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42 CFR Parts 422 and 423

Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions; Final Rule; Medicare Program; Prescription Drug Benefit Program: Payments to Sponsors of Retiree Prescription Drug Plans; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

[CMS–4131–FC;–RIN 0938–AP24]

Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions

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

ACTION: Final rule with comment period.

SUMMARY: This rule contains final regulations governing the Medicare Advantage (MA) program (Part C) and prescription drug benefit program (Part D), and interim final regulations governing certain aspects of the Retiree Drug Subsidy (RDS) Program, and reflecting new statutory definitions relating to Special Needs Plans under Part C. The final regulations revising the Part C and Part D regulations include provisions regarding medical savings account (MSA) plans, cost-sharing for dual eligible enrollees in the MA program, the prescription drug payment and novation processes in the Part D program, and the enrollment and appeals processes for both programs. This final rule with comment period also responds to public comments on the May 16, 2008 proposed rule and takes into account statutory revisions contained in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

DATES: *Effective Date:* These regulations are effective on March 13, 2009.

Applicability Date: The revisions to the definition of ''negotiated prices'' in § 423.100, with the exception of the revision to include a reference to ''other network dispensing provider,'' which is applicable on March 13, 2009, are applicable for contract year 2010. The revisions to the definitions of ''administrative costs,'' ''allowable risk corridor costs,'' and ''gross covered prescription drug costs'' in § 423.308 are also applicable for contract year 2010.

Comment Period: We will consider comments on the provisions concerning the new statutory definitions relating to special needs plans (see section II.A.1 of the preamble to this final rule with comment period) and those concerning negotiated prices and retained rebates under the Retiree Drug Subsidy (RDS) program (see section II.B.5.e. of the preamble to this final rule with comment period), provided that they are received at one of the addresses provided below no later than March 13, 2009.

ADDRESSES: In commenting, please refer to file code CMS–4131–FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.regulations.gov*. Follow the instructions under the ''More Search Options'' tab.

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

Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–4131–FC, P.O. Box 8013, Baltimore, MD 21244–8013.

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

3. *By express or overnight mail.* You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–4131–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201;

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

b. 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7197 in advance to schedule your arrival with one of our staff members.

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

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

FOR FURTHER INFORMATION CONTACT:

Change of Ownership: Scott Nelson, 410–786–1038.

Civil Money Penalties: Christine Reinhard, 410–786–2987.

Definitions related to the Part D drug benefit, Subparts F and G: Deondra Moseley, 410–786–4577, or Meghan Elrington, 410–786–8675.

Definitions related to the Part D drug benefit, Subpart R: David Mlawsky, 410–786–6851.

Enrollment: Jeff Maready, 415–744–3523.

Low-Income Cost-Sharing: Christine Hinds, 410–786–4578.

Medicare Medical Savings Account Plans: Anne Manley, 410–786–1096.

Payment: Frank Szeflinski, 303–844–7119.

Reconsiderations: John Scott, 410–786–3636, or Kathryn McCann Smith, 410–786–7623.

Special Needs Plans: LaVern Baty, 410–786–5480.

SUPPLEMENTARY INFORMATION:

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

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

I. Background and Legislative History

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)) that established 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 Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), (Pub. L. 106–111), amended the M+C provisions of the BBA. Further amendments were made to the M+C program by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), enacted December 21, 2000.

Subsequently, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) was enacted on December 8, 2003. This landmark legislation established the Medicare prescription drug benefit program (Part D) and made significant revisions to the provisions in Medicare Part C, governing what was renamed the Medicare Advantage (MA) program (formerly Medicare+Choice). The MMA directed that important aspects of the new Medicare prescription drug benefit program under Part D be similar to and coordinated with regulations for the MA program. The MMA also created a subsidy program involving payments to sponsors of Retiree Prescription Drug Programs, or the Retiree Drug Subsidy (RDS) Program. This program allows subsidy payments to sponsors of qualified retiree prescription drug plans for Part D drug costs for individuals who are eligible for, but not enrolled in, a Medicare Part D plan.

The MMA also specified that implementation of the prescription drug benefit and revised MA program provisions take place by January 1, 2006. Thus, we published final rules for the MA and Part D prescription drug programs in the **Federal Register** on January 28, 2005 (70 FR 4588 through 4741 and 70 FR 4194 through 4585, respectively). (For further discussion of these revisions, see the respective final rules (70 FR 4588 through 4741) and (70 FR 4194 through 4585).)

Since the publication of these rules, we have gained a great deal of experience with all aspects of these programs. Based on this experience, as well as on recommendations from representatives of both the organizations that provide care and the Medicare beneficiaries that they serve, we determined that proposed changes to the existing Part C, Part D, and RDS regulations were warranted. We believed that these changes would help plans understand and comply with our policies for all three programs, and aid MA organizations and Part D and RDS plan sponsors in implementing their health care and prescription drug benefit plans in ways that will better serve the Medicare population.

Thus, on May 16, 2008, we published a proposed rule (73 FR 28556) that would revise certain aspects of both the MA, Part D, and RDS programs. Many of these proposed revisions were designed to clarify existing policies or codify current guidance for these programs. Subsequent to the publication of that proposed rule, the Medicare Improvements for Patients and Providers Act (MIPPA) (Pub. L. 110–275) was enacted on July 15, 2008. MIPPA included a number of provisions that addressed the same requirements that we had addressed in the proposed rule. In some cases, the MIPPA provisions paralleled our proposed requirements and in other instances they complemented or superseded them. Thus, in order to implement both the new MIPPA provisions and those proposed in our May 2008 proposed rule, we have published a series of rules to set forth the appropriate regulatory changes.

In the September 18, 2008 **Federal Register** (73 FR 54208), we published a final rule that finalized certain marketing provisions, effective October 1, 2008, that paralleled provisions in MIPPA. In the same issue of the **Federal Register** (73 FR 54226), we also published a separate interim final rule that addressed the other provisions of MIPPA impacting the MA and Part D programs.

This final rule responds to comments on the May 16, 2008 proposed rule and generally finalizes provisions of that rule that were not addressed in either of the rules published on September 18, 2008. We received over 100 comments on the proposed rule. Commenters included managed care and prescription drug plans and their representatives, provider groups, and Medicare beneficiary advocates. The comments ranged from general support or opposition to the proposed provisions, to very specific questions or comments regarding a proposed change.

Some of these comments have been addressed in the rules discussed above. All comments pertaining to the provisions set forth in this final rule are discussed below. We are providing brief summaries of each proposed provision, a summary of the public comments we received, and our responses to the comments.

II. Analysis of and Response to Public Comments

In the sections that follow, we discuss the changes to the regulations in parts 422 and 423 governing the MA and prescription drug benefit programs that were proposed in our May 16, 2008 rule, and the comments we received on those provisions as well as conforming changes to the regulations to reflect two new statutory definitions affecting the MA program that were enacted in MIPPA. Several of the revisions and clarifications discussed below affect both the MA and prescription drug benefit programs.

A. Changes to Part 422—Medicare Advantage Program

1. Special Needs Plans

The MMA first authorized special needs plans (SNP), a type of MA plan designed to exclusively, or disproportionately, enroll individuals with special needs. The three types of special needs individuals eligible for enrollment identified in the MMA include—(1) Institutionalized individuals (defined in 42 CFR 422.2 as an individual residing or expecting to reside for 90 days or longer in a long term care facility); (2) individuals entitled to medical assistance under a State plan under title XIX; and (3) other individuals with severe or disabling chronic conditions that would benefit from enrollment in a SNP.

The number of SNPs approved as of January 2008, is 787. This figure includes 442 dual eligible SNPs, 256 chronic care SNPs, and 89 institutional SNPs.

a. *Definitions:* Institutional-Equivalent and Severe or Disabling Chronic Condition (§ 422.2)

Section 164 of MIPPA contained two new statutory definitions that relate to eligibility for SNPs. Although these definitions were not included in our May 18 proposed rule, we are discussing these new definitions here in the context of the more general SNP-eligibility provisions, and incorporating these new definitions in interim final regulations as part of this rule.

Although the statute governing SNPs has always referred to individuals eligible to enroll in SNPs based on institutional status or on having a severe or disabling chronic condition, the statute previously did not define these terms. We believe that discussing these new definitions in this rule will both aid the understanding of the new statutory requirements and complement the eligibility requirements from the proposed rule that we are publishing as final regulations in this rule. In addition, because we received public comment on the May 2008 proposed rule closely related to eligibility for institutional-level and chronic care individuals, we believe that in order to fully respond to these comments it is important to discuss all of the provisions relating to chronic care and

institutional care eligibility. Public comments related to institutional and chronic care SNP eligibility are addressed below.

(1) Institutional-Equivalent Individual

Section 164 of MIPPA adds a new paragraph (2) to section 1859(f) of the Act related to eligibility requirements for institutional SNPs. Beginning on January 1, 2010, institutional SNPs that enroll a special needs individual who is living in the community but requires an institutional level of care (LOC) (*i.e.*, an ''institutional-equivalent individual'') must meet two new eligibility requirements.

First, the determination of institutional LOC must be made using a State assessment tool. States have extensive experience in making LOC determinations, as demonstrated by a recently published survey [1] of State LOC assessment, which references several other investigative sources. The study describes varying State instruments and methodologies, and may be an important resource for institutional SNPs that are not already aware of existing State LOC assessment tools. In States and territories that have not designed a specific tool, SNPs must use the same LOC determination methodology employed in the respective State or territory in which the SNP is authorized to enroll eligible beneficiaries.

Second, the SNP must arrange to have the LOC assessment conducted by an entity other than the respective MA organization. We believe this entity must be both impartial and have the requisite professional knowledge to accurately identify institutional LOC criteria.

As a result of MIPPA provisions concerning institutionalized care, we have revised our definitions section in § 422.2 to incorporate the new statutory definition of ''institutional equivalent'' set forth in MIPPA.

(2) Severe or Disabling Chronic Condition

Section 164 of MIPPA also adds a new clause to section 1859(b)(6)(B)(iii) of the Act to clarify the eligibility requirements for chronic condition SNPs. Beginning on January 1, 2010, chronic condition SNPs that enroll a special needs individual who has a severe or disabling chronic condition must determine that the individual has one or more co-morbid and medically complex chronic condition(s) that are substantially disabling or life-threatening, has a high risk of hospitalization or other significant adverse health outcomes, and requires specialized delivery systems across domains of care. We have also updated our definitions in § 422.2 to incorporate this new statutory definition of severe or disabling chronic condition.

We note that the statute also directs the Secretary to convene a panel of clinical advisors to determine which chronic conditions meet this clarified definition. We will issue separate guidance describing the operational process the Secretary will use to comply with this directive.

b. Ensuring Special Needs Plans Serve Primarily Special Needs Individuals (§ 422.4)

The MMA generally authorized SNPs that ''exclusively'' serve individuals with the above-described special needs. However, section 231(d) of MMA provided the Secretary with the ''authority'' to designate MA plans as SNPs if the SNP only ''disproportionately serve[s] special needs individuals,'' while also serving non-special needs enrollees. Section 231(d) of the MMA provides that ''the Secretary *may* provide'' for such plans in regulations implementing the SNP provisions. In the final rule implementing this MMA provision, we exercised this discretion in *§ 422.4(a)(iv)(B), providing that a SNP could be a plan that ''[e]nrolls a greater proportion of special needs individuals than occur nationally in the Medicare population * * *.''*

In the May 16, 2008 proposed rule, we proposed to amend § 422.4(a) to require that MA organizations offering ''disproportionate share'' SNPs ensure that at least 90 percent of new plan membership consist of individuals that fell into the appropriate special needs category for the plan in question, as defined in § 422.2. Thus, no more than 10 percent of a plan's new enrollees could be non-special needs individuals. Based on the comments received on this proposal, and in light of the fact that section 164 of MIPPA eliminates the authority for disproportionate share SNPs effective January 1, 2010, we are revising the regulations to specify that all new SNP enrollees must be special needs individuals. In other words, we are declining to permit disproportionate share SNPs as permitted, at our discretion, under section 231(d) of MMA. As discussed below, we are amending § § 422.2 and 422.4 to reflect these changes.

Comment: All commenters agreed that the current regulation permitting an MA plan to be designated a SNP if it enrolled special needs individuals in a higher proportion than they exist in the Medicare population diminishes the intended focus of special needs plans on providing care and services to special needs individuals. Commenters generally supported our proposal that at least 90 percent of new enrollees consist of individuals with the targeted condition or status. Many commenters, however, argued for a higher threshold. Some commenters suggested establishing a 95 percent threshold, as recommended by the Medicare Payment Advisory Commission (MedPAC). Still others suggested requiring that entire plan membership (100 percent) be in the targeted special needs group, or at least that all new enrollees fall into the targeted category of individuals. These commenters correctly noted that although section 231(d) of MMA allows plans to enroll a certain portion of members from the non-targeted population, there is no requirement that non-special needs individuals be permitted to join an SNP. Many commenters also indicated that having to monitor the proportion of plan membership that fell into the appropriate category would pose an administrative challenge, and was unnecessarily complex.

Response: After considering all comments, and in light of the fact that disproportionate share SNPs will no longer be authorized as of January 1, 2010, we agree with the commenters who urged that SNPs should not be permitted to enroll individuals who do not meet the qualifying targeted conditions (dual eligibility for Medicare and Medicaid, institutional status, or severe or disabling chronic conditions). Thus, taking into consideration the MIPPA changes and the public comments described above, we are revising our proposal to prohibit the enrollment of nonqualifying members into all SNP plans. We believe that this change will emphasize the need for SNPs to focus on providing care and services to their targeted population.

We recognize that this means that a spouse of an individual in a chronic care SNP generally will not be able to join the same plan (unless the spouse has the same condition), which has been presented in the past as a reason to permit some non-special need individuals to enroll in SNPs. Note that a plan may not disenroll a non-special needs individual who has already enrolled in the SNP consistent with the current disproportionate percentage methodology. Such individuals may

[1] Henderickson, L. Kyzr-Sheeley, G. (2008). Determining Medicaid Nursing Home Eligibility: A Survey of State Level Care Assessment. Retrieved July 27, 2008 from *http://www.hcbs.org/moreInfo.php/nb/doc/2216/.*

remain in their plans unless and until they choose to disenroll. Note that they would not be permitted to re-enroll in another SNP unless they had a qualifying condition. We are revising §§ 422.2 and 422.4 to reflect these changes.

Comment: One commenter requested that the 90 percent disproportionate percentage requirement be measured on an aggregate basis for a given calendar year, rather than on a monthly or day-to-day basis.

Response: Since we are eliminating use of any disproportionate percentage methodology in the future, this issue has become moot.

Comment: Several commenters were confused by the wording of the proposed regulations and asked that CMS clarify whether the proposed 90 percent rule applied only to new members, or applied to the overall membership in the plan. Given the current proportions of special needs individuals in many SNPs, they noted that establishing an overall target of 90 percent would effectively require that all new enrollees be members of the appropriate category in any event.

Response: We recognize that the wording of the proposed requirements left some room for confusion as to the precise intent of the provisions in question. Our proposal would only have applied to new enrollees, so regardless of how many current members were special needs individuals, 10 percent of new enrollees could have been non-special needs individuals under our proposal. However, as explained above, the final regulations clearly specify that the 100 percent requirement applies only to new members.

c. Ensuring Eligibility To Elect an MA Plan for Special Needs Individuals (§ 422.52)

We proposed in § 422.52 that MA organizations be required to establish a process approved by CMS to verify that potential SNP enrollees meet the SNP's eligibility requirements. While this issue is addressed, to some degree, in our manual guidance (section 20.11 of Chapter 2 of the Medicare Managed Care Manual), we believe that it is important to set forth in regulations our explicit authority to establish verification requirements. The proposed regulations were also intended to ensure that plans were aware of, and met, their obligations to verify an applicant's eligibility prior to enrolling individuals in a SNP. As discussed below, we are adopting these changes in final regulations as proposed and, as noted above, we are in interim final regulations codifying the related MIPPA eligibility requirements concerning institutional-level and chronic care SNP. We are also making a conforming change to § 422.52(f) by deleting the currently existing paragraph, which refers to SNPs serving disproportionately special needs individuals.

Comment: Commenters did not object to our proposal to establish in regulations that SNPs must use a CMS-approved process to verify SNP eligibility. However, several commenters requested that we revise either the proposed regulations or manual guidance to specify that SNPs have 60 days to verify enrollment for individuals with special needs. Alternatively, the commenters suggested that CMS take into consideration the amount of time for verifying enrollment status when monitoring plan compliance with the SNP provisions. Another commenter recommended that CMS maintain the previous requirements (established in our May 31, 2007 HPMS memo) for time frames and sources for verification of Chronic Care SNP enrollment qualifications. The commenter suggested that the 30-day timeframe now established in the manual is impractical, and they further recommended that sources other than providers be allowed for verification of chronic care SNP enrollees' eligibility for the SNP.

Response: We are strongly committed to ensuring that SNPs carry out proper verification of all eligibility criteria, consistent with the requirements discussed above concerning SNP enrollment requirements. Thus, we are adopting the proposed requirement that SNPs follow a CMS-approved verification process. Note that although we are not setting out specific verification requirements in the regulations, manual current guidance already requires that prompt verification take place (generally either before enrollment or no later than the end of the first month of enrollment). We continue to believe that prompt verification is necessary to prevent large numbers of subsequent, unnecessary disenrollments from SNPs of individuals who never should have been enrolled.

As noted in the May 2008 proposed rule (73 FR 28559), we have given plans a number of options for meeting the verification requirements, including post-enrollment confirmation under certain circumstances (such as when a pre-enrollment qualification assessment tool is used, as opposed to direct contact with a provider). In addition, to assist SNP plans in obtaining timely verification from appropriate medical professional personnel, we have made clear in subregulatory guidance (Chapter 2, Section 20–11, Medicare Advantage Manual) that for the purposes of verification of chronic care SNP eligibility, verification may be obtained through a provider or provider's office. This includes any licensed health care professional in a position to validate and verify the beneficiary's medical history and status, such as nurse practitioners or pharmacists. However, we are concerned that the use of organizational data alone, such as claims or medical records, may not always be sufficient to confirm SNP eligibility. Thus, we intend to continue to evaluate the issue of when and how data may be appropriately used to verify SNP eligibility and we are willing to consider reasonable alternative proposals presented by plans to verify eligibility. Still, given that the underlying intent of chronic care SNPs is to provide care services to a population with a need for carefully managed services, we do not believe it is unreasonable to expect early contact with a suitable health care professional.

Comment: A commenter suggested that CMS include language addressing pre-enrollment qualification assessment tools and post-enrollment confirmation of eligibility procedures as aspects of the SNP eligibility verification process for all SNPs, not just chronic care SNPs.

Response: We do not believe that such changes are warranted or necessary for non-chronic care SNPs, given the other available sources of eligibility verification. As discussed in our recent interim final rule (73 FR 54228), in accordance with the recent MIPPA legislation, dual-eligible SNPs and institutional SNPs must have arrangements with the appropriate entities to verify Medicaid eligibility or institutional status in an ongoing and routine manner.

Comment: A commenter described our suggestion in the preamble of the proposed rule that dual-eligible SNPs be required to enter into an agreement with state agencies as ''impractical.'' The commenter further suggested that CMS establish a process similar to that used under the Part D low-income subsidy status for determining dual eligibility status for Part C dual-eligible SNP plans, or as an alternative establish a best available evidence policy for dual-eligible SNP plans. Thus, rather than the SNP plan being responsible for obtaining Medicaid eligibility information, the commenter requested that CMS furnish the eligibility information to dual-eligible SNP plans.

Response: The establishment of successful partnerships and processes to

share information about dual status with State Medicaid agencies is a key aspect of the SNP's ability to provide specialized services to this population, ensure beneficiary understanding of both programs' benefits, and provide meaningful coordination between the Medicare and Medicaid programs. Furthermore, section 164 of MIPPA requires dual eligible SNPs to have a contract with a State Medicaid Agency effective as of January 1, 2010, to provide benefits (or arrange for benefits to be provided) that an individual is entitled to receive under the Medicaid program.

With respect to the commenter's suggestion that we establish a process similar to our current Part D ''Best Available Evidence'' policy to allow plans to provide evidence of dual-eligibility status, we decline to establish such a process at this time. We believe that beneficiaries and SNPs would be better served by an arrangement with States to exchange eligibility information on a regular basis. Such arrangements could be incorporated into the contracts between SNPs and the appropriate State Medicaid Agency that will now be required as of January 1, 2010.

d. Model of Care (§ 422.101(f))

In order to ensure that SNPs were providing care targeted to such special needs beneficiaries, under our authority in section 1856(b)(1) of the Act to establish standards by regulation, we proposed that SNPs develop a model of care specific to the special needs population they are serving. In order to more clearly establish and clarify delivery of care standards for SNPs and to codify standards which we have included in other CMS guidance and instructions (the 2008 and 2009 Call Letters, ''Special Needs Plan Solicitation'' [2]), we proposed to add new paragraph (f) to § 422.101. This proposed paragraph specified that SNPs have networks with clinical expertise specific to the special needs population of the plan; use performance measures to evaluate models of care; and be able to coordinate and deliver care targeted to the frail/disabled, and those near the end of life based on appropriate protocols. Section 164 of the MIPPA subsequently added care management requirements for all SNPs as directed in section 1859(f)(5) of the Act (42 U.S.C. 1395w–28(f)). The new mandate required dual-eligible, institutional, and chronic condition SNPs to implement an evidence-based model of care having two explicit components. The first component was an appropriate network of providers and specialists to meet the specialized needs of the SNP target population. The second component was a battery of case management services that includes— (1) A comprehensive initial health risk assessment and annual reassessments; (2) an individualized plan of care having goals and measurable outcomes; and (3) an interdisciplinary team to manage care. This law laid a statutory foundation for much of our proposed regulatory standards for the model of care. Therefore, we address the comments we received on our proposals from both a statutory and regulatory basis.

Comment: The overwhelming majority of commenters expressed support for a required SNP model of care. However, many argued that the proposed language was too weak to permit genuine oversight of SNPs or assure adequate protection for vulnerable beneficiaries. They urged us to require a more prescriptive model of care similar to the PACE program or state integrated care waiver demonstration projects. Among their recommendations were that we require that model of care include elements such as: Care coordination through an individualized care plan; at least one network physician with network hospital privileges and one network provider with access to diagnostics and ancillary health services; transition coverage across care settings, providers, and services to ensure continuity of care; a comprehensive risk assessment on which to base the individualized care plan; public reporting of performance data as evidence that remuneration pays for services actually delivered; a complaint/grievance process used in monitoring activities; SNP staff trained on the respective state Medicaid program; and mandatory publishing of the SNP model of care in marketing materials. One of these commenters specifically advocated that pharmacists be an integral member of a SNP provider network, but was countermanded by another commenter that who opposed prescribing the provider network composition. Finally, one commenter suggested that we require all MA organizations, not just SNPs, to serve enrollees that are frail/disabled or near the end of life.

Response: Over the past 2 years, we collected and reviewed models of care from existing SNPs. We also reviewed models of care such as medical home models and chronic care models published in healthcare books, peer-reviewed journals, and advocacy group and industry reports. Based on our extensive review of models of care for vulnerable populations, we agree with the majority of commenters who indicated that a required SNP model of care that contains certain minimal elements is necessary to provide regulatory oversight and effective monitoring of SNPs. MIPPA demonstrated further support that care management required an organizational structure represented by the model of care. Specifically, MIPPA required SNPs to conduct initial and annual comprehensive health risk assessments, develop and implement an individualized plan of care, and implement an interdisciplinary care team for each beneficiary. We believe that combination of MIPPA's statutory elements and our regulatory prescription for the SNP model of care establishes the standardized architecture for effective care management, yet gives plans the flexibility to design the unique services and benefits that enable them to meet the identified needs of their target population. To illustrate this balance between the model of care architecture and its plan-specific components, we present the following examples. All SNPs must have an interdisciplinary team to coordinate the delivery of services and benefits; however, one SNP may choose to contract with an interdisciplinary team to deliver care in community health clinics and another SNP may hire its team to deliver care in the home setting. Under our final regulations, all SNPs must coordinate the delivery of services and benefits through integrated systems of communication among plan personnel, providers, and beneficiaries; however, one SNP may coordinate care through a telephonic connection among all stakeholders and a second SNP may coordinate care through an electronic system using Web-based records and electronic mail accessed exclusively by the plan, network providers, and beneficiaries. All SNPs must coordinate the delivery of specialized benefits and services that meet the needs of their most vulnerable beneficiaries; however, dual-eligible SNPs may need to provide state-identified services while an institutional SNP may need to facilitate hospice care for its beneficiaries near the end of life. These examples demonstrate the variety of ways SNPs currently implement their systems of care. We will continue to study SNP models of care and issue guidance through our Call Letters and informational memoranda to facilitate improvement in the SNP model of care framework.

[2] The solicitation may be found at *http://www.cms.hhs.gov/SpecialNeedsPlans.*

Comment: One commenter noted that our proposed language required the model of care to deliver services to targeted enrollees as well as those who are frail/disabled or near the end of life. The entity clarified that SNPs do not ''deliver'' care, but provide access to care practitioners.

Response: We acknowledge the distinction that most SNPs are not healthcare providers, but are entities that coordinate care through provider networks. We believe that our references to delivering care can reasonably be read as referring to delivering services through such networks.

Comment: Several commenters supported a requirement for the use of evidence-based or nationally recognized clinical protocols in the delivery of care to special needs beneficiaries. One commenter argued that, if we were to prescribe specific disease management protocols for SNPs in the future, we should do so through published regulations that would permit the medical community to comment. A second commenter urged us to clarify ''protocols'' to include process as well as clinical protocols because nationally recognized protocols do not exist for all clinical conditions.

Response: We agree that SNPs must coordinate and deliver care with healthcare professionals that use protocols, whether clinical or administrative in nature, which are evidence-based or, where possible, derived from nationally recognized guidelines. We refer beneficiaries, plans, and providers to the Agency for Healthcare Research and Quality (*http://www.ahrq.gov/*) which provides public access to both an extensive repository of evidence-based protocols through its National Guidelines Clearinghouse, as well as discussions regarding ongoing research on clinical practice. If we propose future regulation related to the use of clinical or administrative protocols, we will elicit appropriate public comments from all stakeholders. Presently, we expect SNPs to have personnel (employed, contracted, or non-contracted) prepared to discuss their implemented protocols at monitoring visits or other oversight activities. Because we have not prescribed the use of specific protocols, the comment that we should do so through rulemaking does not apply.

Comment: A few commenters proposed that we work with recognized standards organizations to develop better ways to monitor SNPs and inform the public about plan performance. However, one commenter cautioned that, in developing SNP-specific measures, we must address the broad range of special care needs and the limitations of available data sources.

Response: We have contracted with the National Committee for Quality Assurance (NCQA) to develop, collect, analyze, and report on SNP-specific performance measures at the plan benefits package (PBP) level. We will continue to work with NCQA and other quality measurement experts such as the Geriatric Measurement Advisory Panel to explore valid and reliable ways to measure and improve SNP performance. As we identify new directions in quality measurement for vulnerable populations, we will elicit public, professional, and beneficiary comment to inform our regulatory and informational guidance to SNPs.

e. Special Needs Plans and Other MA Plans With Dual Eligibles: Responsibility for Cost-Sharing (§ 422.504(g)(1))

In order to protect beneficiaries and ensure that providers do not bill for cost-sharing that is not the beneficiary's responsibility, we proposed to amend § 422.504(g)(1)(i) and (g)(1)(ii) to require that all MA organizations, including SNPs, with enrollees who are eligible for both Medicare and Medicaid specify in their contracts with providers that enrollees would not be held liable for Medicare Parts A and B cost sharing when the State is liable for the cost-sharing. Plans may not impose cost-sharing that exceeds the amount of cost-sharing that would be permitted with respect to the individual under title XIX if the individual were not in such plan. We also proposed therefore, that contracts with providers state that the provider will do this by either accepting the MA plan payment in full (§ 422.504(g)(1)(iii)(A)) or by billing the appropriate State source (for example, Medicaid) (§ 422.504(g)(1)(iii)(B)). Additionally, we proposed that all MA organizations with enrollees eligible for both Medicare and Medicaid must inform providers of the Medicare and Medicaid benefits and rules for enrollees eligible for Medicare and Medicaid (§ 422.504(g)(1)(iii)). Section 165 of MIPPA only required that full benefit dual-eligible individuals and qualified Medicare beneficiaries in SNPs for dual-eligibles not be held liable for Medicare Parts A and B cost-sharing. Our proposal included all MA plans that have dual eligibles enrolled in their plan.

The above proposals have been superseded in part by section 165 of MIPPA, ''Limitation on Out-of-Pocket Costs for Dual Eligibles and Qualified Medicare Beneficiaries Enrolled in a Specialized Medicare Advantage Plan for Special Needs Individuals,'' which establishes that for full benefit-dual-eligible individuals or qualified Medicare beneficiaries enrolled in a special needs plan, an MA organization may not impose cost-sharing that exceeds the amount of cost-sharing that would be permitted if the individual were under title XIX and were not enrolled in a special needs plan. The effective date of this provision is January 1, 2010.

After considering comments discussed below, we are finalizing our proposal to impose the requirement that MIPPA imposed in the case of dual-eligible SNPs on duals in all MA plans, and on all dual Medicaid eligibility categories for which a State provides a zero cost-share. Consistent with the MIPPA requirements that apply to dual-eligible SNPs, we are specifying in the regulations that these provisions are effective on January 1, 2010.

Comment: Several commenters supported CMS' effort to protect dual eligible individuals from being charged for cost sharing under Medicare Parts A and B when the state is responsible. However, many requested that CMS either allow MA plans to send a notification to the providers of this change or to allow MA organizations to amend contracts at the end of the contract term, in 2 years, or whenever the contracts are renegotiated. Some commenters requested that CMS establish a process for Medicare Advantage Organizations to work with CMS to develop and disseminate this information. Other commenters stated that CMS should go further by requiring all MA plans to provide to all of their physicians and other providers with specific information about when dual eligibles are not liable for cost-sharing and include the matrix CMS developed on cost-sharing and the dual eligibility types.

Several commenters also stated that CMS should go further by requiring plans to have a designated contact person who is knowledgeable about the Medicaid programs who can answer cost sharing questions for providers and that plans should be required to refund any cost-sharing that has been inappropriately charged to dual eligible individuals. One commenter recommended that CMS require this of dual-eligible SNPs only and not all plans that serve dual eligible individuals.

Response: We do not believe it would sufficiently protect dual-eligible enrollees to simply require notice to providers. We also do not believe that these protections should be delayed for up to 2 years, particularly when MIPPA

imposes them in the case of enrollees in dual eligible SNPs effective January 1, 2010. However, we do not believe that it is necessary to require that SNPs necessarily designate a specific person to address dual-eligible issues. We believe that MA organizations should have flexibility in complying with these requirements. As noted above, we disagree with the commenter who believed that these requirements should only apply to dual SNPs as the MIPPA requirement did, because we believe that all dual eligibles need these protections.

2. MA Medical Savings Accounts (MSA) Transparency (§ 422.103(e))

Consistent with the best practices of health savings accounts (HSAs) and other high-deductible health plans, we proposed in a new § 422.103(e) to require that all medical savings account (MSA) plans provide enrollees with information on the cost and quality of services and provide information to CMS on how they would provide this information to enrollees.[3]

Comment: We received a number of public comments on the proposed cost and quality transparency requirements for Medicare MSA plans. Several commented on the developing and pioneering nature of reporting on cost and quality of health care information. Some comments simply expressed general support for the proposal. One comment from a state government human services department expressed general support for this proposal. One comment from a pharmacy association expressed support for providing consumers with cost and quality information.

Three comments were from health insurance plans with experience with Medicare MSAs, which also expressed support for this proposal, but requested flexibility for plans in development of cost and quality transparency information. One organization argued against separate standards for Internet vs. other forms of communication to allow flexibility in how information is communicated. Another comment from a health plan not currently participating as an Medicare MSA indicated its concern for the burden on health plans of transparency, and thought we intended to require that information be sent to all enrollees.

Two comments from major physician organizations requested that providers and other stakeholders have input into the reporting of cost and quality reporting measures. The physician organizations specifically reference guidelines from the Consumer-Purchaser Disclosure Project's ''Patient Charter for Physician Performance Measurement, Reporting and Tiering Programs.''

A number of consumer groups, including organizations representing the disabled, requested that cost and quality information be linked so that consumers can readily see where they meet, and so that consumers are not steered solely by price considerations. Consumer groups were also interested in information being posted on the out-of-pocket costs for enrollees in MSA plans, as well as on information for enrollees on how accounts operate and on any account fees or interest rates.

Response: Public comments indicate support for the proposal, and also indicate interest in making information useful for enrollees and equitable to health care providers on whom the information is reported. We acknowledge these comments of general support. We also understand comments requesting that stakeholders and consumers be allowed input and their interest in making the information fully useful to consumers.

As indicated in the proposed rule in the discussion of calculation of burden on health plans, we are expecting plans to provide the same level of information on cost and quality of services that they provide to commercial enrollees and to provide whatever information is available. Therefore, we are anticipating that the burden level would not be undue on health plans. We hope that consumers will also provide input because they are the parties intended to use the information, and so we expect that consumer demand will shape the design of reporting standards over time. Therefore, we agree with the comment that plans should have flexibility in design of transparency standards. We are not specifying standards for Internet or for other forms of communication at this time. It also makes sense for physicians and other providers and any interested stakeholders to provide input directly to plans or to CMS.

We do not want to specify further requirements at this time for transparency and want primarily to allow plans to work with enrollees to develop that information. Note that the statutory exemption from quality improvement programs for MSAs at section 1852(e) of the Act was recently eliminated by section 163 of MIPPA. MSA and PFFS plans must participate in quality improvement programs beginning in 2010. This new quality improvement requirement implemented in regulations at § 422.152(a), will work in conjunction with transparency efforts and enable transmission of information directly to enrollees of these health care plans.

B. Changes to Part 423—Medicare Prescription Drug Benefit Program

1. Passive Election for Full Benefit Dual Eligible Individuals Who Are Qualifying Covered Retirees (§ 423.34)

We proposed to revise § 423.34(d) to establish an exception to our normal auto-enrollment procedures for full benefit dual eligible individuals who we know to be enrolled in a qualifying employer group plan. Rather than auto-enrolling these individuals into a PDP (no individuals are auto-enrolled into MA-PD), we proposed that such individuals would be deemed to decline Part D coverage if, following a notice of their options, they do not indicate that they wish to receive it. As discussed below, this final rule adopts the proposed regulatory changes to § 423.34(d) in their entirety.

Comment: All commenters supported the policy where full benefit dual-eligible individuals (eligible for both Medicare and Medicaid), who are also qualifying covered retirees, would not be automatically enrolled in a Medicare Part D plan by CMS. Although commenters expressed no objections to the proposed regulatory changes, several commenters objected to a statement in the preamble to the proposed regulation (73 FR 28562) indicating that if a full benefit dual eligible individual with qualifying retiree coverage decided to enroll in a Part D plan at a later time, that enrollment could be made effective retroactively to the date of the dual eligibility. The commenters asserted that retroactive Part D coverage would inappropriately shift the liability for past drug spending to a Part D plan. Other commenters supported the option of retroactive coverage.

Response: Consistent with our proposal, this final rule establishes that full benefit dual eligible individuals with qualified retiree coverage will not be automatically enrolled in a Medicare Part D plan. (That is, we will not auto-enroll individuals for whom we have approved a group health plan sponsor to receive the Retiree Drug Subsidy (RDS)

[3] HSAs are health insurance plans with a high deductible and a savings account for the under 65 population and are administered by the U.S. Department of the Treasury. Medicare MSAs are a type of medical savings account, also with a high deductible and a savings account, designed for the Medicare population and are administered by the U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. HSAs and MSAs are governed by different statutes, and while these health insurance products are similar in many ways, there are also important differences between them. For further information on HSAs, go to *http://www.ustreas.gov/offices/public-affairs/hsa/.*

described in 42 CFR Part 423, Subpart R for the period of time the automatic enrollment in Part D would otherwise cover.) Instead, we will send these individuals a notice informing them that they will be deemed to have declined such enrollment unless they take an affirmative action to choose a plan or opt for auto-enrollment. They may choose to enroll in a Medicare Part D plan at any time, as long as they retain that dual status, but we will not automatically enroll them in a Part D plan.

In general, we believe that dual eligible individuals who decide to enroll in a Medicare Part D plan at a later time should do so on a prospective basis, like most other enrollment elections. These individuals have made an election initially to not enroll in a Medicare Part D plan and instead to remain in their current employer plan. Thus, there is no ''coverage gap'' involved, which obviates the usual premise for retroactive Medicare coverage for dual eligibles. We agree with commenters that retroactive coverage under Medicare Part D could lead to an inappropriate shift of beneficiary drug expenditures to the Medicare program. However, as currently occurs under both the MA and Part D programs, we acknowledge that special circumstances may arise which would justify a retroactive enrollment into Medicare Part D. We will issue clarifying guidance on the appropriateness for retroactive coverage and consider those requests on a case-by-case basis.

Comment: Several commenters requested that other individuals who are automatically enrolled into a Medicare Part D plan, such as individuals eligible for one of the Medicare Savings Programs, also be exempted from automatic enrollment when they have qualified retiree coverage.

Response: Other individuals with qualified retiree coverage, such as non-dual eligible individuals who are also eligible for low-income subsidy assistance under the Medicare Savings Programs, are already excluded from automatic enrollment under Medicare Part D.

Comment: Several commenters suggested that the regulations specify that the notice individuals receive advise them to discuss the impact of Medicare Part D coverage with their group health plan administrator or personnel office. They also suggested that we share the model beneficiary notice with beneficiary representatives for their review.

Response: We do not believe it is necessary or appropriate to specify in the regulations the exact content of the notice that will be sent to the affected individuals, such as where individuals should turn to receive information to help them make a decision. However, in the notice that we send to beneficiaries, we will specify that individuals should discuss their drug benefits with the appropriate retiree staff who handle their coverage and benefits. We will be pleased to share the model beneficiary notice in draft with beneficiary representatives to obtain their input and guidance.

Comment: Several commenters requested we revise the regulations to specify that the notice will be provided to the individual or their representatives to the extent that we are aware that the individual has someone acting on his/her behalf. They expressed concern that some of the affected individuals may lack the capacity to understand the notice and the action to be taken.

Response: We are not modifying the regulations to include this suggested change, because we have no way to collect and retain address information for an individual authorized to act on behalf of a beneficiary, or verify that someone asserting such status is in fact so authorized.

Comment: Several commenters requested that CMS extend the process for non-automatic enrollment into Medicare Part D to full benefit dual eligible individuals with non-qualifying retiree coverage in addition to those individuals with qualifying retiree coverage.

Response: Currently, we receive information only for individuals who have qualifying retiree prescription drug coverage, and for whom we have approved a group health sponsor to receive the RDS. The information we receive, among other data, specifies that the individual's retiree drug coverage is at least equal to the actuarial value of the Medicare Part D defined standard prescription drug coverage, and records are maintained for audit purposes (§ 423.884). We do not have similar information for non-qualifying retiree prescription drug coverage, and thus would be unable to extend the non-automatic enrollment process to cover those situations. To accomplish the request would require soliciting information on the other coverage, verifying its authenticity, and entering it into the database which includes creditable coverage information. Should this information become readily available, we would consider this proposal. However, we note that we would not be certain, in the case of other retiree coverage, whether the coverage had a value to beneficiaries at least as good as that they would get if defaulted to a Part D plan. This would also be a factor for us to consider.

Comment: Several commenters requested that CMS establish a special enrollment period for retroactive disenrollment from Medicare Part D plans for any beneficiary who was auto-enrolled in a plan that conflicted with a retiree plan.

Response: Our current Medicare Prescription Drug Plan guidance permits full benefit dual eligible individuals to opt out of Medicare Part D coverage at any time. If the beneficiary makes the request prior to the effective date of auto-enrollment, then the enrollment is cancelled and the individual is considered not enrolled. If the effective date of the auto-enrollment is retroactive, the beneficiary may request a retroactive cancellation as long as the request is made by the 15th of the month after the month in which auto-enrollment occurred. If the request occurs after those dates, then the disenrollment would be effective with the last day of the month in which the request is made. With the retroactive cancellations, we caution individuals or their representatives to be careful to ensure individuals do not have a gap in prescription drug coverage, given that we have no authority to require that employer plans accept re-enrollments from former members of such plans. We also caution that such a disenrollment would not necessarily retroactively restore eligibility under an employer plan if that eligibility is lost as the result of an enrollment in a Part D plan.

2. Part D Late Enrollment Penalty (§ 423.46)

Under section 1860D–13(b) of the Act, a Part D late enrollment penalty (LEP) generally applies when a Medicare beneficiary has a continuous period of 63 days or longer without creditable prescription drug coverage subsequent to the beneficiary's initial enrollment period. This requirement is codified in regulations at § 423.46. Although § 423.46 describes which individuals are subject to a penalty, it does not specify the role of the Part D plan in the LEP determination process. We have subsequently outlined plan responsibilities in our existing guidance (Chapters 4 and 18 § 80.7.1, of the Medicare Prescription Drug Benefit Manual), and in our May 16, 2008 proposed rule we proposed to clarify the general responsibilities of Part D plans in the regulations.

First, we proposed to clarify under § 423.46(b) that Part D plans must obtain information on prior creditable coverage from all enrolled or enrolling

beneficiaries. Under this process, plans must first query CMS systems for previous plan enrollment information, which is a standard part of the beneficiary enrollment process. When there is a qualifying gap in creditable coverage, however, the process for obtaining creditable coverage information must also include plan interaction with the beneficiary. This is due in large part to the limited information available in CMS' systems about forms of creditable coverage other than Part D coverage or coverage through an employer group under the retiree drug subsidy (RDS). Therefore, it is critical that plans obtain historical creditable coverage information from the beneficiary in order to determine the number of uncovered months, if any, and retain any information collected concerning that determination (as specified under proposed § 423.46(d)).

The related requirement that we proposed under § 423.46(b) is that plans must then report creditable coverage information in a manner specified by CMS. Specifically, plans would report the number of uncovered months to CMS, which would then calculate the penalty and report the penalty back to the plan. The plan would then notify the beneficiary of the determination of the LEP amount and of their ability to request a reconsideration of this determination.

We also proposed under § 423.46(c) that, consistent with section 1860(D)–13(b) of the Act, individuals who are determined to have a late enrollment penalty have the opportunity to ask for a reconsideration of this determination. (Note that existing § 423.56(g) briefly references the ability to ''apply to CMS'' when an individual believes that he or she was not adequately informed that his or her prescription drug coverage was not creditable, and we would cross-reference that section here.) We believe that the statute clearly intends that individuals have an opportunity to provide CMS with additional information related to prior prescription drug coverage in support of a request for reconsideration of a late enrollment penalty determination. While the statute expressly provides for this opportunity only with respect to an argument that proper notice was not given concerning whether existing coverage was creditable, we believe that the same rationale could apply to other arguments that the penalty should not apply (for example, an argument that the individual had prior creditable prescription drug coverage that the enrollee believes may not have been considered).

Finally, we proposed to specify that a beneficiary would not have the right to further administrative review of the reconsideration decision of CMS, or the independent review entity acting under CMS' authority. However, we would, have the discretion to reopen, review, and revise such a decision.

Comment: Several commenters support the regulatory changes proposed; several other commenters, however, raised concerns about the role of Medicare Part D plan sponsors in the creditable coverage period determination process associated with the Part D LEP. Two of these commenters stated that having plans obtain and validate the required information could create inconsistencies in acceptable documentation, possible errors in reports to the government, and additional burden to plans. These two respondents suggested that CMS be responsible for the creditable coverage period determination, and one of them stated that the reporting process should be the same as the one for the Medicare Part B premium surcharge. Additionally, one of these commenters also suggested that, at the very least, and until such time as CMS is able to conduct this verification process without plan involvement, CMS should enhance its current Beneficiary Eligibility Query (BEQ) to provide the number of uncovered months rather than covered months. The commenter suggests that plans would then be able to simply transfer this information to the attestation form that must be sent to the beneficiary rather than have to convert it.

Response: The structure of the Medicare Part D program differs significantly from the Supplementary Medical Insurance program (Medicare Part B) in that beneficiaries interact directly with Part D plan sponsors to enroll in Part D coverage. In contrast, the majority of beneficiaries are automatically enrolled in Part B, while the rest apply at the Social Security Administration. Moreover, since we do not have information about all of the possible forms of creditable coverage for individual beneficiaries, this information has to come directly from beneficiaries. Since Part D plans correspond directly with their members at various times (for example, when the enrollment request is submitted and accepted by the plan), they are better able to determine whether the beneficiary is enrolling late and, if so, whether the beneficiary had creditable coverage. Thus, we continue to believe that plans are the appropriate entity to administer the initial stages of the LEP process.

With respect to the commenter's request that we enhance our BEQ to provide the number of uncovered months rather than covered months, we modified its system to include information about prior creditable coverage so that plans could query our data through the BEQ mentioned above. During this modification, we opted to include the date ranges that correspond to the months in which the individual has, or had, Part D coverage or when the retiree drug subsidy (RDS) is being claimed by an employer for that individual. This creditable coverage history that we provide in the BEQ is based on information we can confirm (that is, Part D or RDS coverage). Therefore, when there is a qualifying gap outside of these covered months, we are unable to determine whether an individual had other creditable coverage during the period in question. Since Part D plan sponsors correspond directly with their members when the enrollment request is submitted and accepted by the plan, they are better able to obtain creditable coverage information from the beneficiary about these uncovered months. Therefore, we decline to change the query at this time.

Additionally, we have developed operational procedures and policies that are intended to be as simple and straightforward as possible and impose minimal administrative burden on plans and beneficiaries. Most recently, on April 11, 2008, we released a memorandum, ''Updated Guidance on Creditable Coverage Determinations and the Late Enrollment Penalty'' via our Health Plan Management System (HPMS). This memorandum further clarified and expanded operational and policy guidance in a number of areas based on our experience implementing this policy and in response to questions and concerns raised. One significant change we made was to allow Part D plan sponsors to accept telephonic attestations in place of a missing or incomplete written attestation. We also expanded the existing timeframes that Part D plan sponsors have to report the creditable coverage information to us, thus affording Part D plan sponsors more time to follow up with beneficiaries to obtain the appropriate information.

Comment: Several commenters suggested that we simplify our creditable coverage documentation requirements for beneficiaries who change plans. For example, enrollees should be able to simply state on their enrollment application that they have had drug coverage, and CMS should then be responsible for verifying this information, since CMS should have

records of all the drug plans in which they were enrolled.

Response: We have already limited the scope of the plans' review when there is prior Part D plan or RDS enrollment in order to further simplify documentation requirements for plans and beneficiaries. If the beneficiary has prior Part D or RDS plan coverage, the plan only needs to determine whether the member has any months without creditable coverage since the date that he or she disenrolled from his or her prior Part D or RDS plan. That is, the current plan does not have to repeat the work done by the prior plan, and beneficiaries do not need to attest again to prior coverage when they simply change plans.

Additionally, if the individual, on his/her own initiative, includes creditable coverage information or documentation or both with the enrollment form, the plan must take that information into account when determining whether there has been a gap in coverage. As mentioned previously, we believe plans are in the best position to make creditable coverage determinations and report such determinations to CMS. We will continue to improve the process in response to comments and concerns from plans and beneficiaries.

Comment: One commenter stated that, although information about an individual's LEP is sent to the beneficiary, many beneficiaries do not open or read their mail. The commenter suggested that the beneficiary's LEP status be included in the Plan Finder, so that the beneficiary (and others assisting the beneficiary) could access such information. The commenter suggests that the Plan Finder include an indication as to whether or not an LEP has been assessed; the percentage of the penalty; and where applicable, LEP exempt status due to low income subsidy (LIS) eligibility.

Response: We appreciate the commenter's suggestion for using the Plan Finder as a tool to display information about a beneficiary's late enrollment penalty, and will consider whether this is viable in the future. However, no changes in the Plan Finder are possible in 2008. In the meantime, we have developed a ''Tip Sheet'' for Partners that provides key points for those assisting beneficiaries to use when answering questions from beneficiaries about the penalty. We are also developing another ''Tip Sheet'' that will focus on beneficiaries' role in responding to information received from their Part D plan sponsor, such as the attestation form. We have also simplified the current attestation form and included a new checklist designed to focus beneficiaries' attention on the form and emphasize the urgency of completing the attestation process. We expect these changes will improve beneficiaries' understanding of the importance of providing information about prior creditable coverage to their Part D plan sponsor.

Comment: Several commenters urged that the regulations include waiver of the LEP for individuals receiving the low income subsidy (LIS).

Response: Section 114 of the MIPPA eliminates the penalty for these individuals. Therefore, we have amended our regulations at § 423.46(a) and § 423.780(e) in a separate interim final rule to reflect this change. (*See* the September 15, 2008 interim final rule with comment period (73 FR 54226)). (Note that, under an existing Part D payment demonstration, CMS has not imposed an LEP on LIS beneficiaries.)

Comment: Several commenters urged that individuals have the full array of appeal rights available with respect to a decision subject to the Part D beneficiary appeals process, including ALJ hearings, and should not be limited to the reconsideration level of review. These commenters also believed that the regulation should contain more information about the reconsideration process, such as procedures and required timeframes for requesting a reconsideration, and that the regulation should at least set out a simple procedure whereby a beneficiary can submit evidence at any time to eliminate or reduce a late enrollment penalty. One commenter asked that members be provided LEP reconsideration rights when they are informed of their LEP. Another commenter indicated support for the existing process, with beneficiaries being permitted to seek reconsideration of their LEP.

Response: We have carefully considered this issue and believe that the current independent review process is sufficient and appropriate. Thus, we do not believe we need to offer beneficiaries expanded LEP appeal rights for several reasons.

First, we are offering significantly more due process to enrollees to dispute the imposition of an LEP than the law requires. The Part D beneficiary appeals process does not by its own terms apply to a decision on the applicability of an LEP, but only to decisions on whether drugs are covered, or how much a beneficiary is required to pay for covered drugs. With respect to the imposition of an LEP, the statute only provides individuals with an opportunity to apply to CMS to have their coverage treated as creditable upon establishing to CMS that they were not adequately informed that their prescription drug coverage was not creditable. (*See* section 1860D–13(b)(6)(C) of the Act.) Providing a reconsideration process to resolve other LEP-related matters, such as the question of whether an individual was enrolled in another plan offering creditable prescription drug coverage, is not required by the statute and is an added beneficiary protection under our current process.

Second, Chapter 18, § 80.7.1 of the Medicare Prescription Drug Benefit Manual and CMS' April 11, 2008 memorandum (cited above) provide beneficiaries with numerous added protections that are intended to help reduce the need for beneficiaries to seek reconsideration of their LEP. For example, plans must submit corrections when they receive a late attestation form that indicates the member had creditable coverage for the period in question if the plan has already reported uncovered months to CMS.

As described above, we have improved the attestation process by simplifying the creditable coverage attestation form, adding a new model checklist, and permitting Part D plan sponsors to allow beneficiaries or their representatives to complete the entire attestation process over the telephone. In addition, CMS guidance now affords Part D plan sponsors additional time to attempt to obtain information missing from the creditable coverage attestation form and to report their creditable coverage determinations to CMS.

Finally, as we noted in the proposed rule, we have the discretion to reopen, review and revise an LEP reconsideration decision. Reopenings are discretionary but may be granted, for example, upon presentation of new and material evidence. Given the flexibility afforded plans in making corrections to previously reported uncovered months if an enrollee submits an untimely attestation or other evidence of prior creditable prescription drug coverage, there should be a minimal need to look at decisions again.

Additionally, we disagree with the comment that we should detail all aspects of the reconsideration process in the regulation. We believe it is more practical to establish timeframes and other specific procedural and operational requirements related to LEP reconsiderations in CMS guidance so that necessary revisions can be made to ensure the needs of beneficiaries and plans are met in a timely manner. Updates to Chapters 4 and 18, § 80.7.1 of the Medicare Prescription Drug

Benefit Manual will be incorporated, as needed.

Lastly, we agree with the comment that member reconsideration rights should be provided to a beneficiary who is informed of his or her LEP. Plans now are required to provide both the LEP reconsideration notice and LEP reconsideration request form at the time they notify the enrollee of his/her LEP. *See* Chapters 4 and 18 § 80.7.1 of the Medicare Prescription Drug Benefit Manual for additional information.

Comment: A number of commenters suggested that the regulations confirm that CMS has the ultimate authority to determine whether previous coverage is creditable, thereby obviating the imposition of the late enrollment penalty. One commenter urged CMS to monitor the implementation of the proposed regulations to ensure that plans adequately inform beneficiaries of the importance of providing evidence of creditable coverage and work with beneficiaries to ensure an adequate timeframe to do so.

Response: We have retained the ability to deem coverage creditable in certain situations, and has defined the procedures for documenting such coverage at § 423.56. Therefore, we decline to take additional steps to address this comment in this regulation. With respect to the commenter's request that we ensure that plans adequately inform beneficiaries of the importance of providing evidence of creditable coverage and work with the beneficiaries to ensure they have adequate time to do so, we have already modified our attestation form and process, which addresses concerns such as these. For example, as previously described, our updated guidance allows Part D plan sponsors more time to follow up with beneficiaries when plans do not receive the beneficiaries' attestation or the attestation form is incomplete. This extended timeframe is in addition to the 30 calendar days beneficiaries already have to attest to prior creditable coverage. Also, if a beneficiary attests to having creditable coverage beyond the prescribed timeframe, again, we require Part D plan sponsors to accept the late attestation and make any corrections to the number of uncovered months previously reported to CMS. Lastly, as with other requirements, we will continue to monitor plans' compliance in this area and will follow up with those when problem areas are identified.

3. Subpart C—Benefits and Beneficiary Protections (Definitions)

a. Incurred Costs

In our May 16, 2008 proposed rule, we proposed to amend the definition of ''incurred costs'' to reflect our current policy that certain nominal co-payments assessed by manufacturer Patient Assistance Programs (PAPs) can be applied toward an enrollee's true out-of-pocket costs (TrOOP) balance or total drug spend (the accumulated total prices for covered Part D drugs paid by the plan or by or on behalf of the beneficiary). We allow PAPs to provide assistance for covered Part D drugs to Part D enrollees outside the Part D benefit. This means that payments made by PAPs do not count toward enrollees' TrOOP or total drug spend balances. However, if a PAP requires their enrollees—including those enrolled in a Part D plan—to pay a nominal copayment when they fill a prescription for a covered Part D drug for which the PAP provides assistance, such amounts would count toward TrOOP if the plan is notified of the copayment. As explained in Appendix C of Chapter 14 (Coordination of Benefits) of the Prescription Drug Benefit Manual, these nominal PAP copayment amounts, when paid by or on behalf of a Part D enrollee, are applicable to the enrollee's TrOOP and total drug spend balances, provided the enrollee submits appropriate documentation to their Part D plan.

Based on the numerous comments we received, we are finalizing the proposed definition of incurred costs to indicate that nominal PAP copayments are included in ''incurred costs.'' This revision to the definition of ''incurred costs'' in § 423.100 is consistent with the proposed changes to the definition of ''gross covered prescription drug costs'', which is also being revised to ensure that nominal PAP copayments are included in ''gross covered prescription drug costs'' and allowable reinsurance costs.

Comment: Several commenters expressed strong support for this proposed change to the definition of ''incurred costs,'' saying it would ensure that nominal PAP copayments are included in TrOOP and total drug spend balances. However, many of these commenters also expressed concern about the potential burden for beneficiaries in submitting these claims to their Part D plans. Some commenters asked us to draft a model form for submitting these claims, and asked us to encourage all Part D sponsors to adopt this model form. In addition, we were asked to provide this model form to SHIPs and other organizations that provide aid to LIS beneficiaries. Other commenters recommended that we require or encourage PAPs to provide one standard form to Part D beneficiaries. We were also asked to encourage pharmacies to fill out the required forms for Part D beneficiaries.

Response: We will consider developing a model form which Part D sponsors could provide to their enrollees. We would make this form available to PAPs, pharmacies, SHIPs, and other organizations as appropriate.

Comment: Some commenters asked us to require Part D sponsors to include instructions regarding the process for submitting the appropriate documentation of nominal PAP co-payments in the Evidence of Coverage (EOC) and other member-communications with Part D beneficiaries. One commenter recommended that we set uniform timelines for plans to include instructions for submitting this documentation in the EOC. This commenter also asked us to give sponsors broad authority for setting timeframes for the submission of PAP claims.

Response: Currently Part D sponsors are required to provide information on how to submit a paper claim to have beneficiary copayments that are paid under a PAP outside the Part D benefit accrue toward an enrollee's TrOOP and gross drug spend balances. Part D sponsors have flexibility in setting reasonable timeframes for the submission of such paper claims, keeping in mind CMS deadlines for submission of prescription drug event (PDE) records for purposes of the Part D payment reconciliation process.

Comment: We received one comment asking us to encourage PAPs to develop a means for transmitting the appropriate documentation electronically—in order to reduce the burden for beneficiaries.

Response: Currently, the Health Insurance Portability and Accountability Act (HIPAA) standard for claims submission does not accommodate the e-transmission of this claim information by PAPs or network pharmacies. We would support any industry efforts to streamline the submission of these and other paper claims.

Comment: One commenter asked that we provide a definition of a Patient Assistance Program (PAP) in order to help differentiate a PAP from a manufacturer sponsored pharmacy benefits card program.

Response: We use the term PAP with respect to pharmaceutical manufacturer sponsored patient assistance programs

that provide free products or assistance through in kind product donations to low income patients—particularly those with incomes below 200 percent of the Federal poverty level (FPL)—with no or insufficient prescription drug coverage. Manufacturer PAPs operate outside of the Medicare Part D program.

Comment: One commenter expressed concern that PAPs tend to promote brand drugs which is inconsistent with the efforts of Part D sponsors to promote generics.

Response: We appreciate the commenter's concern but note that we do not have any regulatory authority over PAPs. To the extent that Part D sponsors learn that their enrollees are purchasing brand drugs outside of the Medicare prescription drug benefit through a PAP, the sponsors may undertake efforts to promote any generic equivalents or therapeutically equivalent drugs available on Part D plan formularies.

Comment: We received a few comments regarding the automation of ''true out-of-pocket costs'' (TrOOP) reporting. One commenter asked that we continue to address challenges associated with TrOOP tracking. Another commenter recommended that we work with the National Council for Prescription Drug Programs (NCPDP) to update HIPAA Standards in order to automate TrOOP reporting and help pharmacies better support the Medicare Part D program.

Response: We are currently working with the industry to implement an automated TrOOP balance transfer process to better facilitate the tracking of TrOOP. Additional guidance regarding this effort will be provided at a future date.

Comment: One commenter noted that in the case of LIS enrollees, it is possible that the nominal PAP co-pay will exceed the LIS cost sharing due from the beneficiary. The commenter asked that we clarify that in such cases, Part D sponsors should reflect the cost sharing due as the LIS cost sharing amount and that we require the Part D sponsors to send the LIS beneficiary a check for the difference between the PAP co-payment and LIS cost sharing amount.

Response: We disagree with this recommendation. LIS beneficiaries do not receive the low-income cost sharing subsidy for drugs they obtain through PAPs because these programs operate outside of the Medicare Part D program. Therefore, there is no coordination of benefits between a PAP and Part D sponsors. Sponsors cannot make adjustments through refund or otherwise to nominal co-payments assessed by PAPs to LIS eligible enrollees. The proposed change to the definition of ''incurred costs'' simply allows affected beneficiaries to have their nominal PAP co-payments included in their TrOOP and gross drug spend balances.

b. Negotiated Prices

In order to address questions that have arisen since the Prescription Drug Benefit final rule was issued, we proposed to amend the definition of ''negotiated prices'' (to be effective for Part D contract year 2010) to require that Part D sponsors base beneficiary cost sharing and price reporting to CMS on the price ultimately received by the pharmacy or other dispensing provider, also known as the pass-through price. We received questions regarding whether Part D sponsors of prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MA–PDs) who utilize the lock-in pricing approach when contracting with a pharmacy benefit manager (PBM) may base beneficiary cost sharing on the price paid to the PBM, also known as the lock-in price. The lock-in pricing approach is a contract method by which the sponsor agrees to pay the PBM a set rate for a particular drug and the PBM negotiates with pharmacies to achieve the best possible price, which may vary from the rate paid to the PBM. Under the lock-in pricing approach, the price paid to the PBM or lock-in price is often greater than the price paid by the PBM to the pharmacy (the pass-through price) due to the inclusion of a ''risk premium'' which the Part D sponsor pays to the PBM to mitigate market risk and shield the Part D sponsor from price variability between pharmacies. This ''risk premium'' is analogous to the cost of drug utilization management, drug price negotiation, and other administrative costs incurred by Part D sponsors. Therefore, the lock-in price includes an administrative fee paid to the PBM by the Part D sponsor.

Beneficiary cost sharing is a function of the negotiated price, either directly as in coinsurance percentages of the negotiated price, or indirectly, as co-payments which are ultimately tied to actuarial equivalence requirements based on negotiated prices. We believe that it is important to ensure that negotiated prices are based upon the actual drug price paid at the point-of-sale and do not include any of the administrative fees paid by Part D sponsors to their intermediary contracting organizations because higher negotiated prices advance beneficiaries through the phases of the Part D benefit more quickly such that a greater number of beneficiaries reach the coverage gap phase of the benefit. In addition, using lock-in prices to determine negotiated prices increases the low-income cost sharing and reinsurance subsidy payments made by the Federal government. The low-income cost sharing subsidy is calculated based on the difference between the maximum cost sharing amounts for LIS beneficiaries as defined by the statute and, if greater, the beneficiary cost sharing charged under the Part D plan. Thus, higher beneficiary cost sharing leads to higher low-income cost sharing subsidy amounts. The reinsurance subsidy, which is calculated as 80 percent of allowable reinsurance costs, is increased as negotiated prices, and therefore, allowable reinsurance costs increase. We believe that continuing to permit Part D sponsors to use lock-in prices as the basis for determining beneficiary cost sharing, and reporting drug costs to CMS could also have the following undesirable results:

- Cost shifting from the government to beneficiaries in the form of higher beneficiary out-of-pocket costs.
- Interference with market competition among Part D sponsors.
- Beneficiary confusion over actual drug prices.
- Difficulties for pharmacies in explaining drug prices to customers and managing cash transfers to Part D sponsors or their intermediary contracting organizations.
- Government risk sharing on amounts that reflect administrative costs, contrary to Congressional intent to exclude risk-sharing on administrative expenses.

Please see the preamble to the May 16, 2008 proposed rule for a more detailed discussion of the potential impact of using lock-in prices to determine negotiated prices and beneficiary cost sharing.

For these reasons, we proposed to revise § 423.100 so that the first part of the definition of ''negotiated prices'' would state that negotiated prices are prices that the Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy, or other network dispensing provider, have negotiated as the amount the network dispensing pharmacy or other network dispensing provider, will receive, in total, for a particular drug. The term ''intermediary contracting organization'' refers to organizations such as PBMs that contract with plan sponsors to perform one or both of the following functions: (1) Pay pharmacies and other dispensers of Part D drugs provided to enrollees in the Part D

sponsor's plan, regardless of whether the intermediary contracting organization negotiates pharmacy contracts on behalf of the plan sponsor or on its own behalf; or (2) negotiate rebates or other price concessions with manufacturers for Part D drugs provided to enrollees in the Part D sponsor's plan, regardless of whether the intermediary contracting organization negotiates on behalf of the plan sponsor or on its own behalf.

Under this proposed definition, Part D sponsors who utilize the lock-in pricing approach when contracting with a PBM would no longer be permitted to base beneficiary cost sharing on the price paid to the PBM (the lock-in price). Thus, our proposed definition would exclude any differential between the price paid to the pharmacy and the price paid to the PBM or other intermediary contracting organization, and instead would treat that differential (or ''risk premium'') as an administrative cost paid to the PBM or intermediary contracting organization rather than as a drug cost under Part D.

We also proposed to revise the definition of ''negotiated prices'' (to be effective upon the effective date of the final rule) to include prices for covered Part D drugs negotiated between the Part D sponsor (or its intermediary contracting organization) and other network dispensing providers. Part D sponsors can contract with providers other than a pharmacy to dispense covered Part D drugs by including them in their network. Therefore, we proposed to amend the definition of negotiated prices to reflect the prices for covered Part D drugs that Part D sponsors (or their intermediary contracting organizations) negotiate with all of their network dispensing providers.

Our proposed changes to the definition of negotiated prices would not interfere with the negotiations between Part D sponsors, pharmacy benefit managers, and pharmacies for covered Part D drugs. Rather, Part D sponsors would be required to use the price ultimately received by the pharmacy (or other dispensing provider) as the basis for calculating beneficiary cost sharing, total drug spend, and cost reporting to CMS. The proposed definition would not require a Part D sponsor to use a particular pricing approach in its contracting agreements with PBMs. Part D sponsors could continue to use either the pass-through or lock-in pricing approach when contracting with a PBM—provided that beneficiary cost sharing, total drug spend, and the drug costs reported to CMS are based on the price ultimately received by the pharmacy, or other dispensing providers. To the extent that Part D sponsors believe that the lock-in pricing approach reduces their total costs, we indicated that we expected that they would continue to use it when contracting with a PBM.

While we did receive some comments in opposition to the proposed changes to the definition of negotiated prices, most of the comments received were in strong support of our proposals. Based on the comments received and the responses provided below, we are finalizing the revisions to the definition of ''negotiated prices'' in § 423.100 as proposed. The change to the definition of ''negotiated prices'' to include prices for covered Part D drugs negotiated between the Part D sponsor (or its intermediary contracting organization) and other network dispensing providers is effective upon the effective date of this final rule. The revision to the definition of ''negotiated prices'' to require Part D sponsors to base beneficiary cost sharing on the price paid to the pharmacy or other dispensing provider will be effective for Contract Year 2010.

Comment: Several commenters agreed with our assertion that the proposed changes to the definition of negotiated prices would increase transparency. One commenter supported the proposed change because it would improve transparency but still allow Part D sponsors to utilize the lock-in pricing approach. Another commenter indicated that the increased transparency would serve as an effective tool for helping to control prescription drug costs. Another commenter indicated that the benefits of transparency and the enhanced ability of beneficiaries to manage their benefit that would result from the proposed changes would outweigh the advantages of lock-in pricing for Part D sponsors. A commenter stated that often plan sponsors are not fully aware of the ''PBM spread.'' This commenter and other commenters recommended that we require PBMs to be compliant and fully transparent with Part D sponsors about pricing structures, rebating, formulary management incentives, marketing, and compliance requirements.

Response: We agree with commenters that the proposed revision to the definition of ''negotiated prices'' would increase transparency by ensuring that the drug prices paid to pharmacies are transparent to beneficiaries and Part D sponsors. We believe that this transparency will help Part D sponsors to better manage their drug costs and negotiate lower drug costs and administrative fees by making them fully aware of the ''PBM spread'' or ''risk premium'' which they are paying to their PBMs. This transparency will also be helpful to beneficiaries as they evaluate and choose among Part D plans. While we understand the final commenter's concern about transparency, we do not have the authority to regulate Part D sponsors' first tier, downstream and related entities to this degree. We contract with Part D sponsors, not with first tier, downstream and related entities, such as a sponsor's PBM, for the provision of the Medicare prescription drug benefit. Therefore, we do not have the direct authority to require PBMs and other intermediary contracting organizations to be fully transparent regarding their pricing structures. However, we strongly encourage Part D sponsors to include provisions in their contracts with first tier, downstream and related entities that ensure compliance with our reporting requirements and enhance transparency. We note that all plan contracts with PBMs must include provisions that allow us to review their financial statements, books, and records.

Comment: Some commenters asserted that the Medicare Part D program currently has transparency in the form of ''price transparency,'' where the prices paid by Part D sponsors are fully known to sponsors and beneficiaries and are also listed on the CMS Medicare Web site. The commenters asserted that the proposed changes to the definition of negotiated prices would instead create ''cost transparency.'' The commenters stated that there are several studies concluding that ''cost transparency'' increases prices because, when aware of one another's costs or discount agreements, competitors no longer offer special or deep discounts that are unnecessary to win the competition.

Response: We disagree. The use of lock-in prices reduces ''price transparency'' for Part D sponsors by combining the administrative fees charged by PBMs with the drug price. The proposed changes to the definition of negotiated prices would increase ''price transparency'' by ensuring that only the actual drug price is used to determine beneficiary cost sharing and report drug costs to CMS. We believe that the competitive nature of the Part D program will continue to provide incentives for Part D sponsors and their contracted PBMs to negotiate with pharmacies and other dispensing providers for lower drug prices. In addition, the revised definition of negotiated prices will provide an additional incentive for Part D sponsors

to negotiate with PBMs for lower administrative fees.

Comment: One commenter stated that under pass-through pricing, Part D sponsors have less transparency regarding their ultimate drug costs because the drug prices are not fixed. The commenter asserted that this makes it difficult for Part D sponsors to predict their drug costs, which could lead to higher risk sharing payments by the Federal government.

Response: We disagree. We do not believe that requiring Part D sponsors to develop their Part D bids and report drug costs to CMS using pass-through prices will make it significantly more difficult for Part D sponsors to predict their drug costs, such that risk sharing will be higher. In addition, Part D sponsors may take several steps to alleviate this concern, including negotiating their drug prices prior to developing their Part D bids and using the lock-in pricing approach when contracting with a PBM.

Comment: Several commenters indicated that the proposed changes to the definition of ''negotiated prices'' would achieve beneficiary cost savings. One commenter indicated that these beneficiary cost savings would ensure improved access to prescription drugs for beneficiaries. In addition, commenters stated that the proposed changes would protect beneficiaries from being prematurely advanced into the coverage gap. However, several commenters stated that elimination of the ''risk premium'' received by PBMs would not decrease out-of-pocket costs for beneficiaries. These commenters stated the ''risk premium'' provides incentives for PBMs to control costs and negotiate deep discounts on prescription drugs that are then passed on by Part D plans to beneficiaries.

Response: We agree with those commenters who believe that the proposed changes would create cost savings for beneficiaries. We believe that lock-in prices are generally higher than the prices paid to pharmacies due to the inclusion of the ''risk premium'' paid to the PBM for shielding the Part D sponsor from price variability. These higher drug prices lead to higher cost sharing for Part D beneficiaries. In addition, beneficiaries are advanced more quickly through the Part D benefit such that a greater number of beneficiaries enter the coverage gap phase where they pay 100 percent of the higher drug price. As a result, we believe that beneficiaries enrolled in Part D plans which currently utilize the lock-in pricing approach generally will experience cost savings under the proposed revision to the definition of ''negotiated prices'' that would require Part D sponsors to base negotiated prices and beneficiary cost sharing on the price paid to the pharmacy, which is generally lower than the lock-in price.

We acknowledge that the ''risk premium'' may provide an incentive for PBMs to negotiate for lower drug prices which would reduce drug costs. Under the revised definition of ''negotiated prices,'' Part D sponsors may continue to pay ''risk premiums'' to PBMs provided that the amount of these risk premiums is appropriately categorized as administrative cost and not drug cost. In addition, Part D sponsors may include other incentives in their contracts with PBMs whereby PBMs would receive higher administrative fees for better managing drug expenditures and reducing overall drug costs. We also note that the increased transparency created under the proposed changes to the definition of negotiated prices would provide Part D sponsors with information regarding administrative fees and the cost of drugs that they can use to negotiate more effectively with PBMs to further reduce the cost of providing the prescription drug benefit.

Comment: One commenter asserted that lock-in pricing is more equitable to beneficiaries than pass-through pricing because it protects beneficiaries who live in less competitive or underserved areas by providing uniform pricing to beneficiaries irrespective of where they live.

Response: While we acknowledge that the uniform pricing provided under the lock-in pricing approach may provide lower cost sharing for some beneficiaries, we believe that using lock-in prices to determine beneficiary cost sharing generally results in higher cost sharing for most beneficiaries. As a result, we believe that requiring plans to determine beneficiary cost sharing based upon the pass-through price paid to the pharmacy or other dispensing provider will reduce out-of-pocket costs for most beneficiaries and slow their advance through the initial coverage phase of the benefit.

Comment: Another commenter agreed with our assertion that Part D premiums may be lower under the lock-in pricing approach. The commenter indicated that these lower premiums result in a more robust benefit that covers more beneficiaries and therefore, results in a healthier population at an overall lower cost to the government.

Response: We agree that lower beneficiary premiums may help to encourage healthier beneficiaries to enroll in Medicare Part D. However, we do not think that it is appropriate to inflate the cost sharing paid by beneficiaries with higher drug utilization in order to reduce premiums for healthier beneficiaries. The goal of the Medicare Prescription Drug Benefit is to make prescription drugs more affordable for all Part D beneficiaries, not just those who are healthier and have lower drug utilization. The proposed revision to the definition of ''negotiated prices'' will lead to higher Part D bids and therefore, higher premiums, for Part D plans which currently utilize the lock-in pricing approach. This increase in Part D bids will increase the direct subsidy payments made by the Federal government as well as the premiums paid by beneficiaries. However, these additional costs to the Federal government would be partially offset by reductions in the low-income cost sharing and reinsurance subsidy payments made by the Federal government. A reduction in low-income cost sharing subsidy payments is expected due to lower beneficiary cost sharing. The reinsurance subsidy, which is calculated as 80 percent of allowable reinsurance costs, is expected to decrease due to lower negotiated prices and therefore, lower allowable reinsurance costs. Moreover, while the beneficiary premiums will increase for plans using the ''lock-in'' pricing methodology, cost sharing would be lower for all beneficiaries enrolled in these plans.

Comment: Some commenters indicated that they agreed with our assertion that the lock-in pricing approach currently creates an uneven playing field for Part D sponsors. They explained that generally beneficiaries tend to weigh premiums more than cost sharing so that plans utilizing the lock-in pricing approach may appear more cost effective to some beneficiaries. However, these commenters stated that, in the end, such plans cost enrollees considerably more than plans using the pass through pricing approach as a result of increased cost sharing.

Response: We agree with the commenter that plans which have lower beneficiary premiums due to the lock-in pricing approach may ultimately be more costly for beneficiaries due to higher beneficiary cost sharing. To ensure that beneficiaries have the resources necessary to assess the premiums and cost sharing of different plan options and make informed plan choices, we will continue our current outreach and education efforts, including the plan comparison information available on the plan finder.

Comment: A few commenters indicated that they would prefer that

CMS retain the current flexibility for Part D sponsors to choose either the pass-through or lock-in pricing approach, and the continued flexibility to reflect lock-in prices as part of drug costs. Commenters indicated that maintaining this flexibility would preserve the competitive nature of the Part D program.

Response: We agree that competition is an important aspect of the Part D program. We believe that this competition will be retained under our proposed approach as Part D sponsors will continue to have the incentive to negotiate for the lowest possible drug prices in order to keep their premiums low and encourage beneficiaries to enroll in their plans. We note that Part D sponsors will continue to have the option to use either pricing approach when contracting with a PBM. However, we believe that the advantages for beneficiaries under the proposed revision to the definition of ''negotiated prices'' outweigh the possible benefits Part D sponsors would receive from continuing to use the lock-in pricing approach.

Comment: One commenter asserted that Part D sponsors are fully aware of the potential that drug costs under the lock-in pricing approach include a risk premium paid to the PBM and understand the value this premium brings in reducing their drug costs.

Response: To the extent that this statement is true, we would expect Part D sponsors to continue providing this risk premium to their contracted PBMs. Even if Part D sponsors are aware that there is a potential for risk premium under the lock-in pricing approach, however, it is unlikely they know the actual amount of the risk premium they are paying if they are not made aware of the price actually paid to the pharmacy. This incomplete information makes it difficult for a Part D sponsor to fully quantify the value of paying this risk premium to a contracted PBM in the first place. The proposed revision to the definition of ''negotiated prices'' would provide Part D sponsors with the increased transparency they need to fully quantify the value of paying the risk premium. We believe that this transparency will provide Part D sponsors with the information needed to more effectively negotiate with PBMs to reduce their risk premiums as well as other administrative fees.

Comment: One commenter indicated that the proposed changes violate the non-interference requirement of the MMA at Section 1860D–11(i)(2), which prohibits CMS interference with negotiations between sponsors and manufacturers or pharmacies and the institution of a price structure for the reimbursement of covered Part D drugs.

Response: Our proposed changes to the definition of negotiated prices do not interfere with the negotiations between Part D sponsors and pharmaceutical manufacturers and pharmacies, nor do they institute a price structure for reimbursement of covered Part D drugs. While Part D sponsors will be required to use the price ultimately received by the pharmacy (or other dispensing provider) as the basis for calculating beneficiary cost sharing and reporting drug costs, Part D sponsors will not be required to use a particular pricing approach in their contractual agreements with PBMs. Part D sponsors may continue to use the pass-through or lock-in pricing approach when contracting with a PBM, provided that beneficiary cost sharing and the drug costs reported to us are based on the price ultimately received by the pharmacy or other dispensing provider.

Comment: We received a few comments indicating that the proposed changes essentially mandate a price structure because it is not feasible to compensate PBMs under the lock-in pricing approach and yet price drugs using pass-through pricing. The commenters assert that this dichotomy would require PBMs to build parallel claims adjudication modules and keep track of a parallel universe of claims.

Response: While we understand that the proposed revisions to the definition of negotiated prices may require some PBMs to implement certain system changes in order to accommodate the requirement to report the price paid to the pharmacy, it is unclear to us why this would not be feasible. Currently, PBMs that offer the lock-in pricing approach have the capacity for dual pricing as they must track both the price they paid to the pharmacy and the lock-in price they received from the Part D sponsor. The proposed changes to the definition of ''negotiated prices'' would simply change which of these two prices is reported to CMS.

Comment: Several commenters indicated that it was not Congress' intent to permit plans to charge higher prices under the lock-in pricing approach as a result of the PBM spread. We received a few comments indicating that the lack of transparency in the spread allows the intermediary to manipulate the spread amount to its advantage which ultimately works against beneficiaries. One commenter recommended that we consider requiring that Part D plans use a fiscal intermediary which will have no personal interest in what the pharmacy is paid.

Response: We agree that a lack of transparency may lead PBMs to charge plans a higher drug price under the lock-in pricing approach in order to generate greater profit for the PBM, and that these higher prices are passed on to beneficiaries and the Medicare program. We believe that the proposed changes to the definition of ''negotiated prices'' would increase transparency for Part D sponsors and enhance their ability to negotiate with PBMs for lower administrative costs by ensuring that they are informed of the actual drug price (the price paid to the pharmacy) and the administrative fees paid to the PBM. Thus, this increase in transparency could affect drug costs. However, we acknowledge that the direct subsidy paid by the Medicare program and the premiums paid by beneficiaries may be somewhat higher under the pass through pricing approach than under the lock-in approach. CMS does not have the authority to require Part D sponsors to use a specific fiscal intermediary or approach when negotiating prices and contracts with pharmacies. Furthermore, in response to the suggestion that we consider requiring Part D plans to use a fiscal intermediary with no personal interest in the amount paid to the pharmacy, we note that it may not be beneficial to the Medicare Part D program to require Part D sponsors to use fiscal intermediaries with no personal interest in the price paid to the pharmacy.

Comment: One commenter indicated that the ''PBM spread'' represents an additional profit for PBMs which will be reduced with greater transparency in pricing. However, we received a few comments which stated that the proposed changes could increase program costs for Medicare Part D by increasing Part D sponsors' administrative costs. One commenter expressed concerns that the proposed changes would require Part D sponsors to re-negotiate their contracts with PBMs. As a result of these negotiations, the commenter stated, PBMs could charge Part D sponsors higher administrative fees, which would lead to higher beneficiary premiums.

Response: While we acknowledge that the administrative fees paid by Part D sponsors to PBMs will be higher as a result of the proposed changes, we believe that when the ''risk premium'' that is currently included in drug prices under the lock-in model is taken into account, overall the administrative fees paid by Part D sponsors will not change significantly. We also believe that the increased transparency would help Part D sponsors negotiate more effectively

with PBMs. In addition, the competitive nature of the Medicare Part D program will continue to provide ample incentives for Part D sponsors to minimize their costs in order to keep their beneficiary premiums low.

Comment: Two commenters indicated that the proposed changes may not reduce costs for the Medicare Part D program, but may in fact increase costs. The commenters explained that the proposed changes would not permit PBMs to utilize all of the tools and incentives needed to provide prescription drug trend management programs, which are benefit management tools designed to keep drug costs down while maintaining and improving beneficiary health outcomes.

Response: It is unclear to us how the proposed changes to the definition of ''negotiated prices'' would prohibit PBMs from providing services to help Part D sponsors manage drug costs. The proposed changes would in no way prohibit Part D sponsors from paying PBMs for these services. To the extent that prescription drug trend management programs provide an important and valued resource for managing and reducing drug costs, CMS would expect Part D sponsors to continue paying administrative fees to PBMs for the provision of such services. The proposed changes to the definition of ''negotiated prices'' would simply ensure that Part D sponsors appropriately report these fees as administrative costs and not as drug costs.

Comment: In the preamble to the proposed rule, we explained that an argument could be made that the lock-in model is discriminatory to the extent it may favor low drug utilizers over high drug utilizers. One commenter asserted that a plan should not be considered discriminatory if it affects certain utilizers more than others. If such plans were considered discriminatory, the commenter argued, any plan type other than defined standard coverage could be considered discriminatory. The commenter stated that Congressional intent was to allow for choice in this regard. Another commenter indicated that differences in plan design and cost sharing cannot be equated with discrimination. There is no discrimination, this commenter stated, against a beneficiary because each beneficiary may make an informed plan choice with all relevant information available.

Response: We continue to believe that certain differences in plan design and cost-sharing can be discriminatory. While it is important to maintain a variety of drug plan choices in Medicare Part D, it is also important for CMS to review plan designs to ensure that they do not inappropriately discourage the enrollment of less healthy beneficiaries or high drug utilizers in certain plans in order to maintain a robust risk pool and preserve the concept of community rating in the Medicare Part D program. It is also of paramount importance for CMS to ensure that there is a level playing field so that true competition can occur that benefits all parties—the taxpayer, beneficiaries, and plans. The actuarial equivalence test for basic Part D coverage is intended to ensure that there is a level playing field between plan types. However, currently two different price bases (pass-through prices and lock-in prices) may be used when determining actuarial equivalence. Furthermore, because Part D plan sponsors that use the lock-in methodology are paying a ''risk premium'' as part of drug costs, they often can negotiate a lower administrative fee with their PBMs. As a result, these plans can submit lower bids in order to receive lower premiums. These lower bids may increase the likelihood that a plan's premium will be below the regional low-income subsidy benchmarks such that the plan will qualify for auto-enrollment and facilitated enrollment of LIS-eligible individuals. As a result, we continue to believe that providing Part D sponsors with the option to develop their Part D bids using either the pass-through approach or the lock-in approach creates an uneven playing field for Part D sponsors who utilize the pass-through pricing approach.

Comment: One commenter indicated that it was unclear why we believed that lock-in pricing would shift costs from the government to beneficiaries in the form of higher beneficiary out-of-pocket costs. The commenter explained that in their observation, the lock-in model has been the dominant pricing model in the commercial market. The ''risk premium'' allows PBMs to carry out a broad spectrum of services which favorably influence overall drug spending trends. The commenter also stated that this pricing model is preferred in the commercial market because it holds PBMs accountable for the drug costs incurred. The commenter indicated that the ''regulated transparency'' resulting from the proposed changes would be less effective in reducing drug costs than vigorous PBM competition. Another commenter indicated that the lock-in pricing approach may generate deeper discounts than the pass-through pricing approach.

Response: The use of lock-in prices to develop Part D bids shifts administrative costs that would be paid primarily by the Federal government as part of the direct subsidy to drug costs paid by beneficiaries through higher cost sharing. The proposed revision to the definition of ''negotiated prices'' would ensure that these administrative costs are not paid by beneficiaries through beneficiary cost sharing. We note that Part D sponsors will continue to have the option to utilize the lock-in pricing approach in their contracts with PBMs, provided that the pass-through price is used to determine beneficiary cost sharing and to report drug costs to CMS. To the extent that the lock-in pricing approach generates deeper discounts or reduces total drug costs, we would expect Part D sponsors to continue using this pricing approach when contracting with PBMs.

Comment: In the preamble to the proposed rule, we requested comments regarding the impact of the proposed changes on pharmacies, particularly small independent pharmacies. We received comments from several pharmacist associations as well as pharmacies. The commenters were generally very supportive of the proposed changes and noted that the proposed changes will not have a negative effect on pharmacies. One commenter indicated that lock-in pricing negatively impacts the ability of pharmacies to serve beneficiaries. Another commenter indicated that the additional transparency created by the proposed changes to the definition of ''negotiated prices'' would likely make competition more difficult for small pharmacies although these pharmacies would not be removed from Part D sponsors' networks due to CMS' pharmacy access standards. Another commenter indicated that small independent pharmacies do not tend to receive higher reimbursement rates and therefore, would not be negatively impacted by the proposed change. The commenter explained that independent pharmacies are often forced to accept whatever price is offered by the PBM. However, because of their size, chain pharmacies are often able to negotiate higher reimbursement rates. One commenter indicated that the proposed change would not have an adverse effect or increased burden on LTC pharmacies. Another commenter expressed concern that the decrease in beneficiary cost sharing resulting from the proposed changes could reduce the operational cash-flow for pharmacies. This commenter recommended developing guidance regarding prompt payment to

pharmacies to help alleviate this concern.

Response: Based on the comments received from pharmacies and pharmacists' associations, which were very supportive of the proposed changes, we have concluded that the proposed changes would not negatively impact pharmacies, including small independent pharmacies. Rather, we believe that the proposed changes will help pharmacies by reducing the administrative burden associated with tracking lock-in prices and addressing beneficiary confusion resulting from discrepancies between the pass-through price charged by the pharmacy and the lock-in price reflected on the beneficiary's EOB. With respect to the comment suggesting that CMS develop guidance regarding prompt payment to pharmacies, we note that section 171 of MIPPA establishes timely claims payment requirements for Part D plans that will become effective for plan years beginning 2010. CMS is currently developing and implementing guidance to ensure prompt payment to pharmacies.

Comment: One commenter expressed concern that Part D sponsors may believe that the proposed revisions to the definition of ''negotiated prices'' will require Part D sponsors to set negotiated prices equal to 340B prices for 340B-participating Part D network pharmacies. The commenter explained that making drugs available to non-340B patients at 340B prices will create significant losses for 340B pharmacies, which must obtain these drugs at prices above 340B levels. Therefore, the commenter asked CMS to clarify that Part D sponsors may not require 340B providers to provide 340B prices to Part D plans under § 423.104(g)(1).

Response: The proposed definition of negotiated prices does not require Part D sponsors to set negotiated prices at 340B prices for 340B-participating Part D network pharmacies. While we understand the commenter's concern that Part D plans may try to require pharmacies to make drugs available to Part D beneficiaries at 340B prices, we note that we generally do not interfere in plan-pharmacy contract negotiations or opine on the reasonableness or relevancy of specific contractual terms. Instead, we use our oversight authority to ensure that Part D sponsors abide by our rules and allow appropriate access to their pharmacy networks. A Part D sponsor offering less than satisfactory or unclear contract terms to a pharmacy would likely find it difficult to retain enough pharmacies to meet our network requirements, and would therefore be unable to renew its Medicare Part D contract. We urge pharmacies to ensure that they understand and agree with all terms of a pharmacy network contract before contracting with a Part D sponsor.

Comment: In the proposed rule, we asked for comments regarding the lack of transparency and the potential for beneficiary confusion as a result of lock-in prices. We received several comments indicating that the proposed changes to the definition of negotiated prices would create greater transparency for beneficiaries. Commenters also expressed concern that lock-in prices may lead to beneficiary confusion. One commenter explained that pharmacies are often unable to customize receipts to reflect the lock-in price. The discrepancy between the lock-in price reflected in the Explanation of Benefits (EOB) and the pharmacy price reflected on the receipt often leads to beneficiary anger and confusion. The commenter asserted that as a result of the additional time spent with beneficiaries to explain the discrepancy, pharmacies' administrative costs have increased. Other commenters stated that lock-in prices do not generate more beneficiary confusion than pass-through prices. These other commenters asserted that pass-through pricing generates greater beneficiary confusion than lock-in pricing by establishing different prices from pharmacy to pharmacy. In addition, these commenters stated that the full retail price is not usually shown on the customer receipt, rather, just the amount due from the beneficiary is shown. As a result, it is rare that the pharmacy receipt would reflect a drug price that conflicts with a lock-in price on the EOB.

Response: We acknowledge that pass-through pricing may result in different prices at different pharmacies, which could create some confusion for Part D beneficiaries. However, it is customary for different pharmacies to charge different drug prices. We believe that the use of lock-in prices may lead to more significant beneficiary confusion due to the discrepancy between the pass-through price charged by the pharmacy and the lock-in price reflected on the beneficiary's EOB. We are aware of a number of cases where beneficiaries have received pharmacy receipts which show prices that differ from the prices indicated on their EOB due to lock-in prices. We also understand the burden this discrepancy places on pharmacies that must try to address beneficiary confusion. We believe implementing the proposed changes to the definition of negotiated prices will help to alleviate this burden.

Comment: One commenter indicated that pharmacies incur significant administrative costs tracking the lock-in price collected from the beneficiary and transferring the additional amounts to the PBM. This burden is exacerbated by the fact that pharmacies are often forced to sell drugs to PBMs at prices below their acquisition cost. Another commenter indicated that the lock-in pricing approach does not require pharmacies to expend more staff resources than the pass-through pricing approach. This commenter explained that pharmacies are required to have accounting processes and the capability to conduct ongoing reconciliations under any pricing approach. Furthermore, the commenter indicated that typically pharmacies are not required to remit payments to PBMs since the amounts owed by the pharmacy are generally offset by the far greater amounts owed to the pharmacy by the PBM.

Response: We agree with the second commenter that pharmacies would not incur additional administrative costs under the lock-in pricing approach from transferring additional amounts to PBMs because generally pharmacies are required to conduct ongoing reconciliations with PBMs and plan sponsors under either pricing approach. However, we believe that pharmacies do incur additional administrative costs from tracking the lock-in price, ensuring that this is the price conveyed to the beneficiary (rather than the price actually paid to the pharmacy by the PBM), and addressing beneficiary confusion regarding the drug price. We believe that the proposed changes to the definition of ''negotiated prices'' would help alleviate some of this administrative burden for pharmacies by ensuring that beneficiary cost sharing is based on the price negotiated with the pharmacy.

Comment: Several commenters recommended that until the proposed changes are made effective in 2010, CMS should require Part D sponsors that utilize the lock-in pricing approach to indicate this policy in their marketing materials in order to create greater transparency for Part D beneficiaries. In addition, they recommended that we require Part D sponsors to inform their enrollees whenever they purchase a drug that is more highly priced because of lock-in prices, and that we require Part D sponsors to advise enrollees of their right to pay a lower cash price during all phases of the benefit.

Response: We agree with the commenters' desire to provide greater transparency for beneficiaries and believe that the changes to the

definition of ''negotiated prices'' to require the reporting of pass through prices effective in 2010 will achieve that result. However, the commenters' recommendations would require Part D sponsors using the lock-in approach to incur significant administrative costs for plan year 2009. Given that these requirements would only be applicable for one year, we do not believe that it would be worthwhile to implement the commenters' recommendations.

Comment: A commenter expressed concern that the proposed changes to the definition of ''negotiated prices'' would make calculating the negotiated price too complicated and therefore requested clarification that the negotiated price does not include post-hoc rebates, price concessions, or other adjustments to prices.

Response: Under the proposed definition of ''negotiated prices'', Part D sponsors would only apply the price concessions that they elect to pass through at the point of sale. We understand the difficulty in applying price concessions that are received after the point of sale purchase to the negotiated price at the point of sale. Part D sponsors would not be required to apply post-hoc rebates or price concessions to the negotiated price at the point of sale. Rather, these post-hoc rebates or price concessions must be reported to CMS outside the drug claim, consistent with our DIR reporting instructions, ''Medicare Part D DIR Reporting Requirements for Payment Reconciliation''.

Comment: Several commenters expressed concern that the proposed definition of negotiated prices would not prevent retail or mail order pharmacies that are wholly-owned by Part D sponsors from charging inflated drug prices under the Part D sponsors' plans. It was recommended that CMS and OIG exercise oversight over related parties to ensure that they are charging prices that are reasonable relative to the underlying drug cost.

Response: We appreciate these concerns and will continue reviewing the prices charged by pharmacies that are wholly-owned by Part D sponsors and other related parties to ensure that their prices are comparable to those offered under other Part D plans, particularly when reviewing Part D bids.

Comment: Several commenters indicated that the proposed definition fails to protect Part D beneficiaries from higher drug prices by not requiring Part D sponsors to pass through rebates and price concessions at the point of sale. They asserted that allowing Part D sponsors not to pass through rebates at the point of sale dilutes the insurance principle of the Part D program by shifting cost to the sickest beneficiaries and not giving these beneficiaries the benefit of the rebates which they generated through their higher volume of drug purchases.

Response: As stated in the January 2005 final rule (70 FR 4244), we interpret the definition of the term negotiated prices in section 1860D–2(d)(1)(B) of the Act as requiring Part D sponsors to pass through some, but not necessarily all, price concessions to Part D beneficiaries at the point of sale. Section 1860D–2(d)(1)(B) of the Act specifically requires that negotiated prices ''shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations * * *'' A phrase other than ''take into account'' would have been used, had the intent been to include all price concessions in the negotiated prices made available to Part D beneficiaries at the point of sale. The plain language of this provision demonstrates Congress' intent to be permissive—that Part D sponsors are permitted to choose how much of their negotiated price concessions to pass through to Part D beneficiaries at the point of sale. Generally speaking, however, rebates and certain price concessions are determined after the point of sale purchase, making it difficult for Part D sponsors to always apply these amounts to the negotiated price at the point of sale.

Comment: One commenter recommended that we delay the implementation date for this proposed definition until 2011 in order to provide PBMs with sufficient time to adapt their information systems. This delay would especially help sponsors that wish to continue using the lock-in pricing approach. Another commenter supported the proposed effective date because it would provide sufficient time for Part D sponsors and PBMs to make any appropriate adjustments in reimbursement to pharmacies.

Response: We understand that the proposed definition may require PBMs to implement some changes in their information systems. However, we believe the effective date of 2010 will provide sufficient time for PBMs to implement any necessary systems changes.

Comment: One commenter asked whether Part D sponsors would be permitted to apply a negative adjustment to their administrative costs in cases where the lock-in price is lower than the pass-through price, rather than being higher.

Response: Part D sponsors would be permitted to adjust their administrative cost estimates appropriately for the PBM spread when developing their Part D bids. However, we note that it is unlikely that overall lock-in prices will be lower than the pass-through prices.

Comment: One commenter indicated that the proposed changes to the definition of ''negotiated prices'' would increase overall program costs, sponsors' '' administrative costs, Part D bids, and beneficiary premiums. The commenter asserted that these cost increases would defeat the purpose of the Medicare Part D program, which is to keep prescription drugs affordable for Medicare beneficiaries.

Response: The goal of the Medicare Part D program is to serve Medicare beneficiaries and make prescription drugs affordable for them. The proposed changes will generally reduce cost sharing for beneficiaries, particularly those who have high drug utilization and, as a result, are most in need of assistance in purchasing prescription medications. We also believe that the increase in Federal costs due to higher plan bids will be balanced by the reduction in costs for Medicare Part D beneficiaries.

Comment: A commenter indicated that the proposed changes to the definition of ''negotiated prices'' should apply equally to prices negotiated with network retail pharmacies and network mail order pharmacies.

Response: We agree. The proposed definition of negotiated prices does not make a distinction between network retail pharmacies and network mail order pharmacies. Thus, the revised definition of ''negotiated prices'', as implemented, would apply to all network pharmacies and other dispensing providers, including network mail order pharmacies.

Comment: One commenter recommended revising the proposed definition of negotiated prices by adding ''any'' before the term ''other network dispensing provider'' to indicate that the term ''negotiated prices'' includes prices negotiated with all network dispensing providers.

Response: We agree that negotiated prices include prices negotiated with all network dispensing providers. However, we believe that the proposed definition appropriately conveys this policy. Therefore, we do not believe that the change proposed by the commenter is necessary. Thus, we are finalizing the proposed revisions to the definition ''negotiated prices'' without modification.

4. Subpart G—Payments to Part D Plan Sponsors for Qualified Prescription Drug Coverage (Definitions and Terminology, § 423.308)

a. Actually Paid (§ 423.308)

In the proposed rule, we proposed to include language in the definition of ''actually paid'' that would codify and clarify our previous guidance, and provide that direct or indirect remuneration includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies or similar entities obtained by an intermediary contracting organization with which the Part D sponsor has contracted for administrative services, regardless of whether the intermediary contracting organization retains all or a portion of the direct and indirect remuneration or passes on the entire direct and indirect remuneration to the Part D sponsor. Similarly, we proposed to clarify that this definition of ''actually paid'' would apply regardless of the terms of the contract between the plan sponsor and any intermediary contracting organization.

After reviewing the comments we received regarding this proposal, which are discussed below, we are implementing the clarifications to the definition of ''actually paid'' as proposed with one change.

Comment: A commenter expressed concern that the term ''intermediary contracting organization'' as described in the preamble of the notice of proposed rulemaking is too broad. The commenter stated that the proposed rule seems to suggest that all contractors that provide administrative services to a Part D sponsor could be considered ''intermediary contracting organizations.'' Based on this interpretation of the term, the commenter stated, remuneration received by entities with which Part D sponsors have contracted for audit services, as well as pharmacies that provide administrative services such as utilization management, could be considered to contribute to DIR which must be excluded from a sponsor's allowable costs. The commenter recommended limiting the term ''intermediary contracting organization'' to only those organizations that provide administrative services, negotiate drug prices, *and* also make payments to dispensing entities on behalf of Part D sponsors.

Response: We agree with some of the concerns expressed by the commenter. It is not our intent to use the term ''intermediary contracting organization'' to refer to all organizations with which Part D sponsors may contract for administrative services. The term ''intermediary contracting organization'' encompasses any entity that contracts with a plan sponsor to perform one or both of the following functions: (1) Pay pharmacies and other dispensers of Part D drugs provided to enrollees in the Part D sponsor's plan, regardless of whether the intermediary contracting organization negotiates pharmacy contracts on behalf of the plan sponsor or on its own behalf; or (2) negotiate rebates or other price concessions with manufacturers for Part D drugs provided to enrollees in the Part D sponsor's plan, regardless of whether the intermediary contracting organization negotiates on behalf of the plan sponsor or on its own behalf. We have revised the proposed definition of ''actually paid'' to reflect this clarification. Specifically, we are removing the phrase ''for administrative services'' from the second sentence of the proposed definition of ''actually paid'' such that it now states that ''Direct and indirect remuneration includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies or similar entities obtained by an intermediary contracting organization with which the Part D plan sponsor has contracted, regardless of whether the intermediary contracting organization retains all or a portion of the direct and indirect remuneration or passes the entire direct and indirect remuneration to the Part D plan sponsor and regardless of the terms of the contract between the plan sponsor and the intermediary contracting organization''.

Comment: We received several comments in support of the proposed changes to the definition of ''actually paid.'' One commenter agreed that rebates retained by PBMs and price concessions received from manufacturers should be treated as part of the true drug cost. Another commenter expressed support for this change as a logical follow-on to our guidance in the April 2006 Call Letter on rebates retained by PBMs. Another commenter stated that the proposed clarification would reduce the overall cost of the Medicare prescription drug benefit and facilitate future efforts to reduce or eliminate the coverage gap from the Part D benefit design.

Response: We appreciate the support received for this clarification. This clarification will help to ensure that all of each sponsor's administrative costs are excluded from allowable reinsurance costs and allowable risk corridor costs as required by sections 1860D–15(b)(3) and 1860D–15(e)(1) of the Act. In addition, this clarification will preserve the competitive nature of the Part D program by ensuring a level playing field for Part D sponsors regardless of their contractual arrangements with PBMs.

Comment: A commenter requested that we delay the effective date of the proposed change until the 2010 contract year to provide Part D sponsors with sufficient time to identify any contractors, other than PBMs, that are covered by the new language in the rule and to allow them to revise their contracts accordingly.

Response: The proposed change to the definition of ''actually paid'' reflects current Part D policy regarding the reporting of rebates retained by PBMs. Therefore, we do not believe that a delay in the effective date of this clarification is warranted.

Comment: One commenter requested clarification regarding whether bona fide service fees are considered direct and indirect remuneration.

Response: All rebates, grants, settlement amounts, or other price concessions received directly or indirectly from pharmaceutical manufacturers (with the exception of bona fide service fees) are considered price concessions that serve to reduce the drug costs incurred by the Part D sponsor and, therefore, must be reported to CMS as direct and indirect remuneration (DIR). Bona fide service fees are fees paid by a manufacturer to an entity, such as a Part D sponsor or the subcontractor of a Part D sponsor, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would perform (or contract for) in the absence of the service arrangement and that are not passed on, in whole or in part, to a client or customer, whether or not the entity takes title to the drug. As a result, bona fide service fees do not reduce the drug costs incurred by the Part D sponsor and therefore, are not considered DIR.

Comment: A commenter recommended changing the definition of ''actually paid'' to reflect the fact that PBMs are actually a source of remuneration.

Response: We disagree with this recommendation. While Part D sponsors may in fact receive remuneration from a PBM, we do not think that it is necessary to revise the definition of ''actually paid'' to reflect this. The definition of ''actually paid'' already indicates that Part D sponsors may receive remuneration from any source.

Comment: One commenter stated that it is widely believed that PBMs collect more in rebates than they report. The commenter stated that PBM-retained rebates may provide incentives for less cost-effective drugs to be placed on preferred formulary lists. This works against both beneficiaries and plan sponsors by increasing their drug costs.

Response: We agree with the commenter that the additional transparency created by the proposed changes to the definition of ''actually paid'' would allow Part D sponsors to better identify the most cost effective drugs for inclusion on preferred formulary lists. By providing Part D sponsors with additional cost information, the additional transparency will help Part D sponsors in their negotiations with manufacturers and PBMs.

Comment: A commenter asked that we limit the proposed definition of ''actually paid'' so that it would only apply to basic Part D coverage and not to enhanced alternative benefits.

Response: We disagree with this request. The definition of ''actually paid'' must be applied uniformly across the Part D benefit to ensure the accurate and consistent reporting of drug costs for Medicare Part D.

Comment: A commenter asked for clarification regarding the appropriate classification of rebates retained by a PBM.

Response: Rebates received from a manufacturer, whether directly or indirectly through a PBM, are price concessions that reduce the drug costs incurred by the Part D sponsor and therefore, are considered direct and indirect remuneration (DIR). To the extent that rebates are retained by a PBM, the dollar amount retained by the PBM represents an administrative fee which the Part D sponsor has paid to the PBM. Thus, the Part D sponsor essentially uses the remuneration from the manufacturer that the PBM retains to pay a portion of the Part D plan's administrative costs. As a result, when developing Part D bids, Part D sponsors should report this amount as an administrative cost.

Comment: A commenter stated that manufacturer rebates negotiated and earned by a PBM are not earned or received by the plan sponsor. The commenter stated that the proposed definition of ''actually paid'' is too narrow in that it defines ''price concessions'' to include amounts, such as PBM-retained rebates, that the plan neither receives nor is entitled to receive, and therefore, cannot properly be viewed as reducing the amount the plan ''actually paid'' for drug costs. Thus, the commenter stated, the proposed changes are inconsistent with the statute and are beyond the scope of authority granted by Congress. The commenter concluded that Congress did not authorize CMS to force a Part D plan to account for rebates earned by a third-party intermediary.

Response: We do not agree. While sponsors may not directly receive such remuneration from the manufacturer, sponsors do receive the amount indirectly through reduced administrative costs. Congress requires CMS to exclude all rebates from allowable costs, including those rebates that are received indirectly. *See* sections 1860D–15(b)(2) and 1860D–15(e)(1) of the Act. Similarly, we are also required to exclude administrative costs from allowable costs. *See* sections 1860D–15(b)(3) and 1860D–15(e)(1) of the Act. Thus, in order to calculate accurately the costs ''actually paid'' by a plan, the costs incurred by a plan must be adjusted to reflect any rebates retained by an intermediary in exchange for reduced administrative costs.

b. Administrative Costs (§ 423.308)

In the May 16, 2008 proposed rule, we proposed adding a definition for the term ''administrative costs'' in order to clarify what costs we consider ''administrative'' as well as to provide additional transparency to Part D plan pricing. We proposed to define ''administrative costs'' as the Part D sponsor's costs other than those costs incurred to purchase or reimburse the purchase of Part D drugs under the Part D plan. Any costs incurred by Part D plans on drug claims that differ from the price charged by a dispensing entity for covered Part D drugs would be included in the definition of ''administrative costs.'' We received several comments on this proposed definition. However, most of the comments received (including those opposed to the proposed definition) and our responses to them are discussed in the Negotiated Prices section of this final rule, as the policies are closely related. Comments that are related solely to the proposed definition of ''administrative costs'' are summarized below along with our responses. While we did receive some comments in opposition to the proposed definition (see below), several of the comments received were in support of the proposed definition. For the reasons discussed in the preamble to the proposed rule and in our responses to comments, we continue to believe that in order to ensure a level playing field for all Part D plan sponsors, the administrative costs reported by Part D plan must include any risk premium that is paid to an intermediary contracting organization. Therefore, we are implementing the new definition of ''administrative costs'' as proposed, to be effective for Part D contract year 2010.

Comment: We received several comments in support of adding the proposed definition for the term ''administrative costs''. One commenter agreed with our assertion that the proposed definition would create transparency and reduce beneficiary cost sharing. Another commenter expressed support for including the difference between the lock-in price and the price paid to the pharmacy in administrative costs, provided that CMS allowed Part D sponsors to continue using the lock-in pricing approach when contracting with a PBM.

Response: We agree that the proposed definition of ''administrative costs'' would increase transparency and reduce beneficiary cost sharing by requiring Part D plan sponsors to report the difference between the lock-in price paid to the PBM and the price paid to the dispensing pharmacy as an ''administrative cost.'' Thus, beneficiary cost sharing and reinsurance and risk sharing payments by the Federal government under the Medicare Part D program will be computed based solely upon actual drug costs. As we stated in the discussion of ''Negotiated Prices'' above and in the proposed rule, Part D sponsors may continue to use the lock-in pricing approach when contracting with a PBM provided that the price paid to the pharmacy or other dispensing provider is used to develop the Part D bid, determine beneficiary cost sharing, and report drug costs to CMS. We appreciate the support received for this clarification.

Comment: One commenter expressed concern that certain aspects of the proposed definition of ''administrative costs'' are ambiguous and overly broad. Specifically, the commenter asked that we define the term ''drug costs'' in the regulations and clarify whether dispensing fees would constitute ''administrative costs'' under the proposed definition. The commenter also requested clarification regarding whether there are any other categories of Part D costs, other than ''drug costs'' and ''administrative costs''.

Response: ''Drug costs'' consist of the ingredient cost, dispensing fee, and sales tax paid to a pharmacy or other dispensing provider for a prescription drug. We do not believe that it is necessary to include a definition for the term ''drug costs'' in the regulation at this time, as the definitions of ''gross covered prescription drug costs'' and ''allowable risk corridor costs'' already provide sufficient context for this term. Since dispensing fees are already considered drug costs under these definitions, such amounts are not considered ''administrative costs''. Any cost incurred by a Part D sponsor under the Medicare Part D program which does not represent ''gross covered prescription drug cost'' incurred by the sponsor to purchase or reimburse the purchase of Part D drugs is considered an ''administrative cost''. Therefore, there is currently no additional category of Part D costs.

Comment: One commenter expressed concern that the proposed definition could lead Part D sponsors to reduce their administrative costs and Medication Therapy Management (MTM). The commenter stated that the proposed definition would shift the ''PBM spread'' (the difference between the lock-in price and the price received by the pharmacy) from drug cost to administrative cost. This change would potentially increase the Part D bids for sponsors who utilize the lock-in pricing approach. The commenter stated that Part D sponsors may elect to reduce their MTM services in order to keep their Part D premiums competitive. The commenter asked that we remind Part D sponsors of MTM program requirements.

Response: We appreciate the concerns expressed by the commenter. The proposed definition may increase Part D bids for sponsors who utilize the lock-in pricing approach by shifting the ''PBM spread'' from drug cost to administrative cost. However, these potential increases may be offset partially by reductions in Part D sponsors' costs due to sponsors negotiating lower drug prices and administrative costs as a result of increased transparency. Furthermore, the proposed change is necessary in order to ensure that these administrative costs are not included in sponsors' allowable reinsurance and risk corridor costs as required by sections 1860D–15(b)(3) and 1860D–15(e)(1) of the Act. We note that the proposed definition does not change the MTM program requirements in any way. Part D sponsors must continue to comply with the MTM program requirements.

Comment: A commenter indicated that the proposed definition of ''administrative costs'' inappropriately includes the PBM spread as an administrative cost. The commenter asserted that the cost to purchase drugs (versus paying for a service) is a drug cost, regardless of from whom the drug is purchased. Generally, the commenter stated, the profit retained by the seller is not considered an administrative cost but rather a part of the drug cost. The commenter explained that regardless of whether PBMs actually take title to prescription drugs, they incur many of the risks of ownership of these drugs. Their role in the supply chain cannot be considered merely ''administrative'' in nature. The commenter indicated that the profit retained by the PBM should be considered a drug cost, just as the profit retained by pharmacies and wholesalers is considered a part of the Part D sponsor's drug cost.

Response: We disagree. The PBM spread represents an amount paid by Part D sponsors to PBMs as a service fee for negotiating prices on behalf of the Part D sponsor or providing other administrative services, and thus represents an administrative cost and not a drug cost paid to a seller.

c. Gross Covered Prescription Drug Costs and Allowable Risk Corridor Costs (§ 423.308)

We proposed revising the definitions of ''gross covered prescription drug costs'' and ''allowable risk corridor costs'' to establish that the amount received by the dispensing pharmacy or other dispensing provider (whether directly or through an intermediate contracting organization) and not the amount paid by the Part D sponsor to the PBM, is the basis for determining the drug costs that must be reported to CMS. This change will ensure that all administrative costs incurred by Part D sponsors, including the ''risk premium'' paid to PBMs to mitigate market risk around the cost of drugs, are excluded from the drug costs used to determine reinsurance and risk sharing payments. In addition, we proposed revising the definition of ''gross covered prescription drug costs'' to clarify that when a beneficiary is responsible for 100 percent of the cost for a covered Part D drug (as in any applicable deductible or coverage gap of a basic plan), and the beneficiary obtains that covered Part D drug at a network pharmacy for a price below the plan's negotiated price, the beneficiary's out-of-pocket costs that are considered ''incurred costs'' for covered Part D drugs count toward both TrOOP and total drug spend.

We received several comments in support of the proposed changes to the definitions of ''gross covered prescription drug costs'' and ''allowable risk corridor costs.'' In addition, we received some comments which opposed the proposed changes. Most of the comments received also included comments on our related proposal regarding the definition of ''negotiated prices'', and, as a result, these comments and our responses to them are discussed in the Negotiated Prices section of this final rule. Comments that relate solely to the definitions of ''gross covered prescription drug costs'' and ''allowable risk corridor costs'' are summarized below along with our responses. Based on our review of all of the comments received on this issue, we are implementing the changes to the definitions of ''gross covered prescription drug costs'' and ''allowable risk corridor costs'' as they appeared in the May 2008 proposed rule to be effective for Part D contract year 2010.

Comment: We received several comments in support of the proposed changes to the definitions of ''gross covered prescription drug costs'' and ''allowable risk corridor costs.'' These commenters indicated that the revised definitions along with the revised definition of ''negotiated prices'' would increase transparency and decrease beneficiary cost sharing.

Response: We appreciate the comments received in support of the proposed changes. We agree that the proposed changes to the definitions of ''gross covered prescription drug costs'' and ''allowable risk corridor costs'' would increase transparency by ensuring that CMS and Part D sponsors are aware of actual Part D drug costs. In addition, Part D sponsors would be made aware of the administrative fees which they pay to their PBMs as part of the ''risk premium''.

Comment: Two commenters recommended that CMS take additional actions to improve transparency and ensure that the appropriate drug costs are reported to CMS. Specifically, one commenter suggested that CMS require Part D sponsors to identify hidden fees which are taken back from pharmacies by PBMs during check cycle payments, such as transaction fees and pharmacy network fees. Another commenter expressed continued concern that the proposed changes may require Part D sponsors that utilize the lock-in pricing approach to depend on information traditionally held exclusively by PBMs. This commenter urged CMS to work with Part D sponsors to ensure compliance from PBMs. One commenter recommended that CMS sample

pharmacy payments and compare them to the prices reported by PBMs on the PDE records to ensure that PBMs are accurately reporting the pass-through price paid to the pharmacy and not the lock-in price.

Response: We will consider what further changes may be necessary to address concerns regarding transparency in the Medicare Prescription Drug Benefit. In addition, we will continue to provide information regarding the appropriate amounts to include in the reporting of drug costs and direct and indirect remuneration (DIR) in subregulatory guidance, such as the Medicare Part D DIR Reporting Requirements for Payment Reconciliation, and the Prescription Drug Event Data Training Participant's Guide. We currently conduct audits of plans' PDE data to ensure that drug costs are accurately reported to us. In the future, these audits will help us to identify discrepancies between the amount paid to the pharmacy and the drug costs reported on the PDE records. We will determine the appropriate corrective actions or penalties for Part D sponsors in cases where inaccurate or incorrect data have been provided. As indicated in the proposed rule, however, we contract with Part D sponsors, not with sponsors' first tier, downstream and related entity(ies), for the provision of the Medicare prescription drug benefit. Under § 423.505(i)(4)(ii), a Part D sponsor is required to include in its contract with downstream contractors and related entities a provision that either revokes the delegation of a Part D reporting responsibility or specifies other remedies if either CMS or the Part D sponsor determines that the downstream contractor or related entity has not performed satisfactorily. CMS may seek revocation of a delegation of the reporting responsibility or any other remedy provided for in the contract between the Part D sponsor and the PBM for non-compliance with delegated reporting responsibilities.

Nevertheless, the Part D sponsor has ultimate responsibility for compliance with the terms of its contract with us, including reporting accurate Part D data. While we will continue to work with Part D sponsors to ensure that the data submitted to us is accurate, we reiterate that Part D sponsors that choose to contract with a PBM or any other third party administrator must take steps necessary to ensure that the data submitted to us on their behalf is accurate and timely.

In the May 16, 2008 proposed rule (73 FR 28571), we also noted that § 423.308 includes a definition of the term ''target amount.'' Due to a technical formatting error, this definition appears to be the second paragraph of the definition of ''gross covered prescription drug costs.'' To clarify that the definition of ''target amount'' is not a component of the definition of ''gross covered prescription drug costs'', but is a separate definition of a different term, we proposed to revise the current discussion of ''target amount'' and to provide an amendatory instruction to add the definition in § 423.308. We also proposed to make technical edits to this definition to ensure that the structure of the definition is similar to that of other definitions in this section. We proposed no substantive changes to the definition.

We received no comments on the proposed technical edits to the definition of ''target amount.'' Therefore, we are finalizing the technical edits to this definition as proposed.

5. Subpart R: Payments to Sponsors of Retiree Prescription Drug Programs (Definitions, § 423.882)

We proposed to make the following additions and revisions to regulations at § 423.882 governing the retiree drug subsidy (RDS) program in order to be consistent with the corresponding existing and proposed Part D definitions under § 423.100 and § 423.308. The proposed definitions under § 423.882 included codification of some of our existing guidance for the RDS program.

a. Actually Paid

We proposed to add this definition to the RDS regulations in order to mirror the proposed revised Part D definition under § 423.308, with the exception of technical changes and clarifications to reflect its application to the RDS program. Specifically, we proposed to define actually paid to mean that the costs must be actually incurred by the qualified retiree prescription drug plan (and/or the qualifying covered retiree) and must be net of any direct or indirect remuneration from any source (including manufacturers, pharmacies, qualifying covered retirees, or any other person) that would serve to decrease the costs incurred under the qualified retiree prescription drug plan. Similarly, we also proposed including language in this definition that would provide that direct or indirect remuneration includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies or similar entities obtained by an intermediary contracting organization with which the sponsor of the qualified retiree prescription drug plan has contracted for administrative services, regardless of whether the intermediary contracting organization retains all or a portion of the direct and indirect remuneration or passes the entire direct and indirect remuneration to the sponsor of the qualified retiree prescription drug plan. Similarly, we clarified that this definition of actually paid applies regardless of the terms of the contract between the sponsor of the qualified retiree prescription drug plan and any intermediary contracting organization.

b. Administrative Costs

We proposed to add this definition to the RDS regulations in order to mirror the proposed revised Part D definition under § 423.308, with the exception of minimal changes to reflect the RDS terminology. Specifically, we proposed to define administrative costs to mean costs incurred by a qualified retiree prescription drug plan that are not drug costs incurred to purchase or reimburse the purchase of Part D drugs and that differ from the amount paid by or on behalf of the plan to a pharmacy or other entity that is the final dispenser of the drug. Similarly, we proposed to include language in this definition that any profit or loss retained by the intermediary contracting organization (through discounts, rebates, or other direct or indirect price concessions) when negotiating prices with dispensing entities is considered an administrative cost.

c. Allowable Retiree Costs

We proposed to make changes to the existing RDS definition of allowable retiree costs to mirror the relevant portions of the existing Part D definition of ''allowable reinsurance costs'' under § 423.308. Specifically, we proposed to revise the definition of allowable retiree costs under § 423.882 by clarifying that allowable retiree costs are the subset of gross covered retiree plan-related prescription drug costs actually paid by the qualified retiree prescription drug plan or by or on behalf of a qualifying covered retiree.

d. Gross Covered Retiree Plan-Related Prescription Drug Costs

We proposed to revise the existing definition of ''gross covered retiree plan-related prescription drug costs'' (or ''gross retiree costs'') to mirror the proposed Part D definition of ''gross covered prescription drug costs'' under § 423.308, with the exception of minimal changes to reflect the RDS terminology. Specifically, we proposed

to revise our RDS program definition of gross retiree costs to clarify that these costs equate to the sum of the negotiated prices (as defined in the definition) actually paid by the qualified retiree prescription drug plan (and/or qualifying covered retirees) and received by the dispensing pharmacy (or other dispensing entity), or received by other entities pursuant to the plan's coordination of benefits (COB) activities. As with our existing definition of gross retiree costs, our proposed definition excluded administrative costs from gross retiree costs.

e. Negotiated Prices

We proposed to add this definition to the RDS regulations in order to mirror the Part D definition of negotiated prices under § 423.100, with the exception of minimal changes to reflect RDS terminology. Specifically, we proposed to define negotiated prices for Part D drugs as the prices that the qualified retiree prescription drug plan (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug, net of discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the qualified retiree prescription drug plan has elected to pass through to qualifying covered retirees at the point of sale. Similarly, we proposed that negotiated prices include any dispensing fees.

Under the foregoing proposed definitions, payments made to RDS plan sponsors of qualified retiree prescription drug plans (or ''RDS sponsors'') would be reported based upon ''pass-through'' prices and not the ''lock-in'' prices that the RDS plan sponsor pays to a PBM or other intermediary contracting organization.

Comment: Two commenters supported the requirement to report negotiated (that is, pass-through) prices for purposes of the RDS program (''negotiated price policy''). Two other commenters objected to extending this negotiated price policy to the RDS program. One of these latter commenters contended that mandating that costs be reported only based on pass-through pricing could cause RDS sponsors to leave the RDS program and place their retirees in the Medicare Part D program. The other commenter objecting to applying the negotiated price policy to the RDS program predicted that doing so would likely result in employers and unions dropping retiree health coverage of drugs altogether. One of these commenters noted that large employers constitute a majority of RDS sponsors, and that they are sophisticated purchasers with a great amount of leverage, and are in the best negotiating position to decide which pricing structure is most appropriate for them. The other commenter reported that such large employers have been using the lock-in approach for many years. Both of these commenters also believed that many employers seek to keep health benefits the same for active employees and retirees, and that requiring reporting based on pass-through prices only would effectively be imposing this one model on active employee plans as well.

Response: As stated in the preamble to the proposed rule (73 FR 28571), the rule requiring reporting based on pass-through costs was proposed for RDS sponsors for many of the same policy considerations that underlie our revisions to the Part D definitions of ''negotiated prices,'' ''administrative costs'', ''allowable risk corridor costs'', and ''gross prescription drug costs''. Specifically, the RDS payment is calculated based on allowable retiree costs, which in turn are a subset of gross retiree costs. The statute requires us to exclude administrative costs from the calculation of gross covered retiree plan-related prescription drug costs. Subsidizing the portion of the lock-in price that as a practical matter amounts to an administrative cost paid to the PBM or intermediary contracting organization would therefore arguably be inconsistent with the statutory requirement to exclude administrative costs from the calculation of gross covered retiree plan-related prescription drug costs.

However, we share the commenters' concern about the possible impact of applying the Part D negotiated price policy to the RDS program, particularly about the possibility that this could cause employers currently participating in the RDS program to either move their retirees to Part D, or drop coverage altogether. In response to these and other concerns expressed by commenters discussed below, we are considering the question of whether we have the statutory discretion to adopt a different policy for the RDS program than the policy we are finalizing in this final rule for the Part D program, and are hereby re-opening the comment period with respect to our proposal to apply this Part D negotiated price policy to the RDS program. Specifically, we are inviting comments on the question of whether we have discretion under the statute to retain the current policy for the RDS program (that is, reporting of lock-in or pass-through prices) while adopting the new negotiated price policy being finalized in this final rule for the Part D program. We discuss three possible legal theories below that, if one or more are found to be valid, would provide us with discretion to maintain the status quo under the RDS program, while making the changes made in this final rule to the Part D program. We accordingly are deferring a final decision on our proposal to apply the new Part D policy to the RDS program pending the outcome of our consideration of comments we receive on our legal authority.

We specifically invite comment from the public on the following three legal theories under which it might be argued that we have discretion to adopt a different policy for RDS than for Part D with respect to the way drug costs are reported:

(1) Legal Theory 1: Interpretation of ''Actually Paid''

The first legal theory on which we invite public comment is the argument that we could interpret ''actually paid,'' as used in the RDS statutory definition of ''allowable retiree costs'' at section 1860D–22(a)(3)(C)(i) of the Act, to exclude any difference between the lock-in and pass-through amount, so that either the lock-in or the pass-through amount can be reported. The RDS subsidy payment is paid based on ''the portion of the retiree's gross covered retiree plan-related prescription drug costs'' that exceeds a specified cost threshold amount and does not exceed a specified cost limit amount for a given year. The actual payment is ''an amount equal to 28 percent of the allowable retiree costs * * * attributable to such gross covered prescription drug costs.'' section 1860D–22(a)(3)(A) of the Act.

The statute defines ''gross covered retiree plan-related prescription drug costs'' as ''the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of part D drugs. * * *'' *Id.* at subsection (a)(3)(C)(ii). The statute defines the term ''allowable retiree costs'' to mean ''with respect to gross covered prescription drug costs under a qualified retiree prescription drug plan by a plan sponsor, the part of such costs that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor. * * *'' *Id.* at subsection (a)(3)(C)(i). While section 1860D–22 of the Act does not itself define the term ''gross covered prescription drug costs,'' this term is defined in section 1860D–15 of the Act, however, which describes subsidy payments to Part D plan sponsors. For

purposes of that section, ''gross covered prescription drug costs'' are defined as ''the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs. * * *'' section 1860D–15(b)(3) of the Act.

Under the legal theory upon which we are inviting comment, it would be argued that when an RDS plan sponsor makes a payment to an entity (such as a PBM) that includes amounts for Part D drug ingredient and dispensing costs and amounts to manage the sponsor's drug benefit plan, the amount of that payment is the ''costs that are actually paid * * * by the sponsor'' for purposes of calculating the subsidy. Under this argument, we would not need to look behind the payment to the PBM to determine how the cost of drugs was determined under the arrangement; rather, it would be sufficient for CMS to calculate the subsidy payment based upon the RDS plan sponsor's payment to the PBM, excluding discounts, chargebacks and average percentage rebates. Under this approach, RDS plan sponsors would be able to use either the ''lock-in'' or ''pass-through'' price for reporting drug costs for purposes of subsidy payments.

A potential problem with this theory is that it arguably reads out of the statute the phrase ''for the portion of the retiree's gross covered retiree plan-related prescription drug costs.'' As noted, the definition of ''gross covered retiree plan-related prescription drug costs'' makes clear that such costs do not include administrative costs, and the ''lock-in'' price may well effectively include administrative costs, since any difference between that amount and the negotiated amount could be retained to cover administrative expenses.

(2) Legal Theory 2: Prohibition on Interference With Benefit Design of Retiree Drug Coverage

The second legal theory on which we invite public comment is the argument that the RDS statute prohibits CMS from interfering in the benefit design of retiree drug coverage, and that, as suggested by a commenter below, requiring use of the ''pass-through'' methodology to report drug costs would interfere with the benefit design of qualified retiree prescription drug plans.

Section 1860D–22(a)(6) of the Act provides a rule of construction for interpreting the RDS section of the statute. Subparagraph (D) of that section provides that ''[n]othing in this section shall be construed as * * * preventing employers to provide for flexibility in benefit design * * * so long as the actuarial equivalence requirement * * * is met.'' It has been suggested by a commenter (see comment below) that a CMS mandate that an RDS plan sponsor report drug costs using the ''pass-through'' methodology interferes with the ability of employers ''to provide for flexibility in benefit design'' of an RDS plan. Under this argument, requiring reporting of the ''pass-through'' price would be administratively burdensome, create an incentive for employers to redesign their RDS plans and their contractual arrangements with PBMs, and perhaps encourage employers to opt out of the RDS Program entirely.

This argument rests on the assumption that—(1) Contractual arrangements between an RDS plan sponsor and a PBM are ''benefit design[s]''; and (2) requiring an RDS plan sponsor to report the ''pass-through'' price for purposes of the subsidy would ''prevent'' employers from providing flexibility in those benefit designs. Again, there is a potential problem with this legal theory. Arguably, section 1860D–22(a)(6)(D) of the Act is most reasonably interpreted to prohibit CMS from mandating a certain benefit package in retiree drug plans, and not to prohibit CMS from mandating requirements that relate only to reporting costs to CMS. The context of the rule of construction in paragraph (6) suggests that Congress was concerned only that CMS not restrict the ability of RDS-covered individuals to enroll in part D; of having their part D premiums paid by an RDS plan sponsor; or from receiving coverage that is more generous than part D. All of these things relate to the benefit design of a retiree drug plan itself, and not to the relationships between an RDS plan sponsor and a contracting partner. Further, even if such contractual relationships could be construed as ''benefit design[s],'' by requiring RDS plan sponsors to report the ''pass-through'' price for drug costs, we arguably would not be preventing RDS plan sponsors from adopting any particular contractual relationship with intermediaries. RDS plan sponsors would still be able to use either the ''lock-in'' or ''pass-through'' arrangement with PBMs, however, they would be required to report the ''pass-through'' price for purposes of subsidy payments.

(3) Legal Theory 3: Change in Interpretation of Waiver Authority

The third legal theory on which we are inviting public comment would involve a change in our interpretation of waiver authority in section 1860D–22(b) of the Act, and the use of that authority to modify requirements for RDS plan sponsors. If we were to adopt this theory, we would need to do so through notice and comment rulemaking, as it would change the interpretation of section 1860D–22(b) of the Act that is set forth in current regulations.

The waiver authority in section 1860D–22(b) of the Act appears in a section of the Act that is otherwise devoted entirely to provisions that apply to the RDS program. In this context, section 1860D–22(b) of the Act provides that employer group waiver provisions in section 1857(i) of the Act (Medicare Part C) ''shall apply with respect to *prescription drug plans* in relation to employment based retiree health coverage in a manner similar to the manner in which they apply to an MA- plan in relation to employers. * * *'' (Emphasis added.) It is noteworthy that this subsection uses the term ''prescription drug plans'' rather than ''qualified retiree prescription drug plans,'' since section 1860D–41(a)(8) of the Act defines ''prescription drug plan'' as a plan offered ''under a policy contract or plan that has been approved under section 1860D–11(e)'' and ''by a PDP sponsor pursuant to, and in accordance with, a contract between the Secretary and the sponsor under section 1860D–12(b).'' This clearly describes a Part D plan, not an RDS plan, that is, a qualified retiree prescription drug plan (QRPDP).

Under ordinary principles of statutory construction, when a term is defined in statute, that definition applies when the same statute employs that term. However, given the fact that this waiver authority appears in a section otherwise devoted to the RDS program, and that the term ''qualified retiree prescription drug plan'' includes the three words, ''prescription drug plan,'' an argument might be made as a matter of statutory construction that in this case the term ''prescription drug plan'' was intended to encompass both a Part D ''prescription drug plan'' and a qualified retiree ''prescription drug plan'' (that is, this waiver authority extends both to PDPs and QRPDPs), as long as the plan is offered ''in relation to employment-based retiree health coverage'' in either case.

As noted above, however, we have already interpreted the waiver authority in section 1860D–22(b) of the Act as applying only to Part D prescription drug plans. The employer group waiver authority in section 1860D–22(b) of the Act is set forth in regulation in § 423.458 of Subpart J, which governs PDPs and MA–PDs, rather than subpart R, which governs QRPDPs under the

RDS program. The final rule preamble discussion of Subpart J states that, for purposes of the discussion that follows in Subpart J, the term ''employer sponsored group prescription drug plan'' means ''a prescription drug plan under a contract between a PDP sponsor or MA organization offering an MA–PD plan and employers, labor organizations, or the trustees of funds established by one or more employers or labor organizations (or combination thereof) to furnish prescription drug benefits under employment based retiree health coverage.'' (See the January 28, 2005 final rule (70 FR 4320)). In other words, the preamble expressly states in its discussion of ''terminology'' that when we use the term ''employer sponsored group prescription drug plan,'' it is referring to a PDP or MA–PD, and not to a QRPDP under the RDS program.

In the discussion of the regulatory provision implementing the waiver authority in section 1860D–22(b) of the Act specifically, the preamble expressly states that ''[s]ection 1860D–22(b) of the Act extends the waiver authority that is provided for MA organizations related to Part C under section 1857(i) of the Act * * * *to prescription drug plans.*'' (Emphasis added.) (See the January 28, 2005 final rule (70 FR 4323).) The next sentence states that ''[t]his waiver authority is intended to provide employment-based retiree health coverage an opportunity to furnish prescription drug benefits to its participants or beneficiaries *through Part D* in the most efficient and effective manner possible.'' *Id.* (emphasis added). Part D and the RDS program are mutually exclusive. An employer may either offer drug coverage through Part D, or receive an RDS payment for coverage it offers independent of Part D, but may not do both in the case of the same Medicare beneficiaries. We also discuss in the preamble only a ''process'' for ''authorizing waivers for *employer sponsored prescription drug plans.*'' *Id.* (emphasis added). As noted above, this term was defined in the preamble as limited to a PDP or MA–PD.

Finally, § 423.454, defines an ''Employer-sponsored group prescription drug plan'' as a plan ''approved by CMS as a prescription drug plan'' (a PDP). Section 423.458(c) specifically provides only for waiving provisions that hinder the design or offering of, or enrollment in, an ''employer-sponsored group prescription drug plan.'' Thus, we believe that the current regulations unambiguously construe the authority in section 1860D–22(b) of the Act as applying only to PDPs and MA–PDs, and not to QRPDPs participating in the RDS program. As a result, if after considering public comments we wished to adopt the interpretation of section 1860D–22(b) of the Act discussed above, we would need to do so through notice and comment rulemaking. In order to preserve our option of implementing this third legal theory, today's **Federal Register** also contains a separate notice of proposed rulemaking seeking public comment as to whether we should adopt the change in our interpretation of section 1860D–22(b) set forth above.

Comment: In objecting to the proposed requirement that RDS sponsors report drug prices by using the pass-through method, one commenter stated: ''As a threshold matter, we do not believe that the administration and operation of drug programs offered in the commercial market are subject to CMS' purview.'' The commenter believes that among the objectives of the RDS program is to allow RDS sponsors flexibility and the ability to maintain their current plan designs (provided the plan is actuarially equivalent to standard Medicare Part D coverage).

Response: We agree with the commenter that among the objectives of the RDS program is to allow RDS sponsors flexibility and the ability to maintain their current plan designs, and share the commenter's concern that requiring reporting on a ''pass-through'' basis could result in sponsors believing that they have to change existing arrangements or possibly leaving the RDS program. As discussed above, for this reason we are exploring the issue of whether we have statutory authority to allow RDS sponsors to continue to report either on a lock-in or pass-through basis, and are specifically inviting comment on whether the rule of construction in section 1860D–22(a)(6)(D) of the Act could be interpreted to allow us to not mandate the Part D negotiated price policy for the RDS program, under the theory that doing so would inhibit employer flexibility in violation of section 1860D–22(a)(6)(D) of the Act, as suggested by the commenter.

Comment: One commenter suggested that RDS sponsors should have at least 1 year lead time for implementation of any changes to the RDS program, while another commenter suggested that CMS grandfather any pre-existing contractual relationships that utilize the ''lock-in'' pricing method until they are renegotiated after the rule becomes effective. Another commenter urged that the ''pass through'' reporting provisions of the proposed rule, as they apply to the RDS Program, not apply to plan years that begin before January 1, 2011. ''This will allow plans [presumably insurers] * * * to become familiar with and renegotiate their commercial business insurance contracts with PBMs so that they can submit the required data.'' This commenter stated that ''Plans and their respective employers will need time to make the necessary revisions to these business relationships.''

Response: We acknowledge that entities such as RDS sponsors and insurers may need to change the terms of their contracts with PBMs to accommodate the pass-through reporting requirement. As discussed, we are deferring finalizing the Part D negotiated price policy for RDS, so no such changes will have to be made in the short term.

Comment: A commenter supported all the proposed revisions to the RDS provisions of the regulations, including the provisions on reporting rebates retained by a PBM or other intermediary contracting organization.

Response: While we appreciate the commenter's support for our proposal, as noted above, we share concerns expressed by other commenters about the possible implications of applying the Part D policies in question to the RDS program, and are considering whether we have the statutory discretion to adopt a different approach for the RDS program than that adopted in this final rule for the Part D program.

Comment: A commenter objected to the definition of ''actually paid'' in the proposed regulations. Specifically, the commenter objected to the fact that the definition states that this amount is net of any direct or indirect remuneration obtained by an intermediary contracting organization with which the RDS sponsor has contracted for administrative services, regardless of whether the intermediary contracting organization retains all or a portion of the direct or indirect remuneration or passes it along to the RDS sponsor, and regardless of the terms of the contract between the RDS sponsor and the intermediary contracting organization. The commenter stated that the requirement for the RDS sponsor to report retained direct or indirect remuneration should not apply in instances where the intermediary contracting organization negotiates such remuneration (or price concessions) on its own behalf, and not on behalf of the RDS sponsor. In such cases, the commenter states, the RDS sponsor has no rights in, or to, the price concessions, and only has a right to any price concessions the intermediary contracting organization agrees to

provide the RDS sponsor in its contract with the sponsor. The commenter states that ''CMS assumes that the rebates and other price concessions received by an intermediary organization reduce the plan's drug costs''. (Emphasis in original.)

Response: We believe that the policy on retained rebates and the policy on negotiated price are linked, and that the same approach should be applied in both cases. In both cases, the policy does not recognize the structure of the arrangements made between the parties, and requires that costs be reported as if a different arrangement were in place. In both cases, amounts available to a third party (in the difference between the negotiated price and lock-in price in one case, and the difference between the total rebate and the amount passed on in the other) are treated as administrative costs when there are arguments that the amounts are different in nature and CMS should not require that they be treated as administrative fees. Also in both cases, there is a question as to whether CMS has the discretion under the statute to adopt one rule for Part D and another for the RDS program.

We believe that the three legal theories discussed above in connection with negotiated price could also have applicability to the issue of rebate amounts that are retained and not directly passed on to a sponsor. We therefore invite comment on whether these arguments would provide CMS with the discretion to adopt a different rule for RDS than for Part D with respect to retained rebate amounts, and if so whether we should do so. As in the case of the negotiated price policy, we will defer our adoption of the Part D retained rebate policy in the RDS regulations pending our consideration of these comments. Again, this will require changes to the proposed regulations text that ensure that the regulatory changes that we are finalizing in Part D regarding retained rebates are not applicable to RDS.

Comment: One commenter observed that CMS indicated in the proposed rule that certain provisions clarify existing guidance. To the extent any such provisions in fact clarify existing guidance, and apply retroactively, the commenter asserts that CMS has violated the prior notice and comments requirements of the Administrative Procedure Act.

Response: As noted above, we are reconsidering our proposed rule applying the Part D policy on the treatment of retained rebate amounts to the RDS program. This also extends to our existing guidance. The commenter's concerns are now moot, as we will make any final decision on our approach for RDS through rulemaking after consideration of public comments.

f. Subpart R Changes Adopted in the Final Regulations

As previously mentioned, we are deferring finalizing the proposed requirements that would have required RDS sponsors to report negotiated prices, and to report direct or indirect remuneration retained by a PBM or other intermediary contracting organization, pending the receipt of comments on the legal arguments previously mentioned. However, to otherwise make RDS regulatory definitions more consistent with Part D regulatory definitions and to ensure that the changes in the Part D regulatory provisions regarding negotiated prices and retained rebates do not affect RDS, we are making the following changes to definitions in Subpart R:

- Adding a definition of ''actually paid'' that includes portions of the proposed RDS definition, but excludes the portion that would operate to require the reporting of direct or indirect remuneration retained by a PBM or other intermediary contracting organization.
- Adding a definition of ''administrative costs'' that includes portions of the proposed RDS definition, but that excludes, from the definition, the difference between the amounts paid by the sponsor to an intermediary contracting organization for Part D drugs dispended to qualifying covered retirees, and the amount paid by the intermediary contracting organization to the pharmacy or other entity that is the final dispenser of the Part D drugs.
- Revising the definition of ''allowable retiree costs'' as proposed without modification.
- Revising the definition of ''gross covered retiree plan-related prescription drug costs, or gross retiree costs,'' to include portions of the proposed RDS definition, but to exclude the reference to ''negotiated prices.'' This revised definition includes the term ''intermediary contracting organization,'' which for purposes of the revised definition is intended to encompass any entity that contracts with an RDS sponsor to perform one or both of the following functions: (1) Pays pharmacies and other dispensers of Part D drugs provided to qualifying covered retirees in the sponsor's plan; or (2) negotiates rebates or other price concessions with manufacturers for Part D drugs provided to qualifying covered retirees in the sponsor's plan.

Additionally, we are slightly revising § 423.888(b)(5)(i) so that it references the term ''gross covered plan-related retiree prescription drug costs,'' which is a term defined in Subpart R, rather than ''gross prescription drug costs,'' which is not.

6. Limiting Copayments to a Part D Plan's Negotiated Price (§ 423.104)

In our May 16, 2008 proposed rule, we proposed to revise the requirements related to qualified prescription drug coverage at § 423.104(g) to make clear that Part D sponsors must provide enrollees with access to, or make available at the point-of-sale, their negotiated prices for covered Part D drugs when the covered Part D drugs' cost share is more than the Part D sponsor's negotiated price. The final rule adopts the revisions to § 423.104(g)(1) set forth in our proposed rule.

Comment: A number of commenters supported our clarification that the negotiated price for a covered Part D drug be made available to Part D enrollees when that price is less than a plan's applicable cost-sharing. Most of these commenters emphasized that CMS should monitor negotiated pricing issues and take corrective action against plans that do not assess their enrollees the negotiated price per the revision. One commenter in particular recommended that the policy be clearly explained in the Medicare handbook and all other materials that are distributed to beneficiaries by CMS and Part D plan sponsors related to their Part D coverage.

Several commenters noted concerns with this policy given that pharmacies' reimbursements may be lowered when the negotiated price for a drug is less than a Part D plan's applicable cost-sharing. While these commenters supported beneficiary access to negotiated prices, they believed it was equally important that pharmacies be adequately compensated for the drugs they dispense. They argued that pharmacies may experience net losses if the total revenue received from Part D enrollees is not sufficient to cover the costs of participating in the program—particularly given the average cost of dispensing prescriptions and the fact that the dispensing fee does not vary regardless of the negotiated price. They also asserted that implementing this policy could result in higher costs for plans and beneficiaries in the form of higher premiums, and could ultimately threaten pharmacy participation in some sponsors' networks. Two commenters, therefore, recommended that CMS modify the changes to

§ 423.104(g)(1) and instead clarify that Part D sponsors and their network pharmacies should be able to freely negotiate patient copayment obligations in order to allow for lower overall patient spending.

Response: We believe that a policy under which the plan sponsor charges the beneficiary the lesser of the applicable cost-sharing amount or the negotiated price for a covered Part D drug is most consistent with the intent of section 1860D–2(d)(1) of the Act, which requires Part D sponsors to offer their enrollees access to negotiated prices for covered Part D drugs. Although we have previously given Part D sponsors the option of applying either the applicable copayment (if the sponsor elected to charge a flat co-payment rather than coinsurance as part of its benefit design) or the actual negotiated price of a formulary drug when that amount is lower than the copayment, we have actually found that the majority of Part D sponsors have administered the benefit such that they apply the lesser of the co-payment or the negotiated price to the enrollee at the point of sale. Therefore, we disagree that our revision at § 423.104(g) will result in undermining the utilization effects of tiered cost-sharing benefit structures, increasing Part D program costs, or significant changes in Part D sponsor pharmacy network participation.

We will monitor beneficiary complaints on this issue, and will take appropriate corrective action against sponsors to the extent that we learn they are not limiting cost-sharing to negotiated prices as required under § 423.104(g)(1). In addition, we will assess our current CMS beneficiary materials, including the Medicare & You handbook, and Part D sponsor marketing models to ensure that this information is clearly and accurately conveyed to Part D enrollees.

Comment: A commenter expressed concern about requiring a 340B pharmacy to charge a 340B drug's price as patient cost-sharing when the 340B price is lower than a plan's cost-sharing. This commenter asserted that when patients know that certain brand-name drugs can be obtained for nominal amounts, they are more likely to request normally more expensive brand name drugs in all cases. The commenter asked that CMS clarify the application of this rule to specify that Part D sponsors may not require 340B providers to provide the 340B price to Part D plans under § 423.104(g)(1).

Response: CMS generally does not interfere in plan-pharmacy contract negotiations or opine on the reasonableness or relevancy of specific terms. Instead, we use our oversight authority to ensure that Part D sponsors abide by our rules and allow appropriate access to their pharmacy networks. A Part D sponsor offering less than satisfactory or unclear contract terms to a pharmacy would likely find it difficult to retain enough pharmacies to meet our network requirements, and would therefore be unable to renew its Medicare Part D contract. We urge pharmacies to ensure that they understand all terms of a pharmacy network contract before contracting with a Part D sponsor.

7. Timeline for Providing Written Explanation of Plan Benefits (§ 423.128)

In our May 16, 2008 proposed rule, we proposed to revised § 423.128(e)(6) to require sponsors to provide an explanation of benefits (EOB) no later than the end of the month following the month in which an enrollee uses his or her Part D benefits. We believe that our proposed revision to § 423.128(e)(6), which we are finalizing in this rule, strikes a reasonable balance between Part D sponsor production constraints and the timely provision of claims information to Part D enrollees. Below are public comments we received on our proposal and our responses.

Comment: Many of the comments received on the EOB timeline suggested that plans continue to be required to send the EOB no later than the 15th of the month following the month in which an enrollee uses Part D benefits.

Response: We have reviewed this comment and have concluded that plan sponsors need the additional time in the month following to process claims from the month in which the beneficiary utilized prescription drug services. Therefore, to ensure that plan sponsors are able to furnish accurate information to beneficiaries for drug benefits utilized within a particular month, CMS clarified that the EOB must be sent no later than the end of the month following any month when prescription drug benefits are provided.

8. Low-Income Subsidy Provisions

a. Low-Income Cost-Sharing and Payment Adjustments for Qualified Prescription Drug Coverage (§ 423.329)

In the May 16, 2008 proposed rule, we stated that we currently make prospective payments to Part D plan sponsors of the low-income cost sharing subsidy (LICS) based solely on estimates provided as part of the annual bidding process. When LICS estimates are too high, excessive prospective payments are made that (under our current process) are not recovered until the year end reconciliation. We proposed to add to the end of § 423.329(d)(2)(i) the following qualifying statement: ''or by an alternative method that CMS determines.'' In its report ''Medicare Part D Sponsors: Estimated Reconciliation Amounts for 2006'' released October 2007, the HHS Office of the Inspector General recommended that CMS explore other payment methodologies to recoup excessive LICS payments earlier. This revision would afford CMS additional flexibility to make mid-year LICS payment adjustments or other modifications to the LICS interim payment methodology, as appropriate. After reviewing and responding to comments (below) we will implement this provision. A summary of the comments and responses are provided below.

Comment: Many commenters supported the change, as it will result in more accurate payments during the actual plan year.

Response: We appreciate the commenters support.

Comment: Many commenters wanted more information on the methodology that CMS will use for mid-year LICS payment adjustments and other modifications to the LICS interim payment methodology that might arise due to the proposed change. Commenters asked that CMS involve stakeholders in any changes it makes to the methodology. Commenters believed interim payment reconciliation would be burdensome to plans and CMS. Others offered suggestions for the methodology such as adjusting payments to Part D plan sponsors in the event that the agency determines interim payments are too low.

Response: This change will correct a technical error in the existing regulation. We are making this change in order to establish a parallel between this section and that relating to the reinsurance subsidy described at § 423.329(c)(2). The language of § 423.329(d)(2)(i) regarding interim payments of the LICS subsidies as currently written has proven overly restrictive and has had the unintended effect of requiring us to make payments to Part D plan sponsors that are subsequently determined to have been significantly different from their actual costs. Some overpayments have not been recovered until payment reconciliation is completed, some years later. In some cases there have also been administrative delays in recognizing or reconciling underpayments. We also recognize, however, that as the program matures, actual costs in this area will come closer to the bid amount. We agree

with the commenter that stakeholder input is necessary.

b. Lesser of Policy for Low-Income Subsidy Individuals (§ 423.782)

To ensure low-income subsidy eligible beneficiaries are not harmed when the statutory low-income subsidy cost-sharing amounts are higher than the cost-sharing imposed under their plan's benefit package, we proposed in the May 16, 2008 proposed rule to codify our existing guidance on this situation in regulation. Specifically, we proposed adding a new paragraph (c) to § 423.782 which would clarify that the cost-sharing subsidy under § 423.782(a) and (b) is not available when an individual's out-of-pocket costs, under his or her Part D sponsor's plan benefit package, are less than the amounts described in § 423.782(a) and (b). After considering public comments on our proposal, we are adopting § 423.782(c) without further modification into this final rule.

Comment: A number of commenters supported our proposal that would require a Part D sponsor to charge the ''lesser of'' the low-income subsidy cost sharing amount or the beneficiary's out-of-pocket costs under the plan. However, one commenter wanted CMS to more explicitly provide that beneficiaries entitled to the low-income subsidy be charged the plan's cost-sharing amount when that amount is less than the statutory low-income subsidy cost-sharing amount.

Response: We believe our regulatory language is sufficiently clear and decline to further amend it. The language in section § 423.782(c) stipulates that out-of-pocket costs for a covered Part D drug under a Part D sponsor's plan benefit package be less than the maximum allowable copayment, coinsurance or deductible amounts under 423.782(a) and (b). Out-of-pocket costs include any cost-sharing amounts (copayment, coinsurance or deductible) the beneficiary would incur under the plan's benefit package.

Comment: Several commenters disagreed with our regulatory revision that would require a Part D sponsor to charge the ''lesser of'' low-income subsidy cost sharing or beneficiary's out-of-pocket costs. The commenters argue that altering statutory cost-sharing rules and their application would undermine a sponsor's ability to limit inappropriate utilization and may discourage the use of generics or certain other low-cost medications. In addition, they assert that pharmacies would be forced to accept reimbursement that could be below cost of dispensing the drug.

Response: We disagree with these commenters. The low-income subsidy cost sharing amounts established in regulation at § 423.782 are maximum amounts charged to beneficiaries eligible for the low-income subsidy. They are not minimum amounts that must be charged even if the ordinary plan cost-sharing that would otherwise apply is lower. The intent of the revised regulation is to provide low-income subsidy beneficiaries access to covered Part D drugs consistent with the out-of-pocket costs incurred by members not eligible for the low-income subsidy and enrolled in the same prescription drug plan. To do otherwise would result in a Part D sponsor violating its contractual obligation to provide the benefit package approved by CMS as defined under § 423.100. We also believe that if the Part D sponsor did charge cost-sharing amounts above that provided under its basic (or when applicable, supplemental) prescription drug coverage, this would violate the uniform benefit requirements at § 423.104, which requires the sponsor offering the prescription drug plan to offer that plan to all Part D eligible beneficiaries in the plan's service area.

We also disagree with the commenter that because of this revision, pharmacies will be forced to accept reimbursement below the cost of dispensing the covered Part D prescription medication. This revision to the regulation in no way impedes the pharmacy's ability to negotiate appropriate reimbursement for dispensing prescription medications directly with the Part D sponsors.

Comment: One commenter in particular noted that this proposal would require 340B pharmacies to charge Part D plan sponsors the same drug price as is available under 340B.

Response: We disagree. This rule does not require that 340B pharmacies charge the 340B drug price; this is an issue that should be the subject of negotiations between the pharmacy and the sponsor. However, as stated elsewhere in this preamble, we note that CMS generally does not interfere in plan-pharmacy contract negotiations or opine on the reasonableness or relevancy of specific terms. Rather, we use our oversight authority to ensure that Part D sponsors abide by our rules and allow appropriate access to their pharmacy networks.

Comment: One commenter requested clarification that this rule applies to all phases of Part D drug coverage, including the pre-initial coverage (deductible) phase. The commenter asserts that individuals eligible for the low-income subsidy should not be required to pay low-income subsidy cost sharing when the approved cost sharing during a deductible phase is less.

Response: The commenter's assumption is correct. An LIS individual will not be required to pay the maximum low-income subsidy cost sharing amounts when the cost-sharing under the plan's benefit package during the deductible period (presumably the negotiated price of the Part D covered drug) is less.

c. Using Best Available Evidence To Determine Low-Income Subsidy Eligibility Status (§ § 423.772, 423.800)

The ''best available evidence'' policy derives from the fact that, while section 1860D–14(c)(1)(A) of the Act provides for CMS to inform sponsors of low-income subsidy eligibility, the sponsor's obligation under section 1860D–14(c)(1)(B) of the Act to reduce premiums and cost-sharing for all such individuals is not contingent upon CMS doing so. While we attempt to identify all subsidy eligible individuals to the full extent possible as soon as possible, experience has shown that this does not necessarily result in every such individual being successfully identified as subsidy eligible. We believe, therefore, that the sponsors have an obligation to take reasonable steps to respond to documentation that identifies such individuals as subsidy eligible when they have not yet been identified by us, in order to fulfill their statutory obligation to reduce premiums and cost-sharing for such individuals.

Given the importance of this policy, we proposed in our May 16, 2008 proposed rule to codify the policy derived from section 1860D–14(c) of the Act in § 423.800(b) and (d). Specifically, we proposed including in regulations text the guidance (*Part D Guidance—Low-Income Subsidy (LIS) Status Corrections Based on Best Available Evidence,* dated June 27, 2007), available at *http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/Final%20Sponsor%20Guidance%20on%20BAE%20062707.zip*) that we have issued to Part D sponsors concerning our best available evidence (BAE) policy.

We proposed amending the regulations to require that Part D sponsors use BAE to substantiate a beneficiary's eligibility for a reduction in premiums and/or cost-sharing in the case of individuals who indicate they are eligible for the low-income subsidy. These include full-benefit dual eligible individuals, partial dual eligible individuals (that is, those who are enrolled in a Medicare Savings Program as a Qualified Medicare Beneficiary,

Specified Low-Income Medicare Beneficiary or Qualifying Individual), people who receive Supplemental Security Income (SSI) benefits but not Medicaid, and people who apply for and are determined eligible for a subsidy. Under the BAE policy we proposed to incorporate into the regulations, sponsors are required to accept and use BAE to correct the beneficiary's low-income subsidy data in the sponsor's system and, as applicable, document requests for CMS to correct the beneficiary's low-income subsidy data in our system or for CMS to work with the Social Security Administration (SSA) to correct the data in their systems, where appropriate, when the change has not occurred as a result of routine reporting.

We anticipate that the BAE policy will remain in place for the indefinite future. As a result, we proposed to modify § 423.800 by adding a fourth paragraph, consistent with our current policy, that would require Part D sponsors to use the CMS-developed BAE process to establish the appropriate cost-sharing for low-income beneficiaries whose information in CMS systems is not correct.

We proposed to define BAE at § 423.772 as documentation or information that is directly tied to authoritative sources, confirms that an individual meets the requirements for the low-income subsidy, and is used to support a change in an individual's low-income subsidy status. We did not propose to specify in the regulation the specific documents that would meet these criteria, as there may be documents that meet these criteria in the future that do not currently exist.

Comment: A number of commenters supported our best available evidence policy and our proposal to codify the policy in regulation. In expressing support for the policy, some commenters noted the importance of the BAE policy to low-income, subsidy-eligible individuals and recommended that CMS strictly enforce sponsor compliance.

Response: We appreciate the support expressed for our policy and the proposed provision. We also recognize its importance to the low-income subsidy eligible population and, as a result, will monitor beneficiary complaints on this issue and take appropriate corrective action against sponsors to the extent that we learn they are not compliant with the BAE policy as specified in § 423.800(d).

Comment: Some commenters expressed agreement with the definition of ''best available evidence'' in § 423.772. One commenter suggested we provide as specific information as possible on what is acceptable BAE. Two commenters, noting the difference between community and institutional pharmacy operations, recommended expanding the definition to specify that an attestation by a provider would qualify as documentation from an authoritative source. One commenter urged CMS to revise the definition to add that authoritative sources are those ''approved by CMS.'' Another commenter believed the definition was unnecessarily restrictive and encouraged CMS to permit information from non-authoritative sources whenever possible.

Response: As we have noted previously, we are not specifying in regulation the particular documents or types of information that meet the definitional criteria as there may be additional documents in the future that meet these criteria. However, we do believe that the definition would be clearer by specifying the sources of the documentation that we have determined are authoritative. Therefore, we have revised the definition to indicate that BAE documentation or other information must be tied directly to the State or SSA systems.

Comment: We received a number of comments recommending that we add regulatory language to incorporate guidance that provides for Part D sponsors to assist individuals who claim to be subsidy eligible but cannot provide acceptable evidence of subsidy eligibility.

Response: Since the intent behind the regulation, as stated in the proposed rule, is to codify our BAE policy, we agree with the commenters that the regulation should address the provision of assistance to individuals without documentation. However, under the process we established for the provision of this assistance, Part D sponsors do not directly assist beneficiaries in securing acceptable documentation. Instead, sponsors are to follow CMS-established procedures, referring the request to the CMS Regional Office, and informing the beneficiary of the results of the CMS inquiry. Therefore, we have added a requirement for Part D sponsors to respond to requests for assistance in securing best available evidence from beneficiaries or the beneficiary's pharmacist, advocate representative, family member or other individual acting directly on behalf of the beneficiary in accordance with the process established by CMS. As described in our memo entitled ''Best Available Evidence Policy—UPDATE'' (available at *http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/MemoClarifiedBAEGuidance_08%2004%2008_wROconts.pdf*), by ''respond'' we mean fulfilling a process specified by CMS to refer to CMS an individual beneficiary who claims subsidy eligibility status and specifically requests assistance obtaining required documentation. This process is intended to assist a beneficiary (or other individual on the beneficiary's behalf) when a specific request for assistance is received by the plan, either directly via a call to plan member services, or indirectly via contact by a pharmacist to the plan's pharmacy help desk line seeking to assist the beneficiary (or other individual on the beneficiary's behalf) making this request at the point of sale. This process is not intended to serve as a general alternative to the subsidy eligibility confirmation process and does not permit pharmacy organizations or any other parties to send beneficiary records to the plan for research in the absence of a request for assistance from the beneficiary (or other individual on the beneficiary's behalf) and in lieu of making reasonable efforts to acquire the documentation from or on behalf of the beneficiary. We note that this process should place virtually no additional burden on the Part D sponsors.

Comment: One commenter recommended that CMS establish a mechanism for correcting CMS data for LIS applicants based on an LIS award letter from SSA presented by the beneficiary.

Response: While we had previously expressed an intention to establish a mechanism for manually correcting the CMS data for beneficiaries awarded LIS based on an application for the subsidy, the establishment of a correction mechanism was not addressed in the proposed provision. We believe this is a topic more appropriately addressed in operational guidance. We are currently working with SSA to improve our data reporting processes and will discuss any process improvements, including a correction mechanism, if established, in future operational guidance.

Comment: Two commenters recommended expanding the list of acceptable documentation for best available evidence to include SSA letters showing the beneficiary receives Supplemental Security Income (SSI).

Response: We agree with these commenters. In addition, in listing the documentation that constitutes best available evidence in the preamble to the proposed rule, we neglected to include an award letter to a beneficiary who applied for the low-income subsidy. Therefore, we are including an amended list of evidence sufficient to

make a change to a beneficiary's low-income status. Currently, any one of the following forms of evidence must be accepted:

- A copy of the beneficiary's Medicaid card that includes the beneficiary's name and an eligibility date during a month after June of the previous calendar year.
- A copy of a State document that confirms active Medicaid status during a month after June of the previous calendar year.
- A print-out from the State electronic enrollment file showing Medicaid status during a month after June of the previous calendar year.
- A screen print from the State's Medicaid systems showing Medicaid status during a month after June of the previous calendar year.
- Other documentation provided by the State showing Medicaid status during a month after June of the previous calendar year.
- A letter from SSA showing that the individual receives SSI.
- For individuals who are not deemed eligible, but who apply and are found LIS eligible, a copy of the SSA award letter.

Further, in order to establish that a beneficiary is institutionalized and qualifies for zero cost-sharing any one of the following forms of evidence must be accepted:

- A remittance from the facility showing Medicaid payment for a full calendar month for that individual during a month after June of the previous calendar year.
- A copy of a State document that confirms Medicaid payment on behalf of the individual to the facility for a full calendar month after June of the previous calendar year.
- A screen print from the State's Medicaid systems showing that individual's institutional status based on at least a full calendar month stay for Medicaid payment purposes during a month after June of the previous calendar year.

Comment: One commenter recommended that we clarify that, if a beneficiary has been auto-enrolled by CMS or was charged a low-income subsidy level cost-sharing level prior to being admitted to an institution, it is not necessary for the individual to provide BAE establishing Medicaid eligibility. The commenter also recommended that, under such circumstances, CMS not require BAE to establish the beneficiary's eligibility for an institutional cost-sharing level since this could be determined from the date of admission to the facility.

Response: We confirm BAE is not necessary to establish an institutionalized beneficiary's Medicaid eligibility if that status is currently reflected in the CMS system, for example, as would be the case if the beneficiary had been auto-enrolled in a month after June of the previous year. However, documentation would be required to establish the beneficiary as an institutionalized individual as defined in § 423.772, and therefore qualified for a zero cost-sharing level. We disagree with the commenter that documentation should not be required to substantiate eligibility for the zero cost-sharing.

Comment: Three commenters believed the provision represents an inappropriate transfer to Part D sponsors of responsibility for determining beneficiary low-income subsidy eligibility. These commenters recommended that if sponsors are to have this responsibility, the sponsors should be protected from liability when good faith efforts are made to determine low-income subsidy eligibility. Another commenter recommended that the regulation make it clear that the primary parties in the BAE process are CMS and the beneficiaries and the only role of the Part D sponsor is to update its system with the eligibility information provided by CMS.

Response: We disagree with the commenters. We recognize that section 1860D–14(c)(1) of the Act requires us to establish a process to notify the Part D sponsor when an individual is low-income subsidy eligible. We have established such a process and we continue to work to improve the data reporting processes. However, we also recognize that the process we employ does not necessarily result in every individual being successfully identified. Therefore, we believe that sponsors have an obligation to take reasonable steps to respond to documentation that identifies such individuals when they have not yet been identified by CMS, in order that the sponsors fulfill their statutory obligation under section 1860D–14(c)(1)(B) of the Act to reduce premiums and cost-sharing for low-income subsidy eligible individuals.

Comment: Several commenters recommended that CMS convene a workgroup of Part D sponsors, pharmacists, beneficiary advocates and State Medicaid representatives to refine and improve our BAE policy, including identifying other reliable evidence of Medicaid eligibility and institutional status.

Response: Our BAE policy is important to ensure low-income subsidy eligible individuals have access to covered Part D drugs at a reduced cost-sharing level. Therefore, we will continue to aggressively respond to complaints from beneficiaries and others acting on their behalf alleging sponsor non-compliance with our policy. We will also consider other ways of monitoring our BAE policy to ensure appropriate access for low-income subsidy eligible beneficiaries.

Comment: Another commenter recommended CMS implement educational outreach programs to augment the regulation.

Response: We plan to undertake a number of initiatives to inform interested parties regarding the requirements associated with our BAE policy. For example, we recently created a BAE page on our Web site containing our policy guidance, and, pursuant to our memorandum mentioned above, Part D sponsors must establish a link to this page on their Web sites and make information about the BAE policy readily available for those who contact the plan's call center.

Comment: A few commenters urged CMS to extend the requirement in § 422.52(g) that special needs plans verify an individual's Medicaid eligibility to all Part D sponsors as a means of curtailing the need for BAE.

Response: The requirement in § 422.52(g) is specific to Medicare Advantage plans for special needs individuals and is intended to ensure that the individuals wishing to enroll in a dual eligible special needs plan are eligible for both Medicare and Medicaid. The verification of Medicaid eligibility is a required element of the plan's enrollment process. The extension of this requirement for all Part D sponsors would be inappropriate as sponsors are required to accept BAE only in those situations in which CMS systems do not reflect a beneficiary's correct low-income subsidy eligibility.

Comment: One commenter noted the rule did not address situations in which a beneficiary's Medicaid application is pending and recommended CMS reaffirm our guidance for handling claims and co-payments in these cases.

Response: We recognize that many LTC pharmacies hold receivable balances in Medicaid-pending situations for cost sharing amounts that will be paid by the Part D sponsor once Medicaid eligibility is determined and we require sponsors to use the date of the Medicaid notification to establish a new timely claims filing period to ensure third party payers and other parties have the opportunity to request reimbursement for claims incurred during the retroactive period.

9. Certification of Allowable Costs (§ 423.505)

We proposed to revise § 423.505(k)(5), to clarify that the certification of allowable costs for risk corridor and reinsurance information includes direct and indirect remuneration that serves to decrease the costs incurred by a Part D sponsor for a Part D drug. The submission of accurate and complete data regarding direct and indirect remuneration that reduces a Part D sponsor's costs for Part D drugs under the Medicare prescription drug benefit is necessary to ensure accurate reinsurance and risk corridor payments. We received several comments on this provision, all of which expressed support for this proposed clarification. Therefore we are implementing this clarification, as proposed.

Comment: Several commenters supported our proposed clarification. One commenter agreed with the policy that the Chief Executive Officer or Chief Financial Officer must certify that the data reported for the purposes of determining allowable costs is accurate. However, this commenter expressed concern that CMS would need to establish penalties for violations in order to ensure compliance with this policy.

Response: We agree with the commenter's concern. We are currently conducting audits of the data reported for determining allowable costs in order to evaluate whether the data submitted (and attested to by the CEO or CFO) by Part D sponsors are accurate, complete, and truthful. In cases where inaccurate or incomplete data have been provided, we will determine the appropriate corrective action or penalties for Part D sponsors. In cases where there were misrepresentations or omissions in the information provided to us for determining allowable costs, we may refer such cases to Federal law enforcement for potential Federal civil action or criminal prosecution or both.

10. Change of Ownership Provisions (§ 423.551)

We are amending the change of ownership provisions in § 423.551, by adding paragraph (g) to clarify that PDP sponsors may not sell or transfer individual beneficiaries or groups of beneficiaries enrolled in any of their plan benefit packages (PBPs). This new provision is simply a clarification of an existing restriction on PDP sponsors' ability to sell portions of their Part D lines of business.

We are adding § 423.551(g) to provide necessary clarification on this change of ownership issue. During the first 2 years of the Part D program, several PDP sponsors have requested our approval of transactions involving the sale of beneficiaries. This clarification will minimize the number of sponsors that mistakenly begin negotiations on such sale agreements.

Comment: We received comments in support of this provision from several Medicare beneficiary advocacy organizations. A commenter from a Part D sponsor requesting a clarification that the provision does not prohibit a sponsor from transferring members from one wholly-owned subsidiary to another wholly-owned subsidiary (or from one contract to another contract) when a consolidation is required by CMS-imposed limits on the number of offerings a sponsor may have.

Response: The Part D sponsor's comment is in reference to requests CMS has made to certain PDP sponsors to adjust their bid submissions for an upcoming contract year to ensure that the sponsor is offering only those Part D plans that afford beneficiaries a meaningful choice among the sponsor's plan offerings. We advise that this change in the regulation will have no impact on our policies concerning the cross-walking, auto-enrollment, or reassignment of beneficiaries.

Comment: A Part D sponsor noted that the regulation is not as clear as the preamble in stating CMS' intent that we would recognize the sale of one or more plan benefit packages (PBPs) as a line of business rather than requiring a sponsor to sell all PBPs under a contract. Also, the regulation does not contain the condition that the sale cannot be apart from the rights and obligations related to the PBP.

Response: We agree that we could make clearer, through regulatory language, our intention that beneficiaries may not be transferred to another sponsor's plan pursuant to a novation without the acquiring sponsor assuming the selling sponsor's PBP obligations as well. Accordingly, we are revising the language of this regulatory provision to incorporate this comment.

We acknowledge the commenter's suggestion regarding the qualification of the sale of fewer than all of a sponsor's PBPs under a PDP sponsor contract as constituting an asset sale that we would recognize through the execution of a novation agreement. We believe this comment addresses an issue outside the scope of the regulation, which was intended solely to ensure that sponsors and potential sponsors understand that a sale of a Part D line of business must include the transfer of the seller's PBP obligations to the acquiring sponsor. We indicated in the preamble of the January 28, 2005 final rule (70 FR 4341), that we could not define all possible business arrangements and transactions and that the rules in Subpart N were intended as a framework, with guidance to be provided on a case-by-case basis. We continue that policy here by declining to accept the commenter's suggestion.

D. Changes to the MA and Prescription Drug Benefit Programs

1. Authorization of Automatic or Passive Enrollment Procedures (§ § 422.60 and 423.32)

In our May 16, 2008 proposed rule, we explained that there are some situations in which we have exercised our authority under section 1851(c)(1) of the Act to establish the method for electing to enroll in an MA plan by providing for ''passive'' enrollment procedures, under which an individual is notified that he or she can elect an enrollment into a particular plan by taking no action. We have done this only in cases in which we believed it was clear that enrollment in that plan was in the best interests of the average individual who did not focus on making an affirmative plan choice (generally in situations where the existing plan was being terminated or non-renewed). We proposed to revise the regulations to codify this practice in a new § 422.60(g) and § 423.32(g), in which the regulations would specify that CMS may authorize plans to carry out ''passive'' enrollment procedures in certain situations, including those involving immediate plan terminations, as well as those in which a failure to elect the enrollment in question would result in potential harm to beneficiaries. Comments on this passive enrollment provision are discussed below.

Comment: Although some commenters supported the provision as proposed, most commenters objected to the policy reflected in our proposal. In particular, several commenters opposed aspects of any process that would passively enroll members of a terminating or non-renewing MA plan into another MA plan. They argued that the passive enrollment process violates section 1851(a)(1) of the Act, which provides for beneficiaries to choose to receive their care either under Original Medicare (fee-for-service Medicare) or with a Medicare Advantage plan. These commenters contended that beneficiaries that have chosen an MA plan have chosen that specific plan, and not necessarily the MA program generally. They expressed concerns with what they describe as a wide variation in MA plan quality, network, benefits, cost sharing and other plan

policies. They suggest that a beneficiary who fails to elect a specific MA plan should always be defaulted to Original Medicare. Additionally, the commenters expressed concern that some beneficiaries do not understand the information provided in notices about passive enrollments and therefore, such notices do not serve as an effective protection against possible beneficiary harm and confusion.

The same commenters did agree that beneficiaries in a stand-alone PDP should be passively enrolled into another stand-alone PDP when their current PDP has been terminated or non-renewed, as these individuals would otherwise be left without prescription drug coverage. However, overall, the commenters argued that, in the event that an MA plan offering Part D benefits is terminated or non-renewed, these individuals should be disenrolled from the terminating or non-renewing MA plan, passively enrolled into a stand-alone PDP, and ''defaulted'' into Original Medicare, rather than being re-enrolled into another MA plan that offers Part D coverage.

Response: We disagree that our policy is inconsistent with section 1851(a)(1) of the Act. As noted in the preamble to the proposed rule, section 1851(c)(1) of the Act grants the Secretary the authority to ''establish a process'' for making the ''elections described in [section 1851(a)] are made and changed, including the form and manner in which such elections are made and changed.'' Under normal circumstances, the manner in which elections are made is for the beneficiary affirmatively to elect a plan, and to default a beneficiary to original Medicare if they fail to do so.

In some cases, however, a beneficiary could be substantially harmed by a failure to elect a particular MA plan, and it is clear that a reasonable beneficiary in such circumstances would elect that plan if they made an informed, affirmative choice. For example, a beneficiary with good employer wrap-around coverage may lose his or her wrap-around coverage if the employer plan changes the MA plan that it wraps around, and provides in its rules that an employee or retiree who fails to choose the new plan would lose his or her wrap-around benefits. In such cases, employees receive notice that they may elect the new MA plan under which they would keep their wrap-around benefits by taking no action, and would need to make an affirmative choice to make an election that would result in them losing their employee coverage. Similarly, MA enrollees could be in plans that buy down their Part B premium or provide other key benefits that would remain available only through another, similar, MA plan. As discussed below, we would require appropriate notice in those situations as well.

We view this as an appropriate exercise of our authority to establish the form and manner for electing an MA plan. In all cases in which this method is adopted, enrollees who determine that they do not, in fact, wish to make this election are permitted to decline this enrollment and enroll in an arrangement of their choice.

As explained in the proposed rule, this process also has been applied in situations in which a beneficiary's MA plan of choice has been suddenly terminated, and there is not adequate time to have a normal special election period. We expect these situations to continue to be limited in occurrence and scope.

In these situations, we consider the plan options available to affected beneficiaries, including the type and cost of such coverage, and the provider networks, and how such coverage and networks compare to those in their current plan. In many such cases, if beneficiaries were to be ''defaulted'' to original Medicare, their costs for Medicare Part A and B services could increase dramatically to a level some of them could not afford. These beneficiaries were relying on the lower out-of-pocket costs and additional benefits provided by their MA plan, which they would lose if suddenly placed into Original Medicare. Rather than have such beneficiaries automatically face large, and in some cases possibly bankrupting, out of pocket costs, we have arranged for them to elect a comparable MA plan by taking no action. We have, where warranted, required that plan to cover services provided by their existing providers and pharmacies during a transition period that would allow them to take the time to make an informed choice of plan options.

Organizations are required to notify affected beneficiaries of the ''passive'' enrollment prior to the effective date of the enrollment or as soon as possible after the enrollment effective date if prior notification is not possible under the circumstances. The notices are approved by CMS, explain the beneficiary's right to choose another plan, describe the costs and benefits of the new plan and how to access care under the plan, and discuss any other conditions of enrollment established by CMS (such as the right to continue seeing non-network providers while paying network cost-sharing amounts). We may also require that the organization notify the affected beneficiaries through other means, such as by telephone, where appropriate. In addition, we also ensure that any form of notification includes important contact information for beneficiaries to use to obtain assistance or additional information.

We believe the above process preserves the beneficiary choice provided for under section 1851(a)(1) of the Act, while also preserving the lower cost Part A and Part B benefits upon which MA plan beneficiaries have been relying in the case of those failing to make a choice, just as passively enrolling beneficiaries in a terminating PDP into another comparable PDP protects their Part D coverage. In both cases, the default is to a plan that we believe clearly would be in the average enrollee's best interests. For these reasons, we are finalizing the proposed regulatory provision specifying our passive enrollment authority.

Comment: Most commenters suggested that, when enrolling affected beneficiaries into a stand-alone PDP, CMS use existing Prescription Drug Event (PDE) data to ensure that beneficiaries are enrolled in the least expensive available PDP that covers all of their current medications.

Response: As stated above, when contemplating passive enrollment, we consider all aspects of the various plan options available to affected beneficiaries, including the type and cost of such coverage, the provider networks, and how these items compare to those of the beneficiary's current plan. Given the limited time typically available in those situations where passive enrollment is appropriate, we do not believe we would have sufficient time to incorporate beneficiary-specific PDE data into our analysis, particularly given the significant lag time between actual drug usage and the submission and analysis of such data. We will consider using such data in the future, if the circumstances allow.

Comment: Most of the commenters advised that CMS grant a special enrollment period (SEP) to individuals who are passively enrolled, and that this SEP last 6 months or until the end of the next Annual Election Period (AEP), whichever is later. They also suggested that the SEP allow the beneficiary to choose to have coverage effective retroactively, but no earlier than the first day of the first month after plan termination, in order to minimize disruption of coverage.

Response: We agree that individuals who are passively enrolled should be provided with an SEP, and already provide an SEP to these individuals.

Generally, this SEP begins the month in which the beneficiary is notified of the passive enrollment, and extends for an additional two months. Generally, we believe that such a 3-month SEP is sufficient and we do not believe it is appropriate or necessary to establish a 6-month SEP in the regulation, as suggested by commenters. However, in keeping with our authority under the current regulations, we will retain the flexibility to extend the SEP based on the unique circumstances of each termination or non-renewal. We also decline to amend the regulations to allow affected beneficiaries to choose to have alternative plan coverage elected under an SEP begin retroactively. Our experience has been that retroactive enrollment changes often are not in the best interests of the beneficiary, given the potential adverse consequences of retroactive cost-sharing and premium liability; thus, we believe that permitting unfettered retroactive changes on a blanket basis could prove problematic. Instead, we will continue to allow retroactive enrollment changes on a case-by-case basis.

Comment: A commenter suggested that, where passive enrollment is provided for, CMS launch an aggressive outreach and education campaign and provide special support to community based counseling organizations, such as local State Health Insurance Assistance Programs (SHIPs) and Area Agencies on Aging (AAA). Several commenters also advised that CMS notify local SHIPs in the affected area of the names and address of all enrollees in a terminating plan who will lose coverage and the effective date of the termination of this coverage.

Response: We recognize that such organizations are important partners in our efforts to educate and reach out to affected beneficiaries, and will continue to work closely with our partners when such situations occur. We will continue to work to provide them with information about such situations as soon as possible, in order to ensure beneficiaries have access to the important counseling services provided by these organizations. However, we decline to commit to providing SHIPs with the names and addresses of all impacted individuals, as we believe that these individuals' privacy concerns, and the administrative burden associated with collecting and disseminating such information, outweigh the potential benefits of sharing such information with these organizations.

Comment: A commenter requested that the passive enrollment provisions be expanded to apply to dual eligible individuals who have actively chosen a plan if the plan premium of that plan is no longer below the amount in which CMS provides the full amount of extra help.

Response: The commenter is actually referring to one aspect of our annual ''reassignment'' process, whereby we reassign LIS-eligible individuals if they are in a plan that will no longer have a premium at or below the LIS benchmark. However, our policy is to reassign only individuals who remain in a plan to which they were auto-enrolled, as opposed to individuals who have actively chosen their existing plan. We considered reassigning these individuals (so-called ''choosers'') to another Part D plan, but decided to honor the individual's choice and allow him or her to make a subsequent choice on his/her own. These individuals receive notice in October of every year from their current plan that advises them of any changes in the plan's benefits and costs, and they have until the end of the calendar year to take action to change plans. Additionally, LIS-eligible individuals have an ongoing SEP that enables them to make changes at any time during the year; so, if an LIS-eligible individual is unaware that a premium will be owed and then decides to change plans upon receiving an unexpected bill for a plan premium, he or she is always free to do so. Note that even in this situation, the subsidized copayments would still apply and the premium due would represent only the difference between the LIS subsidy and the actual premium.

Comment: A commenter recommended that CMS distribute the terminated membership equally among all plans available in the area.

Response: When effectuating a passive enrollment, we review information about the available plans in the affected area, including their benefit packages, provider networks, and cost-sharing premium amounts, in an effort to ensure that beneficiaries who are passively enrolled maintain a level of coverage equal to or better than their current coverage, without incurring additional costs. In cases where these considerations are generally equal, our preference generally would be that affected beneficiaries are distributed equally among the remaining plans in the area. However, in other cases, only one plan may be available that meets these criteria. Therefore, we decline to adopt the commenter's suggestion as a general rule, so that we can continue to exercise appropriate discretion to ensure that affected beneficiaries are enrolled in the most appropriate plans.

2. Involuntary Disenrollment for Nonpayment of Premium (§ § 422.74 and 423.44)

We proposed revising the MA and Part D regulations in § 422.74(d)(1) and § 423.44(d)(1) by adding a new paragraph (d)(1)(iv) to each section to prohibit plans from disenrolling individuals for failure to pay premiums if they either have requested the premium withhold option, or if they are already in premium withhold status. Plans may initiate disenrollments for failure to pay premium only after an individual in ''direct bill'' status has been notified of the premium owed and, in the case of MA plans, provided the grace period required under § 422.74(d)(1)(i)(B), as currently outlined in the MA and Part D regulations discussed above. For Part D, the plan must have made reasonable efforts to collect the unpaid amount, as provided in § 423.44(d)(1)(i), before disenrollment may be initiated. Based on the comments received on our proposal, we are revising the language in § 422.74(d)(1)(iv) and § 423.44(d)(1)(iv) to conform with the changes made to § 422.262(g) and § 422.293(e).

Comment: Numerous commenters supported the provisions as an important beneficiary protection. However, several commenters also expressed concerns with the operational issues experienced with the implementation of the premium withhold option, and the subsequent beneficiary confusion that may arise from these issues. Several of these commenters recommend that CMS define a clear process to resolve withhold problems.

Response: We continue to work in collaboration with the Social Security Administration and our contracting partners to refine the premium withhold process in order to ensure a more timely and equitable outcome for all. We continue to work on this process and have resolved most premium pass-through payment delays. To the extent that problems remain unresolved, however, we will consider what other steps we might take when member premiums are being withheld from SSA checks, but they are not being passed through to the appropriate plan.

Comment: Several commenters proposed that any beneficiary who is in direct bill status despite having requested premium withhold be protected from disenrollment for failure to pay premiums for the duration of the plan year.

Response: In some cases, a request for premium withhold is not implemented

properly when requested, and a beneficiary may be in direct bill status when he or she should be in withhold status. We believe that beneficiaries remain financially responsible for the premium amounts due to the plan. If these amounts are not being withheld from their checks, they remain responsible for payment. Members of an MA or Part D plan who are being billed for payment are subject to involuntary disenrollment (if plan uses that option), after being provided due process—including the opportunity to pay premiums within grace period. In operational guidance, we have asked that our contracting plans make good faith efforts to work with beneficiaries who owe back premiums and to allow members to arrange for repayment over time. That process was viewed as protective of both the beneficiary and plan financial interests.

Comment: Many commenters expressed opposition to the prohibition on involuntary disenrollment due to non-payment of premium while premium withhold is in place. One commenter believed that it does not treat all members in the plan equally, requiring members in direct bill status to pay premiums timely, while those who have elected premium withhold are protected even when the plan does not receive payment.

Response: We disagree that beneficiaries are treated unequally. All members are required to pay premiums timely. By choosing the premium withhold option, beneficiaries have demonstrated their commitment to meet their financial obligation to the plan. In either case, the beneficiary assumes the financial responsibility—whether through direct withholding from his/her Social Security benefit check, or by direct billing by the plan and remittance to the plan by the beneficiary.

Comment: A commenter believed that the prohibition on disenrollments adds more administrative burden to the plan and dictates plan financial policies.

Response: We do not believe this requirement places an undue additional burden on plans. We provide plans with critical information on its membership on a routine, ongoing basis. Plans are required to react to this information as part of the plans' contractual obligations. Further, we disagree that this requirement dictates plan financial policies as these requirements to maintain enrollment for an individual who is in premium withhold status do not waive or otherwise eliminate plan premiums.

Comment: A few commenters suggested that beneficiaries identified with withhold problems be moved to direct bill. One commenter suggested the same, but with a finer point that would allow plans to initiate a move to direct billing when the SSA withhold has not worked for a reasonable period (for example, 60 days). Another commenter recommended that we allow plans to send notices to beneficiaries to inform them that withholding is not working and that a balance is accruing.

Response: We appreciate these suggestions and will take them into consideration as we continue to examine the extent and duration of withhold issues.

Comment: A few commenters requested that CMS establish similar provisions to protect plans from a negative financial impact when the premium withhold process is not successful, since MA organizations sometimes experience delays in payment from CMS. One commenter recommended that CMS institute performance guarantees for SSA payments and/or requiring SSA to pay interest to MA plans for late payments.

Response: As described previously, we continue to work with our internal processes, Social Security, and our contracting partners to refine the premium withhold system. We continue to discuss this process with our contracting partners and will develop operational strategies to successfully implement this process, including timely premium payment to plans.

Comment: Another commenter did not agree with the CMS' legal interpretation to exclude premium payment option from the nonpayment of premium provisions established in statute at section 1851(g)(3)(A) of the Act. The commenter further questions the Congressional intent of such a provision, since neither the statute, as established by the Balance Budget Act of 1997 (BBA), nor the supporting congressional interpretation of the BBA, provides specific exception to exclude premium withhold from this disenrollment provision.

Response: We are not prohibiting involuntary disenrollment solely on the basis that the individual has selected his/her premiums to be withheld from an SSA, RRB, or OPM benefit check. Rather, we are prohibiting such disenrollment when that request has not yet been successfully processed due to a system processing issue within CMS or between CMS and SSA (or RRB and OPM, when that occurs in the future). We are simply establishing this provision to protect the individual beneficiary from negative consequences (involuntary disenrollment) based on a system's issue that is beyond his or her control. This provision in no way relieves the individual of any premiums owed to the plan. The statutory authority at 1851(g)(3)(B)(i) of the Act provides Medicare Advantage organizations the option to disenroll individuals who fail to pay plan premiums, which is also applied to Part D plans—as directed by 1860–D1(b)(1)(A) of the Act to apply rules to Part D program similar to the ones established for the MA program.

With regard to paying the premium, we have established that the individual, by selecting the premium withhold option, is deemed to have made a payment to the plan and therefore is not subject to this involuntary disenrollment for non-payment of premium provision.

Comment: A commenter believed that all members should be treated the same for nonpayment of premium, regardless of the payment method chosen.

Response: We agree and believe that the provision, as written, supports that all individuals are treated equitably.

Comment: Several commenters requested that CMS expand this rule to include other automatic payment situations involving system issues, such as errors with electronic fund transfers or checking accounts.

Response: We decline to extend this provision to include errors that may occur from other financial institutions and maintain that this provision is limited to the premium withhold option, as described at § 422.265(f) and § 423.293.

Comment: Several commenters urged CMS to include additional protections for low-income individuals, specifically, that plans would not be allowed to involuntarily disenroll low-income individuals who receive extra help from Medicare in paying all or part of their Part D plan premiums. In addition, commenters requested that we allow beneficiaries to provide evidence to the plan that supports their low-income status to prevent the disenrollment, if the plan is not aware that the individual receives extra help.

Response: As explained above, section 1851(g)(3)(B)(i) of the Act provides MA plans the option to disenroll members who fail to pay premiums, and this option is also available to Part D plans, as directed by 1860–D1(b)(1)(A) of the Act. Therefore, we cannot prohibit plans from exercising this option if they so choose. However, if a plan chooses to exercise this option, our existing enrollment guidance permits plans to exclude their low-income subsidy eligible members from this policy and allow them to remain enrolled in the plan.

Comment: Several commenters believed that this provision should be extended to beneficiaries whose premiums are paid by a third-party funding source, such as a State Pharmaceutical Assistance Program (SPAP). Further, if involuntary disenrollment occurs when there is such a funding source, one commenter recommends that the individual be reinstated into the plan once the plan is notified of the third-party payer.

Response: We already have provisions in place to prohibit organizations from disenrolling or initiating the disenrollment process, if those organizations have been notified that the Part D portion of the premiums is being paid by an SPAP or other payer and the organization has not coordinated the receipt of the premium payment directly with the SPAP or other payer. Details of these requirements can be found in Chapter 14 of the CMS Medicare Prescription Drug Benefit Manual.

Comment: One commenter requested that disenrollment under the involuntary disenrollment for non-payment of premium provision only occur if the premium in arrears is above a certain threshold, for example at least 2 months premiums are past-due. Otherwise, the commenter believes that plans would be allowed to terminate these important benefits over what amounts to a very insignificant sum of money to the plan.

Response: The commenter raises an interesting issue; however, small amounts, in aggregate, could prove substantial to the organization. To ensure that all beneficiaries are treated equitably, we have established in sub-regulatory guidance that if plans choose to implement this option to disenroll individuals for non-payment of past-due premiums, that they must apply the rule consistently to all similarly situated individuals and for any amount owed and not paid during the grace period.

Comment: CMS should clarify that the prohibition to disenroll enrollees is applicable only to those premiums due after the date the enrollee requested premium withhold status.

Response: We agree that the prohibition on disenrollment is applicable to individuals only for those premiums due after the individual selects the premium withhold option. If, prior to requesting premium withhold, and individual's premiums are already in arrears, the plan can initiate involuntary disenrollment for non-payment of premium related to the premiums that were already past-due at the time premium withhold was requested.

Comment: Commenters urged CMS to add a provision allowing the plan to bill CMS for the amount of any premiums due, including reasonable interest, for the period in which the premiums are owed.

Response: We disagree that we should pay the individual's portion of the plan premium or interest on these premiums, and maintain that the individual is ultimately responsible for his/her premiums.

3. Retroactive Premium Collections and Beneficiary Repayment Options (§ § 422.262 and 423.293)

We proposed to amend the MA regulations at § 422.262 by adding new paragraph (h) and the Part D regulations at § 423.293 by revising paragraph (a) to expressly provide for the proration of past-due premiums over a period of monthly payments when the reason for the premium arrearage is other than a member's willful refusal to remit the premium. In making this proposal, we stated that we believed that beneficiaries should be able to spread out their obligation in such cases over at least the same period as the one during which past-due premiums were accruing. That is, if 7 months of premiums are due, then the member should have at least 7 months to repay. The final rule adopts these revisions by adding a new paragraph (h) to § 422.262 and in § 423.293 by revising paragraph (a) as set forth in our proposed rule. Based on comments, we modified our proposed language to clarify that other mutually acceptable means of repayment of past-due premiums are also permissible.

Comment: Many commenters agreed with the proposed rule. One commenter agreed with the proposed rule, but suggested we clarify that failure to stay current with a repayment agreement would constitute grounds for involuntary disenrollment.

Response: We believe § 422.74(b)(1)(i) already provides ample authority to initiate involuntary disenrollment procedures for a member that does not stay current with his or her repayment agreement.

Comment: Some commenters stated that allowing enrollees to repay past-due premiums over time would place a financial burden on plans. Some stated that direct billing is labor-intensive and that plans should be permitted to charge interest to members on past-due premiums to make up for the lost cash-flow.

Response: We do not have authority to permit plans to charge interest for past-due premiums. The recourse for plans established in statute and codified in regulation is that plans can initiate involuntary disenrollment of members that do not remit premium in a timely manner. Note that direct billing is already a member option, so the burden on plans will be mitigated by systems for direct billing that are already in use.

Comment: Some commenters stated that determinations of ''fault'' would be difficult to make, and that enrollee complaints would increase, including complaints about the disparate treatment of members. Others stated that we should not establish a separate ''right'' for individuals who ''fail'' premium withhold, while not providing the same ''right'' to others who have past-due premiums. Other commenters suggested requiring plans to ''waive'' premiums when the plan sponsor was ''at fault'' in creating the premium arrearage. Some commenters suggested we include a definition of ''without fault'' and include all situations where the individual could not reasonably be expected to make premium payments, including hospitalizations or other situations beyond the beneficiary's control.

Response: We have not further defined ''without fault'' since we believe the language of the regulation is clear. To the extent the member has not been previously notified of proposed involuntary disenrollment for non-payment of premium, the member is ''without fault'' in creating the premium arrearage. In such cases, where the premium arrearage is for more than a single month, the sponsoring organization must permit installment payments. We do not believe this provision will cause disparate treatment of members. Rather, all members with premium arrearages of more than a month and who were not responsible for having created them by either failing to respond to a remittance notice, or by failing to use a coupon book to send in their monthly premium, will have the same ''right'' to installment payment of past-due amounts. We are not further enumerating the possible ''without fault'' situations at this time. That said, we do not believe that being hospitalized would necessarily, in and of itself, constitute a case of ''without fault.'' Note that premiums are due monthly. In the event a hospitalization or lengthy illness prevents timely payment of premium, we would want and expect plan sponsors to be reasonable in their collection efforts.

Comment: Some commenters suggested that while ''without fault'' determinations are being made there should be no recourse against an enrollee. These commenters also suggested developing an appeal process

related to ''without fault'' determinations.

Response: Disputes related to premium payments and involuntary disenrollment actions are already subject to the plan's internal grievance process.

Comment: One commenter stated that members are aware of their monthly premium liability upon enrollment in a plan and therefore should not be permitted to delay payment, when premium arrearages occur. Another commenter stated that extended payment plans are a hardship for beneficiaries.

Response: In some cases members believe they owe no premium or that their premium is being paid through premium withhold or through some other mechanism. In such cases premium arrearages can accrue through no fault of the member. In other words, it is not always the case that knowing premium liability is tantamount to delaying payment. In the case where a member finds hardship in an extended payment plan, remittance by lump sum is also possible.

Comment: Some commenters complained that extending repayment plans beyond the current plan year could result in members still owing past-due premiums at their renewal date. The commenter also stated that some members might disenroll from the plan during the Annual Election Period before they had completely repaid their premiums. Some commenters suggested that repayment plans, therefore, be limited to the number of months left in the current plan year.

Response: All members are free to select a new plan during the Annual Election Period and therefore have an opportunity to stop paying premium toward the end of a plan year, especially if they are considering enrollment in a new plan. Therefore, we do not agree that the potential for selection of a new plan during the Annual Election Period provides a compelling argument that installment plans always guarantee repayment before the end of the current plan year.

Comment: One commenter suggested adding additional options for members to repay past-due premiums, beyond the two mentioned in proposed regulation text.

Response: We agree with this comment and in response to this comment now indicate in the final regulation text that other mutually-agreeable repayment methods, beyond lump-sum and monthly installments, are acceptable.

Comment: One commenter recommended allowing plan sponsors to require repayment of the full past-due amount if it represents less than 2 months.

Response: We agree with this comment. It was not our intention to allow repayment of past-due premium amounts over a greater period of time than the number of months during which the past-due premiums accrued. If the premium arrearage is for a single month, then the member must pay the entire amount in a single payment.

Comment: One commenter suggested allowing the plan sponsor to exercise flexibility in working with members, that mandating specific member rights was inappropriate and that it might lead to premium payment abuses by members.

Response: While we rely on and assume plan reasonableness, we also assume member integrity. We believe we have achieved the correct balance between a plan sponsor's right to impose premium and a plan member's responsibility for payment of such premium.

Comment: One commenter stated that sections 1854(d)(1) and (2) of the Act did not support the interpretation that members should be permitted to pay past-due premiums over time.

Response: We do not agree. Section 1854(d)(1) of the Act is clear in requiring a plan sponsor to permit the payment of premium ''on a monthly basis.'' If, due to a system interface problem, or if, due to the failure, oversight or mistake of another party—for instance, a plan sponsor might neglect to provide a monthly billing statement to a member—and if a member's premium arrearage exceeds a single month, then the member should nevertheless retain the right to pay premiums on a monthly basis.

Comment: One commenter expressed concern that in cases where past-due premiums are owed but members are currently in premium withhold status, that computer systems would not currently support installment payments.

Response: It was never our intent to permit installment payments of past-due premiums through premium withhold. Many premium arrearages are caused by ''failures'' in the premium withhold system. It would be illogical to call on the premium withhold system to withhold past-due premiums that the premium withhold systems caused in the first place.

Comment: Some commenters stated we should limit liability for past-due premiums to three months, where the plan sponsor made no prior effort to collect. Some suggested requiring ''waiver'' of past-due premiums in cases of ''hardship.'' One commenter suggested having the Social Security Administration pay enrollee premiums during periods of temporary cessation of SSA checks—when, for instance, the enrollee is a resident of a State psychiatric institution. Finally, some commenters suggested limiting involuntary disenrollment to only cases where premium arrearages were for two months or more.

Response: We have no authority to limit liability for past-due premiums to only 3 months, regardless of the circumstances surrounding a specific case. Similarly, CMS has no authority to ''waive'' past-due premiums, nor can we require a plan sponsor to do so. Under Part D, there is the income-related subsidy program that would limit premium liability for most low-income individuals. However, there is no premium subsidy program under Part C. We also have no authority to require the Social Security Administration to pay premiums on enrollee's behalf, where premiums have not first been deducted from enrollee's Social Security checks. Finally, we have no authority to restrict involuntary disenrollment to only those cases where more than a single month's premium is past-due.

Comment: Some commenters suggested imposing fines or civil monetary penalties that would be payable to plan members on plan sponsors that send incorrect notices to members related to premiums.

Response: We do not have the authority to require plan sponsors to pay plan members fines or civil monetary penalties for incorrect notices related to plan premiums.

4. Prohibiting Improper Billing of Monthly Premiums (§ § 422.262 and 423.293)

We proposed to amend the MA regulations by adding new paragraph (g) to § 422.262, and the Part D regulations by adding new paragraph (e) to § 423.293, to explicitly prohibit improper billing. We stated it was inappropriate for an MAO or Part D plan to double bill members who have submitted a request that premiums be withheld under section 1860D–13(c) of the Act for Part D or section 1854(d) of the Act for Part C, and who are already having their premiums taken out of their Social Security payments. The final rule adopts the revisions to § 422.262 and § 423.293 with modifications based on comments. Specifically, based on comments we received, we have modified the language to clarify that we only intend to prohibit billing a beneficiary a second time for premiums that the beneficiary has already paid through premium withhold.

Comment: All commenters supported CMS's position that members should not be billed for premiums that had already been paid through premium withhold. However, some commenters suggested that the plan should be paid interest by Social Security or CMS, when the premium was actually withheld from a member's Social Security check, but the premium was not passed on to the plan sponsor in a timely manner.

Response: We will continue to work with plans to ensure timely payment of amounts due. In the case of premium withhold, we are exploring additional systems implementation options that include more robust reporting of premium withhold data, as well as more timely reconciliation of premium pass-through issues.

Comment: Some commenters suggested that when there is a premium withhold ''failure'' that members should be indemnified for the remainder of the plan year.

Response: We do not have the authority to indemnify such members from responsibility for premiums that they actually owe. On the other hand, to the extent members have already paid premiums through premium withholding, we fully intend to protect them from double billing and, in another part of this rule, from improper involuntary disenrollment.

Comment: Some commenters objected to the fact that a plan enrollee could simply request premium withhold and thereby avoid premium liability during the time it takes the plan to set-up premium withhold.

Response: We agree with this comment, and in response to this comment have clarified the regulation text to state that it is only in cases where premiums have already been paid by the member through premium withhold that it is prohibited under this regulation for a plan to bill a member more than once for such premiums.

5. Non-Renewal Notification Timelines (§ § 422.506 and 423.507)

We proposed revising § 422.506(a)(2)(ii), (a)(2)(iii), (b)(2)(ii), and (b)(2)(iii) of the MA regulations and § 423.507(a)(2)(ii), (a)(2)(iii), (b)(2)(ii) and (b)(2)(iii) of the Part D regulations, to change the beneficiary and public notice requirement from at least 90 days to at least 60 days, thus allowing more time for the contract non-renewal process to conclude, and any administrative appeal to conclude, while still allowing for a sufficient beneficiary notice period, prior to January 1st. This change will help ensure that all non-renewal decisions are final, prior to the start of marketing and enrollment activities.

Comment: Numerous comments opposed the reduction of the beneficiary and public notice period. The commenters stated that the reduction of days for beneficiaries to understand the impact of the non-renewal, evaluate their options, and make informed decisions would be difficult. The commenters urge CMS to maintain the 90 day notice period.

Response: The change in beneficiary and public notification timeframes was made to allow time for the notification process to conclude prior to the beginning of open enrollment, since the date for notifying plans regarding nonrenewals is now August 1 of each year. The 60-day beneficiary and public notification may not occur prior to the conclusion of the administrative appeal of a non-renewal determination. Shortening the notification period to 60 days will also increase the likelihood that any administrative appeal and the notification period can conclude prior to the start of the new plan year on January 1.

We believe a 60-day notice is sufficient for beneficiaries to make choices. Currently, beneficiaries cannot enroll, during the annual enrollment period, in a plan until November 15th of each year. The change in the notification timeframe does not limit the enrollment period for beneficiaries. The decrease in the beneficiary notification period only affects the amount of time plans may market to beneficiaries. We believe 60 days is a sufficient amount of time for beneficiaries to make a new health care choice. Therefore, we will not be making any changes based on this comment.

6. Reconsiderations (§ § 422.578, 422.582, 423.560, 423.580)

a. Medicare Advantage Program (§ § 422.578 and 422.582)

We proposed to revise § § 422.578 and 422.582 to allow a beneficiary's physician to request a standard plan reconsideration on the beneficiary's behalf without having been appointed as his or her representative. The final rule adopts the revisions to § § 422.578 and 422.582 as set forth in our proposed rule.

Comment: Many commenters agreed with the proposed change allowing a treating physician, with the enrollee's consent, to request a standard pre-service reconsideration. In addition to supporting the proposed change, one commenter recommended further revising § 422.584 of the regulations to specify that the physician making an expedited request must be currently providing treatment to the enrollee.

Response: We appreciate the commenters' support for this provision, and believe that permitting physicians to request standard pre-service appeals on their patients' behalf will help to make the appeals process more accessible to enrollees. However, we can not revise § 422.584 of the regulations to specify that the physician making an expedited request must be currently providing treatment to the enrollee because section 1852(g)(3)(A)(ii) of the Act permits any physician, regardless of his or her status as an enrollee's treating physician, to request an expedited determination or reconsideration on an enrollee's behalf.

Comment: A commenter requested that CMS clarify in the regulations that only a primary care physician (PCP) would be allowed to request a standard reconsideration of a pre-service request on behalf of the enrollee, not a specialty care physician.

Response: The term ''physician'', as used in subpart M, has the same meaning given to the term in section 1861(r) of the Act. Thus, the term includes any physician who is providing treatment to the enrollee. Therefore, it would be inappropriate to allow only PCPs to request standard pre-service reconsiderations. We continue to believe that any physician who is involved in providing care to an enrollee is in a good position to know whether a request for plan reconsideration is warranted and in the enrollee's best interest. Accordingly, we are not adopting the commenter's suggested revision.

Comment: A commenter asked CMS to clarify in the MA regulations that an enrollee's treating physician is limited to requesting a standard plan reconsideration of a pre-service request on an enrollee's behalf without being the enrollee's appointed representative.

Response: As currently drafted, we believe § 422.578 of this final rule already makes this limitation clear. It states in relevant part that a physician is limited to requesting ''a standard reconsideration of a pre-service request for reconsideration on the enrollee's behalf.'' (*See* 73 FR 28594).

Comment: A commenter was concerned that removing the need for an enrollee to actively appoint a representative could have serious implications for beneficiary rights. This same commenter also noted that the proposed change would raise significant operational issues. For example, the commenter questioned what would happen in a situation where an enrollee objects to being represented by the

physician, and asked whether there are limits on the representation, and if the initial representation would enable the physician to continue the appeals process through additional levels of appeal. Finally, the commenter questioned whether such representation is limited to disputes relating to services provided by the appealing physician. Given these concerns, the commenter suggested that the proposal be given further review prior to implementation.

Response: We appreciate the commenter raising these important issues concerning enrollee rights, limitations on physician representation of an enrollee, and the potential operational issues resulting from this policy. In the MA program, physicians have long been permitted to file coverage requests and plan level expedited appeals on their patients' behalf. The proposed policy represents a modest expansion of that right, but still limits the physician's ability to act on the enrollee's behalf only to plan level appeals, unless the physician is the enrollee's representative. As stated in the preamble to the proposed rule (73 FR 28579), we believe that for any appeal beyond the plan level, the enrollee should be directly involved in a decision to disclose his or her private health information to adjudicators because those adjudicators do not have the same relationship with the enrollee that the plan has. Accordingly, if an enrollee wishes his or her physician to request higher levels of appeal on his or her behalf, the physician must also be the enrollee's representative. If an enrollee does not want his or her physician to request an appeal, we believe the proposed rule addresses the commenter's concern. Consistent with § 422.578, the physician must notify the enrollee before filing the appeal request. We believe this policy will afford the enrollee sufficient opportunity to express any objections about the physician filing the appeal or to refuse the physician's representation. Given our experience with the MA and Part D programs, it is reasonable to believe that in the overwhelming number of cases, the enrollee will welcome the physician's willingness to pursue an appeal on the enrollee's behalf.

With respect to the commenter's question about whether the representation is limited to disputes relating to services provided by that physician, § 422.578 states that a physician who is providing treatment to an enrollee may, upon providing notice to the enrollee, request a standard reconsideration of a pre-service request on the enrollee's behalf. As the commenter notes, the regulation is not prescriptive about the relationship between the care the physician is providing to the enrollee and the need for the reconsideration request. However, we believe that given the treating physician's knowledge of and access to the medical information needed to support such a request, it is reasonable to presume that, in most instances, the treating physician will be the physician requesting the pre-service reconsideration. Finally, we note the receipt of numerous comments from beneficiary advocacy groups and medical associations in support of this provision as an appropriate means of allowing physicians to assist enrollees with the MA and Part D appeals processes. Accordingly, we have finalized the provision as proposed.

Comment: Many commenters asked CMS to clarify what type of documentation a physician would be required to produce to demonstrate that he or she is an enrollee's treating physician.

Response: Since the inception of the MA and Part D programs, we have received numerous comments asking us to make the appeals process more enrollee-friendly by allowing physicians to make initial determination and appeals requests on their patients' behalf without going through the formal appointment of representation process. We developed the proposed policy in response to those requests, and the overwhelming number of comments we received were supportive. Our proposal is a very limited extension of a physician's current appeal rights under the regulations (a physician currently has the right to request an initial determination or an expedited plan-level appeal on behalf of an enrollee without being his or her appointed representative). We merely proposed to extend this right to include standard pre-service plan-level appeals under MA and standard plan-level appeals under Part D. Thus, the process for handling physician-initiated plan-level appeal requests should be the same process that is currently being used to process and adjudicate expedited plan-level appeal requests. In addition, because we intended to make filing a standard plan-level appeal request easier for a physician than if he or she were filing as the enrollee representative, we expect the processes that plans to adopt for verifying a physician's status as the treating physician to be much simpler and more flexible than the process used to verify appointed representative status. If necessary based on experience under this final rule, we believe the proper place to further address this issue is in operational guidance. As such, we will consider the commenters' concerns as we develop future policy guidance, and will update Chapter 13 of the Managed Care Manual and Chapter 18 of the Prescription Drug Benefit Manual as appropriate.

b. Prescription Drug Benefit Program (§ 423.560 and 423.580)

(1) Definitions (§ 423.560)

We proposed to revise the regulation text of § 423.560 by adding a new definition for ''other prescriber'' that encompasses health care professionals, other than physicians, with the requisite authority under State law or other applicable law to write prescriptions for Medicare beneficiaries. In conjunction with the proposed new definition, we proposed to add ''or other prescriber'' after ''prescribing physician'' or ''physician'' throughout subpart M of part 423 in order to authorize these other prescribers to perform the same functions that prescribing physicians are allowed to perform with respect to the coverage determination and appeals processes as set out in subpart M of part 423. This final rule with comment period adopts the revisions to § 423.560 set forth in our proposed rule.

Comment: A few commenters requested further clarification regarding who could qualify as an ''other prescriber.'' One commenter suggested CMS ensure the definition of other prescriber is consistent with the definitions of treating physician and treating practitioner used in section 1861(r) of the Act.

Response: As noted in the preamble to the proposed rule (73 FR 28579), we believe it is important to provide enrollees who have prescriptions written by health care professionals, other than physicians, with prescribing authority under State law or other applicable law the same protections and assistance in the coverage and appeals processes that are currently available to enrollees whose prescriptions are written by a physician. We believe it is appropriate to defer to State law or other applicable law to determine who is considered an ''other prescriber'' under subpart M of the regulations because States are responsible for licensing and regulating such professionals. Although we may provide examples of other health care professionals who have prescribing authority under State or other applicable law in our guidance, any such list would not be exhaustive. Thus, it is ultimately a Part D plan sponsor's responsibility to ensure a health care professional making a request on behalf of an enrollee has

prescribing authority under State law or other applicable law.

(2) Right to a Redetermination (§ 423.580)

We proposed to revise the regulation text of § 423.580 to provide prescribing physicians and other prescribers with the ability to request standard redeterminations on behalf of enrollees, and require them to notify enrollees that they are taking this action. The final rule adopts the revisions to § 423.580 set forth in our proposed rule.

Comment: Although many commenters supported our proposal to allow physicians and other prescribers to request, upon notice to the enrollee, a standard redetermination, we received one comment opposing the proposal. The corresponding change that was proposed, and is being finalized in this rule, for the MA program allows a treating physician to request a plan-level appeal (reconsideration) on behalf of the enrollee for a pre-service request, but does not allow a treating physician to request a standard plan-level appeal for payment. The distinction between pre-service claims and claims for payment in the MA program was made due to the financial interest a treating physician may have in a claim for payment under the MA program. Under existing § 422.574(b), if the physician or other provider that furnished a service to an enrollee formally waives any right to payment from the enrollee for that service, the physician or other provider becomes a party to the organization determination and may request a plan-level appeal. The commenter opposing the proposal disagreed with the statement made in the preamble to the proposed rule that prescribing physicians do not have a financial interest in the payment of Part D claims because a physician who has a relationship with a pharmaceutical manufacturer may be more likely to prescribe one of the manufacturer's drugs. Finally, the commenter also believes that if an enrollee wants a physician or other prescriber to seek a redetermination on his or her behalf, then the enrollee should make that request to the provider in writing.

Response: We appreciate the comments received in support of this provision. We believe a policy of allowing prescribing physicians and other prescribers to request standard redeterminations on behalf of enrollees will help to make the appeals process more accessible to enrollees. With respect to the comment opposing this provision, we understand the commenter's concern about the potential for a prescriber to have some financial interest, but continue to believe that a physician or other prescriber requesting an appeal under Part D does not have a financial interest in the outcome of an appeal in the same manner as a physician requesting an appeal under the MA program. As noted in the preamble, the MA rules already allow a provider who has furnished a service to an enrollee to request a plan-level appeal if the provider waives any right to payment from the enrollee. Under the Part D program, a physician or other prescriber is generally not entitled to payment for the prescribed drug from either the enrollee or the plan and, therefore, is not in the same position as an MA provider with respect to a potential financial interest. Finally, we do not agree with the commenter's suggestion that an enrollee should submit a written request to his or her provider asking the provider to represent him or her in the redetermination process. Adding this requirement would essentially create a process identical to the appointment of representative process, which would not serve to enhance beneficiaries' access to the Part D appeals process.

Comment: A few commenters asked CMS to clarify the process a physician must use to inform an enrollee that he or she is requesting a standard redetermination on the enrollee's behalf. One commenter asked how the physician's notice to the enrollee is communicated to the Part D plan sponsor, and how receipt of such information impacts the adjudication timeframe.

Response: As noted previously, our intention is to make this process flexible for enrollees, providers, and plans. Thus, we have not included in regulation any requirements regarding the format of the physician's notice to either the enrollee or the plan. We believe this approach will allow plans to determine how to best implement these requirements. However, we will take these comments into consideration when developing any necessary operational guidance. If we determine that additional clarification is necessary, we will include any appropriate information in our operational manuals. Therefore, any additional polices we develop related to the issues raised by the commenters above will be added to Chapter 18 of the Prescription Drug Benefit Manual.

c. Miscellaneous Comments

Comment: We received one comment suggesting the provision in § 423.582 requiring prescribing physicians to submit written requests for redeterminations is an unnecessary formality that will frustrate the practitioner's ability to provide the best care for his or her patient.

Response: We believe the commenter's suggestion is outside the scope of the proposed rule because we did not propose to modify the written request requirement in § 423.582. We note that, although the written request requirement in § 423.578 was carried over from § 422.578 in accordance with section 1860D–4(g) of the Act, nothing in the Act or regulations prohibits an MA organization or a Part D plan sponsor from also accepting verbal requests. Rather, the regulations explicitly provide that the MA organization or Part D plan sponsor may adopt a policy for accepting oral requests. (See § 422.582(a) and § 423.582(a)).

Comment: A commenter suggested that a physician in the same specialty or subspecialty as the prescribing physician must be responsible for reviewing a medical necessity denial under § § 423.590(f)(2) and 423.600(e).

Response: The commenter's suggestion is outside the scope of the changes proposed in this rule because we did not propose to modify § 423.590(f)(2) or § 423.600(e). We note that the physician reviewer requirements contained in § 423.590(f)(2) and § 423.600(e) are consistent with § 422.590(g) of the regulations, which requires the reviewing physician to have ''expertise in the field of medicine that is appropriate for the services at issue'' but ''need not, in all cases, be of the same specialty or subspecialty as the treating physician.'' We continue to believe that the level of review provided by a physician having expertise in the field of medicine appropriate for the services at issue is sufficient for medical necessity denials under Part D. The regulatory language also makes it clear that a physician of the same specialty or subspecialty as the prescribing physician may need to review a Part D drug medical necessity denial in some situations.

Comment: Several commenters provided comments on the MA reconsideration process at the independent review entity (IRE) level of review. The commenters stated that IRE reconsiderations are generally limited to evidence and arguments submitted to the IRE by the MA plan and that beneficiaries often have difficulty contacting the IRE and are discouraged from participating in the process. The commenters requested that § 422.592 be amended to include a provision giving beneficiaries the right to submit allegations of fact and law to the IRE

and that such information could be submitted by telephone, fax or electronic mail.

Response: Amending § 422.592 of the MA appeals regulations is outside the scope of this final rule. However, we will consider the commenters' remarks for future rulemaking that involves the MA appeals process. We would like to note that, under the existing standard reconsideration process, when the IRE receives a case file from an MA plan, it sends an acknowledgement letter to the enrollee. The acknowledgement letter informs the enrollee that his or her appeal is being reviewed by the IRE and includes a comprehensive explanation of the enrollee's rights, including the right to provide the IRE with information that may help the enrollee's case.

Comment: We received comments urging CMS to revise § 423.578 to require uniform coverage determination and reconsideration procedures. In addition to making it easier for physicians, advocates, and beneficiaries to navigate the system, the commenters believe uniform requirements will make it easier for CMS to monitor plan performance.

Response: We appreciate the commenters' suggestion, however, amending § 423.578 as suggested is outside the scope of revisions contained in this rule. Moreover, we believe the Part D appeals process established in Subpart M of Part 423 largely establishes a uniform coverage determination and appeals process including, but not limited to, required adjudication timeframes for the plans and the IRE, requirements related to the timing, form and content of notices, and rules related to the exceptions process.

Comment: We received comments urging CMS to amend the Part D regulations at § 423.590 to allow the enrollee to request IRE review if a plan fails to meet its adjudication timeframe and also fails to forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

Response: We appreciate the commenters' suggestion, however, amending § 423.590 as suggested is outside the scope of this rule. However, we will consider this suggestion for future rulemaking regarding the Part D appeals process.

Comment: We received a comment that expressed concern that, except for retrospective self-reporting by plans, there is no mechanism for the IRE or CMS to monitor whether plans are meeting their decisional deadlines. Beneficiaries not represented by persistent advocates who know the rules may face unacceptable delays. The commenter urged CMS to develop a mechanism whereby coverage determinations are tracked in real time so that beneficiary rights to timely action can be protected.

Response: We concur that plans' timely decision-making for coverage determinations and redeterminations are two important areas for monitoring; however, there may be operational barriers to monitoring these transactions in real-time. As the commenter stated, the Part D Plan Reporting Requirements Exceptions and Appeals reporting sections require plans to report data related to these processes, including failure to meet decision timeframes. We consider these plan-reported data, along with other information sources, important first indicators for Plans failing to meet these requirements.

Comment: A commenter stated that to aid in monitoring, as well as to assist beneficiaries who are not receiving promised services, CMS should institute an effective complaint process for beneficiaries. The commenter also stated that complaints should be investigated and also used in CMS monitoring activities and reports. When available, beneficiaries should be allowed to have denied grievances appealed to state independent medical review processes.

Response: The commenter's suggestion to require that beneficiaries should be allowed to have denied grievances appealed to state independent medical review processes is beyond the scope of this rule. However, we note that we implemented a centralized Complaint Tracking Module (CTM) in 2006 in order to help capture and resolve complaints received from Medicare beneficiaries experiencing difficulties with their Part D benefit. The CTM allows CMS and Plan sponsors to work together to investigate and resolve complaints in a timely manner. Beneficiaries can also file a grievance directly with the plan sponsor. Plan sponsors, in turn, report grievance data to CMS as specified in the Part D Plan Reporting Requirements for CMS' monitoring and oversight.

In addition to contract monitoring and oversight, complaint data are incorporated in Part D plan ratings. Part D plan ratings include various operational and quality areas in which Plans' performances are rated for display on the Medicare Options Compare and the Medicare Prescription Drug Plan Finder at *http://www.medicare.gov.* These ratings empower beneficiaries to compare Medicare health and prescription drug plans in their geographic area.

7. Civil Money Penalties (§ § 422.760 and 423.760)

We proposed to clarify our regulations relating to CMPs in both § 422.760 and § 423.760 by adding paragraph (b)(2) of the respective sections to state that CMS may impose a penalty of not more than $25,000 for each enrollee covered under the organization's contract that is adversely affected or substantially likely to be adversely affected by the organization's deficiency (or deficiencies). When determining the amount of a penalty per determination, up to the $25,000 maximum, we will continue to take into account factors such as the severity of the infraction, the evidence supporting the infraction, the amount of harm caused to the Medicare beneficiary, and the organization's past conduct.

Our proposed change is aimed at protecting enrollees by clarifying that penalties can be substantial for noncompliance. CMS has the discretion to establish guidance on how CMPs will be calculated and the monetary limits of CMPs for violations.

Assessing CMPs at the level of each enrollee covered under the organization's contract—which enables the Agency to continue to levy CMPs at the ''per contract'' level—will help provide the necessary flexibility for CMS to better match CMP amounts to the specific violation underlying a CMP. However, we acknowledge that there may be alternative or additional approaches to the ''per beneficiary'' and ''per contract'' schema described here that would likewise meet the Agency's goals of providing meaningful penalties that deter violations of Medicare program requirements and protect Medicare beneficiaries. For example, tying CMP amounts to the number of days that violations existed may likewise be an effective approach for assessing meaningful CMPs. In our proposed rule, we therefore sought comments on our proposed clarification as well as whether any other approaches would more effectively deter MA organizations and Part D sponsors from engaging in conduct which violates CMS requirements. We also requested comments on the appropriate monetary range for CMPs imposed on MA organizations and Part D sponsors and whether some upper limit should exist on the total amount of a penalty imposed on an organization when a deficiency has adversely impacted a large number of enrollees covered by an MA organization or Part D sponsor. As discussed below, we received approximately 30 comments on CMP-related issues, but we did not receive

substantive suggestions on approaches or monetary ranges for CMPs.

Comment: One commenter supported CMS' clarification to the term ''determination'' when referring to CMPs. The commenter suggested that no upper limit for CMPs be specified. The commenter suggested that CMS have the flexibility to impose an appropriate monetary penalty without the constraint of an arbitrary cap.

Response: We agree that we need the flexibility to impose meaningful CMPs on plans. We have decided not to impose an upper limit for CMPs at this time.

Comment: One commenter stated that moving from calculating a penalty based on an organizational level to a membership level imposes significant increased business risk to plans that contract with CMS. This commenter also stated that this would allow CMPs to be levied not on the violation itself but on the membership.

Response: The proposed regulation does not change the basis for the CMP. The basis of the violation remains the same. The proposed regulation clarifies how the penalty is assessed. That is, we proposed to clarify that under some circumstances, determinations can be based on the number of adversely affected, or potentially adversely affected, enrollees. In such instances, a CMP would only be assessed on the number of adversely affected, or potentially adversely affected, enrollees, not the total number of enrollees in the plan. We are not making any changes based on this comment.

Comment: A few commenters stated that CMS' proposal is not appropriate for violations that are unintentional and/or do no harm to beneficiaries. The commenters stated that this level of CMPs would only be appropriate in rare circumstances when an organization intentionally and deliberately violated program rules or where the violations are egregious, knowingly, or willfully undertaken.

Response: The commenters were concerned about CMPs levied for an organization's unintentional acts and/or acts that do not involve harm to members. The current regulations clearly state that to impose a CMP on an organization, we must make a determination that a violation adversely affects, or potentially adversely affects, one or more of the organization's enrollees, regardless of whether such harm was intentional or not. The proposed regulations do not change this current requirement. As for violations that are found to be ''egregious, knowingly, or willfully undertaken,'' the statute and current regulations permit CMS to take into account such types of violations as one of, but not the sole governing factor when determining a civil money penalty. We are not making any changes to the proposed regulation based on these comments.

Comment: A few comments concerning the phrase ''substantial likelihood'' were received. One commenter stated that they were not sure what criteria or standards we would apply to determine when there is a substantial likelihood of a violation adversely affecting members. Another commenter requested guidance on what is meant by ''substantial likelihood of being adversely affected by a deficiency.''

Response: The language of ''substantial likelihood of adversely affecting'' comes directly from section 1857(g) of the Act. We must have the discretion to interpret this language when evaluating whether to impose a CMP, since each case may present a different set of circumstances and any determination of likely adverse effects on enrollees could depend on the specific facts of the case. We are not making changes based on these comments. We will consider whether future guidance should incorporate criteria to help determine when a deficiency has a substantial likelihood of adversely affecting an organization's members.

Comment: A commenter requested clarification to determine what the threshold for willful and purposeful neglect was.

Response: The term ''willful and purposeful neglect'' was not used in the proposed regulation with respect to civil money penalties. CMS is unsure what the commenter is referring to.

Comment: A commenter stated that the regulation should list what types of recourse the MA organization or Part D sponsor has prior to CMS imposing a civil money penalty.

Response: Civil money penalties are imposed for various violations. Some violations may be one time violations that have significant harmful effects on enrollees. In such cases, CMS may not consider it appropriate to offer recourse (such as a corrective action plan), given that the violation has already taken place and has significantly harmed enrollees, even if it is not likely to reoccur. We are not required to provide for recourse, such as a CAP prior to the issuance of a CMP. However, the regulations do provide for appeal rights for those organizations who believe we have inappropriately imposed a CMP. Therefore, we are not making any changes based on this comment.

Comment: One commenter urged CMS to continue to take into account an organization's past conduct when assessing the need for a CMP.

Response: We agree with the commenter and will continue to take into account an organization's past conduct when assessing the need for, or the amount of, a CMP.

Comment: One commenter stated that the language allows for assessment at both the contract level and the enrollee level.

Response: We developed the language to provide for discretion to impose a CMP at either the contract level or the enrollee level. This flexibility is necessary to ensure violations and penalties are appropriately matched.

Comment: A commenter was uncertain whether the deficiency's adverse effects are related only to those who are enrolled in a plan or also to individuals who have expressed interest in a plan.

Response: The statute states that any adverse or substantial likelihood of adverse effect be on ''an individual covered under the organization.'' We believe that this language requires that the individual be an enrollee of the plan and not just one who has expressed interest in the plan.

Comment: A few commenters were concerned that the proposed changes could result in massive penalties for relatively minor infractions if those infractions affect a large number of enrollees.

Response: To impose a CMP, current regulations require us to make a determination that a violation adversely affects or has the likelihood of adversely affecting an enrollee. In addition, we may impose a CMP only for deficiencies that could lead to termination under § 422.510(a) or § 423.509(a) (but not under § 422.510(a)(4) or § 423.509(a)(4)). Sections 422.510(a) and 423.509(a) do not contemplate a termination for a relatively minor infraction.

Comment: One commenter supports CMS' stated intention to consider the severity of the infraction and other extenuating circumstances in determining the amount of the penalty. The commenter also stated that CMS should recognize that PDP revenue is significantly lower than MA revenue and penalties should be tempered accordingly.

Response: Our regulations currently permit us to consider additional factors, as appropriate, in determining the amount of a CMP. These factors include the nature of the conduct, the degree of culpability of the organization, the harm which resulted or could have resulted, the financial condition of the

organization, the history of prior offenses, and other matters as justice requires. Although we may consider the financial condition of an organization, the relative revenue of a PDP sponsor compared to an MA organization would have no bearing on CMS' decision on a CMP.

Comment: One commenter stated that penalties could be excessive for large plans. The commenter stated that CMS should reduce the amount proposed, revise the formula, or not have assessments on a per member per violation basis. The commenter stated that if CMS chooses to retain the per member per violation basis, then CMPs should only be assessed for the most egregious, deliberate, and willful violations of the law or regulations.

Response: The formula to calculate a CMP based on $25,000 per violation is taken from section 1857(g) of the Act. Therefore, a statutory change would be required to change that dollar amount or formula. If an MA organization or Part D sponsor believes a CMP is excessive, the organization or sponsor has the right to request an appeal of the amount before an ALJ prior to paying a CMP.

Comment: A commenter recommended modifying § 422.760(b)(2) and § 423.760(b)(2) to be consistent with § 422.760(b)(1) and § 423.760(b)(1), which require that the deficiency adversely affects or has the substantial likelihood of adversely affecting one or more enrollees.

Response: We did not revise nor intend to revise § 422.760(b)(2) and 423.760(b)(2). We appreciate the comment and will consider it for future proposed regulations. We believe the general public should be provided an opportunity to comment on a change such as this.

Comment: A few commenters stated that there should be a maximum penalty amount designated or that the proposal should indicate that CMS has the discretion to issue guidance establishing a range or a cap for the calculations under this provision.

Response: At this time, we have not provided for maximum penalties. However, we have added language into the preamble stating that we may, if determined necessary, issue additional guidance for the range of penalties or caps associated with violations.

Comment: A number of commenters supported CMS' proposal, allowing CMS to calculate CMPs based upon each enrollee ''directly adversely affected (or with a substantial likelihood of being adversely affected).'' These commenters opposed upper limits on penalties and stated that the penalty should reflect the noncompliance of the organization. These commenters stated that the penalty should be more than the cost of compliance.

Response: We appreciate your comments. CMS also believes that the penalty should better reflect the infractions and the number of beneficiaries affected by the infraction.

Comment: A number of commenters stated that CMS should develop regulatory mechanisms to require Medicare Advantage and Part D plans to make financial compensation to beneficiaries who are harmed.

Response: Currently, there is no statutory authority to permit us to require Part C and Part D plans to compensate beneficiaries who are harmed by MA organizations and Part D sponsors. Such a requirement to compensate beneficiaries could violate section 1854(d)(1) of the Act, which prohibits cash payments to beneficiaries. In addition, there is no statutory provision that permits premiums to be waived. Thus, we believe such a change would require statutory amendment.

Comment: A number of commenters suggested that CMS repeal § 423.760(b)(2), which limits the penalty for uncorrected deficiencies to no more than $10,000 per week. The commenters stated that this penalty is remarkably low for uncorrected deficiencies and that the amount must be large enough to encourage organizations to correct deficiencies.

Response: We appreciate the comment and will consider it for future proposed regulations. CMS believes the general public should be provided an opportunity to comment on a change such as this.

Comment: A number of commenters stated that CMS should repeal § 423.760(b)(3), which limits the total penalty to $100,000. The commenters also stated that regulations at § 423.758 authorize a penalty of $250 per enrollee, or $100,000, whichever is greater. The commenters also stated that there is no reason to create an upper limit for plans with large enrollees.

Response: We believe that the commenters misunderstood the regulations. The regulations at § 423.760(b)(3) provide for penalties of $250 per enrollee, or $100,000, whichever is greater. Therefore, no upper limit exists for penalties.

Comment: Several commenters requested that CMS amend § 423.762 to set limitations on the settlement of CMPs. The commenters suggested that no more than 35 percent of the penalty may be deducted in any settlement.

Response: We appreciate the comment and will consider it for future proposed regulations. We believe the general public should be provided an opportunity to comment on a change such as this.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Listed below is the discussion of the information collection requirements contained in this rule. Previously, we solicited public comments on the requirements in the proposed rule that published on May 16, 2008 (73 FR 28556). However, we are interested in receiving additional public comments pertaining to these requirements; therefore, we are re-soliciting public comments on the following:

A. ICRs Regarding Eligibility To Elect an MA Plan for Special Needs Individuals (§ 422.52)

Section 422.52(g) requires a SNP to establish a process to verify the Medicaid eligibility and special needs status of an individual prior to enrolling the individual in a form and manner specified by CMS. The associated cost with this provision is a time one time event in calendar year 2010, as the provision expires on December 31, 2010. This may require collaborative meetings between MA plan staff and State Medicaid staff to establish the process. This process could include calling the Medicaid eligibility verification system (EVS) and reviewing appropriate used to determine an individual's special need.

The burden associated with this requirement is the time and effort put forth by the SNP to establish a process and to verify eligibility. We estimate it would take one SNP approximately (4680 minutes/78 hours) to comply with

this requirement. The total number of respondents affected would be 324 organizations offering SNPs; therefore, the total annual burden is estimated to be 25,272 hours.

B. ICRs Regarding the Election Process (§ 422.60)

Section 422.60(g)(2) requires the organization that receives the enrollment to provide notification that describes the costs and benefits of the plan and the process for assessing care under the plan. The notification must be provided to all potential enrollees prior to the enrollment effective date (or as soon as possible after the effective date if prior notice is not practical), in a form and manner determined by CMS. Providing notification may include mailing a brochure or fact sheet with the aforementioned information and contacting potential enrollees to respond to any questions regarding the mailer.

The burden associated with this requirement is the time and effort put forth by the organization to provide notification that meets the requirements specified by CMS. We estimate it would take one MA organization (30 minutes/.5 hours) to comply with this requirement. The total number of organizations affected is 5; therefore, total annual burden hours associated with the requirement is 2.5 hours.

C. ICR Regarding Benefits Under an MA MSA Plan (§ 422.103)

Section 422.103(e) requires all MA organizations offering MSA plans to provide enrollees with available information on the cost and quality of services in their service area, and to submit to CMS for approval a proposed approach to providing such information.

The burden associated with this requirement is the time and effort put forth by the MA organization offering MSA plans to provide information to enrollees and to submit the proposed approach to providing such information to CMS. About 3,300 Medicare beneficiaries are enrolled in Medicare MSA plans in 2008.

We expect that the burden upon health plans to develop cost and quality data for use by MSA enrollees would depend upon what data is available in their area. As stated in the preamble, we expect that organizations that already have mechanisms in place in connection with their commercial lines of business for providing their beneficiaries with cost or quality information could offer similar services to Medicare beneficiaries.

We estimate the burden associated with this requirement in terms of time and effort necessary for the two organizations offering MSA plans to develop the information and to submit this information to CMS as a start-up cost of 100 hours per organization to develop this information, with half of that cost occurring in subsequent years for organizations to maintain and update this information. In addition, expected additional entry by organizations in future years would add start-up costs in the initial year that plans enter. The total burden would be 200 hours in year 1 and 100 hours in subsequent years. While this burden is subject to the PRA, it is currently approved under OMB control number 0938–0753 with an expiration date of November 30, 2011.

D. ICRs Regarding Contract Provisions (§ 422.504)

Section 422.504(g)(1)(iii) establishes requirements that MA organizations specify in contracts with providers that enrollees are protected from incurring liability for payment of fees that are the legal obligations of the State. CMS proposed in the May 16, 2008, NPRM (73 FR 28556–28604) that all MA organizations with enrollees eligible for both Medicare and Medicaid, specify in contracts with providers that these enrollees will not be held liable for Medicare Part A and B cost sharing when the State is responsible for paying such amounts.

MIPPA established a limitation on cost sharing for full-benefit dual eligible individuals and qualified Medicare beneficiaries in dual eligible special needs plans. The MIPPA required that organizations offering these plans not impose cost-sharing that exceeds the amount of cost-sharing that would be permitted with respect to the individual under Title XIX if the individual were not enrolled in such a plan. The interim final rule with comment period that was published on September 18, 2008, (73 FR 54225–54254) implemented the MIPPA provisions. The discussion of the burden hours associated with § 422.504 in the interim final rule with comment period should have explained that the requirement was specific to MA organizations with special needs plans. The burden was imposed on the 269 MA organizations offering a total of 436 full-benefit and qualified Medicare beneficiary plans. The total burden associated with § 422.504 in the interim final rule with comment period should have been 90,688 hours for 2010. This final rule with comment period also imposes information collection requirements contained in § 422.504. The requirements associated with this rule affect the remaining 363 MA organizations with a total of 2,964 (non-SNP) plans that were not addressed in the interim final rule with comment period. The burden affecting the 363 MA organizations is 616,512 hours for 2010.

The burden table at the end of this section reflects the burden imposed by § 422.504 on non-SNP plans. While the burden is subject to the PRA, it is currently approved under OMB control number 0938–0753 with an expiration date of November 30, 2011. Moreover, the cost associated with this provision is a one time event in calendar year 2010, as the provision expires on December 31, 2010.

E. ICRs Regarding Right to a Reconsideration (§ 422.578)

Section 422.578 states that any party to an organization determination may request that the determination be reconsidered under the procedures described in 422.582.

While there is burden associated with this requirement, burden associated with reconsiderations is exempt as stated under the Paperwork Reduction Act of 1995. In particular, 5 CFR 1320.4 excludes collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, and/or appeals. Specifically, these actions are taken after the initial determination or a denial of payment.

F. ICRs Regarding the Enrollment Process (§ 423.32)

Section 423.32(g)(2) requires an organization that receives the enrollment to provide notification that describes the costs and benefits of the new plan and the process for assessing care under the plan and the beneficiary's ability to decline the enrollment or choose another plan. Such notification must be provided to all potential enrollees prior to the enrollment effective date.

The burden associated with this requirement is the time and effort put forth by the organization to provide such notification. We estimate it would take one organization 207 hours to comply with this requirement. We estimate 42 organizations would be affected annually by this requirement; therefore, the total annual burden associated with this requirement is 8,694 hours.

G. ICRs Regarding the Late Enrollment Penalty (§ 423.46)

Section 423.46(b) states that Part D sponsors must obtain information on prior creditable coverage from all enrolled or enrolling beneficiaries and

report this information to CMS in a form and manner determined by CMS.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor to obtain the required information. To comply with this requirement, Part D sponsors would expend 15 minutes per new Part D enrollee. We estimate that there will be approximately 500,000 new Part D enrollees. Therefore the total annual burden associated with this requirement will be 125,000 hours/7,500,000 minutes for all enrollees.

Section 423.46(d) requires the Part D plan sponsor to retain all information collected concerning a credible coverage period determination in accordance with the enrollment records retention requirements described in subpart K, § 423.505(e)(1)(iii).

The burden associated with this requirement is the time and effort put forth by the Part D plan sponsor to retain the required information. To comply with this requirement, Part D sponsors would expend 5 minutes per new Part D enrollee. There are approximately 500,000 enrollees. We estimate the total annual burden associated with this requirement will be 41,667 hours/2,500,000 minutes for all new Part D enrollees.

H. ICRs Regarding Contract Provisions (§ 423.505)

Section 423.505(k)(5) states that the Chief Executive Officer, Chief Financial Officer, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify that the information provided is accurate, complete, and truthful and fully conforms to the requirements in §§ 423.336 and 423.343 and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement. While there is burden associated with this requirement, we feel the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(h)(1).

I. ICRs Regarding the Right to a Redetermination (§ 423.580)

Section 423.580 provides information on the ways for an enrollee to seek a redetermination. We made minor changes to this section that would permit a non-physician prescriber to request a redetermination on behalf of a beneficiary. This change would not have any information collection effects, but in any case the burden associated with a redetermination is exempt from the PRA as stipulated under 5 CFR 1320.4.

J. Burden Associated With the ICRs

We received no public comments on the burden estimates associated with the information collections described above. However, we have eliminated the estimates associated with provisions that are no longer included in this final rule (such as marketing provisions, effective October 1, 2008, that paralleled provisions in MIPPA and were set forth in our September 18, 2008 final rule (73 FR 54208)) and we have revised our estimates of the number of respondents who will be affected by some of the provisions in this rule, as detailed in the table below. We estimate that the aggregate annual burden associated with the collection of information section for this rule totals 200,835.5 hours for FY 2010 and 175,463.5 hours for each of the years in FY 2011 through 2018:

OMB No.	Requirements	Number of respondents	Burden hours	Total annual burden hours	Total annual cost**
0938–0753	422.52(g)	324	78	25,272	$549,161
0938–0753	422.60(g)(2)	5	.5	2.5	549,161
0938–0753	422.103(e)	2	100	200	10,996
0938–0753	422.504(g)(1)	363	208	616,512*	33,895,829*
None/Exempt	422.578	N/A	N/A	N/A	N/A
0938–0964	423.32(g)(2)	42	207	8,694	188,920
0938–0964	423.46(b)	500,000	15 min	125,000	2,716,250
0938–0964	423.46(d)	500,000	5 min	41,667	905,423
None/Exempt	423.505(k)(5)	N/A	N/A	N/A	N/A
None/Exempt	423.580	N/A	N/A	N/A	N/A

*The burden associated with requirement 422.504(g)(1) is already accounted for in the regulation CMS–4138–IFC.
**We provide more detail on how we estimate the cost burden associated with these provisions in the regulatory impact analysis section.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this rule; or

2. Mail copies to the address specified in the **ADDRESSES** section of this rule and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, *Attn:* CMS Desk Officer, *CMS–4131–FC @omb.eop.gov.* Fax (202) 395–6974.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. Section II.A.1 of this final rule with comment period addresses section 164 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275) which became law after publication of the May 16, 2008 proposed rule. In this section of the final rule with comment period, we specify that we are adding definitions related to special needs plans to conform our regulations to section 164 of the MIPPA. Because these changes are in accordance with the statutory amendments, we find that it would be unnecessary and contrary to public interest to seek prior public

comment on these provisions. Therefore, we find good cause to waive the notice of proposed rulemaking and to issue these provisions on an interim basis. We are providing a 60-day public comment period.

VI. Regulatory Impact Analysis

A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended) 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). Though we are not finalizing the changes originally proposed for the RDS program in the May 16, 2008 rule, we estimate that this rule will have economically significant effects: The provisions in this final rule, associated with our revision to the beneficiary cost sharing and reinsurance subsidy payments, are estimated to cost $30 million in FY 2010 and a total cost of $530 million in FYs 2010 through 2018. Accordingly, we have prepared an RIA.

We provide a separate estimate of the costs associated with the other provisions not related to the Part D definitions in this final rule. This estimate includes costs regarding: (1) Eligibility to elect an MA plan for special needs individuals (§ 422.52); (2) the election process (§ 422.60); (3) benefits under an MA MSA Plan (§ 422.103); (4) contract provisions (§ 422.504); (5) enrollment process (§ 423.32); and (6) the late enrollment penalty (§ 423.46). In estimating the cost of all the other provisions not related to the Part D definitions discussed in this final rule, we utilize, as appropriate, the figures of $14.68 (based on the United States Department of Labor (DOL) statistics for the hourly wages of word processors and typists) and $37.15 (based on DOL statistics for a management analyst)[4] plus the added OMB figures of 12 percent for overhead and 36 percent for benefits, respectively, to represent average costs to plans, sponsors and downstream entities. (Note that the wages cited for the provisions below include the hourly wage + an additional 48 percent to reflect overhead, benefit costs for total wages of $21.73 and $54.98, respectively). Using these figures the estimated total cost will be approximately $4,381,800 in fiscal year 2010 and $3,821,643 per year in fiscal years 2011 through 2018. This cost will be spread more or less evenly across participating plans, and hence will impose negligible burden on any plan in relation to existing administrative costs.

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 generally are above the revenue threshold required for analysis under the RFA. While a very small rural plan could fall below the threshold, we do not believe that there are more than a handful of such plans.

A fraction of MA organizations and sponsors are considered small businesses because of their non-profit status. For an analysis to be necessary, however, 3 to 5 percent of their revenue would have to be affected by the provisions. We do not believe that any of these provisions rise to that threshold. Again, most of the provisions we are implementing are clarifications of existing policy or require minimal costs. Because MA organizations and Part D sponsors are the only entities that will be affected by the provisions and because of the minimal associated costs, we are not preparing an analysis for the RFA because the Secretary has determined, and we certify, that this rule will not have a significant economic 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 the Secretary has determined, and we certify, 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 approximately $130 million. This rule does not contain mandates that will impose spending costs on State, local, or tribal governments, in the aggregate, or on the private sector, of $130 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule will not have a substantial direct effect on State or local governments, preempt States, or otherwise have a Federalism implication.

With respect to economic benefits, we have no reliable basis for estimating the effects of these changes. Many of the changes clarify or codify existing policies though such clarification could contribute to greater plan efficiency and compliance with program regulations. Accordingly, we estimate that while there could be economic benefits associated with this final rule with comment period, they are difficult to gauge at this time.

Because there are costs to plans and sponsors associated with several provisions of this rule, however, we indicate general areas affected and specify the costs associated with these. For specific burden associated with the requirements and the bases for our

[4] The hourly rates for the burden requirement were developed using the Department of Labor, Bureau of Labor Statistics for May 2006 (National Occupational Employment and Wage Estimates).

estimates, see section III of this final rule with comment period.

B. Specific Impacts

1. Special Needs Plans

Several of the provisions set forth in this final rule with comment period concern special needs plans, in particular the requirement that special needs plans enroll only the appropriate special needs individuals and that they verify that individuals are eligible for the plan into which they wish to enroll. We estimate the total cost of the provision requiring verification of Medicaid eligibility or SNP status prior to beneficiary enrollment as $549,161 ($21.73 × 25,272 hours = $549,161). This cost is only in fiscal year 2010. (As noted above, other proposed provisions related to SNPs, such as the State coordination requirement, are not part of this final rule with comment period and thus have no projected impact for purposes of this rule.)

2. Medicare Medical Savings Account Plans (MSAs)

Costs associated with this provision are for reporting cost and quality information about the plans to enrollees. We estimate the total cost of these provisions as $10,996 ($54.98 × 200 hours) for the first year a plan provides such information, and half that cost in subsequent years to maintain and update the information.

3. Enrollment

We are setting forth requirements concerning Part D sponsor notification of full benefit dual eligible beneficiaries about enrollment options in addition to automatic enrollment. This provision requires that Part D sponsors obtain from Part D plan enrollees or those considering enrolling information concerning prior creditable coverage, and retain information collected concerning creditable coverage period determinations. We estimate the total cost of these provisions as $3,810,593. The annual costs for specific provisions are as follows:

- Notifying dual-eligible beneficiaries of enrollment options in addition to automatic enrollment ($21.73 × 8,694 hours = $188,920).
- Obtaining prior creditable coverage information ($21.73 × 125,000 hours = $2,716,250).
- Retaining prior creditable coverage information ($21.73 × 41,667 hours = $905,423).

4. Marketing

This rule no longer contains any marketing provisions and thus the projected impact is no longer applicable for purposes of this final rule with comment period.

5. Part D Definitions

With respect to the revisions to the Part D definitions, we do not expect a significant impact on small businesses, such as small pharmacies, as a result of changes to the definitions under Part D of negotiated prices, gross covered drug costs, and allowable risk corridor costs in this rule. These changes primarily impact which drug costs are reported to us and how plans calculate beneficiary cost sharing. Moreover, we assume they will require minimal, if any, changes in health plan, PBM and pharmacy operational systems. Even with the changes to the way in which beneficiary cost sharing is calculated resulting from these definition changes, health plans will still be required to ensure that pharmacies receive their contracted rate. We believe that health plans will account for any additional costs associated with the change in the way beneficiary costs are calculated in their Part D bids. As a result, we expect that these changes will increase Part D bids and Federal Government payments such that the total impact estimate for FYs 2010 through 2018 is $530 million. However, we do not expect these changes to significantly increase health plan costs.

With respect to the changes impacting which drug costs are reported to CMS and how Part D plans calculate beneficiary cost-sharing, we believe that the impact on pharmacies will be minimal, as the total compensation received by pharmacies should remain unaffected. However, Part D plans will need to include administrative costs paid to PBMs, which were previously included as drug costs, as administrative cost in their bids. They will also need to factor reductions in beneficiary cost sharing and reinsurance subsidy payments into their bids. The changes in beneficiary cost sharing and reinsurance subsidy payments are expected to increase Part D bids due to increased plan liability and therefore will increase the direct subsidy payments made by the Federal government to health plans. The changes regarding the reporting of drug costs are also expected to reduce the reinsurance payments and low-income cost sharing subsidy payments made by the Federal government. Specifically, the reinsurance subsidy, which is calculated as 80 percent of allowable reinsurance costs, is expected to decrease due to lower negotiated prices and therefore, lower allowable reinsurance costs. A reduction in the low-income cost sharing subsidy payments made by the Federal government is expected due to lower beneficiary cost sharing. We estimate the net cost of these changes to be $30 million for FY 2010 and a total cost of $530 million for FYs 2010 through 2018. These estimated costs reflect an increase in the direct subsidy payments made by the Federal Government and are net of reductions in Federal reinsurance payments and low-income cost sharing subsidy payments. These estimated costs are based on the assumption that overall program costs will remain the same. They do not include any potential reductions in plan administrative costs due to the ability of plan sponsors to negotiate lower administrative fees with PBMs as a result of increased transparency in drug prices.

In addition, we expect that the clarifications may require a small number of Part D sponsors to renegotiate their contracts with their PBMs to account for system changes to reflect the appropriate beneficiary cost sharing. We believe that most PBMs will be unaffected by the changes in reporting drug costs and the calculation of beneficiary cost sharing. Thus, we expect that the financial impact of the rule on PBMs will be minimal. However, certain PBMs that typically use the lock-in pricing approach could experience a financial impact from the drug cost reporting changes.

The proposed rule would have resulted in a decrease of $510 million in payments under the Retiree Drug Subsidy Program over 10 years, due to the requirement in the proposed rule that RDS sponsors report, and receive subsidy based on, pass-through rather than lock-in pricing. Because that requirement is not being adopted in this final rule, this decrease does not apply.

With respect to the changes impacting how Part D plans calculate beneficiary cost sharing, we believe that these changes will increase beneficiary premiums for plans that utilize the lock-in pricing approach but this increase will be more than offset by a decrease in beneficiary cost sharing under these plans. As a result, we expect that certain beneficiaries enrolled in these plans with very low drug utilization will see some increase in the total costs they pay for their prescription drug coverage. However, we expect that most beneficiaries, particularly those with high drug utilization, will see a decrease in the total costs they pay for their prescription drug coverage as a result of reduced beneficiary cost sharing.

C. Alternatives Considered

We considered whether or not the cost to codify these policies outweighed

the need to do so. With one possible exception, we determined that the cost to plans and sponsors to clarify and codify our policies would be minimal and outweighed the minimal costs to implement these.

With respect to the provisions concerning Medicare medical savings account plans, we considered the costs to plans of providing cost and quality information. We believe that such information is readily available to most MSA plans and that it will not be an undue burden on plans to provide such information. As discussed in detail in section II.A.2 of this final rule with comment period, commenters did not dispute this assessment and we have not made any changes to our impact assessment.

As discussed previously, many of the provisions clarify or codify current policy which we discuss in section II. of the preamble to this final rule with comment period. As such, we considered whether or not the cost to codify these policies outweighed the need to do so. With one possible exception, we determined that the cost to plans and sponsors to clarify and codify our policies are minimal and outweigh the minimal costs to implement these provisions.

With respect to the changes to the drug cost-related definitions in the Part D program, we have discussed the two alternatives at length in the preamble section of both the proposed and final rules. The two alternatives are—(1) The current approach of allowing both pass-through and lock-in prices, and (2) the approach of permitting only pass-through prices as the basis for Part D costs. As we discuss in section II.B, we believe there may be significant negative impacts on beneficiaries, market competition, pharmacies, and government expenditures associated with maintaining the current dual pricing approach and, therefore, we will allow only the single ''pass-through'' pricing approach as originally intended in the final rule establishing the Part D prescription drug benefit.

D. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in the Table 1 below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule with comment period. This table provides our best estimate of the increase in costs as a result of the changes. The costs represent transfers by the Federal Government to Part D plans. Also, the cost for all other provisions not related to the Part D definitions is included in Table 1.

TABLE 1—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers (in millions)
Increase in Federal Payments, FYs 2010—2018	
Annualized Monetized Transfers Using the 7% Discount Rate	$55.8.
Annualized Monetized Transfers Using the 3% Discount Rate	57.5.
From Whom To Whom?	Federal Government to Part D Plans.
Category	**Costs ($ Millions)**
Cost for All Other Provisions Not Related to the Part D Definitions for FY 2010–2018	
Annualized Monetized Costs Using the 7% Discount Rate	$3.9.
Annualized Monetized Costs Using the 3% Discount Rate	3.9.
Who is Affected?	MAOs/Part D Sponsors.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMOs), Medicare, Penalties, Privacy, Reporting and recordkeeping.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 1. 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

■ 2. Section 422.2 is amended by—

■ A. Adding the definitions for ''Institutionalized-equivalent'' and ''Severe or disabling chronic condition'' in alphabetical order.

■ B. Revising the definition of ''Specialized MA Plans for Special Needs Individuals''.

The additions and revision read as follows:

§ 422.2 Definitions.

* * * * *

Institutionalized-equivalent means for the purpose of defining a special needs individual, an MA eligible individual who is living in the community but requires an institutional level of care. The determination that the individual requires an institutional level of care (LOC) must be made by—

(1) The use of a State assessment tool from the State in which the individual resides; and

(2) An assessment conducted by an impartial entity and having the requisite knowledge and experience to accurately identify whether the beneficiary meets the institutional LOC criteria. In States and territories that do not have an existing institutional level of care assessment tool, the individual must be assessed using the same methodology that State uses to determine institutional level of care for Medicaid nursing home eligibility.

* * * * *

Severe or disabling chronic condition means for the purpose of defining a special needs individual, an MA eligible individual who has one or more co-morbid and medically complex chronic conditions that are substantially disabling or life-threatening, has a high risk of hospitalization or other significant adverse health outcomes, and requires specialized delivery systems across domains of care.

* * * * *

Specialized MA Plans for Special Needs Individuals means an MA coordinated care plan that exclusively enrolls special needs individuals as set forth in § 422.4(a)(1)(iv) and that provides Part D benefits under Part 423 of this chapter to all enrollees; and which has been designated by CMS as meeting the requirements of an MA SNP as determined on a case-by-case basis using criteria that include the appropriateness of the target population, the existence of clinical programs or special expertise to serve the target population, and whether the proposal discriminates against sicker members of the target population.

■ 3. Amend § 422.4 by revising paragraph (a)(1)(iv) to read as follows:

§ 422.4 Types of MA plans.

(a) * * *

(1) * * *

(iv) A specialized MA plan for special needs individuals (SNP) includes any type of coordinated care plan that meets CMS's SNP requirements and exclusively enrolls special needs individuals as defined in § 422.2 of this subpart.

* * * * *

Subpart B—Eligibility, Election, and Enrollment

■ 4. Amend § 422.52 by revising paragraph (f) to read as follows:

§ 422.52 Eligibility to elect an MA plan for special needs individuals.

* * * * *

(f) *Establishing eligibility for enrollment.* A SNP must employ a process approved by CMS to verify the eligibility of each individual enrolling in the SNP.

■ 5. Amend § 422.60 by adding paragraph (g) to read as follows:

§ 422.60 Election process.

* * * * *

(g) *Passive enrollment by CMS.* In situations involving either immediate terminations as provided in § 422.510(a)(5) or other situations in which CMS determines that remaining enrolled in a plan poses potential harm to the members, CMS may implement passive enrollment procedures.

(1) *Passive enrollment procedures.* Individuals will be considered to have elected the plan selected by CMS unless they—

(i) Decline the plan selected by CMS, in a form and manner determined by CMS, or

(ii) Request enrollment in another plan.

(2) *Beneficiary notification.* The organization that receives the enrollment must provide notification that describes the costs and benefits of the plan and the process for accessing care under the plan and clearly explains the beneficiary's ability to decline the enrollment or choose another plan. Such notification must be provided to all potential enrollees prior to the enrollment effective date (or as soon as possible after the effective date if prior notice is not practical), in a form and manner determined by CMS.

(3) *Special election period.* All individuals will be provided with a special election period, as described in § 422.62(b)(4).

■ 6. Section 422.74 is amended by—

■ A. Revising paragraph (d)(1) introductory text.

■ B. Adding a new paragraph (d)(1)(iv).

The revision and addition read as follows:

§ 422.74 Disenrollment by the MA organization.

* * * * *

(d) * * *

(1) Except as specified in paragraph (d)(1)(iv) of this section, an MA organization may disenroll an individual from the MA plan for failure to pay basic and supplementary premiums under the following circumstances:

* * * * *

(iv) An MA organization may not disenroll an individual who had monthly premiums withheld per § 422.262(f)(1) and (g) of this part, or who is in premium withhold status, as defined by CMS.

* * * * *

Subpart C—Benefits and Beneficiary Protections

■ 7. Amend § 422.101 by adding paragraph (f)(2) to read as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(f) * * *

* * *

(2) MA organizations offering SNPs must also develop and implement the following model of care components to assure an effective management structure:

(i) Target one of the three SNP populations defined in § 422.2 of this part.

(ii) Have appropriate staff (employed, contracted, or non-contracted) trained on the SNP plan model of care to coordinate and/or deliver all services and benefits.

(iii) Coordinate the delivery of care across healthcare settings, providers, and services to assure continuity of care.

(iv) Coordinate the delivery of specialized benefits and services that meet the needs of the most vulnerable beneficiaries among the three target special needs populations as defined in § 422.2 of this part, including frail/disabled beneficiaries and beneficiaries near the end of life.

(v) Coordinate communication among plan personnel, providers, and beneficiaries.

■ 8. Amend § 422.103 by adding new paragraph (e) to read as follows:

§ 422.103 Benefits under an MA MSA plan.

* * * * *

(e) All MA organizations offering MSA plans must provide enrollees with available information on the cost and quality of services in their service area, and submit to CMS for approval a proposed approach to providing such information.

Subpart F—Submission of Bids, Premiums, and Related Information and Plan Approval

■ 9. Amend § 422.262 by adding new paragraphs (g) and (h) to read as follows:

§ 422.262 Beneficiary premiums.

* * * * *

(g) *Prohibition on improper billing of premiums.* MA organizations shall not bill an enrollee for a premium payment period if the enrollee has had the premium for that period withheld from his or her Social Security, Railroad Retirement Board or Office of Personnel Management check.

(h) *Retroactive collection of premiums.* In circumstances where retroactive collection of premium amounts is necessary and the enrollee is without fault in creating the premium arrearage, the Medicare Advantage organization shall offer the enrollee the option of payment either by lump sum, by equal monthly installment spread out over at least the same period for which the premiums were due, or through other arrangements mutually acceptable to the enrollee and the Medicare Advantage organization. For monthly

installments, for example, if 7 months of premiums are due, the member would have at least 7 months to repay.

Subpart K—Application Procedures and Contracts for Medicare Advantage Organizations

■ 10. Subpart K heading is revised to read as set forth above.

■ 11. Amend § 422.504 by revising paragraph (g)(1) to read as follows:

§ 422.504 Contract provisions.

* * * * *

(g) * * *

(1) Effective January 1, 2010, each MA organization must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability (for example, as a result of an organization's insolvency or other financial difficulties) for payment of any fees that are the legal obligation of the MA organization. To meet this requirement, the MA organization must—

(i) Ensure that all contractual or other written arrangements with providers prohibit the organization's providers from holding any enrollee liable for payment of any such fees;

(ii) Indemnify the enrollee for payment of any fees that are the legal obligation of the MA organization for services furnished by providers that do not contract, or that have not otherwise entered into an agreement with the MA organization, to provide services to the organization's enrollees; and

(iii) For all MA organizations with enrollees eligible for both Medicare and Medicaid, specify in contracts with providers that such enrollees will not be held liable for Medicare Part A and B cost sharing when the State is responsible for paying such amounts, and inform providers of Medicare and Medicaid benefits, and rules for enrollees eligible for Medicare and Medicaid. The MA plans may not impose cost-sharing that exceeds the amount of cost-sharing that would be permitted with respect to the individual under title XIX if the individual were not enrolled in such a plan. The contracts must state that providers will—

(A) Accept the MA plan payment as payment in full, or

(B) Bill the appropriate State source.

* * * * *

■ 12. Amend § 422.506 by revising paragraphs (a)(2)(ii), (a)(2)(iii), (b)(2)(ii), and (b)(2)(iii) to read as follows:

§ 422.506 Non-renewal of contract.

(a) * * *

(2) * * *

(ii) Each Medicare enrollee by mail at least 60 days before the date on which the non-renewal is effective. This notice must include a written description of alternatives available for obtaining Medicare services within the service area, including alternative MA plans, Medigap options, and original Medicare and must receive CMS approval prior to issuance; and,

(iii) The general public, at least 60 days before the date on which the non-renewal is effective, by publishing a notice in one or more newspapers of general circulation in each community or county located in the MA organization's service area.

* * * * *

(b) * * *

(2) * * *

(ii) To each of the MA organization's Medicare enrollees by mail at least 60 days before the date on which the non-renewal is effective; and

(iii) To the general public, at least 60 days before the date on which the non-renewal is effective, by publishing a notice in one or more newspapers of general circulation in each community or county located in the MA organization's service area.

* * * * *

Subpart M—Grievances, Organization Determinations and Appeals

■ 13. Revise § 422.578 to read as follows:

§ 422.578 Right to a reconsideration.

Any party to an organization determination (including one that has been reopened and revised as described in § 422.616) may request that the determination be reconsidered under the procedures described in § 422.582, which address requests for a standard reconsideration. A physician who is providing treatment to an enrollee may, upon providing notice to the enrollee, request a standard reconsideration of a pre-service request for reconsideration on the enrollee's behalf as described in § 422.582. An enrollee or physician (acting on behalf of an enrollee) may request an expedited reconsideration as described in § 422.584.

■ 14. Revise § 422.582 to read as follows:

§ 422.582 Request for a standard reconsideration.

(a) *Method and place for filing a request.* A party to an organization determination or, upon providing notice to the enrollee, a physician who is treating an enrollee and acting on the enrollee's behalf, must ask for a reconsideration of the determination by making a written request to the MA organization that made the organization determination. The MA organization may adopt a policy for accepting oral requests.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, a request for reconsideration must be filed within 60 calendar days from the date of the notice of the organization determination.

(c) *Extending the time for filing a request.* (1) *General rule.* If a party or physician acting on behalf of an enrollee shows good cause, the MA organization may extend the timeframe for filing a request for reconsideration.

(2) *How to request an extension of timeframe.* If the 60-day period in which to file a request for reconsideration has expired, a party to the organization determination or a physician acting on behalf of an enrollee may file a request for reconsideration with the MA organization. The request for reconsideration and to extend the timeframe must—

(i) Be in writing; and

(ii) State why the request for reconsideration was not filed on time.

(d) *Parties to the reconsideration.* The parties to the reconsideration are the parties to the organization determination, as described in § 422.574, and any other provider or entity (other than the MA organization) whose rights with respect to the organization determination may be affected by the reconsideration, as determined by the entity that conducts the reconsideration.

(e) *Withdrawing a request.* The party or physician acting on behalf of an enrollee who files a request for reconsideration may withdraw it by filing a written request for withdrawal at one of the places listed in paragraph (a) of this section.

Subpart O—Intermediate Sanctions

■ 15. Amend § 422.760 by—

■ A. Redesignating paragraphs (b)(2) and (b)(3) as paragraphs (b)(3) and (b)(4), respectively.

■ B. Adding new paragraph (b)(2) to read as follows:

§ 422.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.

* * * * *

(b) * * *

(2) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more MA enrollees, CMS may calculate

a CMP of up to $25,000 for each MA enrollee directly adversely affected (or with the substantial likelihood of being adversely affected) by a deficiency.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 16. 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

■ 17. Amend § 423.32 by adding paragraph (g) to read as follows:

§ 423.32 Enrollment process.

* * * * *

(g) *Passive enrollment by CMS.* In situations involving either immediate terminations as provided in § 423.509(a)(5) or § 422.510(a)(5) of this chapter, or other situations in which CMS determines that remaining enrolled in a plan poses potential harm to plan members, CMS may implement passive enrollment procedures.

(1) *Passive enrollment procedures.* Individuals will be considered to have enrolled in the plan selected by CMS unless individuals—

(i) Decline the plan selected by CMS, in a form and manner determined by CMS; or

(ii) Request enrollment in another plan.

(2) *Beneficiary notification.* The organization that receives the enrollment must provide notification that describes the costs and benefits of the new plan and the process for accessing care under the plan and the beneficiary's ability to decline the enrollment or choose another plan. Such notification must be provided to all potential enrollees prior to the enrollment effective date (or as soon as possible after the effective date if prior notice is not practical), in a form and manner determined by CMS.

(3) *Special election period.* All individuals will be provided with a special enrollment period, as described in § 423.38(c)(8)(ii).

■ 18. Amend § 423.34 by—

■ A. Revising paragraph (d)(1).

■ B. Adding paragraph (d)(3).

The revision and addition reads as follows:

§ 423.34 Enrollment of full-benefit dual eligible individuals.

* * * * *

(d) *Automatic enrollment rules.* (1) *General rule.* Except for full-benefit dual eligible individuals who are qualifying covered retirees with a group health plan sponsor as specified in paragraph (d)(3) of this section, CMS automatically enrolls full-benefit dual eligible individuals who fail to enroll in a Part D plan into a PDP offering basic prescription drug coverage in the area where the individual resides that has a monthly beneficiary premium 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.

* * * * *

(3) *Exception for full-benefit dual eligible individuals who are qualifying covered retirees.* (i) Full-benefit dual eligible individuals who are qualifying covered retirees as defined in § 423.882, and for whom CMS has approved the group health plan sponsor to receive the Retiree 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, however, CMS will provide notice to such individuals of their choices and advise them to discuss the potential impact of Medicare Part D coverage on their group health plan coverage. This notice informs such 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.

* * * * *

■ 19. Amend § 423.44 by revising paragraph (d)(1) introductory text and adding paragraph (d)(1)(iv) as follows:

§ 423.44 Involuntary disenrollment by the PDP.

* * * * *

(d) * * *

(1) Except as specified in paragraph (d)(1)(iv) of this section, a PDP sponsor may disenroll an individual from the PDP for failure to pay any monthly premium under the following circumstances:

* * * * *

(iv) A PDP sponsor may not disenroll an individual who had monthly premiums withheld per § 423.293(a) and (e) of this part or who is in premium withhold status, as defined by CMS.

* * * * *

■ 20. Amend § 423.46 by adding paragraph (b) through (d) to read as follows:

§ 423.46 Late enrollment penalty.

* * * * *

(b) *Role of Part D plan in determination of the penalty.* Part D sponsors must obtain information on prior creditable coverage from all enrolled or enrolling beneficiaries and report this information to CMS in a form and manner determined by CMS.

(c) *Reconsideration.* Individuals determined to be subject to a late enrollment penalty may request reconsideration of this determination, consistent with § 423.56(g) of this part. Such review will be conducted by CMS, or an independent review entity contracted by CMS, in accordance with guidance issued by CMS. Decisions made through this review are not subject to appeal, but may be reviewed and revised at the discretion of CMS.

(d) *Record retention.* Part D plan sponsors must retain all information collected concerning a creditable coverage period determination in accordance with the enrollment records retention requirements described in § 423.505(e)(1)(iii).

Subpart C—Benefits and Beneficiary Protections

■ 21. Section 423.100 is amended by—

■ A. Revising the definition of ''incurred costs.''

■ B. Revising the definition of ''negotiated prices.''

The revision reads as follows:

§ 423.100 Definitions.

* * * * *

Incurred costs means costs incurred by a Part D enrollee for—

(1)(i) Covered Part D drugs that are not paid for under the Part D plan as a result of application of any annual deductible or other cost-sharing rules for covered Part D drugs prior to the Part D enrollee satisfying the out-of-pocket threshold under § 423.104(d)(5)(iii), including any price differential for which the Part D enrollee is responsible under § 423.124(b); or

(ii) Nominal cost-sharing paid by or on behalf of an enrollee, which is associated with drugs that would otherwise be covered Part D drugs, as defined in § 423.100, but are instead paid for, with the exception of said nominal cost-sharing, by a patient assistance program providing assistance outside the Part D benefit, provided that documentation of such nominal cost-sharing has been submitted to the Part D plan consistent with the plan

processes and instructions for the submission of such information; and

(2) That are paid for—

(i) By the Part D enrollee or on behalf of the Part D enrollee by another person, and the Part D enrollee (or person paying on behalf of the Part D enrollee) is not reimbursed through insurance or otherwise, a group health plan, or other third party payment arrangement, or the person paying on behalf of the Part D enrollee is not paying under insurance or otherwise, a group health plan, or third party payment arrangement;

(ii) Under a State Pharmaceutical Assistance Program (as defined in § 423.454 of this part); or

(iii) Under § 423.782 of this part.

* * * * *

Negotiated prices means prices for covered Part D drugs that—

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug;

(2) Are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and

(3) Includes any dispensing fees.

* * * * *

■ 22. Amend § 423.104 by revising paragraph (g)(1) to read as follows:

§ 423.104 Requirements related to qualified prescription drug coverage.

* * * * *

(g) * * *

(1) *Access to negotiated prices.* A Part D sponsor is required to provide its Part D enrollees with access to negotiated prices for covered Part D drugs included in its Part D plan's formulary. Negotiated prices must be provided even if no benefits are payable to the beneficiary for covered Part D drugs because of the application of any deductible or 100 percent coinsurance requirement following satisfaction of any initial coverage limit. Negotiated prices must be provided when the negotiated price for a covered Part D drug under a Part D sponsor's benefit package is less than the applicable cost-sharing before the application of any deductible, before any initial coverage limit, before the annual out-of-pocket threshold, and after the annual out-of-pocket threshold.

* * * * *

■ 23. Revise § 423.128(e)(6) to read as follows:

§ 423.128 Dissemination of Part D plan information.

* * * * *

(e) * * *

(6) Be provided no later than the end of the month following any month when prescription drug benefits are provided under this part, including the covered Part D spending between the initial coverage limit described in § 423.104(d)(3) and the out-of-pocket threshold described in § 423.104(d)(5)(iii).

Subpart F—Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

■ 24. Amend § 423.293 by adding new paragraphs (a)(4) and (e) to read as follows:

§ 423.293 Collection of monthly beneficiary premium.

(a) * * *

(4) *Retroactive collection of premiums.* In circumstances where retroactive collection of premium amounts is necessary and the enrollee is without fault in creating the premium arrearage, the Medicare Advantage organization shall offer the enrollee the option of payment by lump sum, by equal monthly installment spread out over at least the same period for which the premiums were due, or through other arrangements mutually acceptable to the enrollee and the Medicare Advantage organization. For monthly installments, for example, if 7 months of premiums are due, the member would have at least 7 months to repay.

* * * * *

(e) *Prohibition on improper billing of premiums.* Part D plan sponsors shall not bill an enrollee for a premium payment period if the enrollee has had the premium for that period withheld from his or her Social Security, Railroad Retirement Board or Office of Personnel Management check.

Subpart G—Payments to Part D Plan Sponsors for Qualified Prescription Drug Coverage

■ 25. Amend § 423.308 by—

■ A. Revising the definition of ''actually paid.''

■ B. Adding the definition of ''administrative costs.''

■ C. Revising the definitions of ''allowable risk corridor costs,'' ''gross covered prescription drug costs,'' and ''target amount''.

The addition and revisions read as follows:

§ 423.308 Definitions and terminology.

* * * * *

Actually paid means that the costs must be actually incurred by the Part D sponsor and must be net of any direct or indirect remuneration (including discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred under the Part D plan. Direct and indirect remuneration includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies or similar entities obtained by an intermediary contracting organization with which the Part D plan sponsor has contracted, regardless of whether the intermediary contracting organization retains all or a portion of the direct and indirect remuneration or passes the entire direct and indirect remuneration to the Part D plan sponsor and regardless of the terms of the contract between the plan sponsor and the intermediary contracting organization.

Administrative costs means costs incurred by a Part D sponsor in complying with the requirements of this Part for a coverage year and that are not drug costs incurred to purchase or reimburse the purchase of Part D drugs. Administrative costs include amounts paid by the Part D sponsor to an intermediary contracting organization for covered Part D drugs dispensed to enrollees in the sponsor's Part D plan that differ from the amount paid by the intermediary contracting organization to a pharmacy or other entity that is the final dispenser of the covered Part D drugs. For example, any profit or loss retained by an intermediary contracting organization (through discounts, rebates, or other direct or indirect price concessions) when negotiating prices with dispensing entities is considered an administrative cost.

* * * * *

Allowable risk corridor costs means—

(1) The subset of costs incurred under a Part D plan (not including administrative costs, but including dispensing fees) that are attributable to basic prescription drug coverage only and that are incurred and actually paid by the Part D sponsor to—

(i) A dispensing pharmacy or other dispensing provider (whether directly or through an intermediary contracting organization) under the Part D plan;

(ii) The parties listed in § 423.464(f)(1) of this part with which the Part D sponsor must coordinate benefits, including other Part D plans, as the result of any reconciliation process developed by CMS under § 423.464 of this part; or

(iii) An enrollee (or third party paying on behalf of the enrollee) to indemnify the enrollee when the reimbursement is associated with obtaining drugs under the Part D plan; and

(2) These costs must be based upon imposition of the maximum amount of copayments permitted under § 423.782 of this part. The costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any prescription drug coverage costs determined to be attributable to increased utilization over standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

* * * * *

Gross covered prescription drug costs mean those actually paid costs incurred under a Part D plan, excluding administrative costs, but including dispensing fees, during the coverage year. They equal the sum of the following:

(1) The share of negotiated prices (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, reimbursement paid to indemnify an enrollee when the reimbursement is associated with an enrollee obtaining covered Part D drugs under the Part D plan, or payments made by the Part D sponsor to other parties listed in § 423.464(f)(1) of this part with which the Part D sponsor must coordinate benefits, including other Part D plans, or as the result of any reconciliation process developed by CMS under § 423.464 of this part.

(2) Nominal cost-sharing paid by or on behalf of an enrollee which is associated with drugs that would otherwise be covered Part D drugs, as defined in § 423.100 of this part, but are instead paid for, with the exception of said nominal cost-sharing, by a patient assistance program providing assistance outside the Part D benefit, provided that documentation of such nominal cost-sharing has been submitted to the Part D plan consistent with the plan processes and instructions for the submission of such information.

(3) All amounts paid under the Part D plan by or on behalf of an enrollee (such as the deductible, coinsurance, cost sharing, or amounts between the initial coverage limit and the out-of-pocket threshold) in order to obtain Part D drugs that are covered under the Part D plan. If an enrollee who is paying 100 percent cost sharing (as a result of paying a deductible or because the enrollee is between the initial coverage limit and the out-of-pocket threshold) obtains a covered Part D drug at a lower cost than is available under the Part D plan, such cost-sharing will be considered an amount paid under the plan by or on behalf of an enrollee under the previous sentence of this definition, if the enrollee's costs are incurred costs as defined under § 423.100 of this part and documentation of the incurred costs has been submitted to the Part D plan consistent with plan processes and instructions for the submission of such information. These costs are determined regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

Target amount means the total amount of payments (from both CMS and by or on behalf of enrollees) to a Part D plan for the coverage year for all standardized bid amounts as risk adjusted under § 423.329(b)(1) of this part, less the administrative expenses (including return on investment) assumed in the standardized bids.

■ 26. Amend § 423.329 by revising paragraph (d)(2)(i) to read as follows:

§ 423.329 Determination of payments.

* * * * *

(d) * * *

(2) * * *

(i) *Interim payments.* CMS establishes a payment method by which interim payments of amounts under this section are made during a year based on the low-income cost-sharing assumptions submitted with plan bids under § 423.265(d)(2)(iv) of this part and negotiated and approved under § 423.272 of this part, or by an alternative method that CMS determines.

* * * * *

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

■ 27. Amend § 423.505 by revising paragraph (k)(5) to read as follows:

§ 423.505 Contract provisions.

* * * * *

(k) * * *

(5) *Certification of allowable costs for risk corridor and reinsurance information.* The Chief Executive Officer, Chief Financial Officer, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of supporting allowable costs as defined in § 423.308 of this part, including data submitted to CMS regarding direct or indirect remuneration (DIR) that serves to reduce the costs incurred by the Part D sponsor for Part D drugs, is accurate, complete, and truthful and fully conforms to the requirements in § 423.336 and § 423.343 of this part and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

* * * * *

■ 28. Amend § 423.507 by revising paragraphs (a)(2)(ii), (a)(2)(iii), (b)(2)(ii) and (b)(2)(iii) to read as follows:

§ 423.507 Nonrenewal of contract.

(a) * * *

(2) * * *

(ii) Each Medicare enrollee by mail at least 60 days before the date on which the non-renewal is effective. This notice must include a written description of alternatives available for obtaining qualified prescription drug coverage within the PDP region, including MA–PD plans, and other PDPs, and must receive CMS approval prior to issuance; and

(iii) The general public, at least 60 days before the date on which the non-renewal is effective, by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

* * * * *

(b) * * *

(2) * * *

(ii) To each of the Part D plan sponsor's Medicare enrollees by mail at least 60 days before the date on which the non-renewal is effective; and

(iii) To the general public, at least 60 days before the date on which the non-renewal is effective, by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

* * * * *

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

■ 29. Amend § 423.551 by adding paragraph (g) to read as follows:

§ 423.551 General provisions.

* * * * *

(g) *Sale of beneficiaries not permitted:* CMS will not recognize as a sale or transfer of a PDP line of business (qualifying as a change of ownership) a transaction that consists solely of the sale or transfer of individual beneficiaries or groups of beneficiaries enrolled in a pharmacy benefit package offered by a PDP sponsor apart from the rights and obligations related to the pharmacy benefit package (PBP).

Subpart M—Grievances, Coverage Determinations, and Appeals

■ 30. Amend § 423.560 by adding, in alphabetical order, the definition for ''Other prescriber'' to read as follows:

§ 423.560 Definitions.

* * * * *

Other prescriber means a health care professional other than a physician who is authorized under State law or other applicable law to write prescriptions.

* * * * *

■ 31. Amend § 423.566 by revising paragraph (c)(3) to read as follows:

§ 423.566 Coverage determinations.

* * * * *

(c) * * *

(3) The prescribing physician or other prescriber, on behalf of the enrollee.

■ 32. Amend § 423.568 by revising paragraph (a) to read as follows:

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

(a) *Timeframe for requests for drugs 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 the receipt of the request, or, for an expedited request, the physician's or other prescriber's supporting statement.

* * * * *

■ 33. Amend § 423.570 by—
■ A. Revising paragraph (a).
■ B. Revising paragraph (b).
■ C. Revising paragraph (c)(1).
■ D. Revising paragraph (c)(3) introductory text.
■ E. Revising paragraph (c)(3)(ii).
■ F. Republishing paragraph (d) introductory text.
■ G. Revising paragraph (d)(1).
■ H. Revising paragraph (d)(2) introductory text.
■ I. Revising paragraph (d)(2)(iii).

The revisions read as follows:

§ 423.570 Expediting certain coverage determinations.

(a) *Request for expedited determination.* An enrollee or an enrollee's prescribing physician or other prescriber may request that a Part D plan sponsor expedite a coverage determination involving issues described in § 423.566(b) of this part. This does not include requests for payment of Part D drugs already furnished.

(b) *How to make a request.* (1) To ask for an expedited determination, an enrollee or an enrollee's prescribing physician or other prescriber on behalf of the enrollee must submit an oral or written request directly to the Part D plan sponsor or, if applicable, to the entity responsible for making the determination, as directed by the Part D plan sponsor.

(2) A prescribing physician or other prescriber may provide oral or written support for an enrollee's request for an expedited determination.

(c) * * *

(1) An efficient and convenient means for accepting oral or written requests submitted by enrollees, prescribing physicians, or other prescribers.

* * * * *

(3) A means for issuing prompt decisions on expediting a determination, based on the following requirements:

* * * * *

(ii) For a request made or supported by an enrollee's prescribing physician or other prescriber, provide an expedited determination if the physician or other prescriber indicates that applying the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If a Part D plan sponsor denies a request for expedited determination, it must take the following actions:

(1) Make the determination within the 72-hour timeframe established in § 423.568(a) 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.

(2) Give the enrollee and prescribing physician or other prescriber prompt oral notice of the denial that—

* * * * *

(iii) Informs the enrollee of the right to resubmit a request for an expedited determination with the prescribing physician's or other prescriber's support and

* * * * *

■ 34. Amend § 423.572 by revising paragraph (a) to read as follows:

§ 423.572 Timeframes and notice requirements for expedited coverage determinations.

(a) *Timeframe for determination and notification.* Except as provided in paragraph (b) of this section, a Part D plan sponsor that approves a request for expedited determination must make its determination and notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request, or, for an exceptions request, the physician's or other prescriber's supporting statement.

* * * * *

■ 35. Amend § 423.578 by—
■ A. Revising paragraphs (a) introductory text and (a)(2) introductory text.
■ B. Revising paragraphs (a)(2)(i) and (a)(3)
■ C. Revising paragraphs (a)(4) introductory text and (a)(5).
■ D. Revising paragraphs (b) introductory text and (b)(2) introductory text.
■ E. Revising paragraphs (b)(2)(i), (b)(4), (b)(5) introductory text, and (b)(6).
■ F. Revising paragraphs (c)(3)(i), (c)(4)(i) introductory text, and (c)(4)(i)(A).
■ G. Revising paragraph (f).

The revisions read as follows:

§ 423.578 Exceptions process.

(a) *Request for exceptions to a plan's tiered cost-sharing structure.* Each Part D plan sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a tiered formulary must establish and maintain reasonable and complete exceptions procedures subject to CMS' approval for this type of coverage determination. The Part D plan sponsor grants an exception whenever it determines that the non-preferred drug for treatment of the enrollee's condition is medically necessary, consistent with the physician's or other prescriber's

statement under paragraph (a)(4) of this section.

* * * * *

(2) The exceptions criteria of a Part D plan sponsor must include, but are not limited to—

(i) A description of the criteria a Part D plan sponsor uses to evaluate a determination made by the enrollee's prescribing physician or other prescriber under paragraph (a)(4) of this section.

* * * * *

An enrollee or the enrollee's prescribing physician or other prescriber may file a request for an exception.

(4) A prescribing physician or other prescriber must provide an oral or written supporting statement that the preferred drug for the treatment of the enrollee's conditions—

* * * * *

(5) If the physician or other prescriber provides an oral supporting statement, the Part D plan sponsor may require the physician or other prescriber to subsequently provide a written supporting statement to demonstrate the medical necessity of the drug. The Part D plan sponsor may require the prescribing physician or other prescriber to provide additional supporting medical documentation as part of the written follow-up.

* * * * *

(b) *Request for exceptions involving a non-formulary Part D drug.* Each Part D plan sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a formulary must establish and maintain exceptions procedures subject to CMS' approval for receipt of an off-formulary drug. The Part D plan sponsor must grant an exception whenever it determines that the drug is medically necessary, consistent with the physician's or other prescriber's statement under paragraph (b)(5) of this section, and that the drug would be covered but for the fact that it is an off-formulary drug. Formulary use includes the application of cost utilization tools, such as a dose restriction, including the dosage form, that causes a particular Part D drug not to be covered for the number of doses prescribed or a step therapy requirement that causes a particular Part D drug not to be covered until the requirements of the plan's coverage policy are met, or a therapeutic substitution requirement.

* * * * *

(2) The exception criteria of a Part D plan sponsor must include, but are not limited to—

(i) A description of the criteria a Part D plan sponsor uses to evaluate a prescribing physician's or other prescriber's determination made under paragraph (b)(5) of this section;

* * * * *

(4) An enrollee, the enrollee's appointed representative, or the prescribing physician or other prescriber (on behalf of the enrollee) may file a request for an exception.

(5) A prescribing physician or other prescriber must provide an oral or written supporting statement that the requested prescription drug is medically necessary to treat the enrollee's disease or medical condition because—

* * * * *

(6) If the physician or other prescriber provides an oral supporting statement, the Part D plan sponsor may require the physician or other prescriber to subsequently provide a written supporting statement. The Part D plan sponsor may require the prescribing physician or other prescriber to provide additional supporting medical documentation as part of the written follow-up.

(c) * * *

(3) * * *

(i) The enrollee's prescribing physician or other prescriber continues to prescribe the drug.

* * * * *

(4) * * *

(i) The Part D plan sponsor may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—

(A) The enrollee's prescribing physician or other prescriber continues to prescribe the drug;

* * * * *

(f) *Implication of the physician's or other prescriber's supporting statement.* Nothing in this section should be construed to mean that the physician's or other prescriber's supporting statement required for an exceptions request will result in an automatic favorable decision.

■ 36. Revise § 423.580 to read as follows:

§ 423.580 Right to a redetermination.

An enrollee who has received a coverage determination (including one that is reopened and revised as described in § 423.634) may request that it be redetermined under the procedures described in § 423.582, which address requests for a standard redetermination. The prescribing physician or other prescriber (acting on behalf of an enrollee), upon providing notice to the enrollee, may request a standard redetermination under the procedures described in § 423.582. An enrollee or an enrollee's prescribing physician or other prescriber (acting on behalf of an enrollee) may request an expedited redetermination as specified in § 423.584.

■ 37. Revise § 423.582 to read as follows:

§ 423.582 Request for a standard redetermination.

(a) *Method and place for filing a request.* An enrollee or an enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee) must ask for a redetermination by making a written request with the Part D plan sponsor that made the coverage determination. The Part D plan sponsor may adopt a policy for accepting oral requests.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, a request for a redetermination must be filed within 60 calendar days from the date of the notice of the coverage determination.

(c) *Extending the time for filing a request*—(1) *General rule.* If an enrollee or prescribing physician or other prescriber acting on behalf of an enrollee shows good cause, the Part D plan sponsor may extend the timeframe for filing a request for redetermination.

(2) *How to request an extension of timeframe.* If the 60-day period in which to file a request for a redetermination has expired, an enrollee or a prescribing physician or other prescriber acting on behalf of an enrollee may file a request for redetermination and extension of time frame with the Part D plan sponsor. The request for redetermination and to extend the timeframe must—

(i) Be in writing; and

(ii) State why the request for redetermination was not filed on time.

(d) *Withdrawing a request.* The person who files a request for redetermination may withdraw it by filing a written request with the Part D sponsor.

■ 38. Amend § 423.584 by revising paragraphs (a), (b), (c)(2)(ii), and (d)(2)(iii) to read as follows:

§ 423.584 Expediting certain redeterminations.

(a) *Who may request an expedited redetermination.* An enrollee or an enrollee's prescribing physician or other prescriber may request that a Part D plan sponsor expedite a redetermination that involves the issues specified in § 423.566(b). (This does not include requests for payment of drugs already furnished.)

(b) *How to make a request.* (1) To ask for an expedited redetermination, an enrollee or a prescribing physician or other prescriber acting on behalf of an enrollee must submit an oral or written request directly to the Part D plan sponsor or, if applicable, to the entity responsible for making the redetermination, as directed by the Part D plan sponsor.

(2) A prescribing physician or other prescriber may provide oral or written support for an enrollee's request for an expedited redetermination.

(c) * * *

(2) * * *

(ii) For a request made or supported by a prescribing physician or other prescriber, the Part D plan sponsor must provide an expedited redetermination if the physician or other prescriber indicates that applying the standard timeframe for conducting a redetermination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) * * *

(2) * * *

(iii) Informs the enrollee of the right to resubmit a request for an expedited redetermination with the prescribing physician's or other prescriber's support; and

* * * * *

■ 39. Section 423.586 is revised to read as follows:

§ 423.586 Opportunity to submit evidence.

The Part D plan sponsor must provide the enrollee or the prescribing physician or other prescriber, as appropriate, with a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. In the case of an expedited redetermination, the opportunity to present evidence is limited by the short timeframe for making a decision. Therefore, the Part D plan sponsor must inform the enrollee or the prescribing physician or other prescriber of the conditions for submitting the evidence.

■ 40. Amend § 423.590 by revising paragraphs (d)(1), (e), and (f)(2) to read as follows:

§ 423.590 Timeframes and responsibility for making redeterminations.

* * * * *

(d) *Expedited redetermination.* (1) *Timeframe.* A Part D plan sponsor that approves a request for expedited redetermination must complete its redetermination and give the enrollee (and the prescribing physician or other prescriber involved, as appropriate), notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request.

* * * * *

(e) *Failure to meet timeframe for expedited redetermination.* If the Part D plan sponsor fails to provide the enrollee or the prescribing physician or other prescriber, as appropriate, with the results of its expedited redetermination within the timeframe described in paragraph (d) of this section, the failure constitutes an adverse redetermination decision, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(f) * * *

(2) When the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the redetermination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the redetermination need not, in all cases, be of the same specialty or subspecialty as the prescribing physician or other prescriber.

* * * * *

■ 41. Amend § 423.600 by revising paragraphs (b), (c), and (e) to read as follows:

§ 423.600 Reconsideration by an independent review entity (IRE).

* * * * *

(b) When an enrollee files an appeal, the IRE is required to solicit the views of the prescribing physician or other prescriber. The IRE may solicit the views of the prescribing physician or other prescriber orally or in writing. A written account of the prescribing physician's or other prescriber's views (prepared by either the prescribing physician, other prescriber, or IRE, as appropriate) must be contained in the IRE's record.

(c) In order for an enrollee to request an IRE reconsideration of a determination by a Part D plan sponsor not to provide for a Part D drug that is not on the formulary, the prescribing physician or other prescriber must determine that all covered Part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the non-formulary drug, would have adverse effects for the individual, or both.

* * * * *

(e) When the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the reconsideration must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the reconsideration need not, in all cases, be of the same specialty or subspecialty as the prescribing physician or other prescriber.

Subpart O—Intermediate Sanctions

■ 42. Amend § 423.760 by—

■ A. Redesignating paragraphs (b)(2) and (b)(3) as paragraphs (b)(3) and (b)(4), respectively.

■ B. Adding new paragraph (b)(2) to read as follows:

§ 423.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.

* * * * *

(b) * * *

(2) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more Part D enrollees, CMS may calculate a CMP of up to $25,000 for each Part D enrollee directly adversely affected (or with a substantial likelihood of being adversely affected) by a deficiency .

* * * * *

Subpart P—Premiums and Cost-Sharing Subsidies for Low-Income Individuals

■ 43. Amend § 423.772 by adding the definition of ''Best available evidence'', in alphabetical order, to read as follows:

§ 423.772 Definitions.

* * * * *

Best available evidence means evidence recognized by CMS as documentation or other information that is directly tied to State or Social Security Administration systems that confirm an individual's low-income subsidy eligibility status, and that must be accepted and used by the Part D sponsor to change low-income subsidy status.

* * * * *

■ 44. Amend § 423.782 by adding new paragraph (c) to read as follows:

§ 423.782 Cost-sharing subsidy.

* * * * *

(c) When the out-of-pocket cost for a covered Part D drug under a Part D sponsor's plan benefit package is less than the maximum allowable copayment, coinsurance or deductible amounts under paragraphs (a) and (b) of

this section, the Part D sponsor may only charge the lower benefit package amount.

■ 45. Amend § 423.800 by—

■ A. Revising paragraph (b).

■ B. Adding a new paragraph (d).

The revision and addition read as follows:

§ 423.800 Administration of subsidy program.

* * * * *

(b) *Reduction of premium or cost-sharing by PDP sponsor or organization.* Based on information provided by CMS under paragraph (a) of this section, or obtained under paragraph (d) of this section, the Part D sponsor offering the Part D plan in which a subsidy eligible individual is enrolled must reduce the individual's premiums and cost-sharing as applicable, and provide information to CMS on the amount of those reductions, in a manner determined by CMS. The Part D sponsor must track the application of the subsidies under this subpart to be applied to the out-of-pocket threshold.

* * * * *

(d) *Use of the best available evidence process to establish cost-sharing.* Part D sponsors must—

(1) Accept best available evidence as defined in § 423.772 of this part received from beneficiaries or other individuals acting directly on their behalf; and

(2) Update the subsidy eligible individual's LIS status. and respond to requests for assistance in securing acceptable evidence of subsidy eligibility from beneficiaries or other individuals acting directly on their behalf in accordance with the process(es) established by CMS, and within the reasonable timeframe(s) as determined by CMS.

Subpart R—Payment to Sponsors of Retiree Prescription Drug Plans

■ 46. Section 423.882 is amended by—

■ A. Adding the definition of ''actually paid'' in alphabetical order.

■ B. Adding the definition of ''administrative costs'' in alphabetical order.

■ C. Revising the definition of ''allowable retiree costs''.

■ D. Revising the definition of ''gross covered retiree plan-related prescription drug costs'', or ''gross retiree costs''.

The additions and revisions read as follows:

§ 423.882 Definitions.

* * * * *

Actually paid means that the costs must be actually incurred by the qualified retiree prescription drug plan and must be net of any direct or indirect remuneration (including discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any manufacturer or pharmacy that would serve to decrease the costs incurred under the qualified retiree prescription drug plan.

Administrative costs means costs incurred by a qualified retiree prescription drug plan that are not drug costs incurred to purchase or reimburse the purchase of Part D drugs.

Allowable retiree costs means the subset of gross covered retiree plan-related prescription drug costs actually paid by the sponsor of the qualified retiree prescription drug plan or by (or on behalf of) a qualifying covered retiree under the plan.

* * * * *

Gross covered retiree plan-related prescription drug costs, or *gross retiree costs*, means those Part D drug costs incurred under a qualified retiree prescription drug plan, excluding administrative costs, but including dispensing fees, during the coverage year. They equal the sum of the following:

(1) The share of prices paid by the qualified retiree prescription drug plan that is received as reimbursement by the pharmacy or by an intermediary contracting organization, and reimbursement paid to indemnify a qualifying covered retiree when the reimbursement is associated with a qualifying covered retiree obtaining Part D drugs under the qualified retiree prescription drug plan.

(2) All amounts paid under the qualified retiree prescription drug plan by or on behalf of a qualifying covered retiree (such as the deductible, coinsurance, or cost sharing) in order to obtain Part D drugs that are covered under the qualified retiree prescription drug plan.

* * * * *

■ 47. Revise § 423.888(b)(5)(i) to read as follows:

§ 423.888 Payment methods, including provision of necessary information.

* * * * *

(b) * * *

(5) *Special rule for insured plans.* (i) Interim Payments. Sponsors of group health plans that provide benefits through health insurance coverage (as defined in 45 CFR 144.103) and that choose either monthly payments, quarterly payments or an interim annual payment in paragraphs (b)(1) and (b)(2) of this section, may elect to determine gross covered plan-related retiree prescription drug costs for purposes of the monthly, quarterly or interim annual payments based on a portion of the premium costs paid by the sponsor (or by the qualifying covered retirees) for coverage of the covered retirees under the group health plan. Premium costs that are determined, using generally accepted actuarial principles, may be attributable to the gross covered plan-related retiree prescription drug costs incurred by the health insurance issuer (as defined in 45 CFR 144.103) for the sponsor's qualifying covered retirees, except that administrative costs and risk charges must be subtracted from the premium.

* * * * *

Authority: (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program) (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 7, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: November 13, 2008.

Michael O. Leavitt,

Secretary.

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