CMS' audits but also extends to internal audit activity undertaken by Medicare health plans that mimics the RADV audits that we undertake for Medicare payment validation. These commenters raised concerns that Medicare health plans were misrepresenting their internal audit activity as official CMS RADV audits.

Response: Section 422.310(e) requires that providers who voluntarily enter into contracts with MA organizations submit data to CMS contractors/IVCs for RADV audits. In an effort to minimize the burden associated with this activity, we have developed best practices that we encourage health plans to employ in their efforts to gather medical records from providers and hospitals. To the extent MA organizations employ these practices, it is our belief that the impact of RADV audits on providers can be minimized.

We also understand the increasing need for providers to be able to distinguish when they are being asked for medical records in association with an MA plan's own audit or in accordance with an official Medicare program RADV audit which is subject to legislative requirements. Therefore, we issue letters on our letterhead that MA organizations must use when requesting medical records from providers when the request is specifically related to an official CMS RADV audit. Providers may rely upon these letters as an indicator that a given medical record request is for CMS' RADV, and providers may request this authorizing letter before responding to requests by the MA plan.

We received a large number of comments from MA organizations, managed care trade associations and a law firm regarding the "one best medical record" policy that CMS proposed to apply to the RADV program. By way of explanation, the "one best medical record" policy specifies that for any one sampled beneficiary—with any one HCC—the MA organization is allowed to select and submit supporting medical record documentation of a face-to-face encounter for a physician or outpatient visit (one date of service) or an inpatient stay (range of dates from admit to discharge). The face-to-face encounter would have needed to occur at some point during the data collection year (from January 1st to December 31st).

Comment: Commenters contended that the one best medical record policy forces plans to omit relevant data that could be supported through documentation that CMS does not permit—such as prescription drug data and lab results.

Response: The RADV risk adjustment model is based upon FFS claims data from specific risk adjustment provider types, and not alternative data sources, such as, prescription drug data or lab results. Therefore, the RADV audit process is based upon supporting medical record documentation from provider data sources that are used to calibrate the model. As for the one best medical record policy, while MA organizations that voluntarily submit HCCs for Medicare payment are prospectively paid based on these unaudited and unvalidated HCCs submissions, we, upon the recommendation of MA organizations, agreed to allow any one medical record from across an entire data collection period to validate an HCC incorporated into the payment to the MA organization.

Comment: Some commenters contend that if CMS is going to rely on the one

best medical record policy to the exclusion of other sources of information that might confirm an HCC, the RADV appeals process should allow for HCC medical record review findings to be appealed.

Response: To address these comments as described in § 422.311(c)(2) of this final rule, we have revised the process so that MA organizations may appeal medical record review determinations in accordance with the procedures specified in § 422.311(c)(2).

Comment: A number of commenters argued that the one best medical record policy is flawed in that it provides an insufficient basis for confirming an HCC for members with chronic diseases when a collection of several records, perhaps from various providers, considered in the aggregate might better verify a patient's condition.

Response: We disagree. In the case of a chronic disease such as congestive heart failure, all that is required is medical record documentation from one visit to a physician or a hospital, over the course of the data collection year, to validate the audited HCC.

Comment: We received several comments comparing the RADV audit and appeals process to varying program attributes of the Medicare FFS program. For example, some commenters argued that CMS' one best medical record rule conflicts with Medicare FFS standards since there is no one best medical record rule applied to Medicare payment error-rate testing for FFS providers.

Response: Payment error-testing under original Medicare is different than payment error testing under Medicare Part C. Under original Medicare, much of what comprises the error testing regimen is aimed at validating that a particular level of service was provided and therefore justifies a given level of Medicare payment. Under RADV, the payment error testing focuses on validating HCCs by examining medical records to determine whether they contain supporting diagnostic codes. This error testing is aimed at validating that a particular Medicare beneficiary indeed has the medical condition for which the MA organization has been paid for, and not whether a particular level of service (for example, level 1 office visit vs. level 2 office visits) was provided. Moreover, there is no evidence to support the notion that the Congress, in establishing the Part C payment process, ever intended the Part C payment process to mimic payment processes under Original Medicare. Indeed, they are fundamentally different.

Moreover, we believe that the one best medical record policy and the operational process associated with it are far less restrictive than Medicare FFS. MA organizations are not limited to the specified date(s) of service they reported to us with regard to selecting a medical record as supporting documentation for a specific HCC. We continue to believe that the one best medical record policy is appropriate for the Medicare Part C risk adjusted payment system which is distinct from a FFS payment system where payment is determined on a claim-by-claim basis. Under Part C, we only require that plans send one HCC for payment for an entire year; it therefore logically follows that we would only require one medical record to validate this HCC.

Comment: Some commenters stated that the one best medical record rule was inconsistent with the mandate that MA payment adjustments be actuarially equivalent to the FFS sector.

Response: It is our belief that health plans are confusing actuarial equivalence in payment amount—which demographic adjustments, risk adjustment methodology, and coding intensity adjustment are all designed to achieve—with differences in the way costs are documented. Because MA organizations are paid on a capitation basis, costs are not covered for a specific service provided. Rather, they are based on the actuarial value of such costs. The risk adjustment methodology uses diagnosis codes as a proxy for higher costs associated with a particular diagnosis. Because, under original Medicare, costs of specific services received are reimbursed, the diagnosis leading to such costs being incurred has a different relevance under original Medicare than they do under the Medicare Part C payment system. The risk adjustment methodology and RADV audit process that we employ to ensure accuracy under Medicare Part C we believe furthers actuarial equivalence, rather than conflicts with it. The differences between MA and original Medicare are simply attributable to differences in how payment is made. It is these differences that necessitate the actuarial equivalence standard in the first place.

Comment: A commenter noted that in Medicare Part A and B appeal contexts, supplemental information and testimony are considered, and given such weight as the fact finder determines is appropriate.

Response: Under our proposed appeals procedures that affords MA organizations the ability to appeal the Part C error calculation specified at § 422.311(c)(3), the CMS Hearing Officer

has the discretion to conduct the hearing in alternative ways beyond conducting the hearing on the record. For example, the Hearing Officer can choose to conduct the hearing by way of teleconference or in person. The CMS Hearing Officer also has the discretion to request supplemental information or to accept testimony, as he or she deems necessary. Also, under the medical record review appeal processes that we specify at § 422.311(c)(2), we afford MA organizations the ability to submit supplemental information—the attestation reviewed by the IVC—to validate the same HCC that the Initial Validation Contractor (IVC) initially determined to be in error.

Comment: Several commenters, focusing on the relationship between MA organizations and their providers, noted that errors in documentation are ultimately attributable to providers, not MA organizations. These commenters argued that, due to the nature of the MA program, while CMS makes a capitated payment to organizations that have relationships with providers, these providers may not have an incentive to document the HCCs which affect payment to the MA organization. The commenters also stated that contract-level payment adjustments penalize MA organizations, while it is providers who are responsible for maintaining adequate records. A commenter also suggested that we accept “other data” to supplement, or substitute, a medical record.

Response: Section 422.504(i)(1) clarifies for MA organizations that they are ultimately responsible for the risk adjustment information submitted to CMS. This section of the regulations states, “Notwithstanding any relationship(s) that the MA organization may have with first tier, downstream, and related entities, the MA organization maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.” MA organizations are further directed in § 422.504(i)(2) that all their “first tier, downstream, and related entities are required to agree that HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect * * * medical records.” Therefore, while we acknowledge the comments, we maintain that it is the responsibility of MA organizations to ensure that they submit accurate risk adjustment information, and that the providers with whom they contract are aware that we have authority to audit medical records to verify this information.

We do not require MA organizations to submit HCCs for beneficiaries; MA organizations choose whether or not to do so. For risk adjustment diagnoses that are submitted, it is the responsibility of the MA organization to obtain appropriate documentation. If MA organizations are not confident in the information they obtain from their providers, they may wish to initiate education efforts, or include provisions in their contracts that ensure providers appropriately document diagnoses and provide medical record documentation to the plan upon request.

In regards to supplemental information, we have determined, and MA plans have been informed multiple times, that the appropriate format for obtaining risk adjustment information is a medical record. For validation purposes, plans are asked to submit the one best medical record documenting the HCC. We carefully determined the one best medical record policy, after consultation and input from the industry supporting this policy. We do not believe that supplemental information would be sufficient, or add value to a record that does not support an HCC for which the plan had been paid.

Comment: Many commenters from the MA industry recommended that before CMS audit MA organizations under RADV, the agency first account for any error rates inherent in Medicare FFS data that affect MA error rates. These commenters stated that through the proposed RADV audit appeal process, CMS is imposing a set of rules regarding physician recordkeeping that were not anticipated in the ICD-9CM coding guidelines, is not consistent with standard practices and is not enforced on original Medicare claims. The result, they allege, is *de facto* MA payment adjustments based on recordkeeping discrepancies without an adjustment to original FFS Medicare risk scores for the same recordkeeping discrepancies.

Response: We recognize that there may be potential merit in further refining the error rate calculation. We are currently studying this issue.

Comment: A number of commenters stated that the CMS-defined attestation process was overly narrow and should be expanded to provide for more widespread use of attestations in the RADV audit process. Commenters contended that attestations should be expanded to provide MA organizations with a greater ability to correct medical record coding-related errors or deficiencies in submitted medical records. Commenters requested that CMS permit MA organizations to submit attestations that attest to the presence of

medical conditions not fully supported in the medical record submitted to CMS. The commenters further argued that CMS should permit attestations to be used to validate not only the physician signature and credentials that are missing from a medical record, but also for patient name, identifier, date of service, and other documentation inadequacies that can result in a RADV medical record coding error.

Response: Taken in the aggregate, commenters’ recommendations regarding an expanded use of attestations in the RADV audit process reflect a misunderstanding of what attestations are intended to accomplish. Many of the comments submitted suggest that we adopt a policy that in effect, allows attestations to stand in the place of the medical records that are required to validate the HCCs that have resulted in higher payments already made to MA organizations. For example, permitting physicians to use attestations to “correct” medical record coding-related deficiencies determined pursuant to medical record review; or allowing attestations to be an acceptable vehicle for the submission of new HCCs that were not otherwise already submitted to CMS for payment.

We believe that we must validate the HCCs that result in additional payment through the existence of clear, unambiguous diagnostic information in a beneficiary’s medical record. A medical record provides the written support for the diagnosis that was made and must meet certain well recognized documentation requirements. Consistent with the Medicare FFS program, medical record documentation, rather than other alternative documentation, such as attestations, is required to validate information provided to us for the purpose of making provider payments. The existence of an accompanying attestation simply provides a mechanism for the physician to validate that the medical record that is missing a signature or credential is in fact his or her patient’s medical record. That is, attestations are intended to complement medical records, not stand in the place of them.

We continue to believe that the Medicare program is best served by limiting the applicability of attestations to instances in which the original diagnosing physician submits a signed and dated attestation to validate that the medical record in question is theirs. We see no justifiable reason for CMS to expand the applicability of attestations beyond this intended purpose and therefore, we are not accepting these comments.

Comment: Several commenters objected to CMS' prohibition on using attestations for inpatient medical-record-related RADV coding errors, and noted that CMS did not provide sufficient explanation why CMS would not permit them. The commenters recommended that CMS permit attestations to be submitted with respect to inpatient records.

Response: We do not believe that permitting attestations for inpatient medical records is justifiable. The decision to permit attestations for RADV was in response to industry concerns about the lack of signatures in medical records that are generated out of physician-office settings and not hospital settings. Upon preliminary evaluation of RADV findings, our data corroborates industry concerns in that it clearly shows that the majority of RADV-identified payment errors associated with lack of provider signatures were derived from medical records submitted and reviewed under the guidelines for physician/outpatients settings. Indeed, the data further corroborates that payment errors related to the lack of signature in inpatient medical records is minuscule.

Note that, with respect to the ongoing use of attestations within the RADV audit context, we reserve the right to continue to evaluate payment error related to physician/practitioner signatures, and the impact that attestations have upon these types of errors. We further reserve the right to amend the regulations in the future regarding the use of attestations should experience under the program justify this change.

Comment: Several commenters recommended that CMS implement an administrative appeals process for reviewing attestation determinations made by CMS.

Response: We understand the commenters' concerns, but do not believe this additional appeals process is necessary. As noted in section § 422.311(c), in light of the changes we are making in this final rule to the proposed RADV appeal procedures that permit MA organizations to appeal medical record review determinations made at the RADV IVC review-level, MA organizations will be permitted to appeal medical record review-related determinations whose outcome was determined by the existence or absence of an attestation.

Comment: Some commenters recommended that CMS allow attestations to be used as acceptable vehicles for introducing new HCCs to the Medicare Part C payment process. Several commenters suggested that MA

organizations be allowed to submit a letter from a provider group or other responsible party, along with an attestation in instances where the diagnosing physician is no longer able to sign and date an attestation—for example, in instances in which the diagnosing physician has died, moved or is no longer working for the medical practice.

Response: As stated previously in our response to earlier commenters' recommendations that we expand the applicability of attestations, we do not agree that attestations are acceptable vehicles for submitting new risk adjustment data and enrollee HCCs for payment to CMS. The data submission period for any given payment year opens 12 to 18 months before the start of payment year, and closes 3 months after the actual payment year ends, providing in total, at least 27 months for MA organizations to submit or correct enrollee HCC data for any given payment year. This provides ample time for MA organizations to voluntarily submit HCCs to CMS for Medicare payment.

Furthermore, a fundamental tenet of RADV is validating the existence of diagnoses information in a medical record. Consistent with Medicare FFS, medical record documentation rather than other documentation, such as attestations, is required to validate information provided to us for the purpose of making Medicare payments. Therefore, we see no justifiable reason to abandon this principle by allowing the submission of unsubstantiated HCCs via attestations, and therefore, reject the commenters' recommendations.

Under our RADV audit policy, to the extent we discover acceptable diagnoses codes contained in the one best medical record that plans submit for purposes of HCC validation that were not earlier submitted to CMS for payment via the Risk Adjustment Payment System (RAPS) system (what are known as "additional HCCs")—we credit these diagnoses codes to the submitting MA organization. Our reason for giving health plans credit for these additional diagnoses is precisely because they existed in beneficiaries' medical record(s)—and not in other types of documentation that would not be acceptable in any Medicare venue for justifying Medicare payment.

Comment: Several commenters stated that the 12-week timeframe for submitting attestations was unreasonably short. These commenters recommended that CMS afford plans additional time to gather and submit attestations.

Response: We do not agree. We proposed that the submission timeframe for attestations line-up with the deadline for submitting medical records in order to simplify the medical record and attestation submission process for plans. Under the proposed process the medical record and associated attestation are submitted together. We strongly believe that 3 months is sufficient time for MA organizations to obtain and submit to us the medical records and attestations necessary to validate audited HCCs. To provide additional time beyond the 12 weeks afforded to MA organizations to submit the requested medical records would split-up and unnecessarily complicate the medical record and attestation submission process. Since the attestation is intended to in effect—make the medical record "whole" by way of the signature and/or credential attestation—we believe it is unreasonable to set up a submission system that separates the attestation from the submission of the medical record. Therefore, we are not accepting this recommendation and instead are finalizing the requirement that attestations be submitted to us by the medical record submission deadline.

Comment: Several commenters recommended that CMS permit health plan officials to amend the CMS attestation form through hand-written annotations or to submit MA organization or provider-developed (that is, attestation forms that were not generated by CMS) attestation forms to CMS. A more limited number of commenters recommended that CMS allow physicians not involved in the diagnostic face-to-face encounter to attest to medical records in instances where the diagnosing physician is either dead or no longer at the medical practice or facility from which the medical record originated. These commenters reasoned that in extenuating circumstances such as the death of a provider or a provider having relocated, another provider within the medical practice could be permitted to sign the attestation on behalf of the treating provider. Under this scenario, the signing provider would annotate the CMS attestation form explaining the situation—for example, "Due to the expiration of Dr. Smith on June 1, 20xx, I am signing this attestation on his behalf."

Response: We believe opening the door to allowing modifications to a CMS payment-related document raises serious program integrity-related concerns and could result in fraud to the Medicare program. The extent to which one provider can reliably and

validly attest to a medical record prepared by another provider is questionable. We consulted with other Medicare program components within CMS that are or will be utilizing attestations or similar-like documents (for example, certificates of medical necessity, attestations used in conjunction with Comprehensive Error Rate Testing (CERT)) that have some bearing on Medicare payment and confirmed that there are very limited circumstances under which we permit external modification to any payment-related documents. Given these program integrity-related concerns, we are rejecting these recommendations.

We received a large number of comments regarding our proposed RADV documentation dispute procedures.

Comment: A commenter noted that the proposed definition of “Documentation Dispute Process” in § 422.2 indicates that MA organizations can “dispute medical record discrepancies that pertain to incorrect ICD–9–CM coding * * *” and appeared to conflict with language in proposed § 422.311(c)(2)(ii)(A) stating that medical record coding discrepancies are ineligible for the documentation dispute process. Another commenter contended that the term “operational processing” as described in the regulation, was vague and needed to be further defined. One commenter recommended that CMS allow MA organizations 60 days to request documentation dispute instead of the proposed 30 days. Several commenters recommended that MA organizations be permitted to appeal documentation dispute review determinations.

Many other commenters asserted that the proposed documentation dispute process was too limited in scope, and effectively amounted to nothing more than a mechanism for rectifying clerical errors that provided no meaningful way to contest the accuracy of the auditors’ interpretation of the medical records submitted, or to supplement the record being audited.

Response: As noted in § 422.311(c) of this final rule, in light of the changes to the proposed RADV appeal procedures that we are making in this final rule that permit MA organizations to appeal medical record review determinations made at the RADV IVC review-level, we are withdrawing the proposed documentation dispute procedures described in the proposed rule. By way of this final rule, MA organizations that wish to dispute RADV medical record review determinations that arise out of operational processing of medical records selected for RADV audit (that is,

determinations that arise from the collection and processing of medical records by CMS’ RADV IVC) will now be permitted to do so via the medical record appeals process described in this final rule at § 422.311(c).

We received many comments from MA organizations and a managed care industry trade association regarding the proposed RADV appeals process at § 422.311(c)(3).

Comment: Many commenters stated that the proposed RADV appeals process was too narrow, and failed to allow for all relevant evidence to be considered as part of the appeal process. Of particular interest to many commenters was the fact that MA organizations were prohibited from appealing the substance of medical record coding determinations, as described in our proposed regulation at § 422.411(c)(3). With regard to the RADV appeals process, these commenters specifically recommended that CMS:

- Expand the scope of issues that may be raised in the appeals process to include, at minimum, challenges to medical record coding decisions and challenges to methodology—audit methodology, sampling methodology, and error-calculation methodology.

- Permit MA organizations to appeal HCC findings from the medical record review process.

- Permit MA organizations to submit coding corrections along with the additional medical records necessary to validate audited HCCs that CMS determines are in error.

- Incorporate diagnoses identified in medical records, but not previously submitted nor assigned to a member (so called “additional”) in its RADV-related payment adjustment calculations.

Response: At proposed § 422.311(c)(3)(ii) we specified that MA organizations would not be permitted to appeal medical record review because medical record review-related issues would be resolved as a result of the medical record review process and the attestation and documentation dispute processes described earlier in the proposed regulation. However, based on the public comments we received, we have reconsidered this proposed restriction, and are for purposes of this final rule, changing our policy to now allow MA organizations to appeal medical record review that occurs at the IVC level.

Therefore, under a new final § 422.311(c)(2), we are implementing a process that would allow MA organizations to appeal medical record review that occurs at the IVC level of medical record review.

In order to be eligible for RADV medical record review appeal, MA organizations must adhere to established RADV audit and RADV appeals requirements, including the submission of medical records and documents in the manner and by the deadlines specified by CMS. Failure to do so will render the MA organization ineligible for RADV medical record review appeal. At § 422.311(c)(2)(i)(1) of this final rule, we specify that in order to be eligible for medical record review determination appeal, MA organizations must adhere to established RADV audit procedures and RADV appeals requirements. Failure to follow our rules regarding the RADV medical record review audit procedures and RADV appeals requirements may render the MA organization’s request for appeal invalid.

At § 422.311(c)(2)(i)(2) of this final rule, we provide that the medical record review determination appeal process applies only to error determinations from review of the one best medical record submitted by the MA organization and audited by the RADV IVC.

MA organizations must submit the original, IVC-audited medical record and any attestation reviewed by the IVC to CMS for consideration under the appeals process. MA organizations’ request for appeal may include the attestation reviewed by the IVC in accordance with § 422.311(c)(1) but may not include any additional documentary evidence.

At § 422.311(c)(2)(ii), we specify that MA organizations may not appeal errors that resulted because MA organizations failed to adhere to established RADV audit procedures and RADV appeals requirements. This includes failure by the MA organization to meet the medical record submission deadline established by CMS. We also specify that any other documentation submitted to us beyond the one best medical record and attestation submitted to and audited by the IVC will not be reviewed by us under the medical record review determination appeal process. MA organizations’ written requests for medical record review determination appeal must specify the audited HCC(s) that we identified as being in error and eligible for medical record review determination appeal, and that the MA organization wishes to appeal. A request for medical record review determination appeal must specify the issues with which the MA organization disagrees and the reasons for the request for appeal.

We describe the manner and timing of a request for medical record appeal at

§ 422.311(c)(2)(iii). We will issue each audited MA organization an IVC-level RADV audit report that provides details on the results of the medical record review findings. This RADV audit report will clearly specify the HCC determinations that are eligible for appeal. MA organizations will have 30 calendar days from the date of the issuance of the RADV audit report to submit a written request for medical record review determination appeal. A request for RADV medical record review appeal must specify the HCCs that we have identified as being eligible for medical record review appeal and that the MA organization wishes to appeal. The request for appeal must also include the IVC-audited one best medical record and may include an attestation form in accordance with the rules at § 422.311(c)(1), but may not include additional documentary evidence. Please note that MA organizations are not obligated to appeal HCCs that we have identified as being eligible for medical record review determination appeal.

At § 422.311(c)(2)(iv), we describe the process that we will undertake to conduct the medical record review appeal. We designate a Hearing Officer to conduct the medical record review determination appeal. The Hearing Officer need not be an ALJ. We also describe procedures for disqualifying a Hearing Officer in the event either party objects to the designation of a Hearing Officer. We provide written notice of the time and place of the hearing at least 30 calendar days before the schedule date. The hearing is conducted by a CMS Hearing Officer who neither receives testimony nor accepts any new evidence that was not presented to the IVC. The CMS Hearing Officer is limited to the review of the record that was before the IVC.

The CMS Hearing Officer reviews the IVC-audited one best medical record and any attestation submitted by MA organizations to determine whether it supports overturning medical record determination errors listed in the MA organization's IVC RADV audit report. As soon as practical after the hearing, the Hearing Officer issues a decision which provides written notice of the Hearing Officer's review of the appeal of medical record review determination(s) to the MA organization and to CMS. Pursuant to the Hearing Officer's decision, we recalculate the MA organization's RADV payment error and issue a new RADV audit report to the appellent MA organization.

As described at § 422.311(c)(2)(v), the decision of the CMS Hearing Officer regarding RADV medical record review

appeal will be final and binding upon the MA organization unless the MA organization requests review by the CMS Administrator. At § 422.311(c)(2)(vi), we indicate that the MA organization has 30 calendar days to request a review of the CMS Hearing Officer's determinations and that the CMS Administrator has discretionary authority whether to review the determination of the Hearing Officer. After receiving a request for review, the Administrator has the discretion to elect to review the Hearing Officer's decision or to decline to review the hearing decision. If the Administrator elects to review the hearing decision, the Administrator must review the CMS Hearing Officer's decision and determine, based upon this decision, the hearing record, and any written arguments submitted by the MA organization or CMS, whether the determination should be upheld, reversed, or modified. The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days of receiving the 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 CMS Hearing Officer is final. It is important to note that notwithstanding our implementing procedures that permit MA organizations to appeal HCC determinations at the IVC level of medical record review that we have identified as being eligible for medical record review appeal and that the MA organization wishes to appeal, the ability of MA organizations to appeal these IVC-level medical record review determinations does not otherwise alter MA organizations' ability to appeal RADV payment error calculations described at § 422.311(c)(3). However, MA organizations cannot appeal RADV payment error calculations until all RADV medical record review-related appeals are finalized.

Comment: Several commenters suggested that CMS afford MA organizations a reasonable amount of time after the medical record submission deadline to submit additional documentation that corroborates an already-submitted medical record.

Response: We do not agree that the amount of time provided to MA organizations to submit medical records under existing RADV audit policy is unreasonable. We provide MA organizations 3 months to obtain and submit to CMS the medical records necessary to validate the HCCs that MA

organizations voluntarily submitted to CMS for Medicare payment. Moreover, a policy that supports submitting corroborating evidence to accompany an already-submitted medical record violates CMS' one best medical record policy. Therefore we are not accepting the commenters' suggestion.

Comment: Several commenters recommended that CMS afford MA organizations 60 days, rather than 30 days, to submit a written request for reconsideration of its RADV payment error calculation to provide sufficient time to prepare for the request.

Response: We do not agree. We continue to believe that 30 calendar days is sufficient time for any MA organization considering appealing its RADV payment error calculation to prepare and submit such a request. We are therefore, rejecting this recommendation.

Comment: Several commenters objected to the fact that all RADV-related appeals tasks are conducted by either CMS employees or agents employed by CMS. The commenters suggest that to ensure impartiality and an independent review of plan appeals, the appeals process should allow for independent reviewers outside of CMS. Plans should be allowed to choose and pay for a third party review of the error-rate calculation under reconsideration—rather than use the CMS contractor.

Response: As described in our proposed rule at § 422.311(c)(3)(v) and (vi), the CMS officials and/or contractors that will adjudicate individual appeal cases will be fully independent of the initial RADV error determinations. One important attribute in constructing an independent appeal structure for the RADV program is ensuring that the review officials or contractors called upon to perform these tasks have the necessary expertise to serve in the capacity of an independent appeal official. It would be altogether unreasonable for us to assume that plans would select appeal officials that meet our standards, not would we be able to validate this process in a timely manner. We cannot be put in the position of having to review the qualifications of plan-selected appeal officials and still be able to effectively administer the appeals process in a timely manner. As such, we are rejecting the suggestion that plans be allowed to choose and pay for their own independent review officials.

Comment: A commenter stated that the CMS' RADV appeal rules should provide for a meaningful way to appeal payment determinations.

Response: We believe that the commenter means that our ability to

adjust payments once RADV audit results are finalized should likewise be subject to appeal. We agree and for this reason, as explained in the proposed regulation, we are providing multiple avenues for MA organizations to appeal the RADV findings, including the ability to appeal mistakes in the contract specific payment error estimate as determined by our payment error estimate calculation methodology. These opportunities to appeal provide ample recourse to MA organizations to have RADV findings fairly readdressed. As part of this process, at § 422.311(c)(3)(vi)(B) and (D), we specified that we would hire an independent RADV payment error appeals contractor to replicate and validate the payment determinations that result in our error calculation. Therefore, MA organizations that seek to appeal their error rate calculation can rest assured that the payment determinations that result in our error calculation are reviewed by an independent contractor.

Comment: Several commenters noted that, although the proposed rule provides for the review of the RADV calculation by a neutral third party, the proposed rule did not specify the criteria that the independent third party will utilize in determining whether the error rate calculations are correct. These commenters recommend that CMS be required to accept the third-party's findings or that CMS otherwise ensure that the decision on the findings is not made by an official who has a role in the RADV payment error calculation that is under review.

Response: The independent third party will utilize the same error-calculation criteria that will be employed by us in calculating its initial error calculation. This methodology will be known to audited MA organizations. In the preamble to our proposed rule and as stated previously in this preamble, we state that we intended to ensure that all MA organizations understand the RADV payment error calculation methodology by providing notice to all MA organizations of the methodology that will be employed for calculating Part C payment errors. We anticipate publishing the RADV error calculation methodology in some type of CMS document—most likely some type of Medicare manual—and annually providing notice of any changes that will be made to this manual. In addition to providing an annual notice of RADV audit methodology, we indicated we would provide an expanded explanation of methodology as part of each RADV audit report that we send to MA organizations that undergo RADV audit.

At proposed § 422.311(c)(3)(v) and (vi), we specified that a CMS official or contractor not otherwise involved in error-rate calculation activity would review the written request for reconsideration, the RADV payment error calculation and any written evidence submitted by the MA organization that pertains to CMS' RADV payment error calculation. We are finalizing that proposal in this rule.

Comment: A commenter believed that the level of detail proposed for the RADV appeals process was too specific. This commenter indicated that because MA organizations' and CMS' experience with data validation is relatively new, CMS should avoid putting a high level of detail into the regulation and should instead, maintain the flexibility necessary to do what makes sense in the context of the data validation.

Response: We do not agree that our experience with data validation is relatively new, since we have been performing RADV audits for over 10 years. The expertise and experience brought to the development of this function in that timeframe has enabled us to present a balanced level of detail with regard to the proposed regulation.

While we certainly appreciate the commenters' concerns regarding the level of specificity proposed—and now finalized—in the regulation, we contend that this level of detail is necessary in order for the public to fully understand how the RADV appeals process will operate. We concur with the recommendation that we remain flexible as we take further steps to implement these rules.

Comment: One commenter stated that the compliance date proposed by CMS is unduly restrictive. This commenter recommended that CMS consider additional evidence and testimony after the compliance date has passed.

Response: We disagree. Based on our experience with appeals of MA and Medicare Part D program contract determinations, it is absolutely essential for us to establish a compliance date to use as a reference point in issuing a ruling regarding RADV audit findings. In proposed § 422.311(b)(2), we specified that the compliance date be the date that MA organizations are required to submit medical records for the validation of risk adjustment data (§ 422.310(e)). By way of this final rule, we are extending the compliance date to include the date that MA organizations that choose to appeal IVC medical record review in accordance with § 422.311(c)(2) must submit medical records for review by the date we determine for the appeal process.

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. The medical record review process could continue ad-infinitum, preventing us from closing out RADV audits and collecting any identified overpayments. The notion of considering additional evidence and testimony after the compliance date has passed negates the intended purpose of establishing a compliance date in the first place, and is therefore rejected.

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

We proposed amendments to § 422.254 to expressly require an actuarial certification for Part C bids. As we noted in the preamble to the proposed rule, operationally we require an actuarial certification to accompany every bid, for both Parts C and D. A qualified actuary 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). We noted that our change in the Part C regulation text will bring the Part C regulation at § 422.254(b)(5) in line with current operational requirements and Part D. We are adopting § 422.254(b)(5) as proposed into this final rule.

Comment: We received three comments supporting the addition of this operational requirement to regulatory text. We also received one comment asking us if this requirement would apply to 2011 Part C bids.

Response: The 2011 Part C bids are due on June 7, 2010, the first Monday of June. Regardless of whether this regulation is final by that date, we will expect MA organizations to submit Part C bids in accordance with current operational guidance, which guidance is consistent with the regulatory language we are finalizing in this rule.

3. Determination of Acceptable Administrative Costs by HMO/CMP Cost Contractors and Health Care Prepayment Plans (HCPPs) (§ 417.564)

We proposed revising the regulations governing payments to health care prepayment plans (HCPPs) authorized under section 1833(a)(1)(A) of the Act and cost HMOs/CMPs authorized under section 1876 of the Act 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.

Specifically, we proposed revising § 417.564(b)(2) to clarify how HCPP and cost contractors authorized under section 1876 of the Act must determine “reasonable” administrative costs. At § 417.564(b)(2)(iii), we proposed that personnel costs claimed for administrative costs in 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 clarified in the proposed rule that this level of information must be available to us upon request or in the course of a review. Additionally, we proposed 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.

In the proposed rule we specifically asked for comments on our clarification of reimbursable administrative costs. As indicated below, after considering the comments we received, we are adopting our proposed § 417.564(b)(2)(iii) and § 417.564(c) without further modification in this final rule.

Comment: We received two comments that supported the list of costs that we proposed must be excluded by HCPPs and HMO/CMP cost contractors when computing reimbursable administrative costs. The commenters agreed that these costs should not be included in cost reports and that the new provision

codifies what they understood to be CMS’ existing policy regarding the exclusion of these costs.

Response: We agree with the commenters supporting our proposal to exclude the costs described in § 417.564(c) when reimbursable administrative costs are computed by HCPPs and HMO/CMP cost contractors. Accordingly, we are adopting § 417.564(c) without further modification in this final rule.

Comment: Two commenters agreed with our proposals to clarify how HCPPs and HMO/CMP cost contractors must determine reasonable administrative costs, and the requirement that this information be available to CMS upon request. However, these commenters wanted CMS to consider the following recommendations with respect to the proposed requirements—(1) providing guidance that would further clarify CMS’ expectations about how cost contractors will document this information, including examples of how time should be tracked and how to evaluate the match between skill level and tasks performed; (2) ensuring that the documentation requirements will be reasonable and structured in a manner that is not unduly burdensome to cost contractors; (3) providing cost contractors an opportunity to comment on this guidance before it is finalized to ensure that operational issues can be fully considered; and (4) applying the requirements to cost years following the year in which the regulation is effective.

One of the commenters also recommended that CMS consider modifying this proposal to clarify the meaning of the term “task,” and limit the tracking of time for the performance of separate tasks performed by a single individual to circumstances when it is necessary to achieve the objectives of the rule (for example, when the tasks, consistent with CMS rules and policy, have different apportionment statistics). The commenter also suggested that CMS clarify in the final rule that when personnel perform some administrative functions that are included in the administrative and general specified cost areas while performing some administrative functions that are viewed as plan administration, only the time spent on the administrative and general functions should be tracked and documented.

Response: We believe that it is important for HCPPs and HMO/CMP cost contractors to have the flexibility to establish their own methodology for determining reasonable administrative costs in order to meet the requirement described in § 417.564(b)(2)(iii);

therefore, we are not providing the specific guidance that was requested by these commenters at this time. We intend to provide further sub-regulatory guidance to HCPPs and HMO/CMP cost contractors on issues that would generally impact all HCPPs and cost contractors. We will also provide assistance to individual HCPPs and cost contractors on a case-by-case basis.

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

In the October 22, 2009, proposed rule, we proposed to revise § 422.306 to eliminate the 2 percent minimum update for all rate calculations other than ESRD. As we noted in the preamble to the proposed rule, 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. Section 5301 of 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 for the year—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.

We noted that 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 proposed to revise § 422.306 to eliminate the 2 percent minimum update for all rate calculations other than ESRD. We are adopting § 422.306(a) as proposed into this final rule.

Comment: A few commenters supported CMS’s proposed requirement. A commenter believed CMS’ interpretation of section 1853(k) of the Act was incorrect and suggested that

CMS retain the 2 percent minimum update requirement and recalculate (and pay) any retroactive payment from prior years (where the 2 percent minimum update would have caused payments to be higher than they would have been in its absence). The commenter contended that section 1853(k)(1)(B) of the Act only removes the minimum percentage increase for years prior to 2004.

Response: We disagree with the commenter. Section 1853(k)(1)(B) of the Act is clear in saying that it applies to years subsequent to 2007, in other words, to payment years beginning with calendar year 2008. Section 1853(k)(1)(B)(i) of the Act applies to all payment years other than years in which rebasing is done in accordance with section 1853(c)(1)(D)(ii) of the Act. In rebasing years, the calculation of MA payment rates is determined by section 1853(k)(1)(B)(ii) of the Act where the amount payable is the greater of: Either the amount calculated under section 1853(k)(1)(B)(i) of the Act, the MA payment amount for the previous year increased by the national per capita MA

growth percentage; or the amount calculated under section 1853(c)(1)(D) of the Act, which is 100 percent of fee-for-service costs. Further, in section 1853(k)(1)(B)(i) of the Act, we are also required to ignore any adjustment under section 1853(c)(6)(C) of the Act for any year before 2004 when calculating the national per capita MA growth percentage. This adjustment, called the “adjustment for over or under projection of national per capita MA growth percentage,” also did not include such an adjustment for years before 2004 when the minimum percentage increase was calculated per section 1853(c)(1)(C)(v) of the Act for years between 2004 and 2006. Finally, the calculation of MA payment increases based on the national per capita MA growth percentage beginning with payment year 2007 were never less than 2 percent. However we note that even if it were, there would be no additional payment due MA organizations on this basis because the 2 percent minimum increase was eliminated beginning with 2007.

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

This section discusses and finalizes four proposals in our October 22, 2009 proposed rule intended to improve Part C and D data collection and use for oversight and quality assessment. The first proposal would address quality improvement programs and data on quality and outcomes measures under Part C. As part of this proposal, we proposed to address data collected by Quality Improvement Organizations for MA quality improvement and performance assessment purposes.

The second and third proposals would address payment for beneficiary surveys and independent yearly audits 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. The last proposal would amend our rules on the collection and use of prescription drug event data for nonpayment-related purposes.

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 § 422.153	N/A	N/A	§ 480.140
Require that Sponsors pay for the Consumer Assessment Health Plan Survey (CAHPS).	Subpart D	§ 422.152(b)(5)	Subpart D	§ 423.156	N/A
Require validation of reporting requirements.	Subpart D	§ 422.516 § 423.514	Subpart D	§ 423.514	N/A
Allow collection of all PDE data elements to be collected for non-payment purposes.	N/A	N/A	Subpart D	§ 423.505	N/A

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

In our October 22, 2009 proposed rule, under the authority in sections 1851(d)(4)(D), 1852(e)(1) and 1852(e)(3)(A) of the Act, we proposed several new requirements related to quality improvement programs and data on quality and outcomes measures under Part C.

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.

a. Quality Improvement Programs

In our October 22, 2009 proposed rule, we noted that under our current regulations at § 422.152(c) and § 422.152(d), MA organizations have flexibility to develop criteria for chronic care improvement programs (CCIPs) and initiate any quality improvement projects that focus on clinical and non-clinical areas based on the needs of their enrolled population. However, based on our experience with MA organizations employing inconsistent methods in developing criteria for their CCIPs and quality improvement projects, we expressed concerns in the proposed rule that giving MA organizations complete discretion to establish their own CCIPs and quality improvement projects does

not allow beneficiaries to effectively compare plans and organizations to manage and report projects. More importantly, we expressed concerns that these projects are not addressing quality improvement areas that we believe best reflects beneficiary needs. For example, some projects may be designed to improve processes only, without linking the processes to clinical outcomes. We are interested in MA organizations focusing on individual as well as population-specific health risk needs, such as MA organizations' use of internal data sources to identify clinical outcomes that not only fail to meet national averages, but also may jeopardize the overall health and quality of life of the beneficiary.

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

We proposed in the preamble to our October 22, 2009 proposed rule to 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. We would convey generally applicable information via the Medicare Managed Care Manual and the Health Plan Management System (HPMS), and convey information that is plan specific directly to the organizations offering the MA plans in question. We are adopting § 422.152(a)(1) and § 422.152(a)(2) without further modification in this final rule and are clarifying, in our responses to comments below, that MA organizations will continue to have the flexibility to develop criteria for CCIPs and quality improvement projects based on the needs of their enrolled population.

Comment: We received many comments that supported our proposals to require that MA organizations conduct CCIPs in patient populations, and quality improvement projects in

areas, identified by CMS. Some of these commenters wanted CMS to consider additional recommendations with respect to our proposed requirements, including: (1) Providing an opportunity for public comments as CMS develops priority areas for MA organizations and on the process that CMS will use to identify specific areas for quality improvement with respect to particular MA organizations; and (2) establishing a fixed time period after CMS establishes its CCIP goals during which CMS could not establish new CCIP goals.

Response: As we develop our requirements, we will offer opportunities for the industry and other interested parties to offer recommendations. While our goal is to keep any such requirements stable, we note that it may be important for us to modify our requirements in keeping with our goal of ensuring that CCIPs and quality improvement projects address those quality improvement areas we believe reflect beneficiary needs.

Comment: Many commenters opposed our proposals to require that MA organizations conduct CCIPs in patient populations, and quality improvement projects in areas, identified by CMS. Some of the concerns commenters raised were: (1) CMS' requirements may not be aligned with MA organizations' identified priorities for benefiting their enrollees; (2) systemic inequities would develop among competing MA plans that would undermine the competitive structure of the MA program; and (3) organizations would lose the flexibility to pursue projects of special clinical and operational value to their enrollees.

Response: We agree that CCIPs and quality improvement projects should be based on the needs of the plan's enrolled population, and in line with the organizations' identified priorities for benefiting their enrollees. We will continue to provide MA organizations generally with the flexibility to identify topics for the development of CCIPs and quality improvement projects based on the particular needs of their members. However, we are finalizing the revisions to § 422.152(a)(1) and § 422.152(a)(2) to require that, under certain circumstances, some 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 populations served by the plans.

To date, we have communicated with MA organizations about specific operational areas and member populations for which we believe, based on data collected through HEDIS, audit findings, member complaints, and other

survey data, there is a need for CCIP or quality improvement projects development due to performance and/or clinical outcomes. We have offered MA organizations identified through this targeted methodology assistance during our initial communication regarding the need for CCIP or quality improvement project development. Technical assistance for the development of CCIPs and quality improvement projects is also available to all MA organizations on an as needed basis.

Using the HPMS, the Medicare Managed Care Manual, and other means of communication that we determine to be appropriate, we will annually inform MA organizations individually and/or generally of the process by which CCIPs and quality improvement projects must be conducted, which tools to use to report activities, and the time frame for submitting data and reports. We will also use these communication methods to identify the patient populations and areas we have determined would benefit most from CCIPs and quality improvement projects. However, as noted previously, this does not preclude MA organizations from developing CCIPs and quality improvement projects that they independently determine to be needed for their population.

Comment: Many commenters suggested alternatives for CMS to consider to its proposed requirements for CCIPs and quality improvement projects. These recommendations generally fell into three groups—(1) CMS should not adopt the proposed policies and should allow MA organizations to develop their own CCIPs and quality improvement projects; (2) CMS should provide general guidance to MA plans on CCIPs and quality improvement projects and develop a process for approving a plan's CCIPs and quality improvement projects prior to the plan implementing them; and (3) CMS should consult industry before making changes to CCIP and quality improvement project requirements.

Some commenters specifically recommended that CMS impose CCIP or quality improvement project obligations on all MA organizations operating within a given geographic area rather than on an MA plan-specific basis and that CMS provide a list of programs and projects for MA plans to choose from and allow plans to select the programs, projects, and populations to which they should apply in order to maximize the benefit to beneficiaries. One commenter suggested that, to address CMS' concern that some plans focus on process, rather than outcomes, CMS focus on those plans, and work with them to identify

more appropriate programs and projects. Another commenter believed that CMS could provide more generalized guidance on the types of measures that are acceptable (for example, the commenter suggested that CMS consider requiring that CCIPs and quality improvement projects link processes to clinical outcomes). Several commenters suggested that CMS consult with experts in the industry to before imposing specific CCIP and quality improvement project requirements on MA plans. One commenter recommended that CMS hold MA organizations accountable for choosing a CCIP based on their own population and data, and prior approve quality improvement project topics and methodologies based on specific quality improvement needs identified by MA organizations. This commenter further indicated that a prior approval process would allow CMS to assist MA organizations in focusing on quality improvement areas that reflect beneficiary needs and include sound methodologies that address clinical as well as process outcomes.

Response: As discussed previously, MA organizations will continue to have the flexibility to choose CCIP and quality improvement project topics that meet the needs of their population and operational processes, and we will offer opportunities for the industry to offer recommendations for fine-tuning our CCIP and quality improvement project requirements. We will take into consideration the specific recommendations offered by commenters as we develop future guidance related to CCIPs and quality improvement projects.

Comment: Several commenters were concerned that the proposed requirements could impinge on the efforts of MA organizations to satisfy accreditation standards for National Committee for Quality Assurance (NCQA) or other accrediting bodies.

Response: MA organizations that participate in the quality improvement deeming program will be subject to the standards of their accreditation organization. We will continue to ensure that standards applied by deeming organizations are at least as stringent as those applied by us.

Comment: Several commenters were concerned about special needs plans (SNPs) meeting the proposed requirements. Commenters recommended allowing MA organizations to customize overall quality improvement programs for their specialized populations in chronic care special needs plans (C-SNPs), deeming all the individual model of care and quality improvement initiatives

required of C-SNPs to fulfill this requirement, and allowing dual-eligible SNPs (D-SNPs) to implement specific projects for the dual-eligible population. Several commenters were concerned that the CCIP and quality improvement project models that CMS develops may not be appropriate for special needs plans (SNPs) and that some SNPs will face significant challenges meeting State as well as MA requirements in the event that CMS requirements for specific quality improvement topics that differ from State requirements.

Response: As discussed previously, MA organizations will continue to have the flexibility to choose CCIP and quality improvement project topics that meet the needs of their population and operational processes. When MA organizations are required to conduct CCIPs in patient populations and quality improvement projects in areas that we identify which are appropriate for SNPs, SNPs will follow the same quality improvement project and CCIP processes identified for other types of MA plans. We will not expect SNPs to employ quality improvement project or CCIP programs that are not appropriate for their population. We note that CMS may use data collected from SNPs to determine if there are population-specific topics that require targeted monitoring in the future.

Comment: A few commenters were concerned about the challenges MA organizations would face in allocating additional resources to meet the proposed requirements as well as the potential for increased administrative costs.

Response: With respect to commenters' concerns about the additional cost of implementing these requirements, we do not believe that MA organizations will experience significant additional financial burdens as a result of these requirements.

b. New Quality Measures

In our October 22, 2009 proposed rule, we stated that as we strengthen our oversight of quality improvement programs implemented by MA organizations, we believe it is necessary 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 the Healthcare Effectiveness Data and Information Set (HEDIS®), the Health Outcome Survey (HOS), and the Consumer Assessment Health Providers Survey (CAHPS). We stated in the proposed rule that we anticipated 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 also noted that we believed the collection of these data to be consistent with our authority under section 1852(e)(3)(A) of the Act, and that we 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. In the preamble to the proposed rule, we noted post-surgical infections or patient falls as examples of additional areas on which we planned to collect data. Therefore, we proposed 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. We also proposed that, consistent with the Paperwork Reduction Act (PRA), we would provide the public at least two opportunities for public comment before imposing additional quality-related collection and reporting requirements.

We are finalizing our proposal to require MA plans to collect, analyze, and report quality performance data identified by CMS as described in the proposed rule and adopting § 422.152(b)(3) and § 422.152(e)(2) without further modification in this final rule.

Comment: A number of commenters supported CMS' proposal 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. Commenters also supported CMS' proposal to provide the public at least two opportunities for public comment before imposing additional quality-related collection and reporting requirements, consistent with the PRA.

Response: We agree with the commenters supporting our proposal to require MA plans to collect, analyze, and report quality performance data of the same type of data that plans are currently required to collect and report, that we identify. Accordingly, we have finalized our proposed § 422.152(b)(3) and § 422.152(e)(2) in this final rule.

Comment: A few commenters did not support our proposal to require MA plans to collect data on additional quality performance measures. Commenters were concerned about the administrative burden and costs associated with additional data collection and recommended that CMS

use existing quality measures rather than require new measures. One commenter questioned whether additional quality measures beyond the HEDIS, HOS, and CAHPS would be useful since these measures are accepted industry standards. One commenter questioned CMS' efforts to use quality measures to "score" plans, indicating that plans with lower enrollment and more direct control over patient care, for example a closed model HMO, could achieve better measures through more intensive interventions.

Response: As the MA program has evolved, attracting an increased number of beneficiaries that present with specialized health concerns, it has become increasingly important for us to focus on developing measures that meet the MA population's needs. We believe that collection of additional data on quality outcomes measures is necessary to better track plan performance in this area. As noted previously, we disagree with commenters that MA plans will experience significant additional financial burden as a result of these requirements.

Comment: Commenters provided suggestions on how to identify the measures for which additional collection of quality performance data will be required. Several commenters recommended that we use existing nationally endorsed, clearly specified measures for any new reporting requirements we place on MA organizations, and that the measures be those of national standard setting organizations. One commenter indicated that it would like to work with CMS to see if any of the new measures should be incorporated into HEDIS. Two commenters requested that the new quality measures be measurable through administrative data instead of chart reviews. One commenter supported the examples we provided of new quality reporting requirements we indicated in our proposed rule, specifically, post-surgical infections or patient falls and recommended that the reporting be expanded to all health care acquired conditions (the Medicare "never events") and all infections. Another commenter indicated that additional broad based measures, such as readmission rates, also could provide critical insights on performance. Additionally, one commenter suggested that CMS consult with the Medicare Payment Advisory Commission, which recently finalized recommendations related to quality in the MA program and the measures that could be adopted to compare MA plans to one another as well as to Original Medicare. Some commenters suggested that CMS involve

the industry in the development of the new measures for which additional collection of quality performance data will be required.

Response: We will identify measures and standards using internal CMS methods as well as nationally recognized methodologies. These measures and standards will be based on the information that is currently collected, as well as any additional data we find to be necessary to collect for this purpose. We have begun a year-long project to research and analyze population specific health outcomes and plan operations data. As an important part of this project, industry leaders, researchers, and individuals with expert knowledge of the Medicare population will be involved in the discussions as we identify appropriate quality measures and standards for the MA program. We plan to use this information to further develop and analyze the effectiveness of the current and future measures associated with health outcomes, operational procedures and processes, and member experience. As indicated in the proposed rule, we will provide the public at least two opportunities for public comment through the PRA process before imposing additional quality-related collection and reporting requirements.

Comment: One commenter encouraged us to explore ways to release timely, plan-specific data to third parties to allow them to experiment with different ways to analyze claims data, and underlying plan performance data, to assist consumers with the identification, selection, and use of their MA plans or PDPs based on plan performance or quality attributes.

Response: We do not collect claims data from MA and Part D plans. However, we do collect Part D prescription drug event (PDE) data, which is based on claims data submitted by pharmacies to Part D sponsors. These data are available for research purposes, consistent with § 423.505. We are working to provide additional public use files based on PDE data in the future. More information on PDE data for research purposes may be found at http://www.resdac.umn.edu/Available_CMS_Data.asp. For the quality and performance data for Part C and Part D plans, we release a database with all of the contract-level individual measures that make up the Part C and Part D plan ratings. These data are available on the CMS Web site at http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/06_PerformanceData.asp.

c. Use of Quality Improvement Organization Review Information

In our October 2009 proposed rule, we asserted that data collected by Quality Improvement Organizations (QIOs) to accomplish their mission represent an important data resource 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.

We discussed several proposed uses of the data collected by the QIOs. For example, 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 also be used to rate plans according to their performance.

We also outlined our plan to develop minimum performance levels and requirements that address clinical and nonclinical areas from the data collected by QIOs, as part of our efforts to provide meaningful information to beneficiaries when selecting an MA plan. In addition to tracking plan performance, these data could also be used to monitor 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 be appropriate for use in a competitive value-based purchasing program based on quality of care.

Finally, we explained our intent to use one particular type of information already collected by QIOs, that is, quality review study (QRS) information (defined in 42 CFR 480.101(b)) and retool the data elements to make them specific to beneficiaries enrolled in MA plans. 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." By QRS information, we mean all documentation related to the QRS process. We proposed to obtain from the QIO only the data that relate to MA plan beneficiaries, providers, practitioners, and services and to then aggregate the data applicable to each MA plan based on beneficiary enrollment.

Accordingly, we proposed adding a new § 422.153 to indicate that we would obtain and use quality review study information that is generated, collected, or acquired by QIOs under 42 CFR part 480. We stated our intent 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.
- Other purposes related specifically to MA plans, as specified by CMS.

We also clarified that we did not plan to disclose any beneficiary identifiable information.

In addition, we proposed amending § 480.140 to add a new paragraph (g), authorizing our use of quality review study information solely for the purposes specified in § 422.153. As described below, we are modifying § 422.153 and § 480.140(g) in this final rule.

Comment: A number of commenters were concerned about the use of data collected from QIOs to measure plan performance and recommended that CMS reconsider its proposal. One commenter recommended that CMS discuss current MA experience with QIO studies and the potential future uses of QRS information with plans. Some of the concerns cited by commenters are that—

- There may be inconsistencies among QIOs on their assessments and findings, which may disadvantage some plans. Individual QIOs may offer consistent and reliable data sources, but aggregating data from multiple State-specific entities may dilute the consistency and reliability that would be required to accomplish CMS' proposed uses;

- Some MA organizations have experienced delays in the receipt of QIO study findings; therefore, the organizations do not have timely notice of any deficiencies and are not able to use the findings in their quality improvement activities. The delay in dissemination of findings may not be sufficiently timely for CMS' intended purpose;

- Depending on the QIO, there is often a substantial lag in the availability of QIO data. Current MA performance assessment should not be assessed based on data that are 2 or 3 years old; and

- There may be additional burden placed on deemed plans that do not submit to the QIOs so that the data could be all inclusive from the QIOs.

Commenters recommended that CMS clarify whether plans that are already

deemed by NCQA would also be required to send additional information to their QIO to comply with the proposed regulation. One commenter indicated that the use of QIO review information would be administratively burdensome and duplicative of current reporting measures such as HEDIS.

Response: We share the concerns raised by commenters about the inconsistency and timeliness of the data collected by QIOs. These concerns relate to QIO review of beneficiary quality of care concerns, medical necessity reviews, appeals, and other case reviews.

After reviewing these comments, we have discovered that the data that will be needed to meet the functions described in § 422.153 is not collected from QIO case reviews. Instead, hospitals report this information to us as part of the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program, which is authorized under section 1886(b)(3)(B)(viii) of the Act. Much of this data is self-reported by hospitals on a quarterly basis, and some is validated for accuracy. Further, the data does not possess any of the timeliness and reliability issues cited by the commenters. Hospitals self-report patient-level quality measure data for patients covered by MA plans, Original Medicare, and other payors to CMS for the RHQDAPU program.

In response to the comments we received, we are narrowing the scope of our proposed § 480.140(g) to provide that QIOs must disclose to us QRS information collected as part of the RHQDAPU program following hospital review of the data (with identifiers of MA plan beneficiaries, hospitals, practitioners, and services) when we request this information for the sole purpose of conducting activities related to MA organizations as described in § 422.153. We believe that restricting our access to include only RHQDAPU hospital quality data that we may use for the functions described in § 422.153 will address the concerns about the timeliness and reliability of this data. We are also modifying § 422.153 to indicate that we will acquire RHQDAPU data from QIOs and may use it for the limited functions described in § 422.153. As proposed, we do not plan to disclose any beneficiary identifiable information. We also do not plan to disclose any provider or practitioner identifiable information.

Comment: Many comments supported our proposal to obtain and use QRS information that is generated, collected, or acquired by QIOs. Commenters also supported CMS's proposal to use these

data to enable beneficiaries to compare health coverage options and select among them, measure performance under the plan, and ensure compliance with plan requirements under Part 422, and other purposes related specifically to MA plans as specified by CMS. Commenters agreed that CMS should not plan to disclose any beneficiary identifiable information.

Some of these commenters asked CMS to consider additional recommendations with respect to our proposals. Some of the recommendations were that CMS should ensure that an adequate sample of QIO data for dual eligibles is reviewed; allow plans to review the information the QIO intends to submit to CMS in order to give plans the opportunity to correct errors; ensure appropriate procedures are available for plans that may dispute the data that CMS intends to make available to beneficiaries before those data are released; provide ample notice to plans of the specific data that CMS intends to collect to allow for programming and testing of data collection tools prior to submission to CMS; and make Original Medicare data available to beneficiaries, where available, along with MA plan data.

One commenter indicated that CMS should develop a methodology to stratify the data so that MA organizations would be grouped by local or regional MA organizations, and defined by statewide or selected geographic areas such as number of counties within a State, benefit design, and plan type. This commenter also indicated that data provided to beneficiaries would be misleading if CMS compared all MA organizations in a State without classifying these organizations by type and service area.

Response: As we refine our work plan for using the data collected under section 1886(b)(3)(B)(viii) of the Act (RHQDAPU data) for the functions described in § 422.153, we will consider these commenters' recommendations to ensure we achieve our goals of providing meaningful information to beneficiaries, developing minimum performance levels and requirements that address clinical and non-clinical areas from the data collected by QIOs, and ensuring plan compliance with MA contract requirements.

Comment: Commenters recommended that CMS ensure that the measures it develops are based on nationally endorsed measures, are collected in a uniform fashion, and have large enough sample sizes to support public reporting as well as any value based purchasing decisions. One commenter recommended that CMS specify that

plans will have multiple opportunities to comment on any performance measures proposed for the MA program.

Response: We will identify measures and standards using internal CMS methods as well as nationally recognized methodologies. The process for developing measures based on data collected by the QIOs is not subject to the PRA review process since it does not represent a new data collection requirement for MA plans.

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

In the October 22, 2009 proposed rule, under the authority of sections 1857(e)(1), 1860D–12, and 1876(i)(3)(D) of the Act to impose additional contract requirements that the Secretary finds “necessary and appropriate,” we proposed to revise the regulations to require that MA organizations, Part D sponsors, and section 1876 cost contractors would pay for the data collection costs of the annual CAHPS survey beginning in 2011. As we noted in the preamble to the proposed rule, in the 2010 Call Letter to Part C and D sponsoring organizations, we informed all MA and Part D contracts with at least 600 enrollees as of July 1 of the prior calendar year that they would be expected to pay for the data collection costs of the CAHPS survey starting with the administration of the 2011 annual CAHPS survey. The proposed rule set forth this requirement in regulations at § 422.152 for Part C, § 417.472 for section 1876 cost contracts, and § 423.156 for Part D.

The proposed rule would require only MA organizations, Part D sponsors, and section 1876 cost contractors with 600 or more enrollees to pay for the data collection costs of the CAHPS survey. 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 determined that plans would need to 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.

In making this proposal, we noted 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, and that this model for data collection is standard industry practice. For example, Federal Employees Health Benefit (FEHB) plans pay for the

administration of the CAHPS survey to their members. Under our proposal, 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. We also noted that this change would provide the sponsoring organizations with the flexibility of adding their own questions to the Medicare CAHPS survey.

We also noted that 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.

Finally, we noted 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 CMS to collect and submit data within specified timeframes.

After reviewing the comments received in response to this proposal, we are adopting the proposed CAHPS data collection requirements as final. However, we are revising § 417.472 and § 422.152 to clarify the distinction between cost contracts under section 1876 and coordinated care plans. Specifically, the revised wording is: “All coordinated care contracts (including local and regional PPOs, contracts with exclusively SNP benefit packages, private fee-for-service contracts, and MSA contracts), and all cost contracts under section 1876 of the Act, 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 Medicare plan enrollees in accordance with specifications and submit the survey data to CMS.”

Comment: CMS received comments concerning the proposed requirements for Part C and D contracts regarding the CAHPS survey. A few commenters noted that CMS did not provide any estimate of, or other information related to, the costs associated with collection

of data for the CAHPS survey, asserting that this information is necessary in order to appropriately account for the costs in their annual bid submissions.

Response: We respectfully disagree. Both the estimated CAHPS costs and burden were addressed in the proposed rule. As stated therein, the estimated mean annual cost per contract is approximately \$5,000 for MA organizations, cost contracts, and Part D sponsors with more than 600 enrollees for the CAHPS annual survey. (74 FR 54711). Data collection is to be performed by a contractor hired by the MAO or Part D sponsor.

Comment: A few commenters noted that proposed § 422.472(i) would require section 1876 cost contractors to contract with approved CAHPS survey vendors to conduct the Medicare CAHPS satisfaction survey for “MA plan enrollees.” However, they assert that cost plans do not have MA plan enrollees. Moreover, cost plans are not “coordinated care plans,” which is a term that describes certain MA plans. The commenters recommend that CMS delete the references to coordinated care plans and other MA references.

Response: We appreciate the commenters’ suggestions and are revising § 417.472 and § 422.172 as follows: “All coordinated care contracts (including local and regional PPOs, contracts with exclusively SNP benefit packages, private fee-for-service contracts, and MSA contracts), and all cost contracts under section 1876 of the Act, 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 Medicare plan enrollees in accordance with specifications and submit the survey data to CMS.”

Comment: Several commenters expressed approval and support for CAHPS, applauding CMS’s efforts to provide enrollees with consumer-tested, standardized information about plan choices. The commenters also support changes that will increase data collection, provide beneficiaries with additional information with which to make plan comparisons, and overall improve quality of plans.

Response: We appreciate these commenters’ support of our quality efforts.

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

In the October 22, 2009 proposed rule, under the authority of sections 1857(e)

and 1860D-12 of the Act, we proposed 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 us.

Additionally, in the preamble we noted that our rationale for making this proposed change, which was also announced in the 2010 Call Letter to Part C and D sponsoring organizations, was 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 noted that we were 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. We intend that these specifications will focus on how organizations and sponsors compile numerators and denominators, take into account appropriate data exclusions, and verify the sponsor's calculations, computer code, and algorithms. In addition, the specifications will be used to inform CMS as to 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 indicated that we expected to make these specifications available on our Web site for public comment early in 2010. We solicited comment on this approach.

Subsequent to publication of the proposed rule, in an HPMS memorandum dated December 23, 2009, we noted that after careful review of the reporting requirements and CMS' continued data needs, the amount of data required to be reported to CMS for CY 2010 and contract years contract beyond was to be reduced. We noted that the reason for the reduction in reporting was that some of the data could be derived from other means (that is, through analyses of prescription drug event data already collected by CMS). We believe these adjustments reduce the overall burden on sponsoring organizations while maintaining the

integrity of the CMS data collection, plan reporting, and plan validation processes so that needed data for monitoring and public reporting are timely, reliable, valid, and comparable among organizations. Specifically, the following changes became effective January 1, 2010:

- Part C Reporting Requirements
 - ++ Reporting of the Agent Compensation and Agent Training and Testing measures will be suspended.
 - ++ The frequency of reporting of two Part C measures will be reduced.
 - Only annual reporting for Plan Oversight of Agents will be required; the quarterly reporting will be suspended.
 - Only annual reporting for Employer Group Plan Sponsors will be required; the semiannual reporting will be suspended.
 - ++ Validation of PFFS Provider Payment Dispute Resolution and PFFS Plan Enrollment verification calls will not be required.
- Part D Reporting Requirements
 - ++ Reporting of five sections will be suspended: Vaccines, Generic Drug Utilization, Transition, Drug Benefit Analyses, and Agent Training and Testing.
 - ++ The frequency of reporting of six Part D sections will be reduced as follows:
 - Only annual reporting for Employer/Union-sponsored Group Health Plan Sponsors, Fraud, Waste and Abuse Compliance Programs, Long Term Care (LTC) Utilization, and Medication Therapy Management Program (MTMP) will be required; the semi-annual reporting will be suspended.
 - Only annual reporting for Plan Oversight of Agents and P & T Committees/Provision of Part D Functions will be required; the quarterly reporting will be suspended.
 - ++ Validation of eight sections will not be required: Enrollment, Access to Extended Days.
 - Supply, Prompt Payment by Part D Sponsors, Pharmacy Support of Electronic Prescribing, P&T Committees/Provision of Part D Functions, Pharmaceutical Rebates, Discounts and Other Price Concessions, Licensure & Solvency, and Fraud, Waste and Abuse Compliance Programs.

We are also excluding PACE organizations from CY 2010 Part D Reporting Requirements, which is consistent with Part C Reporting Requirements.

These changes will be incorporated in the final CY 2010 Part D Reporting Requirements document and the Part C

and D Reporting Requirement Technical Specifications documents, which will be updated and posted to our Web site. The data validation standards will also be updated and provided for comment as part of a PRA package in 2010. We note that these changes do not affect our proposal to require an annual independent audit of Part C and Part D measures. Rather, because these changes reduce the amount of data that must be submitted by plan sponsors, they will make the data validation audits somewhat less time-consuming.

After considering the comments received in response to the proposed rule, in this final rule, we adopt the requirements as proposed.

Comment: Several commenters argued that plans need information regarding the data validation requirement in a timelier manner to allow for consideration during preparation of the 2011 bids. They also noted that CMS should provide plans with sufficient information and time to modify their operations to incorporate any new requirements prior to the data validation mandates taking effect.

Response: With this final rule, we believe that we are providing plans with information in sufficient time to allow for consideration in their 2011 bids. A regulatory impact analysis for this proposed requirement was included in the October 22, 2009 proposed rule. The proposed rule also contained the information collection requirements. Plans should be able to use the burden and cost estimate information to develop an estimate of any increase in resources and costs associated with the implementation of these provisions. Additionally, two HPMS memoranda were released this fall: Part C and Part D reporting requirements and data validation dated November 23, 2009 and Implementation changes in the Medicare Part C and Part D Reporting Requirements and Data Validation dated December 23, 2009. These memoranda contain detailed, updated information on changes in implementation of the data validation requirement. The first memorandum clarified the timing of implementation (that is, the data validation needs to occur in the spring of 2011 for reported 2010 data), while the second memorandum reduced the overall data validation and reporting requirements for Part C and Part D measures.

Comment: While one commenter supported the implementation of the data validation audit requirements for 2011, others recommended we delay codifying the data validation audit requirement. They argued that codifying the requirement before the process has

been evaluated and finalized is premature and will take away CMS' flexibility to refine the requirements as it gains experience with the process. The commenters were also concerned that the validation mechanisms are very preliminary and should be vetted through the subregulatory process. They noted that the validation approach stipulated in the proposed regulation places the full cost burden of the audit on the health plan. One commenter specifically recommended that the proposed new paragraphs (g) be revised by striking Each Part C [Part D] sponsor must and inserting instead, CMS may require each Part C [Part D] sponsor to * * * and strike independent audit and insert audit.

Response: We disagree with the recommendation to delay codifying the data validation audit. We have begun evaluating the data validation audit process and will have completed a pilot evaluation by May 2010, that is, approximately 10 months before the implementation of the data validation audits. Therefore, we believe we will have sufficient time to perform any needed refinements of the requirements well before actual implementation of the data validation process. We strongly believe that it is important to have the data validation audit process in place by 2011 since there is a need to monitor the Part C and D programs effectively and to respond to questions from Congress, oversight agencies, and the public with data that are timely, reliable, valid, and allow for comparisons among plans.

We also disagree that the data validation audit requirements should be provided only in subregulatory guidance. We proposed to implement these requirements through notice-and-comment rulemaking in order to ensure that, if they were adopted, they would be enforceable with the full force and effect of law. Detailed procedures for meeting the regulatory requirements will be provided through sub-regulatory guidance and will also undergo the PRA process. As a result, we believe we will retain sufficient flexibility to make necessary changes before the requirements are implemented as well as to update the procedures in the future as necessary. We further believe that it is necessary to conduct the data validation audit on all plans so that there is assurance that all the data are reliable, valid, and can be used to compare health plan performance. If we find through the data validation audit process that some plans are not reporting accurate data, then it will be possible to take this factor into account when reporting plan performance and in comparing performance among plans.

Comment: Several plans expressed concern that the cost of implementing the data validation audit will be high or excessive.

Response: We do not agree that the costs of implementing the data validation audit will be excessive. In the October 22, 2009 proposed rule (74 FR 54711), we estimated that the costs of these independent audits would be approximately \$5,200 per plan. Because the costs on a per plan basis are not excessive, they will likely be reflected in only minimally higher bid prices across the board.

Comment: Two commenters stated that plans should have the option of using their own internal auditing staff.

Response: We disagree that plans should have the option of using their own internal auditing staff in lieu of an independent, external auditor. The data validation needs to be credible to stakeholders, including Congress and the American public. We believe that only an external independently conducted audit can establish this credibility.

Comment: One commenter requested clarification as to whether CMS intends to issue a list of certified contractors from which an organization may select a vendor. This commenter also recommended that the validation and testing of a plan's compliance with Fraud, Waste, and Abuse (FWA) programs regulations include the use of a certified fraud investigator.

Response: At this time, we do not expect to issue a list of certified contractors from which an organization may select a vendor to conduct data validation audits. Instead, we will be issuing standards for selected vendors. A draft of these standards was issued for informal comments last fall and a revised version will be issued with the PRA package associated with the data validation specifications that will be available for public comment. We also note that the commenter's second recommendation is likely in reference to a CMS program audit. Because this proposal relates to a data validation audit, we do not believe that plans should be required to use a certified fraud investigator.

Comment: One commenter stated that flexible criteria should be considered in the data validation audit's report specifications, that is, CMS should consider using flexible criteria in developing the specifications for the data validation report.

Response: We agree that the criteria used in developing the specifications for the data validation report should accommodate different types of reportable data that a plan collects for

each Part C and D measure. We believe that the standards and procedures under development for the data validation effort provide sufficient flexibility to accommodate different types of available reportable data.

Comment: One commenter states that any final rule on data validation requirements should take into consideration the plan's state regulatory requirements and the plan's processes required to comply with state mandates, laws, and regulations and consider deeming in areas of overlap.

Response: We appreciate that plans may also have state reporting requirements with respect to licensure and solvency. We believe, however, that deeming with respect to issues subject to state reporting requirements is outside the scope of this proposal, which is to require an independent data validation audit of information reported to CMS.

Comment: One commenter questioned whether CMS needed to define performance benchmarks so plans can manage and monitor data before they are submitted to CMS.

Response: We will be defining the data validation standards prior to the data validation audit. Performance benchmarks relevant to these standards will be made available prior to the data validation audit.

Comment: One commenter offered to review the measures on behalf of CMS and explore ways for including them in the HEDIS measurement set and audit program.

Response: Although we appreciate the commenter's interest in this issue, we are not committing to the inclusion of the new Part C and D measures as part of the HEDIS measurement set and audit program at this time.

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

In the October 22, 2009 proposed rule, we proposed to use the authority under section 1860D–12(b)(3)(D) of the Act to collect all additional elements added to the prescription drug event (PDE) record beyond the original 37 elements currently collected under section 1860D–12(b)(3)(D) of the Act. As a result, we would be able to use these data elements for nonpayment-related purposes.

As we explained in the preamble to the proposed rule, 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. We noted that under this authority, in the May 28, 2008 **Federal Register** (73 FR 30664), 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. However, this rule limited what data (hereinafter referred to as PDE elements) we may collect and use for nonpayment purposes to the original 37 elements reported on the PDE record. 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 the October 2009 proposed rule, we also noted that in 2008 the number of PDE elements collected was expanded from the original 37 elements to 39 elements. The additional PDE elements are “Rebate Amount Applied to the Point-of-Sale Price” and “Vaccine Administration Fee.” The “Rebate Amount Applied to the Point-of-Sale Price” is generally the standard 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 charged for the administration of a vaccine separate from the actual vaccine.

In the 2010 Call Letter to Part C and D sponsoring organizations, we noted that we were planning to make mandatory the collection of 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.

Under our proposal, we would be able to utilize these data for non-payment related purposes. Similarly, 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, namely 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.

Our 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 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 record since 2007. Once data have been collected under section 1860D–12(b)(3)(D) of the Act, we may use these data for nonpayment-related purposes and may release PDE data consistent with our minimum necessary policy and our data sharing procedures.

We also noted in the preamble to the proposed rule that we believe the ability to analyze new claims-related elements added to the PDE record will 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, as a result of the proposal, 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 nonpayment 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. However, because we did not propose any change to our data sharing procedures or our minimum necessary data policy, 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.

We also noted our current policy of protecting various Part D elements when

responding to external research requests. Thus, the 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. However, 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.

Because some HHS agencies accomplish their mission through grants, rather than contracts, and hence cannot rely on the access that is provided to HHS contractors and the fact that research performed by HHS grantees will advance the interests of Medicare beneficiaries, who may also be served by other HHS programs, we proposed to revise § 423.505(m)(iii)(C) to permit CMS disclosure to HHS grantees of unencrypted plan identifiers when certain conditions are met. The conditions we proposed to 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 a 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, we will 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 will 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 will review the requestor’s rationale for the importance of study findings to the Medicare program.
- Public reporting, we require an attestation from the requestor that the requestor will not identify specific plans

or plan sponsors in any public reporting.

In the proposed rule, we indicated that we believed that these conditions would mitigate the risk of unauthorized use or disclosure of commercially sensitive plan information. We also solicited comments on whether it would be appropriate to extend the 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. After considering the comments received in response to our proposals, we are finalizing the proposed changes to § 423.505(f) and (m) without modification.

Comment: Some commenters questioned CMS' authority to share PDE data for non-payment purposes given the limiting language in section 1860D-15 of Act. One commenter alleges the approach outlined in the proposed rule would result in a potential violation of the Trade Secrets Act. Another commenter mentioned that section 1927(b)(3)(D) of the Act protects pricing, rebates and other financial information from disclosure except to very specific recipients (such as CBO or the Comptroller), which does not extend to HHS grantees. One commenter does not want the release of rebate data, estimated or otherwise, stating that rebates at point of sale reflect proprietary business information.

Response: We respectfully disagree with the commenters' assertions. In the May 28, 2008 **Federal Register** (73 FR 30664), we published a final rule regarding the collection and use of Part D claims data. This regulation resolved the statutory ambiguity between sections 1860D-12(b)(3)(D) and 1860D-15 of the Act, noting that section 1860D-12(b)(3)(D) of the Act (and its incorporation of section 1857(e)(1) of the Act) provide broad authority to the Secretary to require Part D sponsors to provide the Secretary with "such information as the Secretary may find necessary and appropriate" and that when information is collected through a statutory authority independent of section 1860D-15 of the Act, the restrictions of section 1860D-15 of the Act would not apply. Following the issuance of this Part D claims data final rule, Congress enacted the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Section 181 of MIPPA added clause (ii) to section 1860D-12(b)(3)(D) to provide that any Part D data collected under the authority of section 1860D-12(b)(3)(D) "shall be made available to

Congressional support agencies (in accordance with their obligations to support Congress as set out in their authorizing statutes) for the purposes of conducting Congressional oversight, monitoring, making recommendations, and analysis of the program under this title." While section 181 of MIPPA did not directly address the issues of statutory ambiguity associated with Part D claims data collected by CMS, it can be read as an implicit Congressional ratification of the arguments presented by CMS, in the Part D claims rule, as the legislation only overrides one provision of that rule. Specifically, under section 181 of MIPPA the Secretary must make data collected under section 1860D-12(b)(3)(D) available to Congressional support agencies, without regard to CMS' minimum data necessary standard. Accordingly, for reasons detailed in our May 29, 2008 final rule, we believe the restrictions of section 1860D-15 of the Act do not apply to PDE data collected under the authority of 1860D-12(b)(3)(D) of the Act. As a result, these data may be used for purposes other than payment.

In response to concerns about releasing proprietary data to external entities, we note that this rule pertains to additional elements added to prescription drug event data and does not extend to plan bid or reconciliation payment data provided outside of the PDE. Because PDE data are collected under section 1860D-12(b)(3)(D), rather than section 1860D-2(d)(2), they are not subject to the limitations on disclosure under section 1927(b)(3)(d). In addition, as we explained in the May 28, 2008 final rule (73 FR 30680), because § 423.505(m) was issued under the authority of section 1106 of the Act, any release of potentially proprietary data pursuant to this provision would be also be authorized by law under the Trade Secrets Act. Furthermore, we also note that rebates applied at point of sale are not the same as aggregate rebates estimated by plans as part of their bid or actual rebates received from manufacturers that are submitted outside of the claim for payment reconciliation purposes. Rather, they most often reflect a standard amount that the manufacturer is providing to a particular sponsor for a specific drug that is then passed through to consumers as part of the plans' price at point of sale, the net amount of which is available to beneficiaries as an estimate on the drug plan finder tool. We also remind commenters that we place certain limitations on PDE data when released outside of CMS. Through the application of our "minimum data

necessary policy," additional restrictions to protect beneficiary confidentiality and commercially sensitive data of Part D sponsors, and our data sharing procedures (which ensure the agency's compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Privacy Act of 1974, and other applicable laws), we limit the use and disclosure of Part D claims data to ensure that the data are only used or disclosed as permitted or required by applicable law, and not inappropriately disclosed in a manner which could undermine the competitive nature of the Part D program.

Comment: We received a number of varied comments on the sharing of PDE data. Several commenters provided recommendations related to the sharing of Part D PDE information for non-payment purposes, suggesting that CMS—

- Use only non-identifiable information for any public analysis, arguing that research can be done without an actual plan ID;
- Exclude data elements that could be because of geographic information, and/or other aggregated information indirectly identify plan sponsors; and
- Share information (especially plan IDs, or PHI) *only* with written approval from the sponsor and publish guidance well before adding another element to the PDE format.

Another commenter stated that despite the restrictions in sharing plan IDs, certain plans could easily be identified. A few other commenters stated that CMS has no specific restrictions in the regulation protecting price information.

Response: We believe these comments are outside of the scope of the proposed rule, which was issued not to reopen our May 28, 2008 final rule on Part D claims data but rather to address the use and disclosure of additional PDE data elements beyond the original 37 elements that were the subject of the May 28, 2008 final rule. To the extent the comments are applicable, we disagree with the recommendations on using only aggregate data and obtaining written plan approval prior to use of the PDE data. Our rationale is the same as the one we expressed in response to a similar comment to the May 28, 2008 final rule on Part D claims data: if PDE data are collected only under the authority of section 1860D-15 of the Act CMS, HHS and external entities can never use the data for evaluations, analyses, and research important to public health, and vital to program oversight. In the Part D claims data final rule we provided a detailed description

of the potential purposes for which these data might be used, including evaluating the effectiveness of the prescription drug benefit and its impact on health outcomes, performing Congressionally mandated or other demonstration and pilot projects and studies, reporting to Congress and the public regarding expenditures and other statistics involving the Medicare prescription drug benefit, studying and reporting on the Medicare program as a whole, and creating a research resource for the evaluation of utilization and outcomes associated with the use of prescription drugs. Balancing these important objectives with the potential sensitivity of PDE data, we implemented a rule that ensures that, subject to many safeguards put in place to guard against inappropriate use and disclosure of commercially sensitive and beneficiary identifiable information, Part D PDE data are available for research purposes under similar data sharing processes to those used for sharing Parts A and B claims data. While we agree with the commenter that in some situations, even if we provide samples of PDE data with masked plan identifiers, public information may be added to the PDE record to identify the particular plan, we believe that our data sharing procedures mitigate against any inappropriate use or disclosure. Under these procedures, we require each researcher to sign a Data Use Agreement (DUA) that spells out the multiple restrictions on the use of the data and the penalties for any failure to comply with the terms of the agreement. In addition, we require research using beneficiary identifiable data to be conducted by an experienced entity at a reputable organization, with an appropriate research design, and with assurances to protect beneficiary confidentiality. Research is to be made available to the public and identifiable data is not released for commercial purposes. Further we will only release beneficiary identifiable data for research purposes if the CMS privacy board approves the data release and then, will only release the minimum data necessary for the study. We believe these procedures allow us to safely balance the need to support legitimate research while at the same time guarding against the misuse or inappropriate disclosure of data that is sensitive in nature.

Comment: A commenter asked to what extent are PDE data uses and disclosures subject to requests under the Freedom of Information Act (FOIA).

Response: Requests for Part D PDE data should be directed through our contractor, the Research Data Assistance

Center, at <http://www.resdac.umn.edu/>, as opposed to FOIA. However, as noted in our May 28, 2008 final rule on Part D claims data, if a FOIA request is received for PDE data used for non-payment purposes, we will follow our ordinary FOIA procedures and not release under FOIA data the agency determines are trade secrets, or commercial or financial information protected by FOIA Exemption 4 (5 U.S.C. 552(b)(4)).

Comment: Commenters opposing the rule pointed out that it does not place any perimeters on the type of additional data CMS may classify as claims data, and thereby make available for disclosure. The commenters expressed concern that nothing in the proposed regulation would require confidentiality of rebate and pricing information if it were collected under section 1860D–12 of the Act.

One commenter also questioned CMS' conclusion that we could use section 1860D–12(b)(3)(D) of the Act to collect new elements to the PDE record without undertaking rulemaking for each additional element added in the future.

Response: We reiterate that our authority to collect PDE elements for non-payment purposes has already been decided with the clarification of our authority under 1860D–12(b)(3)(D) of the Act, as set forth in Medicare Part D Claims Data rule published on May 28, 2008. Because that final rule was expressly limited to the 37 original elements of the PDE claim, it was necessary for us to undertake further rulemaking in order to collect new elements that have been added to the PDE record. Rather than proposing to collect only the 3 new elements that have been added to the PDE record since 2007, we concluded that it was appropriate to propose to collect all elements that are currently part of the PDE record or that may be added to the PDE record in the future. As we stated in the preamble to the October 22, 2009 proposed rule, 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 in our ability to conduct program oversight, support operational tasks, and provide more information for use in internal and external healthcare research studies. These rationales apply not only to the collection of the 3 new PDE elements that have been added since 2007, but also to the collection of any new elements that may be added in the future. Furthermore, the addition of more PDE elements beyond those that

are currently collected is at the Secretary's discretion and will be diligently reviewed and accorded the proper protection consistent with the principle outlined in the May 28, 2008 final rule. Plan sponsors will be notified of any changes to the collection of PDE data through the CMS Call Letter to Part D plan sponsors, or via HPMS memoranda. Therefore, we do not believe it is necessary to undertake a separate rulemaking to authorize CMS, to use section 1860D–12 of the Act to collect each new element that we may add to the PDE record in the future.

Comment: Some commenters opposed sharing the Plan identification element from the PDE record in an unencrypted form with HHS grantees expressing concern about the data security and the need to protect sensitive data, and arguing that encrypted data should satisfy most research needs. Other commenters supported the PDE data sharing provisions in the proposed rule, with some supporting a proposed option in the preamble of the proposed rule that would also permit grantees of non-HHS Federal agencies access to plan identifiers. One commenter supporting the rule asked that we go further and with proper restrictions allow access to plan identifiers to all legitimate researchers.

Response: After the Part D Data rule was published in May 2008, we limited the use of actual plan identifiers, but after gaining experience in releasing Part D data it soon became apparent that there was a compelling need for other HHS (such as FDA and NIH) agencies to use plan identifiers in their linking, oversight and research (for example, influence of brand name recognition, and benefit design on consumer choice) under certain conditions. These agencies cannot possibly conduct all of their own research. Accordingly, they engage grantees to perform approved studies. These studies often assist CMS in better understanding and improving the Medicare program. Furthermore, HHS is able to affect more oversight of its own grantees through the threat of future withdrawal of funding—a great disincentive for researchers—should any terms of the data use agreements be broken (as opposed to a study independently funded by a University). Therefore, with this final rule we are permitting access to plan identifiers HHS grantees for nonpayment purposes when the following conditions are present:

- 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 a benefit to the Medicare program; and
- The requestor attests that any public findings or publications will not identify plans or plan sponsors.

While we believe that similar benefits may accrue to grantees of non-HHS entities and to many external researchers conducting studies of beneficiary plan choices, we believe that additional time is needed to evaluate this issue. Therefore, for now, we will limit the exception to the prohibition against releasing unencrypted plan identifier elements to external entities in § 423.505(m)(1)(C) to HHS grantees at this time.

Comment: One commenter asked for clarification on whether or not CMS intended to allow unencrypted data to be transmitted to requesters of data. The commenter had concerns with regard to potential risk of violation of the security rules under HIPAA.

Response: We ensure that any data transmission is done only after undergoing an approval process that requires requesters to detail their security procedures during transmission, storage of and access to Part D data.

Comment: Another commenter wanted clarification as to whether the fields discussed in the proposal had already been added to the PDE layout.

Response: We note that the vaccine administration fee and the rebate at point-of-sale were added to the original 37 elements for CY 2008, and that in the 2010 Call Letter we notified sponsors that a 40th element, Prescription Origin Code, collected on an optional basis in 2009, would be part of the mandatory reporting requirements beginning January 1, 2010.

Comment: A commenter asked about downstream entities, noting that the rule does not specify who may have access to this sensitive data.

Response: We share the commenter's concerns over the re-release of data to entities not included on the DUA. Under our current data sharing procedures, researchers or other external entities wishing to re-release Part D data must notify us and receive express permission for any subsequent release, with appropriate modifications made to any DUAs.

F. Changes To Implement New Policy

This section addresses two policies under Parts C and D respectively. Under Part D, we proposed new regulatory requirements pertaining to the required inclusion of protected drug categories and classes on Part D formularies. While our proposals initially were intended to implement provisions in section 1860D-4(b)(3)(G) as in effect at the time of our October 22, 2009 proposed rule, since

that time on March 23, 2010 section 3307 of the PPACA was enacted.

Rather than specifying statutory criteria for identifying protected classes of drugs, as did section 1860D-4(b)(3)(G)(i) of the Act at the time of the proposed rule, section 1860D-4(b)(3)(G) of the Act now provides that the Secretary shall establish criteria for determining "classes of clinical concern" and until such time as the Secretary establishes such criteria, the following six classes of drugs shall be protected: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection. As there are many provisions in the PPACA affecting Medicare Part D beneficiaries, we believe it is important to take some time to thoughtfully consider how best to establish appropriate criteria. As such, and in accordance with 1860D-4(b)(3)(G) of the Act, we are protecting the six statutorily-specified drug classes and categories of drugs of "clinical concern" and will turn in the future to consider the criteria the Secretary would issue under the statute.

Under Part C, we proposed 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
Provide Criteria and a Process for identifying Protected Classes of Drugs.	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))

In the October 22, 2009 proposed rule, based on comments that we received on an earlier January 16, 2009 interim final rule with comment period (IFC) (74 FR 2881), we proposed criteria and procedures for identifying "protected classes" of drugs, within which all covered Part D drugs must be included in Part D formularies. While we had previously identified six such classes under our authority in section 1860D-11(e)(2)(D) of the Act to ensure that formularies were not discriminatory, section 176 of MIPPA added a new section 1860D-4(b)(3)(G)(i) to the Act which required the Secretary, effective plan year 2010, to address the issue of

protected classes and undertake to identify classes of drugs that met two criteria specified statutory criteria:

- 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.
- 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.

Under section 176 of MIPPA, the Secretary was provided 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 in the protected categories and classes. Section 176 of MIPPA required that such exceptions be subject to a public notice and comment process.

In the October 22, 2009 proposed rule, we proposed interpreting several of the statutory terms used in the criteria set forth in section 176 of MIPPA to better define the scope of the protections afforded under that section. To that end, we proposed to add several new definitions at § 423.100, including: "restricted access," "major or life-threatening clinical consequences," "significant need for access to multiple

drugs,” “a short period of time,” and “multiple drugs.” Further, we proposed that the MIPPA protections did not apply to non-Part D drugs and their exclusion from the formulary requirements would not be based on the exceptions authority under section 1860D–4(b)(3)(G)(iii) of the Act.

We also proposed to add a new paragraph to § 423.120(b)(2) to identify exceptions to the inclusion of all drugs meeting the criteria set forth in section 176 of MIPPA and our implementing regulations. Under proposed § 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.
- 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 welcomed comment on these proposed definitions and clarifications.

Finally, we noted in the preamble to the October 22, 2009 proposed rule that we continue to believe that the best way to determine which drug classes and categories should be identified as a protected class and category 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.

We also offered two approaches for consideration, and solicited comment on which option the public believed would allow us to make timely determinations in a transparent manner. Those options were—

- *Option 1:* Announce protected classes through subregulatory guidance (for example, the Call Letter) that provides a notice and comment process but does not entail formal **Federal Register** notice and comment rulemaking; and
- *Option 2:* Announce the protected classes through formal notice and comment rulemaking.

Since issuance of the October 22, 2009 proposed rule, the PPACA was enacted. Accordingly, new section 1860D–4(b)(3)(G) of the Act replaces section 176 of MIPPA. Section 1860D–4(b)(3)(G) of the Act requires a PDP sponsor to include “all” covered part D

drugs in the categories and classes identified by the Secretary as classes and categories of “clinical concern.” It requires the Secretary to establish criteria to determine, as appropriate, categories and classes of drugs of “clinical concern.” It provides for an exceptions authority similar to the one included in section 176 of MIPPA. Section 3307 of PPACA further requires that until the Secretary establishes criteria to determine classes of “clinical concern,” the following categories and classes of drugs shall be identified and protected as classes of “clinical concern”: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection.

Given that PPACA was recently enacted and there are many provisions affecting Medicare Part D beneficiaries, we need time to thoughtfully consider how best to establish criteria to identify classes and categories of drugs of “clinical concern.” Accordingly, consistent with the PPACA, at this time we are requiring that PDP sponsors include all covered part D drugs in the following categories and classes: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection. This requirement will be in effect for plan year 2011 and until such time as we undertake additional notice-and-comment rulemaking to establish the criteria for identifying classes and categories of drugs of “clinical concern.” Continuing to protect the current six classes of “clinical concern” will ensure that beneficiaries will continue to have access to the medications they need and will not experience a disruption in care. We note that PPACA requires that sponsors cover “all” Part D drugs rather than “all or substantially all” as required under section 30.2.5 of the Prescription Drug Manual.

Consistent with this approach, we have decided to adopt, in regulatory text, neither the criteria we proposed in the October rule which were specified by MIPPA for identifying classes and categories of drugs of “clinical concern,” nor the definitions used to interpret the MIPPA criteria. However, we are retaining the exceptions process in the regulatory text, as new Section 1860D–4(b)(3)(G) of the Act retains the exceptions process established under MIPPA.

Comment: Several commenters expressed opposition to our exception that inclusion of “all covered Part D drugs” on formulary from a protected

class or category does not extend to the inclusion of all brand-name drugs and generic versions of a covered drug in question. They argue that this exception is inconsistent with other CMS formulary requirements, namely our midyear formulary change policy for which they argue that CMS makes it clear that a brand-name drug and its generic counterpart are different “drugs” for the purpose of submitting formulary changes. In addition, one commenter expressed concerns about different exceptions in therapeutic equivalent products, stating that some may not provide the same benefit in the physician’s judgment.

Response: We disagree with the commenters’ arguments. It is important to distinguish our formulary change policy from the definition of a “drug” for the purpose of explaining therapeutic equivalence. For the protection of beneficiaries who may experience cost sharing changes, we require that when a new generic equivalent is released into the market and a plan sponsor proposes to add the new generic to its formulary and remove the brand-name drug, we approve the change and notice be sent to affected beneficiaries to make them aware that a generic equivalent is available and that there may be a change in their cost-sharing if they continue to take the brand-name.

For the purpose of formulary submission to us, our regulations specify at § 423.120(b)(2)(i) that two therapeutically equivalent drugs cannot be used to satisfy our requirement that there be at least two drugs per category and class on formulary. Contrary to the commenters’ assertions, we believe this existing formulary requirement is consistent with our proposal in that both standards acknowledge that therapeutically equivalent products are the same drug. Further, as stated in our January 28, 2005 Part D final rule (70 FR 4260), inclusion of “all covered Part D drugs” within a class or category of clinical concern does not extend to inclusion of all brand-name drugs and generic versions of the covered drug in question. The Orange Book, published by the FDA, is a widely accepted standard for determining therapeutically equivalent drugs within the same class/category (*see* <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>). Therefore, we disagree that our policy stating that inclusion of “all covered Part D drugs” on formulary from a protected class or category does not extend to the inclusion of all brand-name drugs and generic versions of a covered drug in question is somehow inconsistent with other formulary policies.

Finally, with regard to the one comment that some therapeutically equivalent drugs may not provide the same benefit in the physician's judgment, we note that a beneficiary, working with his or her physician, may pursue an exception if they believe that a drug considered to be a therapeutic equivalent is not providing the same benefit as the brand drug originally prescribed.

Comment: Several commenters oppose the application of any utilization management edit applications for protected class drugs. Other commenters contended that our proposal undermines the benefits of formulary and utilization management processes. A few commenters in particular oppose our exception for drugs "with very limited applicability to the Medicare Part D population and non-Part D drugs" to be included on formulary under the regulatory protected classes provision, arguing that if a drug fits the criteria, it should be protected.

Response: We disagree with these commenters. Consistent with the definition of a Part D drug under § 423.100, we do not require inclusion on formularies those drugs that are paid for under Part B (for example, "incident to" drugs supplied and administered by physicians during patient visit and paid for under Part B), and drugs whose regulatory status under the definition of a Part D drug is unknown. To do so when they are not payable under Part D would lead to beneficiary confusion. Therefore, we are maintaining this policy in this final rule.

Comment: A few commenters expressed concern over CMS's proposal permitting the use of utilization management processes that limit the quantity of drugs under protected classes due to safety. One commenter argues that this policy would create a significant opening for plans to expand "restrictive policies" and that CMS should be clear on what we mean by safety edit. The commenter asserted that it is important for CMS to further define what a valid safety edit is and to specifically link it to prevention of imminent harm to the health of the beneficiary. Another commenter asserted that the safety of any course of drug therapy is a clinical concern and it is critical for utilization controls not to interfere with appropriate clinical decisionmaking. This commenter notes that the imposition of safety-based quantity limitations—even where well-intentioned—may harmfully interfere with patient needs if his or her clinical context is not fully taken into account. The commenter suggested that in

evaluating safety-based exceptions, CMS should not rely only on information contained in the package insert, but should also consider clinical trial data and accepted standards of care.

Response: We have been clear on what is meant by a safety edit. As indicated in section 30.2.2.1 of Chapter 6 of the Medicare Prescription Drug Manual (see <http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/R2PDBv2.pdf>), safety edits refer to point-of-sale (POS) edits implemented to satisfy concurrent drug utilization review (DUR) requirements set forth in § 423.153(c)(2). Examples include screening for therapeutic duplication, age or gender-related contraindications, over-utilization, under-utilization, drug-drug interactions, incorrect drug dosage or duration of drug therapy, drug-allergy contraindications, and clinical abuse/misuse. For the protection of beneficiaries, we continue to believe that the protected classes provision must not interfere with this POS DUR to help ensure that adverse events do not occur. We believe that such edits must be consistent with FDA labeling to ensure that they are based on scientific evidence and medical standards of practice. To the extent that an individual's clinical needs require a quantity greater than permitted under the FDA labeling, we believe that the exceptions process is the appropriate vehicle for resolution of such cases. Finally, in response to the comment that permitting the use of safety edits would create a significant opening for plans to establish restrictive policies, we disagree. Rather, our guidance is clear that edits need to conform to FDA labeling. To the extent that a plan sponsor would establish safety edits that were more restrictive than FDA labeling contrary to our guidance, we would likely uncover such edits through complaints or through a review of exceptions and appeals data and would instruct the plan to revise its processes immediately.

Comment: A commenter requested that CMS clarify what is meant by "scientific evidence" and specify how the use of such evidence would be validated with respect to CMS' proposed language that we may identify other exceptions "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)." Another commenter urged CMS to establish any

exception to the inclusion of all drugs and biologicals in a protected category or class only when warranted by scientific evidence and medical standards of practice, and only after a notice and comment period.

Response: We will undertake future rulemaking to identify additional exceptions, as necessary. Further, where appropriate, we will provide the citation for the supporting scientific evidence and medical standards of practice to support our findings. We note that an example of scientific evidence may include information contained in the FDA drug approval records or may include evidence referenced in widely-used treatment guidelines, such as those approved by the Agency for Healthcare Research and Quality (AHRQ).

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

In the October 22, 2009 proposed rule, we proposed to revise the regulations to provide for the pro-rating of the plan deductible under an MA MSA plan in the case of enrollments occurring during an initial coverage election period at a time other than the beginning of the year. As we noted in the preamble to the proposed rule, section 1851(a)(2)(B) of the Act provides that Medicare Advantage Medical Savings Account (MSA) plans are a type of MA plan that a MA-eligible Medicare beneficiary can elect to receive his or her Medicare Part A and B benefits. An MSA plan combines both a tax advantaged Medical Savings Account (MSA) 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 MSA. If an individual enrolls in such a plan midyear, under section 1853(e) of the Act, a pro-rated share corresponding to the number of months remaining in the calendar year is placed into the individual's savings account. However, as provided under § 422.103(d) beneficiaries newly eligible for Medicare who enroll in MSAs midyear pursuant to an initial coverage election period (ICEP) are currently required to pay the full "high 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.

The deductible under an MSA plan is governed by section 1859(b)(3)(B) of the Act, which specifies the maximum amount of what the statute refers to as the “annual deductible” under an MSA plan. In the October 22, 2009 proposed rule, we proposed to infer from the statute’s use of the term “annual” that the deductible amount at issue was intended to apply to a full 12-month period, and thus to specify in a proposed revised § 422.103(d) that an individual who enrolls in an MSA plan under an ICEP other than at the beginning of the calendar year would only be subject to that portion of the “annual” deductible corresponding to the number of months in which the individual is enrolled. Interested beneficiaries would be able to inquire with organizations sponsoring 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. As the result of our review and consideration of commenter support for our proposal, we are modifying § 422.103(d) in this final rule to provide for a pro-rated deductible in the case of any beneficiary enrolling in an MSA plan after January 1, not just an enrollment pursuant to an ICEP.

Comment: A commenter supported as “positive” our proposal to “revise the regulations to specify that beneficiaries who enroll in a Part C MSA during the year” be required to “pay only a pro-rated deductible consistent with a pro-rated deposit.”

Response: While the commenter’s point in support of the policy rationale for our proposed revision to § 422.103(d) was made in the context of our proposal to pro-rate deductibles for beneficiaries who enroll after January 1 under an ICEP, the commenter’s point in support of symmetry between a pro-rated deposit and a pro-rated deductible would apply to any situation in which a beneficiary enrolls in an MSA plan after January 1. It is noteworthy that the language in section 1853(e) of the Act limiting the Medicare payments to

months in which the individual is enrolled is not limited to a late enrollment under an ICEP. We thus believe that the symmetry supported by the commenter should apply in all cases of midyear enrollment in an MSA plan. For example, a beneficiary who receives a special election period for relocating, and enrolls in a MSA plan after January 1, should be required to pay only a pro-rated deductible. Therefore, we are modifying § 422.103(d) in this final rule to allow all beneficiaries who enroll in a MSA plan midyear to pay a pro-rated deductible.

G. Changes to Clarify Various Program Participation Requirements

This section addresses proposals from the October 22, 2009 proposed rule that would either clarify existing regulations or implement new requirements consistent with existing policy guidance, to assist MA organizations with and PDP sponsors in 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 protected 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 determinations.	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 § 417.492 § 417.494 § 417.500 § 417.640	N/A	N/A.

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

In the October 22, 2009 proposed rule, we proposed to revise § 423.104(b) to mirror the language at § 422.100 to specify that Part D sponsors apply uniform premiums and cost-sharing. As we noted in the proposed rule, section 1852(d)(1)(A) of the Act requires a 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 of the statute in our regulations at § 422.100(d) and § 423.104(b) prior to the proposed rule, but believed that § 423.104(b) should be further clarified in regards to the PDP sponsor's imposition of uniform premiums and cost sharing. In this final rule, we adopt this provision as proposed with a minor revision.

Comment: One commenter is concerned about how the uniform requirement would be applied in unusual circumstances that may not be in the enrollee's best interests. For example, the commenter asked what would happen if an enrollee has already paid the applicable cost sharing amount once, but by no fault of the beneficiary, the drug is either no longer usable, or available because of a natural disaster. Waivers should be considered in these special circumstances.

Response: The circumstance the commenter refers to is more appropriately addressed by our emergency access policy and not by a revision to, or waiver of, the uniform benefit requirement. Our emergency access policy is currently provided in Chapter 5 of the Medicare Prescription Drug Benefit Program Manual and

outlines our expectations of Part D sponsors when administering the Part D benefit during a natural disaster or public health emergency.

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

In our October 2009 proposed rule (74 FR 54690), we specified that we interpret the Secretary's right to audit or inspect the facilities of MAOs and Part D sponsors to monitor compliance with MA and Part D program regulations as including the evaluation of compliance with our requirements for maintaining the privacy and security of protected health information (PHI) and other personally identifiable information of Medicare enrollees. In order to clarify our policy that beneficiaries' PHI and other personally identifiable information must remain secure, we proposed to revise § 422.504 and § 423.505 to make this interpretation explicit. In a related change, we proposed to clarify that we interpret the term "facilities" to include an MAO's or Part D sponsor's computer or other electronic systems. We proposed to implement these proposed changes at § 422.504(e)(1)(ii) and § 423.505(e)(1)(ii). We also proposed conforming changes to the contract requirements related to downstream entities at § 422.504(i)(2)(i) and § 423.505(i)(2)(i), respectively. We noted in the preamble to the proposed rule that we may review systems and computer information generated by downstream and related 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, whether in the possession of a downstream or related entity or obtained from such entities by the MAO or Part D sponsor. We are adopting the revisions to § 422.504 and § 423.505 as specified in the proposed rule.

Comment: Several commenters supported the proposed provisions with one commenter suggesting that CMS draw upon its expertise in evaluating

and assessing plan compliance with personal health information-related requirements.

Response: We appreciate the suggestion and will consider this as we develop any additional guidance on PHI-related requirements.

Comment: A commenter questioned CMS' authority to request backup tapes and computer-generated information held by pharmacies as part of CMS' review of privacy/security of PHI requirements. The commenter writes that tapes and computer data can contain information beyond that normally submitted by plans and which is often unrelated to a pharmacy's Part D contract. If CMS is, in fact, asking for information outside of that provided as part of the pharmacies' contracts with Part D plans or claims data that pharmacies routinely submit, the commenter requests that CMS clarify its authority for doing this.

Response: Although we have the authority to review information generated in connection with the downstream or related entity's contract with an MAO or Part D sponsor, including information related to compliance with privacy and security requirements, it has never been our intent to review documents or information unrelated to a pharmacy's or other downstream or related entity's Part C or Part D contract.

3. Requirement for Sponsoring Organizations Under Parts C and D to Report Other Payer Information to the Coordination of Benefits Contractor (§ 422.108, § 423.462, and § 423.464)

In the October 22, 2009 proposed rule, under the authority of sections 1852(a)(4) and 1860D-2(a)(4) of the Act, we proposed to require the reporting of other coverage information in § 422.108 for MA organizations and § 423.462 and § 423.464 for PDP sponsors. Our rationale for proposing these changes was the importance of the other payer information for Medicare Secondary Payer (MSP) procedures and for prescription drug program coordination of benefits. We proposed to limit required reporting to that information

which is reported to the sponsor as being inconsistent with existing information on the COB file.

As we noted in the October 22, 2009 proposed rule, 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 for purposes of their MA plan bids. 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.

A Part D sponsor must also 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. In addition, we noted that 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 provided by 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 (P.L. 110–173) (MMSEA), further expands the other payer information available for MA organization and PDP

MSP procedures and for Part D sponsor COB (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.

Accordingly, given the importance of the other payer information to MA organization and PDP MSP procedures and for prescription drug program coordination of benefits, we proposed 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 (COBC) in accordance with the processes and timeframes established by us. The proposed changes would change the requirement on MA organizations, but would not change current MSP and coordination of benefits policy for the prescription drug program.

We noted that by “credible” we mean information that is consistent with conventions for how group health insurance coverage is identified, for instance, information that includes the name and address of the insurance company and the policy identification number. We also proposed to extend the reporting requirements to MA organizations as they relate to other primary payers. We noted that original Medicare, MA organizations, or Part D sponsors should never be reported to CMS as a “primary” payer. In the absence of another (that is, non-Medicare) primary payer, original Medicare, an MA organization, or a Part D plan are always primary. This is not to say that if an enrollee has primary individual or employer group coverage with 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 original Medicare, an MA or Part D plan themselves as primary serves no purpose and merely causes confusion.

After reviewing the comments received in response to the proposed rule, we are adopting § 422.108(b)(3) and § 423.462(b) as proposed.

Comment: A commenter supported CMS' proposed Part C reporting requirement. Another commenter requested that we revise the new regulatory language to reference the fact that we will only require MAOs and PDPs to report “credible” new information and that CMS either revise the regulatory language or mention in

the preamble discussion to the final rule that we will only require reporting on information that is inconsistent with that in the COB data file.

Response: In this final rule, we are reiterating that the portion of the preamble discussion in the proposed rule related to the requirement to report only MSP and COB information that is inconsistent with existing information on the COB data file. We have also repeated the preamble discussion of what we mean by “credible” new information and confirmed that we only expect MAOs and PDPs to report such “credible” new information to the COBC. We have not modified the regulatory language since we believe it is unnecessary to do so. However, we have added § 423.464(h), which we inadvertently omitted from the proposed rule. Operational guidance, in the form of our implementing instructions, will be consistent with preamble language in both the proposed rule and this final rule.

Comment: One commenter pointed out the apparent discrepancy between the 30-day timeframe for reporting credible MSP/COB information to the COBC we mentioned in the preamble of the October 2009 proposed rule, and the 45-day timeframe for correcting discrepancies in MSP status (with an additional 10 days to submit corrections) discussed in Chapter 5 of the MSP Manual. The commenter requested that CMS retain the existing 45-day timeframe, with an additional 10 days for submission to the COBC.

Response: As noted in the preamble of the proposed rule, section 50.2 of the Coordination of Benefits chapter of the Medicare Prescription Drug Benefits Manual (CMS Publication # 100–18, Chapter 14, last updated in September 2008) provides for reporting within 30 days of receipt and can be accessed on the Internet at: http://www.cms.hhs.gov/prescriptiondrugcovcontra/12_PartDManuals.asp.

We will consider this comment as we develop operational guidance related to the reporting of MSP information related to Part C by MAOs. However, we note that the timeframe for reporting MSP status in section 10.1 of Chapter 5 of the MSP manual is actually *the lesser of 10 calendar days from completion of the evaluation or 45 calendar days from receipt*.

Comment: A commenter asked if the requirements in § 422.108 and § 423.462 apply to only MA plans, or if these requirements also apply to Group Health Plans.

Response: The regulations at § 422.108 apply to MA organizations, while the regulations at § 423.462 apply

to both MA organizations offering Part D benefits as MA-PDs and free standing PDPs. Information on the rules related to Group Health Plan reporting of insurance coverage required by section 111 of MMSEA can be found on the following Internet Web site: <http://www.cms.hhs.gov/mandatoryinsrep/>.

Comment: A commenter noted an inconsistency between the preamble and the regulation language. The commenter stated that CMS seems to have failed to include regulation language at § 423.464 requiring Part D sponsors to report new or changed supplemental prescription drug coverage information.

Response: In the preamble of the proposed rule, we indicated our intention to revise § 423.464 to include a new requirement for Part D sponsors to report new or changed other prescription drug coverage information to the CMS COB Contractor. However, due to an oversight, the regulatory language for this requirement was not included in the proposed rule. However, the preamble discussion of this proposed requirement put interested parties on notice that we were considering imposing a new requirement on Part D sponsors to report new or changed prescription drug coverage information to the CMS COB contractor. Furthermore, we continue to believe that this reporting requirement is necessary to support the effective coordination of prescription drug benefits. Accordingly, we are including this new requirement at § 423.464(h) in this final rule.

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

In the October 2009 proposed rule, we proposed to revise our requirements for MA visitor/traveler benefits under Part C. Section 422.74(d)(iii) currently provides that an MA plan can offer a “visitor” or “traveler” (V/T) type program which would allow its enrollees to remain enrolled in the MA plan while out of the plan’s service area for up to 12 months. Although we stated in the preamble of the final rule in which § 422.74(d)(iii) was promulgated (August 22, 2003 (68 FR 50848)) that the visitor or traveler program must cover the “the full range of services available to other members,” we did not specify in regulation text what we intended by “full range of services.”

In order to clarify an MA organization’s obligation to cover services out of the service area, we proposed to amend § 422.74(d)(4)(iii) to specify that an MA organization may offer an extended enrollment V/T

benefit 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. Under this proposed clarification, MAOs that offer a V/T benefit under an MA plan would be required to make the option available to all plan enrollees. We proposed that 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 to 12 months the member may remain in the area and stay enrolled in the MA plan. We are adopting our proposed revision to § 422.74(d) (4) (iii) without further modification in this final rule.

Comment: A few commenters supported our proposed revisions to the V/T benefit requirements. They indicated that currently there is confusion surrounding the V/T benefit, and many beneficiaries have found the benefit does not provide them with access to Medicare-covered services they expected to have when outside their plan’s network.

One commenter supported providing Medicare-covered services under the V/T benefit, but opposed our proposed requirement to also include optional supplemental benefits. The commenter believed that this change would require organizations to adjust plan premiums and could ultimately impact an organization’s decision to offer optional supplemental benefits if a plan is not able to develop and meet network access requirements in the areas in which it intended to offer the V/T benefit.

Another commenter objected to the fact that the proposed revisions are less flexible than the existing rules governing V/T benefits and opposed the proposed requirement to provide supplemental benefits under the V/T benefit. The commenter indicated that it may be more feasible for MA organizations to enter into arrangements with providers in other areas of the country to provide access to Medicare-covered benefits than supplemental benefits. The commenter recommended that CMS defer incorporating the proposed changes into the MA regulations and instead issue draft sub-regulatory guidance for public comment.

Response: We agree with the commenters supporting our proposal to require MA organizations that offer a V/T benefit under an MA plan to furnish all plan-covered services (Medicare Parts A and B services and all

mandatory and optional supplemental benefits) at in-network cost sharing in the areas where the V/T benefit is offered. We note that it is optional for MA organizations to offer a V/T benefit and that a V/T benefit gives MA organizations the flexibility to retain their members when they are outside the service area for extended periods of time when they might otherwise be required to disenroll them for residing outside the service areas for more than 6 months. We do not agree that supplemental benefits should be excluded from a V/T benefit. Since MA organizations will receive full capitation payments for enrollees that reside outside the plan’s service areas for more than 6 months, we believe that requiring the plan to cover all plan-covered benefits will allow the enrollees to continue to realize the complete benefit package for which they enrolled in the plan. An MA organization that is not able to form a network of direct contracted providers to furnish supplemental benefits may, with CMS approval, allow its enrollees to obtain these services from non-contracted providers in the areas in which it offers the V/T benefit. We are therefore retaining our proposed changes to § 422.74(d)(4)(iii) in this final rule.

5. Medication Therapy Management Program Requirements (§ 423.153)

In the October 22, 2009 proposed rule, we proposed to codify our policy guidance regarding medication therapy management programs (MTMPs) in the Part D regulations at § 423.153. As we noted in the preamble to the proposed rule, based on the experience garnered from the first few years of the Part D program, and as we await further development of MTMP outcomes measures that can serve the Part D program, we have determined that it is necessary to have more specific Part D MTMP requirements for enrollment methods, targeting procedures, and MTM services. The 2010 Call Letter included policy guidance regarding the implementation of MTMPs that reflected common practices among Part D MTMPs that were derived from extensive review of MTMP applications, plan-reported data, exploratory research on MTM, informational interviews with Part D sponsors, and other relevant literature and data. In the proposed rule, we indicated that codifying this MTM guidance in the Part D regulations would promote greater consistency across the Part D program, and 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 proposed to add the following regulatory requirements regarding MTMPs—

- Section 423.153(d)(1)(v) to require Part D sponsors to enroll beneficiaries in their MTMPs using only an opt-out method of enrollment. The 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;

- Section 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; and

- Section 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 addition, we proposed to revise § 423.153(d) to clarify which beneficiaries should be targeted for MTMP services.

In this final rule, based on the public comments we received in response to the proposed rule, we adopt these provisions with some modification, as explained below. Specifically, at § 423.153(d)(2)(iii), we adopt a specific dollar threshold of \$3,000 in incurred annual costs for covered Part D drugs, instead of, as proposed, relying on the Initial Coverage Limit (ICL) as the threshold at which plans must target beneficiaries for MTM services. The \$3,000 cost threshold will be indexed using the annual percentage increase in average per capita aggregate expenditures for Part D drugs, which is found in § 423.104(d)(5)(iv). We note that these provisions are consistent with the changes made in PPACA.

Comment: One commenter is concerned that the proposed rule does not ensure adequate payment to pharmacies for MTM services. The commenter believes plan sponsors may shift costs associated with MTMPs to providers (specifically pharmacies) through lowered payments. The commenter urges CMS to require quarterly reporting of payment to pharmacies for MTM services and should ensure that pharmacies are paid adequately for furnishing these services.

Response: We disagree with the commenter's recommendation that CMS

require reporting of MTM payment data to ensure payment adequacy. The non-interference provision at section 1860D–11(i) of the Act explicitly provides that the Secretary may not interfere with the negotiations between pharmacies and PDP sponsors, which would include payment negotiations between the Part D sponsors and pharmacies for MTM services.

Comment: One commenter encouraged CMS to require Part D sponsors to disclose to CMS their criteria for determining whether a comprehensive medical review (CMR) will be performed face-to-face or by phone.

Response: We appreciate this comment, but believe that as long as the CMR is interactive and person-to-person, plans continue to have the discretion to determine whether it can be achieved through a phone or other alternative real-time method. We will monitor MTM program outcomes and performance to ensure best practices are adopted. In the event we receive data revealing weaknesses in this approach to CMR, we may consider revising the CMR minimum requirements in future rulemaking.

Comment: One commenter suggests that when enrollees are provided with a written summary of the interactive consultation, such summary be provided promptly to all prescribers involved in an enrollee's care.

Response: We agree with the commenter and believe such written summaries should be provided promptly to the provider. However, we believe the timeframe for the release of such summaries to providers is better addressed in the agreements between the MTM providers and the plans. The written summaries from the CMR will vary in complexity, depending upon an individual's diagnoses and medication usage; therefore, the time needed for preparation of such summaries will vary.

Comment: A few commenters indicated that the outcomes of MTMPs would be enhanced by requiring at least one initial face-to-face consultation with a pharmacist to review the patient's drug regimen and by offering another face-to-face consultation at least quarterly. Another commenter indicated that the quarterly reviews should be done person-to-person as this interaction permits evaluation of cues that may otherwise be missed if performed through lower touch interventions. Furthermore, periodic re-evaluations must be conducted and MTMPs should initiate programs to detect proactively, on a monthly-basis, under-utilization of prescribed

medicines for all chronic therapies. MTMPs should also be required to initiate interventions to address underutilization on at least a quarterly basis.

Response: We appreciate these comments, but not all beneficiaries can access the MTM services face-to-face or at the provider's location. Furthermore, we believe permitting alternative interactive methods (for example, by telephone or Web cam) will allow the sponsors to try innovative techniques that may better serve the beneficiary, especially when the beneficiary resides in a remote location or cannot travel to the provider's location. We emphasize, however, that when using alternative interactive methods, the CMR interaction must remain a real-time interaction.

We do not require the quarterly assessment to be interactive because we believe lower touch interventions, coupled with the annual comprehensive medication review will allow the patient to be adequately served. However, we encourage plans, to follow up with a person-to-person interaction if the quarterly review reveals that the patient is facing medication related problems.

Comment: One commenter indicated that CMS should clarify what it means by interactive, person-to-person consultation. For some hearing impaired or technically savvy beneficiaries the Internet is a valuable communication tool. CMS should allow the use of emerging technologies to conduct the CMR.

Response: As indicated in an earlier response, we agree that the use of alternative interactive methods be used by Part D sponsors, as long as the CMR is conducted in real-time.

Comment: One commenter recommends sponsors have the flexibility to determine if an MTMP intervention should be for member, prescriber or both. Another commenter indicated that additional clarification is needed about any and all prescriber interventions to ensure that MTM services are coordinated with and do not adversely impact on, or interfere with, the relationship between the enrollee and his/her prescriber.

Response: Section 423.153(d)(1)(vii), would require Part D sponsors to offer interventions to the enrolled beneficiary and his/her prescriber. As indicated in the preamble to the proposed rule, this does not mean that all interventions must be targeted to both the beneficiary and prescriber. Instead, sponsors must determine, based upon the specific nature of the intervention, whether it should be targeted to the beneficiary,

the prescriber, or both, in order to promote coordinated care.

Comment: One commenter indicated that it is important that CMS clarify how the MTM requirements will be applied, if at all, in the long-term care setting. Furthermore, this commenter asked how Part D sponsors will coordinate their efforts with the consultant pharmacists who conduct monthly drug regimen reviews for all residents in Medicare/Medicaid certified facilities.

Response: The same MTM program requirements apply to long-term care residents as apply in the outpatient setting, except that Part D sponsors are not required to offer an interactive CMR to targeted beneficiaries in an LTC setting. The Part D sponsor will still be required to do the quarterly medication reviews and offer interventions targeted to the individual's prescribers. Part D sponsors are not required to coordinate their MTM services with the monthly drug regimen reviews of the facilities' consultant pharmacists at this time.

Comment: We received several comments regarding performance measures for pharmacists. Commenters made the following recommendations:

- CMS should continue to use validated performance-based measures for pharmacy providers, such as the Pharmacy Quality Alliance (PQA) measures. These measures will give further definition to MTMPs, distinguish among different pharmacy providers and the types of MTMPs provided and appropriately compensate pharmacists that are able to improve quality of care.

- CMS should consider additional performance measures, in conjunction with participating pharmacists, and the performance measures should be made available publicly, on a yearly basis. The commenter suggested that CMS adopt only performance measures established by national voluntary consensus building.

- CMS should continue to allow as much flexibility as possible until evidence can demonstrate what aspects of an MTMP bring desired results.

- CMS should expand upon existing data collection and reporting requirements. At a minimum, reported data should include—

- ++ Number of adverse drug events avoided, categorized by reason;

- ++ Data on adherence and persistence by enrollees to their prescribed drug therapies;

- ++ Information on the form, frequency, and types of interventions; and

- ++ Data on the per capita administrative and drug costs under each program.

Response: We appreciate the commenters' interest in this issue. We will continue to utilize valid performance measures such as the measures developed by the PQA. In addition, we will evaluate MTM outcome data that we receive under the Part D reporting requirements to ensure that Medicare beneficiaries are receiving effective and appropriate MTM services. We will also continue to evaluate MTMPs to ensure consistent guidelines are applied, and issue best practices when necessary. We note that an MTM contract was awarded through 2010 to assist CMS in monitoring and evaluating sponsor's MTM programs.

Comment: Two commenters indicated that MTM services should be included as part of access standards for retail pharmacies. Another commenter requested that CMS ensure that pharmacists working in community pharmacy practice settings (network pharmacies), and pharmacists unaffiliated with network pharmacies, have the opportunity to contract with Part D plans to provide MTM services.

Response: These comments are outside the scope of this rulemaking and therefore we will not be addressing them in this rule.

Comment: A few commenters recommend that CMS consider requiring, or signaling a preference for, pharmacists to provide MTM services. Another commenter requested clarification regarding the characteristics of an "other qualified provider" in the regulation and at a minimum, a requirement that the provider have demonstrated expertise in medication use management.

Response: At present, 99 percent of the MTMPs are utilizing the services of pharmacists. While CMS believes pharmacists will continue to be the main provider of MTM services, the statute at 1860D-4(c)(2) of the Act permits plans the flexibility to use other qualified providers to perform the MTM. At this time, CMS does not believe it is necessary to issue regulations to govern the qualifications for providers of MTM services, but may consider rulemaking in the future, if further data reporting and experience reveal that additional refinement of the policy is needed.

Comment: Several commenters recommend that CMS not set specific program requirements in regulatory language, but continue to use the subregulatory mechanism offered by the annual industry call letter. They believe there is insufficient experience to include MTM policies in regulation, and the implications of the more detailed

criteria for targeting beneficiaries for MTMPs are not yet clear.

Response: We disagree with these commenters regarding placing the requirements in regulation. This rulemaking process has afforded both Part D plans and the public the opportunity to comment on the MTMP requirements prior to any changes being made to the existing requirements. Furthermore, because the MTMP requirements are being incorporated in our regulations, in the event a Part D sponsor fails to meet its MTMP services requirements, our ability to enforce those requirements has been enhanced. Accordingly, we believe that including these MTMP requirements in our regulations will help to ensure that targeted beneficiaries receive appropriate MTM services.

Comment: One commenter recommends that CMS develop standardized billing and documentation data sets to eliminate the need for pharmacists to utilize specific platforms to obtain payment from different plans. A standardized data set should include a measure of a patient's clinical outcomes as well as the rates at which the patient's providers accept the pharmacist's recommendations.

Response: We agree that the adoption of standardized documentation for MTM could be helpful in measuring the outcome of MTM. However, we believe any such standard documentation or billing be developed via an industry standard-setting group, and not by CMS.

Comment: Several comments were received regarding the MTM targeting criteria. Specifically, commenters suggested that CMS—

- Decrease the maximum number of medications that a plan could require for a targeted beneficiary to be eligible for MTM services; currently that number is eight. One commenter recommended decreasing the number to six, to prevent patients taking combination drug products from being unintentionally excluded from the program because a single medication has replaced two separate drug products;

- Allow Medicare beneficiaries who do not qualify for MTM services to receive MTM services through a referral or prior authorization process initiated by their prescriber or pharmacist. Some patients with only one chronic disease or less than 8 medications may still have medication use issues that would benefit from participation in their plan's MTM program; and,

- Require MTM services upon discharge from the hospital or anytime a beneficiary undergoes a transition of care. In both situations beneficiaries

would benefit from receiving MTM services because MTM has the potential to reduce costly hospital readmissions due to medication misuse or non-adherence.

Response: The regulation governing the number of prescriptions an individual must take before he or she is targeted for MTM services sets both a ceiling and a floor on the number of prescriptions that may be required. Therefore, a plan sponsor has the discretion to determine whether to target beneficiaries taking anywhere from two to eight medications. Our data indicate that 85 percent of the plans reviewed targeted beneficiaries in a range of two to eight medications.

As for targeting certain other beneficiaries for MTMP services, our regulations provide that sponsors must provide a minimum level of MTM services to targeted beneficiaries. To the extent a Part D plan wants to offer additional MTM services, or provide MTM services to individuals who do not meet the targeting criteria, including those individuals who have undergone a transition in their level of care, they may do so. However, additional administrative reimbursement will not be available for the provision of these additional services.

Comment: We received some comments regarding MTM targeting frequency. One commenter indicated that CMS should consider increasing the minimum requirements regarding the frequency with which plans conduct outreach to eligible beneficiaries for enrollment in MTM programs, and specifically recommended that beneficiaries be targeted for enrollment at least monthly.

Response: The requirement of quarterly targeting that was included in the proposed rule, and that is being adopted into this final rule, is a floor that Part D sponsors may build upon. Sponsors may adopt more frequent targeting than the minimum quarterly outreach threshold required under the regulation. We will also continue to monitor and evaluate MTM programs to determine if there is any significant difference in MTM outcomes when beneficiaries are targeted more frequently and will consider making further changes to our requirements if warranted.

Comment: One commenter believed a better method for targeting beneficiaries would be to examine an individual's historical and expected aggregate health care spending using a cost threshold for eligibility that is based on total projected Medicare spending, rather than just Part D spending.

Response: We do not agree with this approach. Pursuant to section 1860D–4(c)(2)(A)(ii)(III) of the Act, targeted beneficiaries are defined as Part D eligible individuals who “are identified as likely to incur annual costs for covered Part D drugs that exceed a specified level by the Secretary.” Accordingly, the statute does not afford CMS the flexibility to permit plans to target individuals for MTM services based upon their expected aggregate health care spending. Furthermore, given the complexity of this suggested alternative, we believe the collection and review of health care spending data prior to determining whether an individual will be targeted for MTM services would only delay access to MTM services.

Comment: One commenter indicated that a Part D sponsor's use of an opt-out only enrollment process for placing beneficiaries in its MTM programs must be carried out thoughtfully and carefully. CMS should require MTM program policies that promote patient collaboration with their physicians, provide adequate enrollment notification and include clear instructions on opt-out. CMS should also undertake an outreach initiative to physicians.

Response: We appreciate the commenter's concerns regarding the application of the opt-out method to enroll beneficiaries into MTMPs. However, we believe the opt-out approach is critical for the health and well-being of the Medicare population. The elderly and disabled populations are most at risk of polypharmacy consequences. Therefore, an opt-out enrollment policy that requires no further action by the enrollee helps to ensure that vulnerable individuals will be enrolled in MTMPs, which we believe will reduce adverse drug reactions and ensure safe prescription drug practices, before their health is at risk. In addition, CMS has found that the opt-out enrollment method is the preferred method among Part D sponsors to increase the number of beneficiaries participating in MTMPs. In 2008, fewer than 15 percent of MTMPs utilized an opt-in method. We will continue to monitor Part D plans to ensure they engage in best practices when applying the opt-out enrollment method to their plan members.

Comment: One commenter was concerned that the use of the initial coverage limit (ICL) as a targeting benchmark for Part D MTM may elevate cost considerations over clinical considerations in targeting beneficiaries for the Part D MTM program.

Response: To the extent that the commenter appears to be stating that it is improper to consider cost considerations in targeting beneficiaries for the MTM program, we disagree. As discussed above, section 1860D–2(c)(2)(A)(ii)(III) of the Act expressly instructs CMS to consider costs for Part D drugs when targeting beneficiaries for MTM. However, following further consideration of this issue, reliance on the ICL, which is specifically tied to the cost structure of the Part D benefit to target beneficiaries for MTM may be problematic. There have been further legislative proposals to restructure the Part D benefit, including revising the ICL, that may have unintended consequences for basing the MTM targeting criteria on the ICL. Accordingly, we believe the establishment of a specific dollar threshold is more appropriate and are reverting back to the \$3000 limit, which we previously established in the 2010 call letter. Consistent with statutory requirement that drug costs be considered in targeting beneficiaries for MTM, we will apply an index that is equal to the annual percentage increase in average per capita aggregate expenditures for Part D drugs. Specifically, we will adjust the \$3000 threshold by the index used to increase the ICL, as originally proposed, which is currently found at § 423.104(d)(5)(iv).

The decision to apply a \$3000 threshold is based upon program experience and our analysis of PDE data. We originally established the initial \$4000 cost threshold at the inception of the Part D program. At that time, it was estimated that approximately 25 percent of the Part D eligible population would meet the three criteria and be targeted for MTM services. After two years of experience and analysis of plan reported data, we found that only 10.0 percent of beneficiaries enrolled in a Part D plan with an approved MTMP were eligible for MTMP in 2006 (13.1 percent were eligible for MTMP in 2007). In 2008, we conducted an analysis using PDE data from contract years 2006 and 2007 obtained from the Integrated Data Repository (IDR) system. The total gross drug cost and number of beneficiaries that incurred annual drug costs (below) or (greater or equal) to the \$4000 cost threshold was determined. The average number of PDE fills and average cost per beneficiary was also calculated. Further analysis examined cost breakouts in \$500 increments to determine the distribution of beneficiaries, as well as the number of fills, and gross drug cost for beneficiaries with annual drug costs

within these breakouts. It was determined that close to 25 percent of Part D enrolled beneficiaries with drug utilization (beneficiaries with at least one PDE during the study period) during 2006 and 2007 had annual gross drug costs of at least \$3000. Therefore, CMS lowered the cost threshold to \$3000 in the 2010 Call letter. Based upon our analysis of the most recent data, it appears that this threshold will continue to ensure that approximately 25 percent of these beneficiaries utilizing the Part D benefit receive MTM services. Accordingly, we are adopting the \$3000 cost threshold in this final rule.

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

In the October 22, 2009 proposed rule, we offered further clarifications surrounding our formulary requirements associated with pharmacy & therapeutics (P&T) committees. As we explained in the preamble to the proposed rule, section 1860D–4(b)(3)(A) of the Act requires Part D sponsors to use a 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, pharmacoeconomic 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.

Based upon our experience with the formulary development process since the beginning of the Part D program, we have come to recognize that the application of prior authorization (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. Therefore, in accordance with section 1860D–4(b)(3)(A) and (b)(3)(B) of the Act, we proposed adding new paragraph § 423.120(b)(1)(ix) to require 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.

In this final rule, we adopt these provisions as proposed.

Comment: One commenter is concerned that utilization management (UM) requirements have become barriers to timely access, especially for the low-income population for whom the exceptions, reconsideration, and appeals processes are difficult to navigate. While UM tools may be used appropriately by a Part D plan, they may also result in impeding appropriate and timely access to prescribed medications and in themselves, can be discriminatory in beneficiary selection of the Part D plans to the extent that beneficiaries are even aware of the restrictions.

Response: It is our intention that the changes adopted specifying the responsibilities of the P&T committee in this final regulation will address this commenter's concern regarding potentially discriminatory practices that may affect beneficiary protections. We believe P&T committees are in the best position to ascertain whether certain UM tools, when applied to covered Part D drugs, will inappropriately impede access to these drugs, since the committee's membership includes independent practicing pharmacists and physicians with the clinical knowledge necessary to provide an unbiased review of the impact of UM tools on the Part D sponsor's formulary.

Comment: One commenter indicates that it supports CMS' improvement of the rigor of evidence supporting decisions of P&T committees, but encourages CMS to strengthen its evidence requirements even further. This commenter is concerned that the widely used treatment guidelines or clinical literature standard may not be specific enough and recommends that CMS amend § 423.120 to provide that a Part D sponsor may require that beneficiaries try drugs supported solely by off-label indications only if the sponsor demonstrates that there are generally accepted, widely used and evidence-based treatment guidelines or substantial and credible clinical literature that recommend patients use an off-label indication.

Response: The policy regarding a plan member's use of drugs for off-label indications is out of the scope of this final rule. However, we have recently adopted in our guidance (see the 2010 Call Letter released on March 30, 2009) that as part of our assessment of a formulary's appropriateness, Part D sponsors will not be permitted to require an enrollee to try and fail drugs supported only by an off-label

indication (an indication only supported in the statutory compendia) before providing access to a drug supported by an FDA approved indication (on-label indication) unless the off-label indication is supported by widely used treatment guidelines or clinical literature that we consider to represent best practices. Generally, we require such authoritative guidelines to be endorsed or recognized by Federal government entities or medical specialty organizations.

Comment: One commenter indicated that they agree, theoretically, that the P&T committee should not have to approve administrative PA criteria, such as Part B versus Part D coverage, but their experience has been that plans utilize administrative criteria as excuses not to cover drugs. Therefore, they believe P&T committees should review the administrative criteria to make sure they are being applied properly. Another commenter indicated that CMS allow plan sponsors to implement non-clinical UM criteria without the input and prior approval of their P&T committees.

Response: Consistent with the operational guidance in Chapters 6 and 7 of the Medicare Prescription Drug Benefit Program Manual, we continue to require Part D sponsors to submit utilization management requirements, such as prior authorization, step therapy and quantity limits not based upon the FDA's maximum daily dose limits, as part of their Health Plan Management System (HPMS) formulary submission. We believe these UM tools should be reviewed by Part D sponsor P&T committees for the reasons stated above.

However, we continue to believe that the administrative criteria a plan uses should not be subject to the P&T committee review because they do not require clinical information or justification. Moreover, we believe that when a beneficiary is subject to an administrative UM tool (that is, one that is not a coverage determination) that the beneficiary believes unfairly denies access to his/her prescription drugs, such cases can be addressed through the plan's grievance process. In accordance with § 423.564, Part D sponsors must provide meaningful procedures for timely hearing and resolving enrollee grievances. Chapter 18 of the Medicare Prescription Drug Benefit Manual defines a grievance as any complaint or dispute other than one that involves a coverage determination or a low-income subsidy or late enrollment penalty determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D sponsor, regardless of whether

remedial action is requested. Because another avenue exists for redress of a beneficiary's concern about administrative criteria such as "B versus D" determination, we decline to adopt the commenter's suggestion.

Comment: One commenter questioned the value of committing the resources of a P&T committee to review and approve quantity limits.

Response: We believe there is value to P&T committees reviewing quantity limits since the imposition of quantity limits can affect clinical outcomes. As we previously stated in the preamble to the proposed rule, quantity limits are as important to the clinical soundness of a plan's formulary as the drugs that are included on the formulary. The P&T committee, as a body of clinicians, should review the quantity limits to ensure restrictions do not affect a plan member's access to covered Part D drugs that could lead to health or life-threatening outcomes, especially when quantity limits are not based upon the FDA's maximum daily dose limits.

Comment: One commenter indicated that CMS provide Part D sponsors with minimum standards for P&T committees' clinical review and make those standards publicly available to further strengthen the clinical appropriateness of formularies.

Response: We disagree with the commenter's suggestion that we dictate minimum standards for P&T committees' clinical review. Section 1860D-4(b)(3)(B) of the Act requires the P&T committee base clinical decisions on the strength of scientific evidence and standards of practice, including accessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and on such other information as the P&T committee determines to be appropriate. Since the statute specifically directs P&T committees to make these clinical decisions, we believe it does not have the authority, or the capability, to establish clinical review criteria for the P&T committees.

Comment: One commenter urged CMS to continue to engage in robust formulary review to ensure that a plan formulary appropriately reflects the clinical needs of Medicare beneficiaries.

Response: We appreciate the comment, but changes to CMS' formulary review are outside the scope of this final rule. We are not making any further changes to our current formulary review process at this time because we believe we already conduct a robust formulary review consistent with the statutory and existing regulatory parameters, and current guidance.

Comment: One commenter indicated that plans inform beneficiaries of utilization management criteria prior to selecting their plans.

Response: As provided in § 423.128(c)(2), a Part D plan, upon the request of a Part D eligible individual, must provide the procedures the Part D plan uses to control utilization of services and expenditures. CMS guidelines for marketing materials spell out that as part of a plan's formulary, Part D plans must indicate any applicable utilization management tools (such as, prior authorization, step therapy, and quantity limit restrictions) for the drug. Also, formulary and utilization management criteria must be appropriately displayed on the plan's Web site.

Comment: One commenter requested that CMS require that P&T committee decisions be in writing, including the rationale behind formulary and utilization management policies, and that the committee's decisions be made public.

Response: As stated in response to the previous comment, utilization criteria are made available to the public prior to enrollment, and to enrollees of the plan. Additionally, § 423.120(b)(1)(viii) requires the Part D sponsor's P&T committee decisions regarding formulary development or revision, as well as utilization management activities, be documented in writing. However, the Part D sponsors may consider decision by their P&T Committees to be proprietary and for this reason, we decline to require plans to make them public.

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

In the October 22, 2009 proposed rule, we proposed revisions to part D requirements related to the disclosure to Part D enrollees who are residents of long term care institutions of any differential in pricing of drugs dispensed compared to generic equivalents. As we explained in the preamble to the proposed rule, 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).

When we issued the January 28, 2005 (70 FR 4273) Part D final rule, 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 were 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). However, 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.

We also came to realize that the generic equivalent information provided on the EOB is of no value to the long-term care beneficiary. Unlike the enrollee standing at the retail pharmacy counter at time of service, enrollees in long-term care institutions have limited opportunities to effect a switch to a lower-priced generic substitute before dispensing.

For the aforementioned reasons, we proposed revising § 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. In this final rule, we adopt these provisions as proposed.

Comment: A number of commenters supported this change. One commenter wanted to go even further and eliminate this requirement for all areas of pharmacy practice because it imposes an unreasonable administrative burden.

Response: We disagree that elimination of this requirement should be extended to all areas of pharmacy practice. Providing this information to the beneficiary at the time of purchase enables the beneficiary to choose the lowest priced product available at the pharmacy. The pharmacy can avoid the administrative burden by dispensing the lowest priced product.

Comment: Only one commenter did not support this change and thought that providing this information in the EOB would help identify fraud, waste, and abuse and enable the beneficiary to change at a later date.

Response: Although we agree that this information may have some value to a beneficiary in the long-term care setting,

the primary reason for removing this requirement is that it is unworkable from a plan operational standpoint considering the variable nature of generic pricing and the programming maintenance effort required, and we continue to believe that the value to the beneficiary, given the circumstances, does not justify the burden of maintaining the requirement.

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

In the October 22, 2009 proposed rule, we made corrections to current regulatory requirements that would align the 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. As we noted in the preamble to the proposed rule, 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. These standards are—

- *Urban*—a pharmacy within 2 miles of 90 percent of the beneficiaries;
- *Suburban*—a pharmacy within 5 miles of 90 percent of the beneficiaries; and
- *Rural*—a pharmacy within 15 miles of 70 percent of the beneficiaries.

We adopted into regulation the TRICARE 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. For example, a Part D sponsor may offer a high and low option at one price in

part of the contract’s service area, and also offer a high and low option at a different price in the remaining portion of the contract’s service area.

We noted that 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 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 also noted in the preamble 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 multistate regions. We noted that this approach is necessary to ensure that pharmacies are not unduly clustered in one part of the region.

Therefore, based on the preceding, we proposed to revise the text of the regulation that discusses pharmacy access in § 423.120(a)(1) 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 was necessary to correct the terminology in that location as well. Therefore, we proposed revising § 423.112(a) to specify the establishment of service areas for PDP sponsors. We are adopting the above changes without further modification into this final rule.

Comment: One commenter fully supported the proposed revision to the regulation clarifying access to Part D drugs be measured at the sponsor level, rather than at the plan level.

Response: We appreciate the support.

Comment: One commenter asked CMS to exercise its statutory authority to adopt regulations that would apply access standards more favorable to

beneficiaries to Part D sponsors by increasing the urban and suburban percentages to 95 percent, and increasing the rural standard to 10 miles and 85 percent. This commenter believes that the current access standards are too lax, especially in rural areas. Additionally, this commenter noted that measuring distance “as the crow flies” when evaluating pharmacy access may not be representative of true driving distance in certain locations.

Response: Our proposed regulatory change addressed only the organizational level at which the pharmacy access standards would be applied, not whether a change in those standards is warranted. While we appreciate the comment, we will not address it at this time as it is outside the scope of our proposal.

However, we wish to allay the commenter’s concern that measuring distance “as the crow flies” may actually underrepresent true driving distance. Presently, the software used by Part D sponsors to demonstrate they meet our retail pharmacy access standards has a feature that allows distance to be measured as estimated driving distance, and sponsors are instructed to use this feature.

Comment: One commenter suggested that CMS move toward a more automated and streamlined process for conducting the initial review and ongoing monitoring of Part D sponsor’s retail pharmacy networks. The commenter suggests CMS consider establishing a certification process whereby a first tier entity, such as a PBM, may submit one set of access reports in support of its certification. If found acceptable by CMS, all Part D sponsors using that PBM could demonstrate their compliance with the pharmacy access standards by submitting an attestation that the network they are using is already CMS-approved.

Response: We appreciate the comment and note that we are working on developing a more automated system for the submission of pharmacy network information. That said, the issue of our review of network adequacy and the processes we use is outside the scope of our proposal, and we therefore decline to address it in this rule.

Comment: One commenter urged CMS to create retail pharmacy access standards to ensure that beneficiaries have the choice of obtaining medication therapy management (MTM) services from their retail community pharmacies.

Response: This comment concerns the administration of MTM programs, not the methodology for the calculation of retail pharmacy access standards.

Therefore, we will not address this comment as it concerns an issue outside the scope of our proposed regulatory change.

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

In the October 22, 2009 proposed rule, we proposed to make several changes to § 423.568 related to the standard timeframes and notice requirements for coverage determinations under Part D. The first change we proposed was a technical change that would require Part D plan sponsors to accept standard coverage determination requests orally and in writing. This 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. As we explained in the preamble to the proposed rule, we proposed this change to § 423.568 because section 1860D-4(g) of the Act requires Part D sponsors to follow the same procedures as MA organizations with respect to organization determinations and reconsiderations, and we were proposing to make an identical revision to § 422.568 of the MA appeals regulations.

We also proposed to revise the timeframe for a Part D plan sponsor to notify an enrollee of a payment determination in § 423.568(b), and proposed to establish a regulatory timeframe for making payment to an enrollee when a decision is partially or fully favorable. The regulation currently requires a plan sponsor to notify an enrollee of its payment determination no later than 72 hours after receipt of a request, and manual guidance requires plan sponsors to make payment for fully or partially favorable decisions within 30 days of the request. The proposed revisions to § 423.568(b) would require a Part D plan sponsor to notify an enrollee of a payment decision no later than 14 calendar days after receiving a reimbursement request. If the decision is partially or fully favorable, the plan sponsor must also make payment within the same 14-day timeframe. For example, for partially and fully favorable decisions, a plan sponsor must both notify the enrollee of the decision and make payment no later than 14 calendar days after receiving the request). As noted in the preamble, we proposed to revise the reimbursement timeframes because we believe the existing 72-hour requirement is virtually impossible for plan sponsors to meet, and as a result, plan sponsors are issuing perfunctory denials. This outcome is not in the best interest of

Medicare's Part D enrollees. We were also concerned that the existing requirement would in effect force enrollees into the Part D appeals process despite the fact that the majority of these claims could have been paid within the 30-day reimbursement timeframe. Based on our experience and previous discussions with Part D plan sponsors, we determined Part D plan sponsors generally are capable of making reimbursement decisions and payment within a 14-day period following receipt of reimbursement requests. We believe the proposed revision to the timeframes for notifying enrollees of payment determinations will significantly increase the number of timely payment-related decisions by plan sponsors, and the revised timeframes for making payment will be more meaningful for the typical Medicare beneficiary who often cannot afford to wait 30 days to be reimbursed.

Finally, we proposed to add new paragraphs (d) and (e) to § 423.568, to explain the form and content of favorable coverage determination decisions. In § 423.568(d), we proposed requiring plan sponsors to send written notice of fully favorable decisions to enrollees. We also proposed to allow 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. In § 423.568(e), we proposed to require notice of fully favorable decisions to include the conditions of the approval in a readable and understandable manner. We noted these changes were 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.

After reviewing the comments received in response to these proposals, in this final rule, we adopt the proposed changes without modification. In addition, as explained below, we are adding paragraph (a)(3) to § 423.568, which will require plan sponsors to establish and maintain a method of documenting all oral requests and retaining the documentation in the case file.

Comment: Several commenters supported the proposed technical change that would require Part D plan sponsors to accept standard coverage determination requests orally and in writing, except for standard requests for payment which must be submitted in

writing. A commenter asked CMS to clearly articulate how plans are to record, track, and report oral requests. Another commenter suggested allowing plan sponsors to require the use of plan-specific forms for payment requests.

Response: We appreciate the comments we received in support of this proposal, and the commenter's concern about the processes plan sponsors should have in place to record, track, and report oral requests. We agree that it is important for plan sponsors to document and track requests that are submitted orally in order to determine if plan sponsors are processing requests in a timely manner. Therefore, in this final rule, we are adding a new paragraph (a)(3) to § 423.568, which will require plan sponsors to establish and maintain a method of documenting all oral requests and to retain that documentation in the case file. We do not agree with the suggestion to require the use of plan-specific forms for payment requests. We have, since the inception of the Part D program, required plan sponsors to accept any written request submitted by enrollees and prohibited plan sponsors from requiring the use of plan-specific request forms. We do not believe there is a compelling reason to depart from this standard. During this time, we have also received numerous requests to standardize the Part D coverage determination and appeals processes in order to create consistency and predictability for Part D enrollees, and we are continuously looking to improve the coverage determination and appeals processes. Allowing each plan to require the use of different forms for different requests moves us further away from creating a process that is easier for enrollees to navigate. Although we understand plan sponsors often need enrollees to submit specific information with reimbursement requests, requiring the use of a specific form does not guarantee that an enrollee will provide all information a plan sponsor needs to process the request (for example, an enrollee may not complete part of the form). When a reimbursement request is not complete, plan sponsors must either obtain the missing information or deny the request within the applicable decision making timeframe. Because we are extending the timeframe for resolving payment requests in this final rule, plan sponsors have more time to evaluate payment requests and obtain missing information when necessary.

Comment: We received many comments in response to the proposed revisions to § 423.568(b), which would require a Part D plan sponsor to notify an enrollee of a payment decision and,

if appropriate, make payment no later than 14 calendar days after receiving a reimbursement request. Some commenters that supported the 14-day timeframe for making a decision opposed the requirement to make payment within the same 14-day timeframe. The commenters objected because a 14-day payment cycle is not consistent with current industry standards, and moving the payment cycle to 14 days would require great expense to update current processes and systems, and would not offer any real benefit to enrollees who already have the prescription drugs in dispute. For these reasons, the commenters suggested maintaining the current 30-day payment timeframe. As an alternative, some of the commenters suggested allowing plan sponsors an additional 14 calendar days to make payment after a decision has been made. Other commenters suggested that CMS defer implementation of the 14-day timeframe until 2011.

We also received support for the proposed 14-day timeframe from a number of commenters, but the commenters also opposed extending the 72 hour decision-making timeframe. The commenters objected because extending the timeframe would cause an additional financial hardship for enrollees who pay out-of-pocket for prescriptions. The commenters argued the proposal would extend the appeals process by up to eleven days for enrollees who receive denials, and would prevent those enrollees from obtaining a decision by the Part D Independent Review Entity before a 30-day prescription runs out. For that reason, most of the commenters suggested retaining the 72-hour decision-making timeframe for reimbursement requests. As an alternative, a few of the commenters suggested that CMS maintain a 72-hour decision-making timeframe for payment requests that involve exceptions, and a 14-day decision-making timeframe for all other payment requests. Finally, one commenter believed that a 7-day timeframe would be acceptable for making payment-related decisions.

Response: After careful review and consideration of the numerous comments and suggestions we received about this provision, we continue to believe that the timeframes established in proposed § 423.568(b) strike the right balance between ensuring plan sponsors have enough time to properly adjudicate reimbursement requests, and creating a reimbursement timeframe that does not impose an undue hardship on Medicare beneficiaries who often cannot afford to wait 30 days before being reimbursed.

Some commenters raised concerns about plan sponsors not being able to make payment within 14 calendar days after receiving a reimbursement request in large part because most Part D plan sponsors process reimbursement requests under a 30-day billing cycle, which is the industry standard. However, we note that plan sponsors already have prior experience processing some reimbursement requests in less than 30 days. Pursuant to section 171 of MIPPA and the PDP Sponsor Application, Part D plan sponsors are required to make payment for certain reimbursement requests from out-of-network pharmacies within 14 calendar days. Although the 14 calendar day MIPPA requirement applies to reimbursement requests that are submitted electronically, we note the MIPPA requirement to illustrate that a 14-day timeframe for processing reimbursement requests is not unprecedented under the Part D program, and that plan sponsors currently have systems in place to accommodate billing cycles that are less than 30 calendar days. As noted in the preamble to the proposed rule, our experience and previous discussions with Part D plan sponsors on this issue led us to conclude that plan sponsors are capable of processing reimbursement requests and sending payment, when required, to enrollees within 14 calendar days after receiving a reimbursement request. In the 2009 Call Letter, we indicated that we would exercise our enforcement discretion to decline to bring an enforcement action for non-compliance with the 72-hour timeframe in § 423.568 if the plan sponsor processes a reimbursement request and submits reimbursement (when appropriate) within 14 calendar days after receipt of the request. As a result, plan sponsors have been permitted the option of either notifying enrollees of their reimbursement decisions within 72 hours and making payment within 30 days, or, providing notice of a reimbursement decision and sending payment (when a decision is partially or fully favorable) to the enrollee within 14 calendar days after receiving a reimbursement request.

We also understand the concerns about enrollees receiving decisions as quickly as possible. In particular, some commenters indicated the need for shorter timeframes when a request involves an exception. We agree, but note that the reimbursement process was intended primarily for use in resolving out-of-network issues. Consequently, we do not believe that it is the most efficient way to obtain

coverage decisions for non-formulary drugs or drugs subject to a utilization management requirement. Furthermore, using the reimbursement process to obtain coverage decisions for non-formulary drugs or drugs subject to a utilization management requirement does not obviate the need to provide medical documentation either demonstrating that an exception is needed or that a utilization management requirement has been met. In the former case, if the reimbursement request is submitted without a prescriber's supporting statement, the plan sponsor's decision making timeframe is tolled until the statement is received. Thus, we believe enrollees who need prescription drugs that either are non-formulary, or are subject to utilization management requirements that they cannot meet, would be better served by using the exceptions process. Under § 423.568(a), a plan sponsor must respond to a standard exception request within 72 hours of receiving the request and the prescriber's supporting statement, and consistent with § 423.572(a), a plan must respond to an expedited request within 24 hours of receiving the request and the prescriber's supporting statement.

Finally, we appreciate some commenters' concerns that the 14-day timeframe may result in enrollees receiving unfavorable payment determinations beyond the current 72-hour timeframe. Thus, in order to ensure that enrollees are able to access the appeals process as quickly as possible, we encourage plan sponsors to issue unfavorable determinations sooner than 14 days.

Therefore, we are finalizing the proposed revisions at § 423.568(b) to require Part D plan sponsors to notify an enrollee of a payment decision no later than 14 calendar days after receiving a reimbursement request. If the decision is partially or fully favorable, the plan sponsor must also make payment within the same 14 calendar-day timeframe.

Comment: We received a number of comments supporting the proposal to allow Part D plan sponsors to make the initial notice of favorable standard coverage determination decisions orally, so long as a written confirmation of the decision is mailed to the enrollee within three calendar days of the oral notice. However, one commenter suggested revising the three calendar day requirement to three business days.

Response: For the reasons noted in our response to a similar comment about the timeframe for providing written follow-up of notice of a fully favorable expedited redetermination decision, we do not agree that it is

necessary to revise “calendar days” to “business days.”

Comment: We received numerous comments supporting the proposal to require plan sponsors to include specific information (such as, the conditions of approval) in favorable coverage determination notices. However, one commenter opposed the proposed requirement and suggested allowing plan sponsors to provide the approval conditions on request.

Response: As noted above in our response to a similar comment relating to favorable redetermination decisions, we believe requiring plan sponsors to provide the condition(s) of approval in writing is an important enrollee protection that helps ensure continuity of care for Medicare beneficiaries who receive prescription drugs under Part D, and the commenter’s suggested approach would diminish that important protection.

Comment: We received several comments asking us to develop a model letter for fully favorable coverage determination decisions under § 423.568.

Response: As noted in our response to a similar comment regarding fully favorable redetermination decisions, we will explore developing either a model or standard notice for favorable decisions, and will publish any such notice in Chapter 18 of the Medicare Prescription Drug Benefit Manual.

10. Expediting Certain Coverage Determinations (§ 423.570)

In the October 22, 2009 proposed rule, we proposed to make a technical change to § 423.570 by removing the cross reference to § 423.568(a) and inserting a cross-reference to § 423.568(b). This change is necessary to be consistent with the proposed revisions to § 423.568. We did not receive any comments with regard to our proposed revision. Therefore, this final rule adopts this revision without change.

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

The October 22, 2009 proposed rule includes a proposed revision to § 423.572(b) that would require plan sponsors to send written notice of fully favorable expedited coverage decisions to enrollees, and allow 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 proposed to add paragraph (c)(2), which would require notice of a fully favorable expedited coverage determinations to provide the

conditions of the approval in a readable and understandable manner. As noted in the proposed rule, the rationale for adding these requirements is consistent with our rationale for adding form and content requirements for favorable standard coverage determination decisions, and in so doing, ensures enrollees are able to maintain continuity in their prescription drug treatment.

Finally, we proposed to revise § 423.572(c)(2)(i) by requiring plan sponsors to issue adverse expedited coverage determination decisions using CMS approved language in readable and understandable form. As noted in the preamble to the proposed rule, this proposed change would reconcile a discrepancy in the regulations by requiring plan sponsors to use the standardized denial notice (Form CMS–10146) for both standard and expedited adverse coverage determinations. Currently, the regulations require the use of the standardized denial notice only for standard adverse coverage determinations. The only comment we received on this provision was supportive of the change. Accordingly, we are adopting the proposed revision to § 423.572(c)(2)(i) as set forth in the proposed rule without change.

Comment: We received a number of comments supporting the proposal to allow Part D plan sponsors to make the initial notice of favorable expedited coverage determination decisions orally, so long as a written confirmation of the decision is mailed to the enrollee within three calendar days of the oral notice. However, one commenter suggested revising the three calendar day requirement to three business days, and another commenter recommended allowing plan sponsors to send the first notice in writing, but not requiring plan sponsors to send additional written notices when any related refills are approved.

Response: For the reasons noted in our response to a similar comment about the timeframe for providing written follow-up of notice of a fully favorable expedited redetermination decision, we do not agree that it is necessary to revise “calendar days” to “business days.” Also, as previously noted, we believe a written notice should follow every favorable decision, including favorable decisions to approve refills. This policy will help to ensure continuity of care for Medicare beneficiaries who are obtaining refills of prescription drugs under Part D. We note that additional favorable decisions for refills are not necessary if the coverage determination or appeal decision specifically authorizes refills for the remainder of the plan year.

Comment: We received numerous comments supporting the proposal to require plan sponsors to include the conditions of approval in favorable decision notices. However, one commenter opposed the proposal and suggested allowing plan sponsors to provide the approval conditions on request. A different commenter asked CMS to exempt Special Needs Plans (SNPs) from the written-notice requirement for favorable decisions because SNPs hire nurse case managers to make sure an enrollee’s medication supply is not interrupted. Thus, enrollees receiving medications from SNPs do not need to know the conditions of an approval.

Response: As noted in our responses to similar comments, requiring plan sponsors to provide the conditions of approval in writing is an important enrollee protection that helps ensure uninterrupted drug coverage for Medicare beneficiaries who receive prescription drugs under the Part D program. We believe implementing the commenters’ suggestions would diminish this important protection because without this requirement, enrollees would likely not receive timely notice of the coverage limits for approvals. Without this information, enrollees may experience interruptions in coverage. Thus, the best way to ensure that enrollees receive timely notice and understand the conditions that apply to their approvals is to require plan sponsors to consistently provide this information, in writing, to all enrollees.

Comment: We received several comments asking us to develop a model letter for fully favorable decisions issued under § 423.572.

Response: As noted in our response to an earlier comment, we will explore developing either a model or standardized notice for use in issuing favorable notices and will publish any such notice in Chapter 18 of the Medicare Prescription Drug Benefit Manual.

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

In the October 22, 2009 proposed rule, we proposed revisions to § 423.551 and proposed adding a new paragraph § 423.551(g) to restrict the situations in which we will approve the novation of a PDP sponsor’s contract. A change in ownership of an existing sponsor’s PDP contract(s) can promote the efficient and effective administration of the Part D 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 all of the PDP contracts held by that PDP sponsor. Therefore we have proposed these revisions in order to restrict a 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 recommended becoming more prescriptive in this area because our experience gained over the first 4 years of the program indicates this is necessary. As we noted in the preamble to the proposed rule, our policy goals are not served when a sponsor uses the novation process to purchase a piece of another sponsor's contract with CMS for less than the full line of PDP business. We do not agree that picking and choosing which markets a sponsor wishes to serve at any given time and to profit from its exit from a given PDP region is most efficient when a simple nonrenewal for that region is an option available to the sponsor. Moreover, this process should not be used as an instrument for moving LIS beneficiaries when a particular sponsor has missed the benchmark.

We believe that the change we proposed creates consistency between the Part C program and the Part D program, because the Part C regulations only permit novations that include the entire MA line of business (that is, all MA contracts held by a single legal entity).

We adopt these provisions as proposed. As noted below, we amend § 423.551 to clarify that these provisions do not apply to changes of ownership between subsidiaries of the same parent organization.

Comment: Several commenters expressed concern that the proposed policy could cause greater disruption for beneficiaries by limiting sponsors' ability to divest and acquire certain Part D contracts in situations where those transactions would have few effects on beneficiaries. The commenters believe that the proposed change may result in Part D sponsors withdrawing plan benefit packages and bid submissions, prevent acquisitions and mergers, or cause mid-year terminations, if the novation option no longer is available in many situations. The commenters also believed that this change could impact CMS efforts to consolidate PBPs and service areas under one contract number.

Response: We believe that there are adequate PDP choices for beneficiaries, and that restricting novations as proposed is in the best interest of the Part D program. We do not believe that the proposed change would negatively impact a sponsor's ability to consolidate PBPs even if the plans are located in different geographical areas. To the extent that this comment concerns the application of this policy to novations among subsidiaries of the same parent organization, CMS agrees that those types of transactions should be permitted and would not require the transfer of an entire line of Medicare business. Novations between the subsidiaries of the same parent organization do not involve the buying and selling of beneficiaries; rather, they are usually undertaken to accommodate an organization's change to its internal corporate structure. Therefore, we have modified our proposed regulatory language to clarify that the new policy does not apply to changes of ownership between subsidiaries of the same parent organization.

Comment: One commenter stated that no change is needed in the current regulation to accomplish CMS' policy goal. The commenter, citing § 423.552(a)(3)(ii), believed that CMS already has authority to determine whether a proposed novation is in the best interest of the Medicare program and that CMS did not need to change the regulation to keep this authority. The commenter expressed concern, however, that the proposed change would limit CMS's flexibility to approve a novation of some but not all of an entity's Part D contract(s), even if CMS determined that it was in the best interest of the program to approve the novation. The commenter added, that if CMS does not retain the authority to approve a novation representing less than an organization's entire line of PDP business, the acquiring company would have to terminate the contract, causing substantial member disruption.

Response: We believe that a change to the regulation is necessary to provide clarity to sponsors regarding the circumstances under which a PDP novation would be approved by CMS. Additionally, we believe that beneficiary disruption in situations where a sponsor nonrenews a contract because it is not eligible to be novated, is minimized by comprehensive nonrenewal beneficiary rights and required notifications, and that beneficiary election rights trump any member disruption that occurs due to a nonrenewal.

Comment: One commenter stated that it agreed with CMS that the novation

process should not be used, either in Part C or Part D, to pick and choose profitable markets, but it did not interpret the current Part C regulation related to the novation process to only allow novations that include the entire MA line of business (that is, all MA contracts held by a single legal entity). The commenter stated that there are unique circumstances where a change of ownership may be specific to Special Needs Plans (SNPs) that may be better served under new ownership that has a specialized model. The commenter suggested that the proposed provision be modified (and our Part C regulations modified as well) to allow for exceptions, especially with regard to SNPs.

Response: We have consistently interpreted the Part C regulation to limit novations in situations involving the sale of less than an entity's entire MA line of business. Also, SNP plans do not present unique circumstances that would require an exception to our proposed policy change. If a SNP plan can no longer serve its enrollees, there is existing regulatory authority pursuant to which the failing SNP can non-renew or terminate its Medicare contract. CMS can then exercise its regulatory authority related to plan enrollment to ensure that affected beneficiaries either elect or are assigned to an appropriate new plan.

Comment: Several commenters supported this change to the regulation, and agreed with the underlying reasoning used by CMS to make this change and become more prescriptive in this area.

Response: We appreciate these comments.

Comment: A few commenters stated that CMS should allow novations of one contract, where a selling sponsor holds multiple contracts, because otherwise PDP sponsors will have to resort to holding PDP contracts under different legal entity names in order to avoid having to novate all contracts as required under the proposed requirement, or terminating a contract, which would result in beneficiary disruption.

Response: A sponsor is already afforded ample opportunity to leave a particular Medicare market through the contract non-renewal process. That process does not require that a sponsor non-renew all of its contracts, so there is no need for organizations to hold contracts through multiple legal entities. The beneficiary disruption in this instance would be no more than that already contemplated by the Congress and CMS when it adopted and implemented a program which featured

the right of beneficiaries to elect their own health and drug plan coverage. Therefore, we believe that limiting novation to the entire line of PDP business is the best interest of the Part D program.

Comment: One commenter asked CMS to clarify that the proposed change would not prevent a sponsor from novating its Part D contract in connection with sale of an MA–PD Plan while retaining the entity’s stand-alone Part D Plan contract or vice versa.

Response: We agree that in the scenario described by the commenter, the organization would be permitted to retain a stand-alone PDP sponsor contract after it had transferred ownership of all of its Medicare Advantage contracts, including those through which it had been offering Part D benefits. We believe that the regulation makes this point clear on its face as the language specifically mentions only PDP contracts.

Comment: One commenter encouraged CMS to reconsider its proposed position that a Part D contract can only be novated when the “entire line of business” is involved. The commenter stated that there are important differences between Part C and Part D contracting including the notion that Part D contracts are national in scope and Part C contracts generally conform to State boundaries. The commenter stated that the suggested alignment between Part C and Part D contract novation policy as discussed in the preamble is not true when the practical impact of that policy is considered.

Response: The commenter has not made clear, and we are unable to determine on its own, how the stated difference between Part C and D service areas affects the novation policy we adopt in this regulation. Therefore, we retain our belief that a change to the regulation to limit PDP novations to the entire line of business is in the best interest of the Part D program.

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

Under the authority in section 1876(i)(3)(D) of the Act to impose “other terms and conditions” under contracts authorized by the statute that the Secretary finds “necessary and appropriate,” and in implementation of the requirements in section 1876 of the Act set forth below, we proposed in our October 22, 2009 proposed rule to apply the following MA program requirements to cost contracts authorized under section 1876 of the Act:

- The MA program requirements on appeals processes for contract determinations and intermediate sanctions under the authority in section 1876(i)(1) of the Act to terminate or non-renew contracts, and the authority in section 1876(i)(6) of the Act to impose intermediate sanctions and CMPs (To the extent that the CMPs 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

- The MA program’s marketing requirements 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 specific revisions we proposed are summarized below.

a. Cost Contract Determinations (§ 417.492 and 417.494), Civil Money Penalties (§ 417.500), and Intermediate Sanctions (§ 417.500)

We proposed requiring cost contracts to follow the contract determination appeal procedures under Subpart N of Part 422. We proposed codifying these requirements in § 417.492(b)(2), concerning notice of appeal rights, and § 417.494, concerning notice of termination.

We proposed revising § 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. We proposed, in new paragraph (c), to 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.

Our proposed revisions 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).

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.

We are adopting our proposed changes to § 417.472, § 417.492, § 417.494, § 417.500, § 417.640, § 417.640, § 417.642 through § 417.694, and § 417.840 without further modification in this final rule.

Comment: Two organizations expressed concerns about extending the MA requirements for appeals of contract determinations to cost contract plans. Both commenters point to differences in cost contract plans and MA plans as their basis for seeking revisions to our proposals.

One commenter suggested that CMS’ approach of cross referencing the MA appeals provisions in the cost plan requirements is unworkable for three reasons: (1) There are provisions of Part 422, Subpart N, that would not apply to Medicare cost plans, for example, organizations may not submit an application to obtain a new section 1876 contract; (2) there are termination/non-renewal provisions under part 417 that are not addressed under Part 422, for example, the obligation to non-renew a portion or all of the service area under the so called two-plan competition test at § 417.402(c); and (3) simply indicating that part 422 references should be read as Part 417 references does not provide the reader with guidance regarding the applicable provisions. This commenter asserts that, without specific cross references, the reader is left to guess which sections of part 417 would substitute for the sections of part 422 cited in part 422 subpart N and that, in some cases, there are no directly analogous provisions under part 417. Thus, it is unclear in this commenter’s view whether CMS intended to create a new requirement for cost plans in a specific provision, or whether the provision does not apply. The commenter recommends that CMS not simply cross reference subpart N, part 422, in part 417 but revise the language in part 417 to incorporate structure that is similar to the part 422 rules for terminations, but includes relevant part 417 cross references and is modified to appropriately apply to Medicare cost plans.

The second commenter also believed that CMS’ proposed approach would not provide sufficient clarity to cost contracts regarding the requirements that apply to them. For example, there are provisions of part 422, subpart N

that would not apply to cost contracts, and there are termination/non-renewal provisions under part 417 that are not addressed under part 422. Accordingly, the commenter recommended that CMS revise the language in part 417 to incorporate a structure that is similar to the part 422 rules and is modified to appropriately apply to Medicare cost plans.

Response: We agree with the commenters that there are differences between cost plan and MA plan procedures in this area but believe that the differences are minimal with respect to the application of the MA provisions concerning appeals of contract determinations. We stated clearly in the preamble of the proposed rule that the part 422 regulations concerning appeals of non-renewals, terminations, and imposition of intermediate sanctions and CMPs would apply to cost contracts. Therefore, we believe there should be no ambiguity in this regard. In other words, if there is no “analogous provision” under part 417, as one of the commenters wrote, cost plans would follow the part 422 requirements. Concerning the possibility of confusion resulting from different CMPs for cost plans and MA plans, we did acknowledge in the proposed rule, in both the preamble and regulations text at § 417.500(c), that CMPs for cost plans would be assessed according to the statutory requirements at section 1876(i)(6)(B) of the Act. We do not agree with the commenter that additional regulations for part 417 are necessary to capture this distinction.

With respect to the other discrepancies that the commenter asserts make incorporation of the part 422 regulations “unworkable,” we do not believe that there should be any confusion about appeal of contract determinations as a result of cost plan competition requirements. The application of such requirements is statutory, and non-renewal of a cost plan based on the statutory requirement is not appealable. We note that the current regulations for Part 417 do not indicate that such a decision may be appealed. Concerning the commenter’s other example of an allegedly unworkable discrepancy, the fact that there may be no new cost plans and thus no new applications, we note that the part 422 contract determinations include not only decisions on new applications, but determinations concerning non-renewals and terminations, and thus have relevance to cost contracts. The part 417 regulations are clear that there may be no new cost plans, as is CMS guidance, and we do not believe that the part 422 contract

determination provisions would lead anyone to believe otherwise.

Finally, we believe it is most efficient to cross-reference the part 422 regulations as specified in the proposed rule and are, therefore, adopting the language in that rule.

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

As noted above, based on the authority in section 1876(c)(i)(C) to regulate marketing and the authority in section 1876(i)(3)(D) to specify new section 1876 contract terms, we proposed 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 proposed that cost contracts authorized under section 1876 of the Act follow the same standards, with respect to definitions concerning marketing materials, as MAOs under § 422.2260, including how marketing materials are defined. We also proposed that the part 417 marketing regulations be revised to provide that, consistent with the requirements regarding review and distribution of marketing materials at § 422.2262, cost contractors 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.

We proposed to apply the same standards with regard to CMS review of marketing materials 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 proposed that, in markets with a significant non-English speaking population, cost contract plans be required to provide materials in the language of these individuals.

We proposed 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.

We proposed to extend to cost contract plans the following provisions at § 422.2268—

- Plans may not offer gifts to potential enrollees, unless the gifts are of nominal value (as defined in the CMS Medicare Marketing Guidelines), 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;

We proposed to extend to cost contract plans authorized under section 1876 of the Act the following requirements for MAOs under § 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 CMS 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.

We proposed 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.

We are adopting our proposed changes to § 417.428 without further modification in this final rule.

Comment: All commenters support applying the MA marketing requirements to cost contract plans. A few of these commenters note, however, that CMS is not applying one of the marketing sections (§ 422.2276) which exempts from the prior review and approval requirements marketing materials designed for members of an employer group. While one of the commenters on the employer group requirement notes that cost contracts are not eligible to offer 800-series plans for their medical benefits, the commenter notes that cost contracts have always been permitted to negotiate with employers to offer additional benefits to their employer group members. The commenter believes there is no statutory or policy reason for treating cost contracts differently than MA plans with respect to marketing materials furnished for employer groups and asks that all MA marketing provisions, including § 422.2276, apply to cost plans. Another commenter believed that while it makes sense, in general, to apply the MA marketing requirements to cost contract plans, there are several differences between MA and cost contract plans, and that these should be reflected in updated Medicare Marketing Guidelines.

Response: In order to permit employer group health plans to tailor plans best suited to their enrollees and to communicate such information to enrollees, we have permitted waivers of the requirement that MA-eligible individuals in an MA plan service area be eligible to enroll in the plan in order to permit an MA plan to be composed solely of members of an employer group plan (an “800 series plan”). Because non-employer group members are not eligible to enroll in such plans, and the employer generally provides information to group members, we have waived certain requirements, such as the prior review and approval requirement for marketing standards for 800 series plans based on the statutory authority to permit such waivers at 1857(i)(1) of the Social Security Act. There is no such general waiver authority with respect to other MA plans or cost plans that would permit

such plans to limit enrollment to a particular group, or to waive statutory marketing requirements, and CMS thus would not have the authority to exempt cost plans from such marketing requirements. We are, therefore, adopting the language from the proposed rule. Concerning the suggestion that CMS update the Medicare Marketing Guidelines to reflect any difference between cost plans and MA plans, we are unsure to which specific provisions, if any, the commenter is referring but in revising the guidelines, will point out any necessary distinctions between MA and cost plan procedures and policies.

Comment: One commenter recommends that CMS amend the cost plan enrollment regulations to allow beneficiaries the option of electronic enrollment into cost plans in the same manner as MA organizations.

Response: This comment is outside the scope of this rulemaking, and therefore, is not addressed in this final rule.

14. Out of Scope Comments

Comment: A number of commenters asked CMS to revise § 423.562(a)(3) to eliminate the option of posting Form CMS-10147 Medicare Prescription Drug Coverage and Your Rights, also known as the Pharmacy Notice, in network pharmacies. The notice instructs enrollees to contact their plan sponsors to request coverage determinations or exceptions when they disagree with the information provided at the pharmacy counter. The commenters recommended requiring plan sponsors to arrange with network pharmacies to give enrollees copies of the Pharmacy Notice whenever prescription drugs are not covered or are covered but subject to utilization requirements that cannot be resolved at the point-of-sale, or if an enrollee pays out-of-pocket for prescription drugs for either of these reasons.

Response: The commenters' suggestion is outside the scope of the proposed rule. However, we agree that receiving a written copy of the Pharmacy Notice in any of the situations described by the commenters is more beneficial for an enrollee than being referred to a copy of the notice posted in the pharmacy. We will consider this suggestion for future rulemaking.

Comment: A number of commenters asked CMS to allow an enrollee to send an appeal request to the Part D Independent Review Entity (IRE) when a coverage determination or redetermination decision is not received timely. The commenters also asked CMS to closely monitor plan compliance to

determine if coverage determination and redetermination requests are timely forwarded when appropriate, and impose sanctions on plan sponsors that are not meeting these requirements.

Response: The commenters' suggestion is outside the scope of the proposed rule. However, we want to note our disagreement with the commenter's proposal to allow enrollees to request appeals when plan sponsors fail to make timely decisions. We currently require plan sponsors to automatically forward redetermination requests that are not timely decided to the Part D Independent Review Entity for review once the decision-making timeframe has expired, and we have processes in place to monitor and plan performance in this area and impose sanctions when necessary. Furthermore, the Part D IRE currently tracks the volume of cases that are automatically forwarded from plan sponsors. The current auto-forwarding rate of 30 percent is not insignificant, so it appears that plans are appropriately auto-forwarding cases when they miss the decision-making timeframes.

Comment: Numerous commenters asked CMS to allow public access to the prescription drug compendia used to determine if a drug may be approved under the Part D exceptions process.

Response: The commenters' suggestion is outside the scope of the proposed rule. We note that any private or public entity may obtain access to the prescription drug compendia by contracting with the publishers.

Comment: A commenter, in response to the revisions proposed to § 423.590, requested clarification that the Part D Independent Review Entity is responsible for completing expedited reconsideration reviews.

Response: We did not propose to revise any of the regulatory provisions pertaining to the Part D reconsideration process, which is conducted by the Part D Independent Review Entity for both expedited and standard appeals. However, we did propose to revise the Part D expedited redetermination process conducted by the Part D plan sponsor. In the related preamble discussion, we referenced the expedited reconsideration process conducted by MA organizations under § 422.590 to illustrate a discrepancy between that process and the expedited redetermination process conducted by Part D plan sponsors under § 423.590. We believe the reference to the MA expedited reconsideration process may have confused the commenter, and given the impression that we were proposing changes to the Part D

reconsideration process when we were not.

H. Changes To Implement Corrections and Other Technical Changes

In this section, we address six technical changes to the regulations

proposed in our October 22, 2009 proposed rule outlined in the Table 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	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)

In the October 22, 2009 proposed rule, we proposed a technical correction to the regulations governing Health Care Prepayment Plans (HCPP) intended to ensure that HCPP enrollees have access to fast-track appeals for comprehensive outpatient rehabilitation facility (CORF) services furnished by an HCPP. As we explained in the preamble to the October 22, 2009 proposed rule and in the January 28, 2005 MA final rule, we required cost plans (HMOs), including HCPPs, that are 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. In applying the MA appeals procedures to HCPPs by regulation, we adapted and implemented the section 1869 appeal rights that apply to Original Medicare beneficiaries to the circumstances of beneficiaries enrolled in an HCPP. Because HCPPs only provide Part B services, in our January 28, 2005 final rule (70 FR 4194), we explicitly limited the application of subpart M, for the HCPPs, to those provisions affecting Part B services delivered to HCPP enrollees, and intended to encompass all Part B services. However, in doing so, we inadvertently failed to include the fast-track appeal rights regarding Part B services provided by a CORF. In a proposed revision to § 417.840, we proposed to correct this oversight, and ensure that HCPP enrollees have access to fast-track appeals for CORF services furnished by an HCPP. This revision would also ensure that HCPP enrollees received the fast track appeal rights provided for under section 1869 of the Act with respect to such services (which

parallel those available to section 1876 cost enrollees and Part C enrollees).

We received only one comment on this clarification, and the commenter supported our proposed technical revision. Accordingly, we are revising § 417.840 as set forth in the proposed rule without change.

2. Generic Notice Delivery Requirements (§ 422.622 and § 422.626)

In the October 22, 2009 proposed rule (74 FR 54700), we proposed to make technical revisions to § 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 currently 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, our intent was to make delivery of the IM the hospital's responsibility, and the form instructions for the IM state this. Similarly, § 422.626 of subpart M inadvertently states that delivery of the Notice of Medicare Non-Coverage (NOMNC) is the MA organization's responsibility. Again, consistent with the form instructions for the NOMNC, our intent was to make delivery of the notice the provider's responsibility. To address these technical errors, we proposed replacing "MA organization" with "hospital" in § 422.622, and "provider" in § 422.626.

The only comment we received regarding these provisions was supportive of the proposed technical revisions. Thus, we are making these revisions as set forth in the proposed rule without change.

3. Revision to Definition of Gross Covered Prescription Drug Costs (§ 423.308)

In the October 22, 2009 proposed rule, we proposed to revise the definition of "gross covered prescription drug costs" in § 423.308 to correctly reference both "negotiated prices" paid to network pharmacies and "usual and customary prices" paid to out-of-network pharmacies. Specifically, we proposed 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)." 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."

As we noted in the preamble to the October 22, 2009 proposed rule., the January 12, 2009 final rule (74 FR 1494) included revisions to the definition of "gross covered prescription drug costs" in the Part D regulations at § 423.308. In amending § 423.308 in that final rule, we made a technical error in the definition of "gross covered prescription drug costs" (74 FR 1545) by referencing "negotiated price" as 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" in that final

rule, 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. Since 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 must include costs incurred for covered Part D drugs at out-of-network pharmacies, as well as costs incurred at network pharmacies. Therefore, we needed 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. We received two comments, both of which supported the proposed revision to the definition of “gross covered prescription drug costs.” The commenters agreed with our proposed correction to add a reference to “usual and customary prices” paid to out-of-network pharmacies in the definition of “gross covered prescription drug costs.” Therefore, we are adopting this revision to the definition of “gross covered prescription drug costs” in § 423.308 as proposed.

4. Application Evaluation Procedures (§ 422.502(c) and (d) and § 423.503(c) and (d))

In the October 22, 2009 proposed rule, we proposed two amendments to regulations governing the application evaluation procedures at § 422.502(c) and (d), and § 423.503(c) and (d). In addition, at § 422.502(c)(3)(iii) and § 423.503(c)(3)(iii) we proposed to make a technical correction and delete the language “right to reconsideration” and replace it with “right to request a hearing”.

As we noted in the preamble to the proposed rule, currently, § 422.502(c)(3)(iii) and § 423.503(c)(3)(iii) state that if we deny the application, CMS gives written

notice to the contract applicant indicating the applicant’s right to request reconsideration. In our 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.

In the October 22, 2009 proposed rule, we also proposed to delete § 422.502(d) and § 423.503(d). Sections 422.502(d) and 423.503(d) currently provide that we have the ability to oversee the sponsoring organization’s continued compliance with our 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. We noted that this regulation is not an appropriate regulation for a section dedicated to the evaluation and determination procedures for approving or denying a contract application.

We received no comments on these provisions. Accordingly, we are adopting these provisions as proposed.

5. Intermediate Sanctions (§ 422.750(a) and § 423.750(a))

In the October 2009 proposed rule (74 FR 203), we made three technical changes to each intermediate sanction regulation at § 422.750 (a) and § 423.750(a) to more accurately reflect the statute. First, we changed § 422.750(a)(1) and § 423.750(a)(1), which stated that we may impose a suspension of enrollment of Medicare beneficiaries. This regulation did not adequately reflect the statutory language which specifies that the enrollment suspension applies to the “sponsoring organization’s enrollment of Medicare beneficiaries.

We also changed the language of § 422.750(a)(2) and § 423.750(a)(2), which stated 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, which states that suspension of payment may be imposed for Medicare beneficiaries enrolled after the date we notify the organization of the imposition of an intermediate sanction.

We also proposed to change § 422.750(a)(3) and § 423.750(a)(3), which stated we may suspend all marketing activities to Medicare beneficiaries by a sponsoring

organization for specified MA or Part D “plans.” We deleted the words “for specified” MA or Part D “plans” because those did not conform to the statutory language that applies intermediate sanctions at the organization level.

We received no comments on these provisions. Accordingly, we are adopting these provisions as proposed.

6. Basis for Imposing Intermediate Sanctions and Civil Money Penalties (§ 422.752 and § 423.752)

In the October 22, 2009 proposed rule, we proposed 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 statutory language and to ensure accuracy, consistency, and uniformity. Specifically, we proposed to amend § 422.752(a)(1) and § 423.752(a)(1) to conform with 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.

We also proposed to amend § 422.752(a)(3) and § 423.752(a)(3) to conform with statutory language and stated 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.

Additionally, we proposed 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.

As we noted in the proposed rule, sections 1857(g) and 1860D–12 of the Act provide a list of the 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.

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.

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.

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.

Finally, we made 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 deleting the reference to § 422.510(a)(4) and § 423.509(a)(4) and replace with a reference to § 422.510(a)(2)(iii) and § 423.509(a)(2)(iii).

We received no comments on these provisions. Accordingly, we are adopting these provisions as proposed.

III. Provisions of the Final Rule

Except as otherwise noted below, this final rule adopts the provisions of the proposed rule. The provisions of this final rule that differ from the proposed rule are as follows:

- Changes to Strengthen Our Ability to Distinguish for Approval Stronger Applicants for Part C and D Program Participation and to Remove Consistently Poor Performers.
- Notice of Intent to Apply. We modified § 422.503(b)(2) and § 423.502(b)(2) to clearly indicate that the decision not to submit an application after submission of a notice of intent will not result in any compliance consequences.
- Compliance Programs under Parts C and D—

++ We made changes made to § 422.502(b)(4)(vi)(B) and § 423.504(b)(4)(vi)(B) to provide that the compliance officer must be an employee of the sponsoring organization, parent organization or corporate affiliate and clarify that they may not be an employee of a first tier, downstream or related entity of the sponsoring organization and must be accountable to the governing board of the sponsoring organization.

++ At § 423.504(b)(4)(vi)(C)(3), we adopt a new regulation for the Part D program to specify that first tier, downstream, and related entities have met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program and accreditation as a Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) supplier are deemed to have met the training and educational requirements for fraud, waste, and abuse.

- Termination of Contracts under Parts C and D. We did not finalize the modifications to § 422.510(a)(2)(i), § 423.509(a)(2)(i) (failure to comply with regulatory requirements), § 422.510(a)(2)(ii) and § 423.509(a)(2)(ii) (failure to comply with performance standards).

- Maximum Allowable Out-of-Pocket Cost Amount for Medicare Parts A and B Services. At § 422.100(f)(4) with one modification regarding its applicability to all MA plans.

- Transition Process Under Part D (§ 423.120(b)(3)). At § 423.120(b)(3), we are modifying proposed paragraph (iii) to clarify that transition notices must be sent to beneficiaries within 3 business days of adjudication of a temporary fill.

- Beneficiary Communications Materials Under Parts C and D

++ Revised paragraph § 422.2260(5)(vii) to retain materials

about membership activities (for example, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or annual notification materials) in the definition of marketing materials.

++ Added a new paragraph § 422.2260(6) to specifically exclude from the definition of marketing ad hoc customized or situational enrollee communications from the definition of marketing materials.

- Use of Standardized Technology under Part D. At § 423.120, we clarify that the effective date for the requirement for a unique RxBIN or RxBIN/RxPCN combination and a unique Part D Rx identifier for each individual Part D member will be January 1, 2012.

- Notice of Alternative Medicare Plans Available to Replace Nonrenewing Plans Under Parts C and D.

- Revised § 422.506 and § 423.507 to require that both Part C and Part D organizations inform beneficiaries of both MA and PDP available options.

- Made minor technical changes to § 422.254(a)(4), § 423.265(b)(2), § 422.256(b)(4)(i) and § 423(b)(3)(i).

- RADV Appeals Processes.

++ In § 422.2 we are—

— Removing the definition of

documentation dispute process; and

— Adding the definition of initial validation contractor (IVC).

++ In § 422.311 we are revising the audit dispute and appeals processes.

- Changes to Improve Data Collection for Oversight and Quality Assessment

++ At § 480.140(g), we clarify that QIOs must disclose quality review study information collected by the QIOs as part of the RHQDAPU program, as defined in section 1886(b)(3)(B) of the Act, to CMS.

++ We also modify § 422.153 to indicate that we will acquire quality review study information from QIOs as defined in part 475.

- CAHPS Survey Administration Under Parts C and D. At § 417.492 and § 422.152, we clarify that all cost contracts under section 1876 of the Act 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 Medicare plan enrollees in accordance with CMS specifications and submit the survey data to CMS.

- Protected Classes of Concern under Part D. We are not finalizing our proposed revisions to § 423.120(b)(2)(v).

- Pro-rating the Plan Deductible for Part C MSA Enrollments Occurring

During an Initial Coverage Election Period. We are modifying § 422.103(d) in this final rule to allow beneficiaries who enroll in a MSA plan mid-year to also pay a pro-rated deductible. Medication Therapy Management Programs Under Part D—At § 423.153(d)(2)(iii), we adopt the establishment of a specific threshold of \$3,000 for MTM eligibility, instead of relying on the ICL as the proposed target for MTM eligibility.

- Standard Timeframe and Notice Requirements for Coverage Determinations Under Part D. We add paragraph (a)(3) to § 423.568, which will require plan sponsors to establish and maintain a method of documenting all oral requests and maintaining the documentation in the case file.

- Novations. We amended § 423.551 to provide clarity to sponsors regarding the circumstances under which a PDP novation would be approved by CMS, noting that they do not apply to changes of ownership between subsidiaries of the same parent organization.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The following sections of this document contain paperwork burden but not all of them are subject to the information collection requirements (ICRs) under the PRA for reasons noted.

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. 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.

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 COB Contractor in accordance with the processes and timeframes specified by CMS. In the proposed rule, we estimated the burden associated with this requirement to be the time and effort necessary to report the specified information to CMS on an ongoing basis. We estimated that 624 MA organizations and 456 Part D plan sponsors would need to comply with these requirements, a total of 1,080 entities. We also estimated that, on average, each entity would produce one report thereby yielding a total of 1,080 reports annually for involved entities. We estimated that it would take each entity an average of 2,885 hours to report the required information to CMS. The estimated annual burden associated with these requirements was 3,115,800 hours, and the cost associated with meeting these requirements was \$77.9 million.

We have now determined that the information collection burden imposed by § 422.108 and § 423.462 is generally part of the information being captured in CMS-10265—Mandatory Insurer Reporting information collection request (ICR). The OMB control number (OCN) is 0938-1074. Therefore, no new ICR is required.

The collection approved under OCN 0938-1074 takes care of virtually all of an MAO's MSP reporting responsibilities; the MAO is now reporting on their own primary, commercial insurance coverage. The small number of cases where an MAO will need to report either a new primary carrier or the termination of such coverage, that is not captured by OCN 0938-1074 is covered by existing authority under OCN 0938-0753. Under our previous Part C coordination of benefits policy, we required MAOs to survey members annually and to report results to CMS.

The reporting burden under our previous Part C coordination of benefits policy was to report both survey non-responders (approximately 10 percent of enrollees) and those who reported that they had other third party health insurance coverage (less than 2 percent). MAOs were not required to report to us on members that responded to the survey and said that they did not have other third party health insurance coverage—over 85 percent. Under the new system MAOs will only have to report to CMS those for whom MSP status changes from what is showing on the current COB file. We estimate this will be less than 1 percent. The burden of reporting is less now than it was before the change, but the actual reporting process is new. The new reporting process is slightly more burdensome than the old process and we believe the overall burden will be similar to what it was before this change.

D. ICRs Regarding Disclosure Requirements (§ 422.111)

Proposed § 422.111 states that we may require an MA organization to disclose to its enrollees or potential enrollees, the MA organization's performance and contract compliance deficiencies in a manner specified by CMS.

Our intent is to invoke this disclosure authority when we become aware that an MA organization has serious compliance and performance deficiencies such as those that may lead to an intermediate sanction or require immediate correction and where we believe beneficiaries should be specifically notified. The primary purpose of this requirement is to

promote transparency and informed choice especially in those situations where we believe beneficiaries need or should have access to this information. The burden associated with this requirement would be the time and effort necessary for the MA organization to make the aforementioned disclosures. We have not developed a burden estimate for this requirement because we do not believe that we will exceed the PRA threshold of 10 organizations per any 12 month period. We have based this assumption on past experience. For example, while this requirement does not just apply to those organizations who have been sanctioned, in 2009, CMS imposed intermediate sanctions on a total of 4 sponsoring organizations (which is the highest number of intermediate sanctions imposed in any year or 12 month period from 2006 through 2009) and, it is important to note, that not all of the organizations sanctioned in 2009 were required to make such a disclosure. Additional organizations (not under sanction) experience compliance deficiencies, however we intend to utilize this disclosure requirement in instances where we become aware of serious deficiencies which may lead to the imposition of intermediate sanctions and/or require immediate correction. For any of these instances, we will then evaluate and determine whether it is appropriate that beneficiaries be specifically notified of the underlying deficiencies to achieve our stated goals of promoting transparency and/or informed choice. Therefore, we do not believe that we will impose the disclosure requirement on 10 or more sponsoring organizations within any 12-month period which would not require the development of a burden estimate.

E. ICRs Regarding Quality Improvement Program (§ 422.152)

Section 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. Section 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 coordinated care plan to collect, analyze and report quality performance data to CMS. In the proposed rule, we estimated that it would 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 was 624,000 hours. The estimated annual cost associated with these requirements was \$36.9 million. The new quality measures will be identified during CY 2011 at which time it will go through the PRA review and approval process. CMS has begun drafting the PRA package for the new quality measures. However, the PRA package cannot be completed until the measures have been developed.

Section 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 in Section 417.472, private fee-for-service contracts, and PDPs under Section 423.156 with 600 or more enrollees in July of the prior year) must contract with approved Medicare 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. The associated burden is currently approved under OMB control number 0938-0732. For the CAHPS requirements, the requirement will go into effect in 2011 when the contracts select approved vendors to collect and submit CAHPS data on their behalf. The data collection begins in February 2011. We have revised the currently approved ICR to include the requirements contained in this section. The burden associated with these requirements is the time and effort necessary for an MA organization, Section 1876 Cost Plan, or PDP sponsor to collect, analyze and report quality performance data to CMS. We estimate that it will require 54 hours per MA organization or per PDP, to comply with these requirements. The 54 hours includes the time to select a CAHPS survey vendor and the survey administration time of the CAHPS survey vendor for which the MA or PDP contract pays. There are 624 contracts (both MA and PDPs). The estimated annual burden associated with these requirements is $54 \times 624 = 33,696$ hours for the affected contracts.

F. ICRs Regarding Risk Adjustment Data Validation (RADV) Appeals (§ 422.311)

We received comments from an MA organization disputing CMS's burden estimate associated with RADV audit appeals. This organization contends that

CMS has underestimated the amount of time, effort, and cost associated with complying with CMS's RADV appeals processes, as proposed.

While we acknowledge that there can be differences regarding the exact burden estimate CMS developed for RADV appeals, we continue to believe that the overall impact analysis we provided regarding RADV appeals-related procedures is reasonable. To date MA organizations have not been afforded appeal rights under RADV audits and CMS has no historical data to verify what we believe is an inherently reasonable level of effort and associated burden-estimate. Also, since invoking an MA organization's appeal rights is entirely voluntary on the part of MA organizations, we likewise have no altogether accurate way to estimate the level of activity that MA organizations will undertake in appealing eligible RADV-related audit provisions. Indeed, we think it is entirely possible that various MA organizations could take altogether different approaches in requesting an RADV appeal. For example—some organizations might employ internal resources to process an appeal request (for example, employ in-house medical record and legal staff) while other organizations could hire external medical record consultants and/or law firms to process their appeals requests. Given this uncertainty, CMS must rely upon what we believe are reasonable level of effort and burden-estimates, as described in our proposed rules and finalized here.

In section § 422.311 of the proposed rules, CMS proposed a multi-step Risk Adjustment Data Validation (RADV) dispute and appeals process. One important change to the RADV dispute and appeal process that we have implemented pursuant to public comment is removal of the documentation dispute process described at § 422.311(c)(2)(ii) and development of a process that would allow MA organizations to appeal medical record review determinations that occur at the IVC level of medical record review. We describe this new process that we are implementing at § 422.311(c)(2). In effect, the new medical record review appeal procedures provides MA organizations with two opportunities to appeal—first, to appeal RADV medical record review determinations and second, to appeal the RADV payment error calculations. It's our belief that the level of effort necessary to process a request for documentation dispute will be roughly the same level of effort necessary to request Medical record review appeal

since both processes involve sending CMS medical record documentation to support identified RADV errors identified pursuant to CMS's initial level of medical record review. However, the scope of the eligibility criteria for what CMS will allow MAOs to appeal under medical record review appeal could be broader when compared with what CMS would have allowed under the now removed documentation dispute process. We therefore have calculated a new burden estimate for medical record review appeal.

Whereas under documentation dispute, RADV contract-level audit statistics indicated that approximately 55 percent of RADV audit errors would have been of the type that could be eligible for documentation dispute, we estimate that fully 100 percent of RADV audit errors will be eligible for medical record review appeal. The historical contract-level RADV audit error rate to date is approximately 15 percent. Utilizing the statistics regarding the number of organizations that we expect to undergo RADV audit (70) annually, we estimate that 100 percent of these organizations will invoke their medical record review appeal rights and appeal their medical record review errors. On average, CMS audits approximately 200 beneficiaries per contract; and each beneficiary selected for testing has approximately 2.5 Hierarchical Condition Categories (or HCCs, which are the base-level unit of analysis under RADV audits) equating to roughly 500 HCCs tested per annual RADV contract-level audit. Applying the 15 percent contract-level RADV audit error rate to the 500 tested HCCs renders an estimate of 75 HCCs ($500 \times .15$) eligible for medical record review appeal per audit. This equates to approximately 5,250 HCCs ($70 \text{ audits} \times 75 \text{ HCCs/audit}$) that could be appealed annually under medical record review appeal. Each HCC that is appealed will require production of one medical record to overturn the RADV testing error. We continue to estimate that it will take approximately 1 hour to prepare the necessary documentation to dispute one HCC via medical record review appeal. This equates to 5,250 burden hours at approximately \$59.20/hour (based on U.S. Dept. of Labor statistics for hourly wages for management analysts)—or, an annual dollar burden on the MA industry of \$310,800.

CMS also estimates that beyond product of medical records, MAOs pursuing medical record review appeal would incur legal costs in the preparation of the formal request for appeal. Again, we assume all MAOs will

appeal their medical record review determinations found to be in error (70 MAOs). We estimate 40 hours by an attorney costing \$60 per hour (Bureau of Labor Statistics, 1/28/2010), and 20 hours by a health care administrator costing \$30 per hour (Bureau of Labor Statistics, 1/28/2010); for a total cost of \$3,000 in labor costs per MAO per appeal. This equates to an additional aggregate annual dollar burden of \$210,000 ($\$3000 \times 70 \text{ audits}$). Total estimated aggregate annual dollar burden to the MA industry annually equals \$520,800 ($\$310,800 \text{ for medical record preparation} + \$210,000 \text{ for legal preparation of appeal case}$). The total aggregated burden is 9,450 hours.

G. ICRs Regarding Application Requirements (§ 422.501 and § 423.502)

Section 422.501(b) and § 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 § 422.501(b) and § 423.502(b), the Notice of Intent to Apply, are 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, § 422.501(c) and § 423.502(c) 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 application to complete all parts of a certified Part C or Part D application. While the burden associated with the requirements contained in § 422.501(c) and § 423.502(c) are 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.

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. The burden associated with this requirement is the time and effort put forth by the sponsoring organization to prepare a compliance plan that meets the requirements of this section. While these requirements are subject to the PRA, it is currently approved under OCN 0938–1000.

I. ICRs Regarding Contract Provisions (§ 422.504 and 423.505)

Section 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, § 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 sections contain recordkeeping requirements. The burden associated with § 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).

J. ICRs Regarding Nonrenewal of Contract (§ 422.506 and § 423.507)

Section 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) 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 will also have to provide information about alternative enrollment options by complying with at least one of the requirements specified in § 422.506(a)(2)(ii) or § 423.507(a)(2)(ii). In addition, § 422.506(b)(2) and § 423.507(b)(2) state

that an organization must 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. We believe that fewer than 10 contracts will be terminated on an annual basis, and therefore, these requirements are exempt from the PRA process.

K. ICRs Regarding Request for Hearing (§ 422.662 and § 423.651)

With respect to Medicare contract determinations and appeals, § 422.662 and § 423.651 provide the methods and time period for when an MA organization or Part D plan sponsor may request a hearing after a contract determination or intermediate sanction has been imposed. 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. This is an existing regulation and in this rule we are only modifying the language “after receipt of the hearing decision” to conform to other regulations. Furthermore, we believe the associated burden is exempt from PRA under 5 CFR 1320.4. Information collected during the conduct of an administrative action or audit is not subject to the PRA.

L. ICRs Regarding Time and Place of Hearing (§ 422.670 and § 423.655)

Section 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 10 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. Furthermore, we believe the associated burden is exempt from the PRA 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)

Section 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. This is an existing regulation and in this rule we are only modifying the language “after receipt of the hearing

decision” to conform to other regulations. Furthermore, we believe the associated burden is exempt from PRA under 5 CFR 1320.4. Information collected during the conduct of an administrative action or audit is not subject to the PRA.

N. ICRs Regarding Procedures for Imposing Intermediate Sanctions and Civil Monetary Penalties (§ 422.756 and § 423.756)

Section 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 after 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. This is an existing regulation and we are only modifying the language “after receipt of the hearing decision” to conform to other regulations. Furthermore, we believe the associated burden is exempt from PRA under 5 CFR 1320.4. Information collected during the conduct of an administrative action or audit is not subject to the PRA.

O. ICRs Regarding Disclosure Requirements (§ 423.128)

Proposed § 423.128 states that we 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.

Our intent is to invoke this disclosure authority when we become aware that a Part D sponsor has serious compliance and performance deficiencies such as those that may lead to an intermediate sanction or require immediate correction and where we believe beneficiaries should be specifically notified. The primary purpose of this requirement is to promote transparency and informed choice especially in those situations where we believe beneficiaries need or should have access to this information. The burden associated with this requirement would be the time and effort necessary for the Part D sponsor to make the aforementioned disclosures. We have not developed a burden estimate for this requirement because we do not believe that we will exceed the PRA threshold of 10 organizations per any 12 month period. We have based this assumption on past experience. For example, while this requirement does not just apply to

those organizations who have been sanctioned, in 2009, CMS imposed intermediate sanctions on a total of 4 sponsoring organizations (which is the highest number of intermediate sanctions imposed in any year or 12 month period from 2006 through 2009) and, it is important to note, that not all of the organizations sanctioned in 2009 were required to make such a disclosure. Additional organizations (not under sanction) experience compliance deficiencies, however we intend to utilize this disclosure requirement in instances where we become aware of serious deficiencies which may lead to the imposition of intermediate sanctions and require immediate correction. For any of these instances, we will then evaluate and determine whether it is appropriate that beneficiaries be specifically notified of the underlying deficiencies to achieve our stated goals of promoting transparency and informed choice. Therefore, we do not believe that we will impose the disclosure requirement on 10 or more sponsoring organizations within any 12-month period which would not require the development of a burden estimate.

P. ICRs Regarding Validation of Part C and Part D Reporting Requirements (§ 422.516 and § 423.514)

In this final rule, we are amending § 422.516 and § 423.514 to state that each Part C and Part D sponsor will 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 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.

In the proposed rule, we estimated the total 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 to be 215,840. In addition, we estimated the total yearly burden for procuring and supporting the auditor would be 85,200 hours (120 hours per sponsor × 710 sponsors). Therefore, the total estimated burden was 301,040 hours. At that time, we assumed that the auditing organizations would audit all thirteen measures that comprised the Part C reporting requirements and all 21 sections that comprised the Part D reporting requirements. For Part C, two of the original thirteen reporting

requirements were suspended—agent compensation structure and agent training and testing. Additionally, two of the remaining eleven Part C measures will not undergo the data validation—PFFS Plan enrollment Verification Calls and PFF Provider Payment Dispute Resolution Process. We estimate that Part C reductions alone will reduce the annual hourly burden for all auditing organizations to perform the annual audit by 66,412 hours ($215,840 \times 4/13$). This reduction leads to an estimate of 149,428 hours to perform the annual audit for Part C measures. The CY2010 Part D Reporting Requirements PRA package approved by OMB in October 2009 included burden estimates for data validation and auditing activities. The PRA package included the burden for plans to audit 17 of the 21 Part D reporting sections. This number has now been decreased because only 8 reporting sections will be audited. The elimination of 9 reporting sections from the requirements for data validation and auditing for Part D will result in the following reduction in labor hours: $0.5 \text{ hours} \times 9 \text{ sections} \times 715 \text{ plans} = 3,218 \text{ hours}$.

The combined Part C and Part D reductions in data validation requirements from those in the proposed rule will result in 69,630 fewer labor hours. The total estimated labor hours is therefore $301,040 - 69,630 = 231,410$.

Q. ICRs Regarding Drug Utilization Management, Quality Assurance, and Medication Therapy Management Programs (MTMPs) (§ 423.153)

The 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 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.

R. ICRs Regarding Timeframes and Notice Requirements for Standard Coverage Determinations (§ 423.568)

The Part D plan sponsor must, under paragraph (a)(3), establish and maintain a method of documenting all oral requests for standard coverage determinations and retain the documentation in the case file.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors to maintain the required documentation outlined in this section. We estimate that, on an annual basis, 90 percent of all coverage determination requests will be standard requests, and three percent of those requests will not involve reimbursement issues. Of the estimated 1,013,881 requests received annually, we estimate that approximately 90 percent (912,493) will be made orally. We estimate that it will take a Part D plan sponsor 3 minutes to document and retain the required documentation in the case file. Thus, it will take each of the 456 Part D plan sponsors 100 hours to maintain the required documentation on an annual basis, for a total annual burden of 45,625 hours.

If a Part D plan sponsor makes a completely favorable standard decision under paragraph (d) of this section, it must give the enrollee written notice of the determination. Pursuant to paragraph (d) of this section, the initial notice of a favorable decision 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 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 a 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 § 423.568(d) is 380,206 hours. For § 423.568, we will update 0938–0964 to include the burden estimates associated with this requirement.

S. 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 the 456 Part D plan sponsors will issue a combined 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.

T. ICRs Regarding Access To Covered Part D Drugs (§ 423.120)

Section 423.120(b)(3)(iv) requires sponsors to provide enrollees with appropriate notice regarding their transition process within three business days 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 will 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.

Section 423.120(c)(4) requires 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. Section 423.120(c)(4) requires 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. We estimate the yearly burden to be 38,640 hours for CY 2010. This is a one time only burden for programming. The collection burden for these provisions will be reflected in a revised submission of the ICR approved under OMB control number 0938–0964.

U. ICRs Regarding Timeframes and Responsibility for Making Redeterminations (§ 423.590)

Section 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. In the proposed rule, we estimated a burden. We subsequently discovered that appeals notices, including those for Part D, are exempt from PRA under 5 CFR 1320.4. We will update 0938–0964 to include the § 423.590 exclusion language.

Comment: A commenter questioned our evidence of costs or time that

support CMS' burden estimates and questioned the basis of the estimates.

Response: We believe that we provided evidence for both the cost and time estimates in the COI and regulatory impact analysis sections of the October 2009 proposed rule. The commenter did not provide any cost estimates that would call into question the validity of these estimates.

V. Annual Information Collection Burden

Table X shows our estimates of the annual reporting and recordkeeping burden based on the discussion detailed in sections III.A. through III.V. of this final rule.

TABLE 9—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDENS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total labor cost of reporting (\$ millions)	Total capital/maintenance costs (\$ millions)	Total cost (\$ millions)
\$ 422.108 and \$ 423.462	0938-1074	1,080	1,080	2,885	3,115,800	25.00	77.9	0.0	77.9
\$ 422.152(b)(3)(ii) and \$ 422.152(e)(2)(ii)	0938-New	*624	624	1,000	624,000	59.13	36.9	0.0	36.9
\$ 422.152(b)(5) and \$ 423.156	0938-0732	624	624	54	33,969	91.26	3.1	0.0	3.1
\$ 422.311(c)(2)	0938-New	9,450	9,450	1	9,450	52.91	.5	0.0	.5
\$ 422.516(g) and \$ 423.514(g)	0938-New	*710	710	327.1	231,410	138.71	32.2	.1	32.2
\$ 423.120(b)(iv)	0938-0964	710	1,350,000	0.25	337,500	21.93	7.4	0.0	7.4
\$ 423.120(c)(3)	0938-0964	28	28	1,380	38,640	25.88	1.0	4.8	5.8
\$ 423.153	0938-0964	*456	1,875,000	0.5	937,500	120.00	112.5	0.0	112.5
\$ 423.568(a)(3)	0938-0964	456	912,493	0.05	45,625	39.45	1.8	0.0	1.8
\$ 423.568(b)	0938-0964	456	760,411	0.5	380,206	41.03	15.6	0.0	15.6
\$ 423.572(b)	0938-0964	456	87,103	0.5	43,550	41.33	1.8	0.0	1.8
Total	12,348	4,997,523	5,797,650	290.6	4.9	295.5

Note: Provisions regarding \$ 422.152(b)(5) and \$ 423.156 and \$ 423.514(g) will not go into effect until contract year 2011. They are included here because they will be in effect for the period of 2010-2015. Therefore, the totals in this table will not agree with the totals for CY 2010 in the RIA Table of costs (Table 10) in the section V.C of this final rule.

V. Regulatory Impact Analysis (RIA)

A. Need for Regulatory Action

This final rule makes revisions to the regulations governing 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 revisions strengthen various program participation and exit requirements; strengthen beneficiary protections; ensure that plan offerings to beneficiaries include meaningful differences; improve plan payment rules and processes; improve data collection for oversight and quality assessment, implement new policy such as a Part D formulary policy, and clarify program policy.

B. 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. HHS uses as its measure of significant economic impact on a substantial number of small entities, a change in revenue of more than 3 to 5 percent. We do not believe that this threshold would be reached by the requirements in this final rule because this rule will have minimal impact on small entities. Therefore, an analysis for the RFA will not be prepared because the Secretary has determined that this final rule will not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because 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 \$135 million. This final 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 final rule

imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

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.

Because there are costs to plans and sponsors associated with several provisions of this rule, we indicate general areas affected and specify the associated costs. For specific burden associated with the requirements and the bases for our estimates, see section IV. of this final rule.

C. Increase in Costs to MA Organizations and Part D Sponsors

The provisions of this final rule would require MA organizations and Part D sponsors an estimated cost of approximately \$260.3 million for CY 2010.

We believe the following requirements will result in costs to MA organizations and Part D sponsors between 2010 and 2015: Medicare Secondary Payer Procedures (§ 422.108), CAHPS Survey Costs for MAs and PDPs (§ 422.152(b)(5) and § 423.156), Quality Improvement program (§ 422.152(b)(3)(ii), § 422.152(e)(2)(ii)), and § 423.156, Validation of Reporting Requirements (§ 422.516 and § 423.514), Access to Covered Part D Drugs (§ 423.120(b)(iv)), Pharmacy Use of Standard Technology under Part D (§ 423.120(c)(3)), Drug Utilization Management, Quality Assurance, and Medication Therapy Management (§ 423.153), Documenting Oral Requests for Standard Coverage Determinations (§ 423.568(a)(3)), Timeframe and Notice Requirements for Standard Coverage Determinations (§ 423.568), and Timeframes and Notice Requirements for Expedited Coverage Determinations (§ 423.572(b)). It is true that all of the costs, besides those associated with MIPPA 176, are labor or capital, primarily labor. We expect that these costs will all be reflected in higher bid prices that will be federally-funded. Therefore, all the requirements, except MIPPA 176, will result in costs to MA organizations and Part D sponsors between CY 2010 and CY 2015.

We believe that the regulatory provisions implementing the MIPPA 176 provision will result in savings to the Medicare Program.

TABLE 10—ESTIMATED COSTS AND SAVINGS BY PROVISION FOR CYs 2010–2015
[\$ in millions]

Provision(s)	Regulation section(s)	Calendar year						Total (2010–2015)
		2010	2011	2012	2013	2014	2015	
Medicare Secondary Payer Procedures.	§ 422.108 and § 423.462	77.9	77.9	77.9	77.9	77.9	77.9	467.4
Quality Improvement	§ 422.152(b)(3)(ii) and § 422.152(e)(2)(ii).	36.9	36.9	36.9	36.9	36.9	36.9	221.4
CAHPS Survey Costs for MAs and PDPs.	§ 422.152(b)(5) and § 423.156.	0	3.1	3.1	3.1	3.1	3.1	15.5
RADV	§ 422.311	0.5	0.5	0.5	0.5	0.5	0.5	3.0
Data Validation	§ 422.516 and § 423.514	0.1	32.1	32.1	32.1	32.1	32.1	160.6
Transition Notification	§ 423.120(b)(iv)	7.4	7.4	7.4	7.4	7.4	7.4	44.4
Pharmacy Use of Standard Technology.	§ 423.120(c)(3)	5.8	0	0	0	0	0	5.8
Drug Utilization Management	§ 423.153	112.5	112.5	112.5	112.5	112.5	112.5	675.0
Documenting Oral Requests for Standard Coverage Determinations.	§ 423.568(a)(3)	1.8	1.8	1.8	1.8	1.8	1.8	10.8
Standard Coverage Determinations Notification.	§ 423.568(b)	15.6	15.6	15.6	15.6	15.6	15.6	93.6
Expedited Coverage Determinations Notification.	§ 423.572	1.8	1.8	1.8	1.8	1.8	1.8	10.8
MIPPA 176	0	–160	–340	–460	–520	–570	–2,050
Total	260.30	129.60	–50.40	–170.40	–230.40	–280.40	–341.70

D. Expected Benefits

Beginning in CY 2013, we expect net savings due to the combined impact of these new final provisions. We expect that the net impact across the 6-year period from CY 2010 through CY 2015 will be a cost of \$308.3 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 Advantage and Medicare Prescription Drug programs and strengthen beneficiary protections within these programs. Specifically, we believe that the requirements in this final rule 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 requirements in this final rule will be beneficial to PBMs in administering the Part D benefit for Part D sponsors. Proposed codification of the transition process requirements and establishment of the 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 COB 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 calculate a beneficiary's gross covered prescription drug costs.

The original Medicare savings in 2007, resulting from the Medicare Secondary Payer (MSP) Procedures were estimated 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 the 35.5 million original Medicare enrollees and thus equates to approximately \$183 per original Medicare enrollee. In 2009, MA penetration was higher consisting of 11 million MA enrollees out of approximately 45 million total Medicare enrollees. This translates to an estimated 24 percent MA penetration. We assume a similar MSP take up rate for MA enrollees as that obtained in the original 2007 Medicare savings and therefore project a total MSP savings of approximately \$2 billion by 2010.

The estimated impact of MSP on 624 MA organizations and 456 PDPs based on 3.1158 million burden hours at approximately \$25 per hour (based on U.S. Department of Labor (DOL) statistics for the hourly wages of claims analysts of \$22.20 per hour and for

management analysts of \$59.20/hour), is approximately \$77.9 million. All labor rate calculations in the RIA are derived from the May 2008 wage statistics supplied by the Department of Labor (DOL), Bureau of Labor Statistics and include fringe benefits and overhead costs. 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 estimate the work mix to be completed to be 90 percent by the claims analyst and 10 percent by the management analyst.

We note that MAOs expenses for processing claims related to MSP recoveries are considered part of their administrative overhead costs. 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 decreases with the benchmark remaining constant, the rebate amount increases. That is, as more MSP dollars are collected or avoided, medical expenses 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, it will be proportionally lower as overall medical costs go down, providing MA organizations offering such plans with an additional competitive edge.

In sections 422.152(b)(3)(ii) and 422.152(e)(2)(ii), we require MA organizations to collect, analyze, and report quality performance data identified by CMS that are of the same type of data that MA organizations are currently required to collect and report to CMS. The mean estimated burden per MA contract as indicated in section IV. E of this final rule is 1,000 hours. The estimated mean cost per hour for these MA contracts is \$59.20. The mean cost per MA contract is \$59,200. Since the number of MA contracts is estimated to be 624, the overall estimated cost across all contracts is \$36.9 million ($624 \times \$59,200$).

In § 422.311 we describe the Risk Adjustment Data Validation (RADV) dispute and appeals process that audited MAOs can voluntarily choose to participate in. In our proposed rule, we estimated that upwards of 100 MAOs would be selected for contract-level RADV audits annually. We now believe that a more accurate estimate of the number of MAOs that will be selected for contract-level RADV audits is between 60 and 80 MAOs. Here, we will assume that CMS selects 70 MAOs for contract-level RADV audit. On average, CMS audits approximately 200 beneficiaries per contract; and each beneficiary selected for testing has approximately 2.5 Hierarchical Condition Categories (or HCCs, which are the base-level unit of analysis under RADV audits) equating to roughly 500 HCCs tested per audit. To date, the average contract-level RADV error rate has been approximately 15 percent. Thus, we assume a total burden to audited MAOs of approximately 5,250 HCCs ($(500 \times .15) \times 70$) that will require validation medical records (each HCC is typically associated with one medical record.)

We continue to estimate that it will take approximately 1 hour to prepare the necessary documentation to dispute one HCC via medical record review appeal. At a per plan-level estimate, this equates to \$4,440 per medical record review appeal. Annualized across all audited MAOs, this in turn equates to 5,250 burden hours at approximately \$59.20/hour (based on U.S. Dept. of Labor statistics for hourly wages for management analysts)—or, an annual dollar burden on the MA industry of \$310,800.

We also estimate that beyond production of medical records, MAOs

pursuing medical record review appeal would incur legal costs in the preparation of the formal request for appeal. Again, we assume that all MAO will appeal their medical record error determinations (70 organizations.) We estimate 40 hours by an attorney costing \$60 per hour (Bureau of Labor Statistics, 1/28/2010), and 20 hours by a health care administrator costing \$30 per hour (Bureau of Labor Statistics, January 28, 2010); for a total cost of \$3,000 in labor costs per MAO per appeal. When annualized across all contract-specific RADV audits, this in turn equates to an additional aggregate annual dollar burden of \$210,000 ($\3000×70 audits). Total estimated aggregate annual dollar burden to the MA industry annually equals \$520,800 ($\$310,000$ for medical record preparation + \$210,000 for legal preparation of appeal case).

The validation of reporting requirements (§ 422.516 and § 423.514) focuses 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 IV.O. of this final rule. We believe the auditor, who 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 DOL, 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 discussions with program experts, we developed an estimate of the blended 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. Thus, the mean cost per sponsor to procure and support the auditor is \$5,177 ($1200 \times \43.14). Furthermore, with the 710 estimated number of sponsors, the overall cost across all sponsors to complete the work involved in procuring and supporting the auditing contractors is \$3.7 million ($710 \times \$5,177$). The number of hours is 85,200.

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 146,210 hours. The mean cost per hour is estimated to be \$194.21. Therefore, the estimated annual cost for auditing contracts involving all 710 sponsors is \$28.4 million. The estimated total annual cost for auditing contracts and for the procurement and audit support time and effort of the sponsors is \$32.1 million ($\28.4 million + $\$3.7$ million). The total estimated burden hours, including the hours for sponsors to procure contractors, is 231,410. Lastly, there is a one-time cost to develop the software that will allow data entry into HPMS. This is a Federal cost estimated at \$100,000 or \$0.1 million for CY 2010.

Beginning in 2011 MA organizations under § 422.152(b)(5), section 1876 Cost plans under § 417.472, and Part D sponsors under § 423.156 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, section 1876 Cost plan or Part D sponsor. The mean estimated burden per contract, as indicated in section IV. of this final rule, is 54 hours. The 54 hours includes the time to select a vendor and the survey administration time of the survey vendor that the contract pays. The estimated cost per contract is \$5,023. Beginning in 2011, the overall estimated annual cost across the 624 contracts is \$3.1 million.

Section 423.120(b)(iv) requires 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). In section IV.S. of this final rule, we estimated that 1.35 million notices would be required with an average preparation time of 15 minutes. As a result, the estimated total burden is calculated at 337,500 hours. At an estimated \$20.15 in hourly labor cost of reporting, the total cost is \$6.8 million ($337,500 \times \20.15). In addition, we estimated an additional cost of printing, supplies, and postage of \$0.475 per notice. This yields a cost of \$641,250 for the 1.35 million notices. Therefore, the total cost for sponsors to provide enrollees with appropriate notice regarding their transition process within a reasonable amount of time after providing a temporary supply of

nonformulary Part D drugs is estimated at \$7.4 million.

As indicated in section IV.R of this final rule, developing 760,411 written notices outlining favorable standard coverage determinations (§ 423.568(d)) is estimated to result in an annual burden of 380,206 hours. At an estimated cost of \$40.00 per hour, the total annual cost of this change is \$15.2 million. In addition, the aggregate cost of printing, supplies and postage associated for all the notices is \$361,195. Therefore, the overall total cost for providing written notices of a favorable standard coverage determination (§ 423.568(d)) is estimated to be \$15.56 million.

Section § 423.120(c)(3) requires 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. The yearly burden is therefore estimated to be 38,640 hours for CY 2010 (1,380 × 28). This is a one-time burden for programming. At an average labor cost of \$150.00 per hour, we estimate the overall cost in CY2010 to be \$5.8 million.

The 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 burden associated with this requirement was estimated at 937,500 hours, as reflected in section IV.P of this final rule. At an estimated average hourly labor cost of \$120.00, the total cost is \$112.5 million for 2010 (937,500 × \$120.00).

Establishing and maintaining a method of documenting all oral requests for standard coverage determinations and retaining the documentation in the case file (§ 423.568(a)(3)), are estimated to result in an annual burden of 45,625 hours. At an estimated cost of \$40.00 per hour, the estimated total annual cost of this change is \$1.8 million.

As indicated in section IV.S of this final rule, developing 87,103 written notices for favorable expedited coverage determination (§ 423.572(b)) is estimated to result in an annual burden of 43,552 hours. At an estimated cost of \$40.00 per hour, the total annual cost of

this change is \$1.74 million. In addition, the aggregate cost of printing, supplies and postage associated for all the notices is \$41,374. Therefore, the overall total cost for providing written notices of an expedited coverage determination (§ 423.572(b)) is estimated to be \$1.78 million.

Since issuance of the October 22, 2009 proposed rule, PPACA was enacted. Accordingly, new section 1860D–4(b)(3)(G) of the Act replaces section 176 of MIPPA. Section 1860D–4(b)(3)(G) of the Act requires a PDP sponsor to include “all” covered part D drugs—in the categories and classes identified by the Secretary as classes and categories of “clinical concern.” It requires the Secretary to establish criteria to determine, as appropriate, categories and classes of drugs of “clinical concern.” It provides for an exceptions authority similar to the one included in section 176 of MIPPA. Section 3307 of PPACA further requires that until the Secretary establishes criteria to determine classes of “clinical concern,” the following categories and classes of drugs shall be identified and protected as classes of “clinical concern”: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection. Consistent with this approach, we are removing from the regulatory text the criteria specified by section 176 of MIPPA for identifying classes and categories of drugs of “clinical concern,” as well as the definitions used to interpret the MIPPA criteria. We are retaining the exceptions process in the regulatory text, as new section 1860D–4(b)(3)(G) of the Act retains the exceptions process established under section 176 of MIPPA. The estimated cost of implementing section 176 of MIPPA for FY 2010 budget baseline projections was \$4.9 billion for FY 2010 through 2019. The removal of the section 176 MIPPA criteria eliminates the cost included in the baseline generating savings of \$4.9 billion for FYs 2010 through 2019.

E. Anticipated Effects—Effects of Maximum Out-of-Pocket Cost (MOOP) Limit and Cost Sharing Thresholds

We are finalizing our proposal to establish and require local MA plans to have a maximum out-of-pocket (MOOP) limit on members’ out-of-pocket cost sharing, the amount of which will be established annually by CMS. In addition, we are finalizing our proposal to require cost sharing thresholds for Parts A and B services, the amounts of which will be determined annually by CMS. These changes provide significant

protection for MA enrollees from out of pocket costs and will lend greater predictability and transparency to benefit packages, so that beneficiaries will better understand and anticipate their out-of-pocket expenditures. However, we do not believe these changes will, by themselves, have a significant impact on plan participation or significantly increase plan premiums.

We believe the impact on enrollee premiums will be limited for several reasons. First, we have made a voluntary MOOP available for the past years (2008, 2009, and 2010). For CY 2010, the voluntary MOOP for all Parts and B services was set at \$3,400. About 40 percent of current MA plans have adopted the voluntary MOOP while remaining competitive (and enrolling approximately one-third of all MA enrollees), and they do not appear to have incurred significant costs in administering a MOOP limit.

Second, as we described elsewhere in this preamble, it is our intention to set both the MOOP and Parts A and B cost sharing thresholds at levels that, while affording reasonable financial protection for those beneficiaries with high health care needs, do not result in significant new operating costs for MA plans or increased out-of-pocket costs for beneficiaries to the extent that MA plans pass along any increased costs to their enrollees in the form of premium increases. We will develop the MOOP and Parts A and B cost sharing thresholds using data provided by our Office of the Actuary (OACT) to ensure this result. In addition, given a competitive marketplace and Medicare beneficiaries’ sensitivity to premium amounts, we believe that MA plans may choose instead to modify their benefit packages to reduce costs elsewhere. Furthermore, we estimate that beneficiaries in plans that currently offer the CY 2010 voluntary MOOP limit of \$3,400 (about 40 percent of MA plans) will experience no cost increases as a result of these provisions. In fact, to the extent they instead choose the higher, mandatory MOOP limit, we would expect a net decrease in costs. We estimate that the maximum impact of these requirements on beneficiary premiums for those plans that currently have no MOOP limit of any kind (31 percent of all CY 2010 MA plans) would average \$5. The average impact on premiums would be lower for plans that currently have a nonqualified MOOP—one with an amount higher than the voluntary MOOP limit of \$3400 established for CY 2010 and/or that does not include all Parts A and B services. Approximately 29 percent of all CY 2010 plans had such a MOOP. However,

given competitive market pressures, we believe MA plans may instead choose to modify their benefit packages rather than increase premiums.

Finally, we believe that the many advantages for beneficiaries as a result of the new MOOP and cost-sharing threshold requirements will outweigh any small premium increases that may result. All MA plan enrollees will be protected against high out of pocket costs, and will be better able to compare plans by focusing on differences in premium and plan quality. Furthermore, enrollee cost-sharing will be more predictable and transparent. As we have explained in the preamble of the final rule, our goal is to set cost-sharing limits at a level that should not result in significant new costs for MA plans or beneficiaries.

F. Alternatives Considered

1. Strengthening CMS' Ability To Take Timely, Effective Contract Determinations or Intermediate Sanctions (Part C and D)

We are finalizing our modifications to the regulations which more clearly and accurately reflect our existing statutory authority to terminate a contract. The existing enumerated list of determinations that are the basis to terminate a contract are not all inclusive. Initially it was our belief that continuing to add to the existing list may fail to stress to sponsoring organizations that failure to comply with all of our regulations and contract and performance requirements may be used to support a termination decision. After receiving numerous comments concerning this provision we have decided, however, not to remove the enumerated list and instead to add language to provide additional examples of determinations that could support a decision to terminate a contract. Also, we have revised the proposed regulatory language to clarify that the failure to comply with 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.

2. 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 finalizing our change to the standards of review and clarification of the standard of proof when an appeal of a contract determination or intermediate sanction is requested and an evidentiary hearing is conducted. The existing 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 have deleted 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 have explicitly stated 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 have clarified the standards of review, which vary according to the type of contract determination or intermediate sanction. In particular, the 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 have clarified 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, but ultimately rejected that option.

3. Clarify That CMS May Require a "Test Period" During an Enrollment/Marketing Sanction

We are finalizing our proposal 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.

We considered leaving the existing regulations unchanged. However, we believe the requirements in this final rule will strengthen our ability to adequately assess compliance with our requirements. Also, it will help us avoid situations where we may lift a sanction based on inadequate testing of an organization's systems/processes, only to find that the deficiencies have not been corrected, thereby requiring us to reinstate the sanction.

4. Right for CMS To Require an Independent Audit of Sponsoring Organizations Under Intermediate Sanction

We are finalizing language in the October 2009 proposed rule which states that CMS may require sponsoring organizations that are 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 in order to assist CMS in its determination whether to lift the sanction. The purpose of this provision is to provide us with additional assurances, through a neutral third party evaluation, whether the sponsoring organization is in compliance with CMS requirements and the bases for the sanction have been corrected and are not likely to recur.

Another option we considered was to not require sanctioned sponsoring organizations to hire an independent auditor but rather to allow sponsoring organizations the discretion to hire an independent auditor. We believe that this alternative proposal is not necessary to promulgate in regulation as sanctioned sponsoring organizations

already have the discretion to hire an independent auditor.

We also considered leaving the regulations unchanged. However, 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 evaluation of the correction of these deficiencies, we believe this additional assurance and access to expertise (such as a qualified independent auditor) is appropriate and will benefit both plan sponsors and CMS.

5. The Ability for CMS To Require Sponsors To Disclose to Current and Potential Enrollees Compliance and Performance Deficiencies

We are finalizing our proposal that we may require certain sponsoring organizations to disclose their current compliance and/or performance deficiencies to existing and potential enrollees. Our intent is to invoke this disclosure authority when we become aware that an MA organization has serious compliance and/or performance deficiencies such as those that may lead to an intermediate sanction or require immediate correction and where we believe beneficiaries should be specifically notified. The primary purpose of this requirement is to promote transparency and informed choice especially in those situations where we believe beneficiaries need or should have access to this information. An additional purpose is to provide appropriate incentives for sponsoring organizations 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.

6. Reducing Duplicative and Low Enrollment Plans (Parts C and D)

We are implementing regulations to reduce duplicative benefit packages based upon our authority to add such additional terms to our 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 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 submission, 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 by addressing the issue generally in regulations text, we maintain our flexibility to adjust our review processes and criteria consistent with current market trends.

7. Validation of Part C and Part D Reporting Requirements and CAHPS Survey Administration

Several of the required changes 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 necessary 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 as a result of 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. We believe these changes actually benefit the plans by informing them of the issues that, from the beneficiaries’ perspectives, needs attention.

G. Accounting Statement

As required by OMB Circular A–4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), in Table 11, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. The accounting statement is based on estimates in Table 10 (our best estimate of the costs and savings as a result of the changes) discounted at the 7 percent and 3 percent for the time period of CY 2010 through CY 2015.

TABLE 11—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM CY 2010 TO CY 2015
[\$ in millions]

Category	TRANSFERS (MIPPA 176)			
	Year dollar	Units discount rate		Period covered
		7%	3%	
Annualized Monetized Transfers	2009	–\$318.64	–\$331.65	CYs 2010–2015
From Whom To Whom?	Federal Government to MAO and Part D Sponsors			

TABLE 11—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM CY 2010 TO CY 2015
[\$ in millions]

Category	COSTS (All other provisions)			
	Year dollar	Units discount rate		Period covered
		7%	3%	
Annualized Costs to MAOs and Part D Sponsors	2009	\$283.86	\$284.35	CYs 2010–2015

Compared to the proposed rule, the annualized costs to MAOs and Part D sponsors have decreased from \$319.51 million and \$319.46 million, at the 7 and 3 percent annualized discount rates, to \$283.86 million and \$2284.35 million at the 7 and 3 percent discount rates for the final rule.

H. Conclusion

We estimate that the cost of implementing these provisions will be \$260.3 million in CY 2010. This is \$61.4 million less than the estimated cost in the proposed rule (\$321.7 million). Sponsors will experience additional costs which they are likely to pass on to CMS through direct subsidy payments and to beneficiaries through increases in premiums as reflected in their bids. Beginning in CY 2012, we expect that these provisions will generate a net savings to the Medicare program on an annual basis. For the entire estimated time period, CYs 2010 through 2015, we estimate the overall impact to be a savings of \$341.70 million (undiscounted).

In accordance with the provisions of Executive Order 12866, this final 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 amends 42 CFR chapter IV as set forth below:

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 1. The authority citation for part 417 continues to read as follows:

Authority: Sec. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

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, contracts with exclusively SNP benefit packages, private fee-for-service contracts, and MSA contracts), and all cost contracts under section 1876 of the Act, 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 Medicare 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,” “Hierarchical condition categories,” and “Initial Validation Contractor.”
- 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 revisions 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.

* * * * *

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 component of the enrollee risk score that are applied to MA payments.

* * * * *

Initial Validation Contractor (IVC) means the first level of medical record review under the RADV audit process.

* * * * *

Point of service (POS) means a benefit option that an MA HMO plan can offer to its Medicare enrollees as a 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) means the clinical documentation for a single encounter for care (that is, a physician office visit, an inpatient hospital stay, or an outpatient hospital visit) that occurred for one patient during the data collection period. The single encounter for care must be based on a face-to-face encounter with a provider deemed acceptable for risk adjustment and documentation of this encounter must be reflected in the medical record.

- 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—
 - (1) Be at least 2 months; and
 - (2) Begin on the first day of the month for which the premium is unpaid or the

first day of the month following the date on which premium payment is requested, whichever is later.

* * * * *

- (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)(4)(iii)(D) of this section 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—
- A. Revising the introductory text for paragraph (f).
- B. In paragraphs (f)(1) and (f)(2) removing the “,” and adding a “.” in its place.
- C. Adding new paragraphs (f)(4) through (f)(6).

The revisions and additions read as follows:

§ 422.100 General requirements.

* * * * *

(f) *CMS review and approval of MA benefits and associated cost sharing.*

CMS reviews and approves MA benefits and associated cost sharing using written policy guidelines and requirements in this part and other CMS instructions to ensure all of the following:

* * * * *

(4) Except as provided in paragraph (f)(5), MA local plans (as defined in § 422.2) must have an out-of-pocket maximum for Medicare Parts A and B services that is no greater than the annual limit set by CMS.

(5) With respect to a local PPO plan, the limit specified under paragraph (f)(4) applies only to use of network providers. Such local PPO plans must include a total catastrophic limit on beneficiary out-of-pocket expenditures for both in-network and out-of-network Parts A and B services that is—

- (i) Consistent with the requirements applicable to MA regional plans at § 422.101(d)(3) of this part; and
- (ii) Not greater than the annual limit set by CMS.

(6) Cost sharing for Medicare Part A and B services specified by CMS does not exceed levels annually determined by CMS to be discriminatory for such services.

* * * * *

■ 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 or during any other enrollments occurring after January 1.

* * * * *

■ 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 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 the following:

(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,

contracts with exclusively SNP benefit packages, private fee-for-service contracts, and MSA contracts), and all cost contracts under section 1876 of the Act, 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 Medicare 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 defined in part 475 of this chapter only data collected under section 1886(b)(3)(B)(viii) of the Act and subject to the requirements in § 480.140(g). CMS will acquire this information, as needed, and may 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) of this chapter 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 or 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," as provided under § 422.254(a)(4) of this subpart, 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 or 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 section 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(e), 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 dollars.

(iii) The contract-level payment adjustment amount to be made in dollars.

(iv) An approximate timeframe for the payment adjustment.

(v) 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.

(3) Medical record review appeal. MA organizations that do not agree with the medical record review determinations for audited HCCs may appeal the medical record review determinations of the initial validation contractor to CMS in accordance with paragraph (c)(2) of this section.

(c) *RADV audit dispute and appeal processes*—(1) *Attestation process*—(i) *Submission requirements for attestations*. MA organizations—

(A) May submit CMS-generated attestations from physician/practitioner(s) in order to dispute signature-related or credential-related RADV errors in accordance with the attestations provisions of this section.

(B) 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 record with a missing signature or missing credential or both.

(iii) *RADV audit-related errors and documentation ineligible for attestation process*.

(A) Attestations from providers for anything other than signature-related and credential-related errors will not be permitted.

(B) Inpatient provider-type medical records are not eligible for attestation.

(iv) *Manner and timing of a request for attestation*. (A) CMS will provide MA organizations selected for RADV audits with attestations and accompanying instructions at the time the organization receives its audit instructions.

(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) Contain only CMS-generated attestations.

(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 eligible risk adjustment 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*. CMS—(A) Reviews each submitted attestation to determine if it meets CMS requirements and is acceptable for use during the medical record review; and

(B) 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's attestation determination*. (A) CMS' attestation determination is final.

(B) An MA organization may choose to appeal its medical record review determinations for audited HCCs following initial validation contractor review using a CMS-administered medical record review determination appeal process.

(2) *RADV-related medical record review errors and documentation eligible for medical record review determination appeal process*: (i) *General rules*. (A) In order to be eligible for medical record review determination appeal, MA organizations must adhere to established RADV audit procedures and RADV appeals requirements. Failure to follow CMS rules regarding the RADV medical record review audit procedures and RADV appeals requirements may render the MA organization's request for appeal invalid.

(B) The medical record review determination appeal process applies only to error determinations from review of the one best medical record submitted by the MA organization and audited by the RADV initial validation contractor (IVC).

(C) MA organizations that choose to appeal the IVC's medical record review determination(s) may only submit the IVC-audited one best medical record and IVC-reviewed attestation, previously submitted in accordance with paragraph (c)(1) of this section, to CMS for re-review.

(D) MA organizations' request for medical record review determination appeal may not include additional documentary evidence beyond the IVC-audited one best medical record and IVC-reviewed attestation.

(ii) *RADV-related audit errors and documentation ineligible for medical record review appeal process*. (A) MA organizations may not appeal errors that resulted because MA organizations failed to adhere to established RADV audit procedures and RADV appeals requirements. This includes failure by the MA organization to meet the medical record submission deadline established by CMS.

(B) Any other documentation submitted to CMS beyond the one best medical record and attestation submitted to and audited by the IVC will not be reviewed by CMS under the medical record review determination appeal process.

(C) The MA organization's written request for medical record review determination appeal must specify the audited HCC(s) that CMS identified as being in error and eligible for medical record review determination appeal, and that the MA organization wishes to appeal.

(iii) *Manner and timing of a request for medical record review determination appeal*. (A) At the time CMS issues its IVC RADV audit report to audited MA organizations, CMS notifies these MA organizations of any RADV HCC errors that are eligible for medical record review determination appeal.

(B) MA organizations have 30 calendar days from date of issuance of the RADV audit report to file a written request with CMS for medical record review determination appeal.

(C) A request for medical record review determination appeal must specify the determinations with which the MA organization disagrees and the reasons for the request for appeal.

(iv) *Medical record review determination appeal review and notification procedures*. (A) *Designation of a hearing officer*. CMS designates a hearing officer to conduct the medical record review determination appeal. The hearing officer need not be an ALJ.

(B) *Disqualification of hearing officer*. (1) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(2) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(3) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(i) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(ii) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to CMS.

(v) *Hearing officer's review*. The hearing officer reviews the IVC-audited one best medical record and the IVC-reviewed attestation submitted by the MA organization to determine whether it supports overturning medical record review determination errors listed in the MA organization's IVC-level RADV audit report.

(vi) *Hearing procedures*. (A) CMS provides written notice of the time and

place of the hearing at least 30 calendar days before the scheduled date.

(B) The hearing is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented to the IVC. The CMS hearing officer is limited to the review of the record that was before the IVC.

(vii) *Hearing officer's decision.* As soon as practical after the hearing, the hearing officer issues a decision which provides written notice of the hearing officer's review of the appeal of medical record review determination(s) to the MA organization and to CMS.

(viii) *Computations based on hearing decision.* In accordance with the hearing officer's decision, CMS recalculates the MA organization's RADV payment error and issues a new RADV audit report to the appellant MA organization.

(ix) *Effect of hearing decision.* The hearing officer's decision is final and binding, unless the MA organization requests review of the hearing officer appeal determination by the CMS Administrator.

(x) *Review by the CMS Administrator.* (A) A MA organization that has received a hearing officer decision may request review by the CMS Administrator within 30 calendar days of receipt of the hearing officer's determination. A request for CMS Administrator review must be made in writing and filed with CMS.

(B) After receiving a request for review, the CMS Administrator has the discretion to elect to review the hearing officer's decision or to decline to review the hearing decision.

(C) If the CMS Administrator elects to review the hearing decision, the CMS Administrator—

(1) Acknowledges the decision to review the hearing decision in writing; and

(2) Reviews the decision and determine based upon all of the following whether the determination should be upheld, reversed, or modified:

(i) The hearing record.

(ii) Written arguments submitted by the MA organization or CMS.

(xi) *Notification of Administrator determination.* (A) The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days of acknowledging his or her decision to review the hearing decision.

(B) The decision of the hearing officer is final if the Administrator—

(1) Declines to review the hearing decision; or

(2) Does not make a determination regarding review within 30 calendar days.

(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.* MA organizations may not—

(A) Appeal RADV medical record review-related errors as part of the RADV payment error calculation appeal process. In accordance with paragraph (c)(2) of this section, MA organizations that wish to appeal medical record review determinations may do so following issuance of the IVC RADV audit report of findings.

(B) Introduce new HCCs to CMS for payment consideration in the context of their RADV payment error calculation appeal.

(C) Appeal RADV errors that result from an MA organization's failure to submit a medical record.

(D) Appeal CMS' RADV payment error calculation methodology.

(iii) *Manner and timing of a request for appeal.* (A) MA organizations may not appeal their RADV error calculation until any appeals of RADV medical record review determinations filed by the MA organization have been completed and the decisions are final.

(B) At the time CMS issues either its IVC or post-medical record review appeal RADV audit report, CMS notifies affected MA organizations in writing of their appeal rights around the RADV payment error calculation.

(C) MA organizations have 30 calendar 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) 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 initial 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 (c)(3)(vi)(B) of this section provides his or her determination to a CMS reconsideration official not otherwise involved in the RADV payment error calculation to review the reconsideration determination.

(vi) *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.

(vii) *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 a 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 calendar days of the date CMS and the MA organization receives the CMS reconsideration officer's 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) CMS provides written notice of the time and place of the hearing at least 30 calendar days before the scheduled date.

(B) 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.

(C) The hearing is conducted by the 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 either its initial RADV payment error calculation determination or its post-medical record review appeal 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.

(vi) *Review by the CMS Administrator.* (A) CMS or a MA organization that has received a hearing officer's decision upholding or overturning a CMS initial or reconsideration-level RADV payment error calculation determination may request review by the CMS Administrator within 30 calendar days of receipt of the hearing officer's decision.

(B) At his or her discretion, the CMS Administrator can choose to either review or not review a case.

(C) If the CMS Administrator chooses to review the case, the CMS Administrator—

(1) Acknowledges his or her decision to review the hearing officer's decision in writing; and

(2) Determines whether to uphold, reverse, or modify the Hearing Officer's decision based on his or her review of the following:

(i) The Hearing Officer's decision.
(ii) Written documents submitted by CMS or the MA organization to the Hearing Officer.

(iii) Any other any other information included in the record of the Hearing Officer's decision.

(D) The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days of receiving the request for review.

(E) If the Administrator chooses to review, the Administrator's determination is final and binding.

(F) The decision of the hearing officer is final if the Administrator—

(1) Declines to review the hearing decision; or

(2) Does not make a determination regarding review within 30 calendar days.

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.

(3) An organization's decision not to submit an application after submitting a Notice of Intent To Apply will not form the basis of any action taken against the organization by CMS.

(c) * * *

(1) In order to obtain a determination on whether it meets the requirements to become a 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 and addition 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 paragraphs (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 and are accountable to the organization's chief executive or other senior management.

(1) The compliance officer, vested with the day-to-day operations of the compliance program, must be an employee of the MA organization, parent organization or corporate affiliate. The compliance officer may not be an employee of the MA organization's first tier, downstream or related entity.

(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.

(1) If the MA organization discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.

(2) The MA organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation referenced in paragraph (b)(4)(vi)(G)(1) of this section.

(3) The MA organization should have procedures to voluntarily self-report potential fraud or misconduct related to the MA program to CMS or its designee.

* * * * *

(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 protected 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 entities related to CMS' contract with the MA organization.

* * * * *

(m)(1) CMS may determine that an MA organization is out of compliance with a Part C requirement 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 in fulfilling Part C requirements 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, MA-PD plan, and PDP 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.

- (b) * * *

(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 notice specifying the MA organization's deficiencies and a reasonable opportunity of at least 30 calendar days to develop and implement a corrective action plan to correct the deficiencies.

(ii) 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—
- A. Revising paragraphs (a), (b) introductory text, and (b)(2)(i).
- B. Redesignating paragraphs (b)(2)(ii) and (b)(2)(iii) as (b)(2)(iii) and (b)(2)(iv), respectively.
- C. Adding a new paragraph (b)(2)(ii).
- D. Revising paragraph (c).

The revisions and addition read as follows:

§ 422.510 Termination of contract by CMS.

(a) *Termination by CMS.* CMS may at any time terminate a contract if CMS determines that the MA organization meets any of the following:

- (1) Has failed substantially to carry out the contract.
- (2) Is carrying out the contract in a manner that is inconsistent with the efficient and effective administration of this part.
- (3) No longer substantially meets the applicable conditions of this part.
- (4) Based on creditable evidence, 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.
- (5) Substantially fails to comply with the requirements in subpart M of this part relating to grievances and appeals.
- (6) Fails to provide CMS with valid data as required under § 422.310.
- (7) Fails to implement an acceptable quality assessment and performance

improvement program as required under subpart D of this part.

(8) Substantially fails to comply with the prompt payment requirements in § 422.520.

(9) Substantially fails to comply with the service access requirements in § 422.112 or § 422.114.

(10) Fails to comply with the requirements of § 422.208 regarding physician incentive plans.

(11) Substantially fails to comply with the marketing requirements in subpart V of this part.

(12) Fails to comply with the regulatory requirements contained in this part or part 423 of this chapter or both.

(13) Fails to meet CMS performance requirements in carrying out the regulatory requirements contained in this part or part 423 of this chapter or both.

(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) The procedures specified in paragraph (b)(1) of this section do not apply if—

(A) 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; or

(B) The MA 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; or

(C) The contract is being terminated based on the grounds specified in paragraph (a)(4) of this section.

(ii) CMS notifies the MA organization in writing that its contract will be terminated on a date specified by CMS. 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 notice specifying the MA organization's deficiencies and a reasonable

opportunity of at least 30 calendar days to develop and implement a corrective action plan to correct the deficiencies.

(ii) 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.* The MA organization will not be provided with an opportunity to develop and implement a corrective action plan prior to termination if—

(i) 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;

(ii) The MA 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; or

(iii) The contract is being terminated based on the violation specified in (a)(4) of this section.

* * * * *

■ 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.

§ 422.566 [Amended]

■ 37. Section 422.566 is amended by—

- A. Republishing paragraph (b) introductory text.
■ B. Revising paragraph (b)(4).
■ C. Redesignating paragraph (b)(5) as (b)(6).
■ D. Adding a new paragraph (b)(5).
■ E. In paragraphs (c)(1)(i), and (c)(2)(i) removing the parenthetical phrase “(including his or her authorized representative)” is removed and “(including his or her representative)” is added in its place.

The revision and addition to read as follows:

§ 422.566 Organization determinations.

* * * * *

(b) *Actions that are organization determinations.* An organization determination is any determination made by an MA organization with respect to any of the following:

* * * * *

(4) Reduction, or premature discontinuation, of a previously authorized ongoing course of treatment.

(5) Reduction of a previously authorized course of treatment if the enrollee believes that continuation of the course of treatment is medically necessary.

* * * * *

■ 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 designated paragraph (d).

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 verbal payment requests).

* * * * *

(d) *Written notice for MA organization denials.* The MA organization must give the enrollee a written notice if—

(1) An MA organization decides to deny service or payment in whole or in part, or reduce or prematurely discontinue the level of care for a previously authorized ongoing course of treatment.

(2) 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.

* * * * *

■ 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.* Except as provided in (c)(2) of this section, CMS mails notice to the MA organization 90 calendar days before the anticipated effective date of the termination.

(2) *Exception.* If a contract is terminated in accordance with § 422.510(b)(2)(i) of this part, 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) A contract terminated in accordance with § 422.510(b)(2)(i) of this part will be terminated on the date specified by CMS and will not be postponed if a hearing is requested.

■ 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 10 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 revising paragraphs (a) introductory text, (a)(1), (a)(3), and (a)(4) to 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 are 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” and adding a new paragraph (6) to read as follows:

§ 422.2260 Definitions concerning marketing materials.

* * * * *

Marketing materials. * * *

(5) * * *

(vii) *Membership activities* (for example, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or nonclaim specific notification information).—

(6) *Marketing materials exclude ad hoc enrollee communications materials,* meaning informational materials that—

(i) Are targeted to current enrollees;

(ii) Are customized or limited to a subset of enrollees or apply to a specific situation;

(iii) Do not include information about the plan’s benefit structure; and

(iv) Apply to a specific situation or cover claims processing or other operational issues.

■ 56. Section 422.2262 is amended by—

■ A. Revising the section heading.

■ B. Revising paragraphs (a)(1) and (b).

■ C. Adding new paragraphs (c) and (d).

The revisions and additions read as follows:

§ 422.2262 Review and distribution of marketing 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) *Ad hoc enrollee communication materials.* Ad hoc 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 as set forth in this section) 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 or the first day of the month following the date on which premium payment is requested, whichever is later.

* * * * *

(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 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 area.

* * * * *

(d) * * *

(2) * * *

(iii) Tiered cost sharing under paragraph (d)(2)(ii) of this paragraph 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 paragraphs (b)(1)(ix) as paragraph (b)(1)(x).
■ C. Adding a new paragraph (b)(1)(ix).
■ E. Revising paragraph (b)(3).
■ F. Redesignating paragraph (c) as paragraph (c)(1).
■ G. 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.

* * * * *

(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 (b)(3)(ii) of this section (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 93 days in 31 day supply increments, with refills provided, if needed, unless a

lesser amount is actually prescribed by the prescriber.

(iv) Ensure written notice is provided to each affected enrollee within 3 business days after adjudication 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) Beginning January 1, 2012, a part D sponsor must assign and exclusively use a unique—

(i) Part D BIN or RxBIN and Part D processor control number (RxPCN) combination in 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 meet all of the following:

(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.

(iii) Are likely to incur the following annual Part D drug costs:

(A) For 2011, costs for covered Part D drugs greater than or equal to \$3,000.

(B) For 2012 and subsequent years, costs for covered Part D drugs in an amount greater than or equal to \$3000 increased by the annual percentage specified in § 423.104(d)(5)(iv) of this part.

* * * * *

■ 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 section 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 or 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 or 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 or plan costs represented by that bid are substantially different as provided under § 423.265(b)(2) of this subpart from the benefit package or plan costs 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 or plan costs represented by that bid are substantially different from any benefit package or 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), (g), and (h) 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.

(h) *Reporting requirements*. A Part D sponsor must report credible new or changed supplemental prescription drug coverage information to the CMS Coordination of Benefits Contractor in accordance with the processes and timeframes specified by CMS.

■ 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.

(3) An organization’s decision not to submit an application after submitting an Notice of Intent to Apply will not form the basis of any action taken against the organization by CMS.

(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 revision 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 and are accountable to the Part D plan sponsor's chief executive or other senior management.

(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, parent organization or corporate affiliate. The compliance officer may not be an employee of the Part D plan sponsor's first tier, downstream or related entity.

(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.

(3) First tier, downstream, and related entities who have met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program or accreditation as a Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) 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 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.

(1) If the Part D sponsor discovers evidence of misconduct related to payment or delivery of prescription drug items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct;

(2) The Part D sponsor must conduct appropriate corrective actions (for example, repayment of overpayments and disciplinary actions against responsible individuals) in response to the potential violation referenced above.

(3) The Part D plan sponsor should have procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to CMS or its designee.

(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 protected 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 entities 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 in fulfilling Part D requirements 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 MA plan and PDP 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 notice specifying the Part D sponsor's deficiencies and reasonable opportunity of at least 30 calendar days to develop and implement a corrective action plan to correct the deficiencies.

(ii) 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—

■ A. Revising paragraphs (a), paragraph (b) introductory text, and paragraph (b)(2)(i).

■ B. Redesignating paragraphs (b)(2)(ii) and (b)(2)(iii) as (b)(2)(iii) and (b)(2)(iv), respectively.

■ C. Adding a new paragraph (b)(2)(ii).

■ D. Revising paragraph (c).

The revisions and addition read as follows:

§ 423.509 Termination of contract by CMS.

(a) *Termination by CMS.* CMS may at any time terminate a contract if CMS determines that the Part D plan sponsor meets any of the following:

(1) Has failed substantially to carry out the contract.

(2) Is carrying out the contract in a manner that is inconsistent with the efficient and effective administration of this part.

(3) No longer substantially meets the applicable conditions of this part.

(4) Based on credible evidence, 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.

(5) Substantially fails to comply with the requirements in subpart M of this part relating to grievances and appeals.

(6) Fails to provide CMS with valid risk adjustment, reinsurance and risk corridor related data as required under § 423.322 and § 423.329 (or, for fallback entities, fails to provide the information in § 423.871(f)).

(7) Substantially fails to comply with the service access requirements in § 423.120.

(8) Substantially fails to comply with either of the following:

(i) Marketing requirements in subpart V of this part.

(ii) Information dissemination requirements of § 423.128 of this part.

(9) Substantially fails to comply with the coordination with plans and programs that provide prescription drug coverage as described in subpart J of this part.

(10) Substantially fails to comply with the cost and utilization management, quality improvement, medication therapy management and fraud, abuse

and waste program requirements as specified in subparts D and K of this part.

(11) Fails to comply with the regulatory requirements contained in this part.

(12) Fails to meet CMS performance requirements in carrying out the regulatory requirements contained in this part.

(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) The procedures specified in (b)(1) of this section do not apply if—

(A) 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;

(B) The Part D plan sponsor 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; or

(C) The contract is being terminated based on the violation specified in paragraph (a)(4) of this section.

(ii) CMS notifies the MA organization in writing that its contract will be terminated on a date specified by CMS. If a termination in 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 notice specifying the Part D plan sponsor's deficiencies and a reasonable opportunity of at least 30 calendar days to develop and implement a corrective action plan to correct the deficiencies.

(ii) 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.* The Part D plan sponsor will not be provided with an

opportunity to develop and implement a corrective action plan prior to termination if—

(i) 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;

(ii) The Part D plan sponsor 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; or

(iii) The contract is being terminated based on the violation specified in (a)(4) of this section.

* * * * *

■ 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 with the exception of the sale or transfer of a full contract between wholly owned subsidiaries of the same parent organization which will be recognized and allowed by CMS.

(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).

(3) The Part D plan sponsor must establish and maintain a method of documenting all oral requests and retain the documentation in the case file.

(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.* Except as provided in (c)(2) of this section, CMS mails notice to the Part D plan sponsor 90 calendar days before the anticipated effective date of the termination.

(2) *Exception.* If a contract is terminated in accordance with § 423.509(b)(2)(i) of this part, 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) A contract terminated in accordance with § 423.509(b)(2)(i) of this part will be terminated on the date specified by CMS and will not be postponed if a hearing is requested.

* * * * *

■ 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 10 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 revising the paragraphs (a) introductory text, (a)(1), (a)(3), and (a)(4) to read as follows:

§ 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 are 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 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.

* * * * *

■ 102. Section 423.800 is amended by adding a new paragraph (e) to read as follows:

§ 423.800 Administration of subsidy program.

* * * * *

(e) *Timeframe for refunds and recoveries due to retroactive adjustments to cost sharing.* Sponsors must process retroactive adjustments to cost-sharing for low-income subsidy eligible individuals and any resulting refunds and recoveries in accordance with the timeframe specified in § 423.466(a) of this part.

Subpart V—Part D Marketing Requirements

■ 103. Section 423.2260 is amended by revising paragraph (5)(vii) of the definition “marketing materials” and adding a new paragraph (6) to read as follows:

§ 423.2260 Definitions concerning marketing materials.

* * * * *

Marketing materials. * * * * *
(5) * * *

(vii) Membership activities (for example, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or nonclaim-specific notification information).

(6) Marketing materials exclude ad hoc enrollee communications materials, meaning informational materials that—
(i) Are targeted to current enrollees;

(ii) Are customized or limited to a subset of enrollees or apply to a specific situation;

(iii) Do not include information about the plan's benefit structure; and

(iv) Apply to a specific situation or cover member-specific claims processing or other operational issues.

■ 104. 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 standardized 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) *Ad hoc enrollee communication materials.* Ad hoc 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

■ 105. 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).

■ 106. 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 to CMS quality review study information collected as part of the Reporting Hospital Quality Data for Annual Payment Update program, under section 1886(b)(3)(B)(viii) of the Act following hospital review of the data. The quality review study information must include identifiers of MA plan beneficiaries, hospitals, practitioners, and services 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: March 11, 2010.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: April 2, 2010.

Kathleen Sebelius,

Secretary.

[FR Doc. 2010-7966 Filed 4-6-10; 4:15 pm]

BILLING CODE 4120-01-P