Federal Register

Friday,
May 16, 2008

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

[CMS 4131–P]

RIN 0938–AP24

Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would make revisions to the Medicare Advantage (MA) program (Part C) and prescription drug benefit program (Part D). The regulation contains new regulatory provisions regarding special needs plans, medical savings accounts (MSA) plans, and 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, appeals, and marketing processes for both programs. We are proposing these changes based on lessons learned since 2006, the initial year of the prescription drug program and the revised MA program.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on July 15, 2008.

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

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

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' and enter the filecode to find the document accepting comments.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–*4131*–P, P.O. Box 8016, Baltimore, MD 21244–8016.

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

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–*4131*–P, 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 (one original and two copies) 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 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) 786–7195 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.

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

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

FOR FURTHER INFORMATION CONTACT:

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

Contracts with MA Organizations—Chris McClintick, 410–786–4682.

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

Enrollment—Lynn Orlosky, 410–786–9064.

Payment—Frank Szeflinski, 303–844–7119.

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

Reconsiderations—

- John Scott, 410–786–3636.
- Kathryn McCann Smith, 410–786–7623.

Marketing—Elizabeth Jacob, 410–786–8658.

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

Low-income Cost-Sharing—Christine Hinds, 410–786–4578.

Definitions related to the Part D drug benefit. Subparts F and G—Deondra Moseley, (410) 786–4577 or Meghan Elrington, (410) 786–8675. Subpart R—David Mlawsky, (410) 786–6851.

SUPPLEMENTARY INFORMATION:

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

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

I. Background

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

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) was enacted on December 8, 2003. The MMA established the Medicare prescription drug benefit program (Part D) and made revisions to the provisions in Medicare Part C, governing what is now called 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 directed implementation of the prescription drug benefit and revised MA program provisions by January 1, 2006. The final rules for the MA and Part D prescription drug programs appeared in the **Federal Register** on January 28, 2005 (70 FR 4588 through 4741 and 70 FR 4194 through 4585, respectively). Many of the provisions relating to applications, marketing, contracts, and the new bidding process, for the MA program, became effective on March 22, 2005, 60

days after publication of the rule, so that the requirements for both programs could be implemented by January 1, 2006. All of the provisions regarding the new Part D prescription drug program became effective on March 22, 2005.

As we have gained more experience with the MA program and the prescription drug benefit program, we are proposing to revise areas of both programs. Many of these revisions clarify existing policies or codify current guidance for both programs. We believe that these changes would help plans understand and comply with our policies for both programs and aid MA organizations and Part D plan sponsors in implementing their health care and prescription drug benefit plans.

B. Relevant Legislative History and Overview

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) established a new ''Part C'' in the Medicare statute (sections 1851 through 1859 of the Social Security Act (the Act)) which provided for a Medicare+Choice (M+C) program. Under section 1851(a)(1) of the Act, every individual entitled to Medicare Part A and enrolled under Medicare Part B, except for most individuals with end-stage renal disease (ESRD), could elect to receive benefits either through the original Medicare program or an M+C plan, if one was offered where he or she lived. The primary goal of the M+C program was to provide Medicare beneficiaries with a wider range of health plan choices.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), Public Law 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.

As noted above, the MMA was enacted on December 8, 2003. Title I of the MMA added a new ''Part D'' to the Medicare statute (sections 1860D–1 through 1860D–42) creating the Medicare Prescription Drug Benefit Program, the most significant change to the Medicare program since its inception in 1965.

Sections 201 through 241 of Title II of the MMA made significant changes to the M+C program which was established by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33). Title II of the MMA renamed the M+C program the MA program and included new payment and bidding provisions, new regional MA plans and special needs plans, reestablished authority for medical savings account (MSA) plans that had been provided in the BBA on a temporary basis, and other changes. Title I of the MMA created prescription drug benefits under Medicare Part D, and a new retiree drug subsidy program.

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

II. Provisions of the Proposed Regulations

In the sections that follow, we discuss the proposed changes to the regulations in parts 422 and 423 governing the MA and prescription drug benefit programs. Several of the proposed revisions and clarifications affect both programs. In our discussion, we note when a provision would affect both the MA and prescription drug benefit and include in section II C, a table comparing the proposed Part C and D program changes by specifying each issue and the sections of the Code of Federal Regulations that we propose to revise for both programs.

A. Proposed Changes to Part 422—Medicare Advantage Program

1. Special Needs Plans

The Congress first authorized special needs plans (SNP) to exclusively or disproportionately serve individuals with special needs. The three types of special needs individuals eligible for enrollment identified by the Congress 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. Ensuring Special Needs Plans Serve Primarily Special Needs Individuals (§ 422.4)

Section 231 of the MMA authorized MA organizations to offer a specialized MA plan that ''exclusively,'' or ''disproportionately,'' ''serves'' one of three categories of ''special needs'' individuals: Individuals dually-eligible for both Medicare and Medicaid, institutionalized individuals, and individuals with severe or disabling chronic conditions that the Secretary determines would benefit from enrollment in a SNP.

As noted above, the final rule implementing the MMA changes to the MA program, including these SNP provisions, was issued on January 28, 2005 (70 FR 4588). In the preamble to the proposed rule we proposed to interpret the term ''serves'' special needs individuals to mean markets to, and enrolls, special needs individuals. This was intended to permit an MA Plan with existing non-special needs enrollees to be designated a SNP if it prospectively, exclusively, or disproportionately enrolled special needs individuals.

We also proposed to interpret the statutory phrase, ''disproportionately serve[s] special needs individuals'' to refer to a SNP that enrolls special needs individuals in a proportion greater than such individuals exist in the area served by the plan (69 FR 46874). We asked for public comments regarding whether we should specify a percentage, such as 50 percent or more, as the minimum enrollment for a plan to be considered a SNP.

We did not receive any comments on this proposed provision. Therefore, in the final rule we established the disproportionate percentage methodology based on the test we proposed in the proposed rule, that is, a comparison of the proportion of the special needs individuals the plan enrolls relative to non-special needs enrollees and the proportion of special needs individuals in the plan's service area. If the proportion of special needs to non-special needs individuals being enrolled in the plan was greater than the proportion in the plan's service area, the plan could be considered a disproportionate share SNP. Our expectation was that only a limited number of non-special needs individuals would be likely to enroll in a SNP, such as spouses or children of special needs individuals who wish to enroll in the same MA plan as the spouse or parent. However, such plans may be attractive to other non-special needs individuals because they may

offer additional benefits beyond what Medicare covers. Also, individuals who are in the early stages of one of the chronic conditions covered by a disproportionate percentage, chronic care SNP may find the benefits or the network of participating specialists attractive.

Disproportionate percentage SNPs have proliferated since the implementation of the Part D program, due, in part, to the fact that both dual eligible individuals and institutionalized individuals are permitted to enroll in MA plans year round, and dual eligible and institutional SNPs are thus permitted to market year round. CMS' information shows that a significant number of the dual-eligible disproportionate percentage SNPs may have between 25 percent and 40 percent of their enrollment composed of non-special needs individuals. As a result, we are concerned that disproportionate percentage SNPs are enrolling significant numbers of non-special needs individuals, thus diluting the focus on serving those individuals with special needs.

Therefore, in order to ensure that existing and future SNPs maintain a primary focus on individuals with special needs, we are proposing to amend our regulations at § 422.4(a)(1)(iv)(B) to require that MA organizations offering SNPs limit new enrollment of non-special needs members to no more than 10 percent of new enrollees, and that 90 percent of new enrollees must be special needs individuals as defined in § 422.2. We believe this threshold would continue to allow the small number of non-SNP eligible spouses and children to continue to enroll in the same MA plan as their SNP eligible spouse or parent while ensuring that the SNP retains its focus on serving the special needs individuals for which it is specifically designed.

We understand that the majority of SNPs that currently enroll both special needs and non-special needs individuals have current enrollments of non-special needs individuals that exceed 10 percent. Because the new limitation only applies to new enrollees, these plans would be able to continue to serve their existing membership. Organizations offering disproportionate enrollment SNPs would not be permitted to enroll new non-special needs individuals, however, without first enrolling enough special needs individuals to ensure that the percentage of new non-special needs enrollees remains below 10 percent. Furthermore, as specified in § 422.4, those enrollees deemed continuously eligible per § 422.52(d) are considered special needs individuals for the purpose of determining the disproportionate percentage.

On an ongoing basis plans would need to monitor their enrollment to ensure that the 10 percent limit on new enrollments is met. This means that plans would need to monitor their enrollment to ensure that they were enrolling nine special needs individuals for every non-special needs individual to keep the ratio of new enrollees who were non-special needs individuals below 10 percent of new enrollees. MA organizations offering disproportionate SNPs would have to have a mechanism to ensure that a non-special needs individual could not enroll until a sufficient number of special needs individuals were enrolled to keep new enrollment of non-special needs individuals below 10 percent of new enrollments. For example, if a SNP receives completed enrollment elections from non-special needs individuals when such an enrollment would push the percentage of new enrollees over 10 percent, it could—(1) deny the enrollment due to the onset of the limit; or (2) place the enrollment on a waiting list to be processed after a sufficient number of special needs individuals have been enrolled. The plan would need to ensure that once enrollments are accepted for non-special needs individuals, that this is done on a non-discriminatory basis. We believe that this approach will encourage SNPs to design benefit packages that best serve the certain special needs populations for which they have been created.

We welcome comments on the appropriateness of the 10 percent standard for new enrollees, as well as the most effective and least burdensome ways for plans to monitor the proportions of new enrollments.

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

In order to elect a SNP, an individual must meet the eligibility requirements for the specific type of SNP in which the individual wishes to enroll. For example, to enroll in a dual eligible SNP, the individual must be eligible for both Medicare and Medicaid. It is the responsibility of the MA organization offering the SNP to verify eligibility during the enrollment process.

We are concerned that some dual eligible SNPs may not be appropriately verifying Medicaid eligibility of applicants for enrollment, and therefore may be enrolling beneficiaries who are not eligible for both Medicare and Medicaid. Similarly, some chronic care SNPs may encounter difficulties having providers verify that the applicants have the condition(s) established as the focus of the chronic care SNP.

We propose to clarify in our regulations that MA organizations must establish a process to verify that potential SNP enrollees meet the SNP's specific 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 ensure that plans are aware of and meet their obligations to verify an applicant's eligibility prior to enrolling individuals in a SNP through rule making.

Therefore, we are proposing in § 422.52(g) that MA organizations offering SNPs for dual eligible beneficiaries establish a process approved by CMS to obtain information from the State about the applicant's Medicaid status and that this verification must be obtained prior to enrollment. This would likely require the SNP to enter into an agreement with the State to obtain this information on a routine and timely basis. We address the issue of a relationship with the State Medicaid program in the case of a dual eligible SNP in more detail in section II, below. Those organizations offering chronic care SNPs must attempt to obtain verifying information directly from the beneficiary's provider or the organization may use the disease-specific pre-qualification assessment questions developed by, and available from CMS (model language) as an alternative methodology.

In the 2008 MA application solicitation, we required SNPs to identify their processes for verifying a beneficiary's chronic condition before enrollment. Specifically, each applicant was required to contact the enrollee's physician to verify eligibility for the specific chronic condition SNP. We subsequently received industry comments that SNP staff sometimes experience significant delays in obtaining physician verification of the beneficiary's chronic condition and, as a consequence, there was delay in enrolling an eligible beneficiary.

In response to this information, we developed an additional option to facilitate chronic condition verification. In a May 31, 2007 memorandum, we notified chronic condition SNPs that they could develop a pre-enrollment qualification assessment tool to expedite verification that beneficiaries had the chronic condition for which they were enrolled (see *https://32.90.191.19/hpms/upload_area/NewsArchive_*

MassEmail/000001696/CHVHPMS%20v2.pdf). We simultaneously posted an example of an acceptable verification tool for coronary artery disease, congestive heart failure, and/or cerebrovascular accident (stroke) on HPMS (see *https://32.90.191.19/hpms/upload_area/NewsArchive_MassEmail/000001696/Draft%20pre-Qual%for%20chronic%20SNP%20verification%205%2007%20(2).pdf*).

The notification memorandum instructed SNPs to draft a verification tool, complete an attestation form asserting compliance with CMS conditions listed on the form, and to submit the tool to CMS for review and approval prior to using the tool. Concurrently, we collaborated with physician experts in chronic disease management to develop a series of questions related to several chronic conditions listed in HPMS as of January 2, 2007, representing potentially severe or disabling primary chronic conditions. Questions similar to the above example were developed for chronic obstructive pulmonary disease, diabetes mellitus, hypertension, chronic renal failure, depression, schizophrenia, bipolar disorder, dementia, and chronic alcohol or drug dependence.

Because chronic condition SNPs request CMS approval for their proposed pre-enrollment qualification assessment tools, we use the disease-specific questions to guide the SNP in the design of an appropriate tool. Having the additional option of using a pre-enrollment qualification assessment tool gives SNPs three means of meeting the verification requirement—written documentation from the beneficiary's former physician, telephonic confirmation by the beneficiary's former physician, or use of the verification tool followed by post-enrollment confirmation by any physician.

Similarly, organizations offering a SNP for institutionalized individuals must verify each enrollee's institutional status with the facility or appropriate State agency.

c. Model of Care (422.101(f))

As noted above, the MMA permitted MA organizations to offer care targeted to beneficiaries with special health care needs through SNPs. The MMA specified that a special needs individual was an individual who was ''institutionalized'' (as defined by the Secretary), is entitled to medical assistance under a State plan under title XIX (Medicaid), or ''meets such requirements as the Secretary may determine would benefit from enrollment'' in a SNP for individuals ''with severe or disabling chronic conditions.'' In order to ensure that SNPs are 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 are proposing 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 [1]''), we propose to add new paragraph (f) to § 422.101. Section 422.101(f) would specify that SNPs must 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. We believe that these measures are critical to providing care to the types of special needs populations served by SNPs.

For example, CMS anticipates that a chronic condition SNP serving beneficiaries having severe or disabling diabetes mellitus would establish a provider network that afforded access to diabetes experts such as endocrinologists who consult on pharmacotherapy for the fragile diabetic, vitreo-retinal ophthalmologists for diabetic retinopathy management, nephrologists for diabetic nephropathy management, neurologists having diabetic neuropathy expertise, nurses having specialized training in diabetes education, and nutritionists with expertise in diabetic counseling.

The SNP might enroll diabetic beneficiaries who develop chronic renal failure related to diabetic nephropathy and require dialysis. The SNP might choose to contract or partner with these specialized diabetes experts and/or dialysis facilities, but, as a special needs plan targeting beneficiaries with specialized diabetic needs, the SNP is obligated to provide services to manage the expected disease-specific complications of a diabetic with severe or disabling disease progression. We also expect that the chronic condition SNP serving diabetic beneficiaries would develop diabetes-specific performance measures to evaluate its own systems, experts, and health outcomes related to its diabetes management.

The SNP's own internal quality assurance and performance improvement program should examine the effectiveness of its model of care for diabetes management. For example, if the SNPs provider network applied the American Diabetes Association's clinical practice guideline for reducing the risk of or slowing the progression of diabetic nephropathy by optimizing glucose control (see National Guidelines Clearinghouse, 2008; *http://www.guideline.gov/summary/summary.aspx?doc_id=10401*), an appropriate performance measure to evaluate management of diabetic beneficiaries would be a process measure to determine the percentage of diabetics having glycosylated hemoglobin (Hgb A_{1C}) measured in the last 6 months or an outcome measure to determine how many diabetics had an A_{1C} measuring less than 7 percent (see National Quality Measures Clearinghouse, 2008; *http://www.guideline.gov/browse/xrefnqmc.aspx*).

We recognize there is a broad range of chronic disease management systems and evidence-based clinical practice guidelines available to SNPs; consequently, we have deliberately guided SNPs toward the conceptual framework of a model of care without being prescriptive about the specific staff structure, provider network, clinical protocols, performance improvement, and communication systems. We also expect that within the target population of beneficiaries having severe or disabling diabetes mellitus, SNPs would have a subpopulation of diabetics who are frail, near the end of life, or disabled by other morbidities (for example, neurological disorders, mental disorders, etc.) that would need additional specialized benefits and services that should be addressed in the model of care. For example, the diabetic beneficiary with diabetic complications who is near the end of life might require assisted living or institutional services for which the SNP would develop different goals, expanded specialty services and facilities in their provider network, different performance measures, and additional protocols.

d. Dual Eligible SNPs and Arrangements With States (§ 422.107)

CMS' review of SNPs targeting beneficiaries eligible for both Medicare and Medicaid (dual eligible SNPs) over the past few years suggests to us that for such SNPs to serve this population of beneficiaries, a plan should have a documented relationship with the State Medicaid agency in the State in which its members reside. Dual eligible SNPs that have not established a working relationship with the State may

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

encounter difficulties verifying eligibility for Medicaid prior to enrollment in a SNP and, thus, may inappropriately enroll members who are not eligible for Medicaid. Also, without an arrangement with the State, SNPs may not have the information necessary to guide beneficiaries to providers that can deliver both Medicare and Medicaid services. Further, Medicaid often provides additional health services not covered by Medicare through the SNP. Medicare Advantage organizations (MA organization) with no State relationship may be advising dual eligible members that services are not covered at all because they are not covered under the SNP, even though the services are covered through Medicaid. Consequently, if the MA organization is not aware of the benefits available to its members through other sources, such as Medicaid, it cannot ensure that the model of care it delivers offers adequate coordination of the essential services.

In order to ensure that beneficiaries are able to access essential services that are available through Medicaid in addition to those benefits available through the SNP, we propose to add a new § 422.107 which would require that an MA organization seeking to offer a SNP to serve the dual eligible population must have, at a minimum, a documented relationship, such as a contract, memorandum of understanding (MOU), data exchange agreement, or some other agreed upon arrangement with the State Medicaid agency for the State in which the dual eligible SNP is operating, in an effort to improve Medicare and Medicaid integration.

We propose in § 422.107(a) that all SNPs, whether entering the market or already established at the time these regulations become effective, must have in place a dual eligibility verification arrangement and information sharing on Medicaid providers and benefits.

We also propose in § 422.107(b) that within 3 years of the effective date of these regulations, all dual eligible SNPs already offering contracts are required to develop additional formal arrangements with States, and that new SNPs offering contracts after these regulations are effective, are required to have formal arrangements by their third contract year. CMS is allowing 3 years because we understand that it may take this long for contractual arrangements between the State and an MA plan to be implemented, particularly if Medicaid capitation and a request for proposal (RFP) are involved. We believe that by providing States and MA organizations with the maximum amount of flexibility for having a documented relationship, it will encourage States to actively participate in the development of integrated Medicare and Medicaid products with MA organizations. We believe 3 years is a reasonable and sufficient amount of time for MA organizations to develop documented arrangements with their respective States. We understand that some States are not yet ready to engage and participate in providing health care through MA organizations for their Medicaid-eligible populations and, are, therefore, providing a 3-year window for development and implementation.

Examples of additional formal arrangements range from documentation of a cooperative arrangement with the State to coordinate benefits to a contractual arrangement between the State Medicaid agency and the MA organization offering the SNP, under an RFP process, or under a Medicaid capitation arrangement.

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

CMS' review of MA plans serving dual eligible beneficiaries over the past few years has identified that a number of providers are charging the beneficiaries Medicare Parts A and B cost sharing that is the responsibility of the State. Additionally, many dual eligible enrollees are unclear about the Medicare and Medicaid rules and benefits. Some new enrollees have experienced interruptions in treatment, resulting in a negative impact on their health. These experiences suggest that additional requirements are needed to ensure that both providers and beneficiaries understand Medicare and Medicaid rules and that beneficiaries do not pay cost-sharing for which they are not responsible.

In order to protect beneficiaries and ensure that providers do not bill for cost-sharing that is not the beneficiary's responsibility, we have amended § 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 will not be held liable for Medicare Parts A and B cost sharing when the State is liable for the cost-sharing. We are proposing, 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 are proposing 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)).

Medicare Advantage organizations have flexibility in establishing arrangements with States. The arrangements could include discussing and identifying both the Medicare and Medicaid benefits and rules. A list of the services, as well as the rules applicable to enrollees eligible for Medicare and Medicaid could be disseminated to providers and updated as necessary. A contact person or liaison could be identified for each MA plan who could assist with questions and with the maintenance of current information.

2. MA MSA Transparency (§ 422.103(e))

As noted above, the MMA restored authority for ''Medical Savings Account'' (MSA) plans that had been provided for in the BBA on a temporary basis, but which expired without any such plan ever being offered. MSA plans are MA plans under which a portion of the total MA capitation rate is paid to the MA organization for a high-deductible policy that covers Medicare covered services after the high deductible is met. The remainder of the amount is placed into a savings account to be used to cover health care costs until the deductible is met. Any amounts not used in a given year accumulate for use in a future year.

As noted, under the original BBA authority, no MA organization chose to offer an MSA plan. We believe that this might be attributable in part to differences between the rules for MSA plans and the more popular health savings account (HSA) arrangements available for non-Medicare beneficiaries. In order to encourage the offering of MSA plans, and to test whether changing some rules would be beneficial, we initiated an ''MSA demonstration'' under which some MSA rules were waived. As part of this demonstration, we required that participating MA organizations provide MSA plan enrollees with cost and quality information that they could use to make informed choices as to where they would get health care.

Consistent with the best practices of HSAs and other high-deductible health plans, we propose in new § 422.103(e) to require that all MSA plans provide enrollees with information on the cost and quality of services as specified by CMS and provide information to CMS

on how they would provide this information to enrollees.[2]

The purpose of reporting cost/quality information to consumers, a practice known as ''transparency,'' is to permit plan enrollees to compare costs for specific services and to compare providers on cost and quality, with the high deductible acting as an added incentive to shop around. This proposal would implement a basic tenet of high-deductible health plans, the availability of useful cost and quality information to support consumer shopping.

We recognize that the Congress exempted MSA plans from the quality improvement program requirements in section 1852(e)(1) of the Act, and thus from the data collection and reporting requirements in section 1852(e)(3) of the Act. We would not, under this requirement, be mandating the same level of data collection required under those provisions, or the reporting of quality data to CMS. Rather, we are presuming that MA organizations in the business of offering an MSA product are committed to facilitating the intended benefits of this model—that consumers make informed choices as to their health care purchases during the deductible period and beyond. We would expect that such organizations already have mechanisms in place, in connection with their commercial lines of business, for providing their beneficiaries with cost or quality information. Indeed, in the case of Medicare participating providers, such information is available from CMS through our own transparency initiatives.

Our view that quality and cost information would be available, or reasonably accessible, to organizations in the business of offering an MSA plan is supported by the fact that the MA organizations participating in the MSA demonstration have agreed to provide the information to their enrollees. We invite public comments on this issue. We are proposing to revise the regulations to require that MA organizations offering MSA plans provide their enrollees with quality and cost information, to the extent available, concerning services in the plan's service area, and to report to CMS on its approach to providing this information. Below are examples of what a plan could be expected to address:

- How the organization will provide cost and quality information to enrollees, including screenshots for any Web-based tools used to meet this requirement.
- If they will use a Web-based product to meet this requirement, how they will provide this information to enrollees that do not have access to the Internet.
- How their organization will obtain information regarding cost and quality in the requested service area and whether this information will be personalized to the member.

B. Proposed 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)

Section 1860D–1(b)(1)(C) of the Act, and implementing regulations at 42 CFR 423.34(d), require that CMS automatically enroll a full-benefit dual eligible (FBDE) individual who has (1) failed to enroll in a prescription drug plan (PDP) or MA–PD into a PDP at or below the premium subsidy amount, and, per the last sentence in section 1860D–1(b)(1)(C) of the Act, (2) has not declined Part D enrollment, into a PDP with a premium at or below the full premium subsidy amount. Further, the statute requires that if there is more than one such plan the ''Secretary shall enroll such an individual on a random basis among all such plans in the PDP region.'' Our general policy in implementing these provisions is to notify individuals in advance about their pending auto-enrollment, and to include in that notice information about other plans available to the individual and about how to decline Part D coverage, and thus opt out of the default enrollment process.

For the overwhelming majority of FBDE individuals, default enrollment into a PDP is a favorable outcome that ensures that they receive prescription drug coverage without costs for premiums and deductibles, and with only nominal costs for cost sharing. In many cases, the Part D enrollment is also beneficial for FBDE individuals with retiree coverage, since the Part D drug coverage may well be available at a lower cost than the coverage offered through the employer plan. However, for a significant number of FBDE individuals with drug coverage through an employer group plan—especially those with full health care coverage—automatic enrollment into a PDP can have serious and sometimes irreversible negative consequences, either for the beneficiary and/or for family members. For example, under the terms of a particular employer group plan, an individual may lose employer group retiree medical coverage upon enrollment in a Part D plan, or worse, an individual's automatic enrollment in a PDP can result not only in the individual's disenrollment from the employer plan, but the disenrollment of a spouse or other family member. Although we were aware of this possibility at the outset of the program, we had no information about the extent to which FBDE individuals might already have retiree group coverage, and we believed that to the extent there were individuals in this situation, the number would be extremely small. Thus, we did not make any special rules for this population.

Since January 2006, however, we have received a relatively small, but steady, series of complaints about this issue. We have attempted to work with employers to resolve individual situations as they arose, but have not had complete success. A recent survey of large employers found that 36 percent of the firms indicated retirees would lose all retiree medical coverage upon enrollment in a Part D plan, and another 32 percent specified the retirees would lose their employer group drug coverage only. More importantly, 82 percent of employers indicated that if a retiree is enrolled in a Medicare Part D plan, the spouse of that individual would not be allowed to keep employer sponsored coverage. Finally, 57 percent of the firms surveyed indicated that they would not allow retirees to rejoin the company's coverage in the future, should they decide that they would prefer the employer coverage to the Part D coverage in which they were automatically enrolled based on their FBDE status. (See December 13, 2006, Kaiser/Hewitt Survey Report of Large Employers at *http://www.kff.org/medicare/med121306nr.cfm*).

To address those concerns, we propose to revise § 423.34(d)(1), and add new § 423.34(d)(3), to establish a process under which FBDE individuals who we know to be enrolled in a qualifying employer group plan 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 a result, these individuals would not be part of the group that is subject to default auto-enrollment. In order to ensure that only individuals with creditable employer coverage would be

[2] 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/*.

included in this process, we would limit the applicability of this process to individuals enrolled in a plan for which CMS is paying an employer subsidy. Under our proposal, the individuals would be notified in advance by CMS of their prospective auto-enrollment, and of the need to carefully consider the possible repercussions of such an enrollment, including the impact that enrollment into Medicare Part D would have on their retiree coverage for themselves and other family members. We would recommend contacting the sponsor or administrator of the retiree group plan to discuss the effect of enrollment in Medicare Part D on the retiree coverage.

Individuals would further be informed that by taking no action, they will be deemed to have elected to decline enrollment into a Part D plan. We would further inform them that they could enroll in a Part D plan at any time in the future if they wish to do so, and that the enrollment could be made retroactive. Thus, absent a confirmation of the individual's desire to be auto-enrolled into a Part D plan, he or she would retain the employer group coverage.

In considering whether to adopt this approach, we recognized that to the extent that declining Part D could possibly have any negative consequences for FBDE individuals who are not auto-enrolled, CMS has the discretionary authority to make retroactive enrollment changes that can address such problems. In contrast, CMS has no authority to insist that a retiree plan sponsor allow individuals back into its plan should the retirees or their family members be adversely affected by auto enrollment. Given that 56 percent of employers surveyed have specifically stated that they would not allow re-enrollment into their retiree plans after an individual began Part D coverage, we believe that our proposed change in policy would clearly be in the best interests of the FBDE population with retiree coverage.

2. Part D Late Enrollment Penalty (§ 423.46)

Section 1860D–22(b) of the Act established a Part D late enrollment penalty (LEP) for beneficiaries who have a continuous period of 63 days or longer following the end of an individual's Part D initial enrollment period without creditable prescription drug coverage. This requirement is codified in § 423.46. Although § 423.46 describes which individuals would be 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 (Chapter 4 of the Medicare Prescription Drug Benefit Manual) and now propose to clarify the general responsibilities of Part D plans in our regulations.

First, we would 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 first query CMS systems for previous plan enrollment information, which is a standard part of the beneficiary enrollment process. When no previous enrollment information exists, 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 are proposing under § 423.46(b) is that plans must then report creditable coverage information in a manner specified by CMS. Specifically, that would entail reporting the number of uncovered months to CMS, which will then calculate the penalty and report the penalty back to the plan. The plan then notifies the beneficiary of the determination of the LEP amount and of their ability to request a reconsideration of this determination.

Thus, we would also establish under § 423.46(c) that, consistent with section 1860(D)–22(b)(6)(C) 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, or an independent review entity acting under CMS' authority, 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 is eligible for a waiver of the penalty under a demonstration project).

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

3. Medicare Prescription Drug Benefit Program Definitions

These proposed clarifications to our policies associated with the Medicare Prescription Drug Benefit (also known as Medicare Part D) include refining our definitions related to what may be included in the drug costs Part D sponsors use as the basis for calculating beneficiary cost sharing, reporting drug costs to CMS for the purposes of reinsurance reconciliation and risk sharing, as well as submitting bids to CMS. We also propose a new definition for administrative costs in order to further clarify costs that must not be included in Part D drug costs. We also propose to create corollary definitions for drug cost reporting for purposes of the Retiree Drug Subsidy (RDS). We propose that the effective date of these changes be the effective date of a final rule with the exception of specific changes to the Part D definition of ''negotiated prices'', ''gross covered prescription drug costs'', and ''allowable risk corridor costs'' related to the use of pass-through versus lock-in prices, which we propose to be effective for coverage year 2010. We propose that the effective date of the RDS definitions be the effective date of a final rule, that is, for all plan years beginning after the effective date of a final rule.

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

i. Incurred Costs

CMS is proposing 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 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). CMS allows 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. We are proposing to revise the definition of incurred costs to clearly indicate that these 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 has also been revised to ensure that these nominal PAP copayments are included in gross covered prescription drug costs and allowable reinsurance costs.

ii. Negotiated Prices

In the January 2005 final rule, CMS defined a number of terms related to drug prices and costs in order to identify the costs that should be used to calculate beneficiary cost sharing, to advance the beneficiary through the benefit, and to calculate final plan payments for reinsurance subsidies and risk sharing during payment reconciliation. For instance, under § 423.104(d)(2)(i), beneficiary cost sharing under the initial coverage limit is equal to 25 percent of ''actual cost.'' (70 FR 4535) ''Actual cost'' is defined in § 423.100 as ''the negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of-network pharmacy consistent with § 423.124(a).'' (70 FR 4533) And in § 423.100, the term ''negotiated prices'' is defined as ''prices for covered Part D drugs that (1) are available to beneficiaries at the point of sale at network pharmacies; (2) are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remunerations 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. (70 FR 4534)

Since that time, we have received questions over what we meant in this last definition when we refer to prices for covered Part D drugs that are available to beneficiaries at the point of sale. These questions are particularly important because beneficiary cost sharing is a function of the negotiated price, either directly as in coinsurance percentages of negotiated price, or indirectly, as copayments are ultimately tied to actuarial equivalence requirements based on negotiated prices. That is, for instance, the higher the negotiated prices, the higher the fixed copayments must be to result in actuarial equivalence to 25 percent in the aggregate in the initial coverage phase.

The ''total drug spend'' (the accumulated total prices for covered Part D drugs paid at the point of sale by the plan or by or on behalf of the beneficiary) also is a function of the negotiated price. Because the total drug spend is used to determine when the beneficiary advances through the deductible and the initial coverage phases of the Part D benefit, higher negotiated drug prices would cause the beneficiary to more quickly advance through those various phases. Accordingly, because higher negotiated prices would advance the beneficiary through the initial coverage phase more quickly, fewer prescriptions on average would be subsidized by the plan through the initial coverage period. Also, a beneficiary enrolled in basic prescription drug coverage (as defined in § 423.100) would reach the coverage gap more quickly, with the costs of covered Part D drugs purchased during the coverage gap phase financed entirely by the beneficiary. In addition, since beneficiaries must have access to the same negotiated prices during the coverage gap, the higher the negotiated prices, the higher the amounts paid by beneficiaries for drugs in the coverage gap may be. Similarly, higher negotiated prices would mean higher cost-sharing for beneficiaries who reach the catastrophic threshold. Because cost-sharing for the catastrophic phase of the benefit generally is based on 5 percent of the negotiated price, the higher the negotiated price, the higher the cost-sharing at the catastrophic level.

For all these same reasons, higher negotiated prices would mean higher low-income cost sharing subsidies paid by the government. Under the low-income cost sharing subsidy, low-income subsidy eligible individuals pay reduced or no cost sharing for covered Part D drugs. The government subsidizes the cost sharing for these beneficiaries by reimbursing Part D sponsors for the difference between the cost sharing paid by other Part D beneficiaries and the cost sharing paid by low-income subsidy (LIS) eligible individuals. Higher negotiated prices would result in higher cost sharing paid by other Part D beneficiaries and therefore, higher low-income cost sharing subsidies paid by the government to plan sponsors.

Because higher negotiated prices (and therefore, higher total drug spend) will advance beneficiaries through the phases of the Part D benefit more quickly, a greater number of beneficiaries will reach the catastrophic phase of the benefit more quickly. In addition, higher negotiated prices generally will result in higher covered Part D drug costs during the catastrophic phase. As a result, the reinsurance subsidies paid by the government to Part D sponsors to reimburse 80 percent of the covered Part D drug costs in the catastrophic phase of the benefit will be higher.

We believe that, in a competitive market, negotiated prices would be minimized when such prices are fully transparent to plan sponsors and beneficiaries. Consequently we strove to base our guidance on the principle of limiting drug costs to the price paid at the pharmacy (meaning any pharmacy, including mail-order pharmacies). In the preamble to the final rule we explained that drug costs include: Ingredient cost, dispensing fee, and sales tax (70 FR 4307). These three terms refer to specific fields on the automated prescription drug claim transaction that unambiguously indicate the amounts paid to the pharmacy by the payer of the claim. Therefore, by using these terms, CMS intended to refer to the price paid at the pharmacy and not the price paid by the sponsor to the PBM. Furthermore, the preamble states that ''we assume that ingredient cost and dispensing fee reflect point of sale price concessions in accordance with purchase contracts between plans (or their agents, such as PBMs) and pharmacies * * *'' (70 FR 4307), and that ingredient cost and dispensing fee reflect the drug price paid to the pharmacy and should reflect any point-of-sale price concessions from the pharmacy whether they are provided directly to the Part D sponsor or indirectly through a contracted PBM. Thus, we intended to define the term ''negotiated prices'' consistent with ''pass-through'' prices, an industry term for the prices negotiated with and paid to the pharmacy (either directly by the sponsor or indirectly through an

intermediary contracting organization, such as a PBM on the sponsor's behalf). With ''pass-through'' prices, the price paid to the pharmacy is the price passed on to the beneficiary (and, in the case of LIS eligible individuals, to the government) at the point of sale.

However, after publication of the final rule and issuance of clarifying subregulatory guidance in Spring 2006, CMS received comments that the notice and comment rulemaking had not made this point clearly, and that the regulation could be read to allow an alternative interpretation of the price paid at the point of sale. Specifically, these comments asserted that the ''lock-in'' pricing approach, a contract method by which a plan sponsor agrees to pay a PBM a set rate for a particular drug which may vary from the price that the PBM negotiates with each pharmacy, also met the definition of negotiated prices issued in the regulation.

Under such pricing arrangements, the PBM consistently bills one ''lock-in'' price negotiated with the sponsor for a drug (often based on AWP), but may pay a variety of different prices to network pharmacies based on varying contractual terms. On any given drug purchase, the PBM may pay the pharmacy a higher or lower price than it will bill the plan sponsor. However, we assume that the prices billed to the plan sponsor are generally higher than the prices paid to pharmacies, resulting in an overall net profit to the PBM that is marketed as a ''risk premium'' earned for shielding the sponsor from price variability. We welcome comments on this assumption. Commenters argued that these stable prices negotiated between the sponsor and the PBM also met the definition of ''negotiated prices'' in the final rule. (We note that when the negotiated price under the plan is the lock-in price, if the pharmacy price is lower than the lock-in price, the pharmacy will still have to collect the higher lock-in price from the beneficiary during the deductible or coverage gap and transfer the excess amount to the PBM in some manner.) On the basis of that alternative interpretation, some Part D sponsor applicants who held network contracts through PBMs based on the lock-in pricing methodology had based their 2006 and 2007 bids on such prices and could not renegotiate such contracts easily.

Consequently, on July 20, 2006, we issued guidance to Part D sponsors stating that, in order to minimize disruption to plan operations, for 2006 and 2007, sponsors could, at their option, base beneficiary cost-sharing not on the price ultimately charged by the pharmacy for the drug, but on the ''lock-in'' price, the price the sponsor paid a pharmacy benefit manager (PBM) or other intermediary for the drug. We also stated our intent to issue a proposed rule that would require a single approach for calculating beneficiary cost sharing, based upon the price ultimately received by the pharmacy.

Therefore, we are now proposing to amend our definition of negotiated prices. We previously proposed to amend this definition in the notice of proposed rule making, Policy and Technical Changes to the Medicare Prescription Drug Benefit (72 FR 29403–29423). However, we chose not to finalize this proposed definition in the final rule (73 FR 20486–20509) in order to further examine the impact of this proposal and provide the public with an additional opportunity to comment on this proposed definition. We have noted below, some of the impact concerns for which we would like to receive additional comments. We will consider the comments received on this definition from the previous proposed rule, as well as comments received on this proposed rule when determining whether to finalize this policy.

In order to resolve the confusion caused by the Prescription Drug Benefit final rule, we are now proposing 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 on the price ultimately received by the pharmacy or other dispensing provider. Specifically, we are proposing 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 pharmacy benefit managers (PBMs) that contract with plan sponsors to provide one or more of a variety of administrative functions on the sponsor's behalf, such as negotiating pharmacy contracts, negotiating rebates and other price concessions from manufacturers, and/or providing drug utilization management or benefit adjudication services. The term ''intermediary contracting organization'' encompasses any entity that contracts with a plan sponsor to pay pharmacies and other dispensers for 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. Similarly, the term ''intermediary contracting organization'' encompasses any entity that negotiates 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 the rebate agreements explicitly on behalf of the plan sponsor or on its own behalf. Our proposed definition excludes any differential between the price paid to the pharmacy and the price paid to the PBM or other intermediary contracting organization, and instead treats that differential (or ''risk premium'') as an administrative cost paid to the PBM or intermediary contracting organization rather than a drug cost under Part D. We elaborate on our reasons for in effect proposing to require the reporting of ''pass-through'' versus ''lock-in'' prices for Part D drug costs further below, as well as solicit specific comments from multiple stakeholders to ensure we are aware of all of the ramifications of this proposed policy.

We would also revise the definition of ''negotiated prices'' (to be effective upon the effective date of a 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, including them in their network. Therefore, we are amending 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 their network dispensing providers.

There are a number of reasons for our decided preference for drug costs at the point of sale to be based on the amount actually paid to the pharmacy or other dispensing provider (hereafter referred to as pass-through prices) as opposed to the amount paid to the PBM (hereafter referred to as lock-in prices). In addition to our original intentions discussed above, we believe that continuing to allow lock-in prices to be used for Part D drug cost calculations and reporting could have several undesirable results:

1. Continued and probably increased cost shifting from the government to beneficiaries in the form of higher beneficiary out-of-pocket costs.

2. Interference with market competition among Part D sponsors.

3. Beneficiary confusion over actual drug prices.

4. Difficulties for pharmacies in explaining drug prices to customers and managing cash transfers to Part D sponsors or their intermediary contracting organizations contracting.

5. Continued and possibly increased risk of government risk-sharing on amounts that reflect administrative costs, contrary to Congressional intent to exclude risk-sharing on administrative expenses.

First, relative to pass-through prices, lock-in prices result in a cost shift from costs that would otherwise be fully paid by the government in the administrative cost portion of the basic Part D bid to costs that are paid in full or in part by the beneficiary. When the differential between the price paid to the pharmacy and the price paid to the PBM (sometimes referred to as ''PBM spread'' or ''risk premium'') is treated as a drug cost, this amount is part of the cost basis on which beneficiary cost sharing is calculated. This is true whether the beneficiary is paying the total cost of the drug in the deductible or coverage gap in a basic plan, or whether cost sharing is structured as coinsurance or fixed copayments. Again, cost sharing for the basic portion of a Part D plan is based on the negotiated prices either directly, as a coinsurance percentage of the price of the drug, or indirectly, as a fixed copayment derived to result in actuarial equivalence in the aggregate to 25 percent of drug prices in the initial coverage phase or to approximately 5 percent in the catastrophic phase. Thus, when the PBM spread is added to the pharmacy's price in computing cost sharing, a beneficiary who utilizes drugs will generally pay more in cost sharing both during covered benefit intervals and during deductible and coverage gap periods for their drugs when the negotiated price is based on lock-in prices rather than pass-through prices, resulting in higher out-of-pocket beneficiary costs.

On the other hand, when the PBM spread is included in the administrative costs component of a Part D sponsor's bid, as opposed to being treated as a drug cost, the plan sponsor's bid would be increased by these amounts. Consequently, all other things being equal, the sponsor's bid must be higher with pass-through prices than with lock-in prices. While a higher bid increases premiums for the beneficiary and direct subsidy costs for the government, because of the formulas for calculating premiums and federal subsidies, the beneficiary only pays about 25 percent of this increase and the government pays the other approximately 75 percent.

Under the pass-through approach, therefore, for the vast majority of beneficiaries who utilize Part D drugs, total out-of-pocket costs, including both monthly Part D premiums and cost-sharing, are lower because (1) cost sharing per script is lower, (2) the lower drug costs advance the beneficiary through the benefit more slowly—allowing in general more scripts to be subsidized in the initial coverage phase, and (3) increased premium costs are principally borne by the government. On net, beneficiaries who utilize their drug benefits pay less under our proposed approach with negotiated prices based on pass-through prices because out-of-pocket costs are 100% borne by the beneficiary, but the beneficiary only pays about 25% of the premium.

We believe that the beneficiary is almost always better off paying the lowest possible point-of-sale price. Under the lock-in pricing approach, the lock-in prices that some plan sponsors pay to their PBMs are uniform for each drug across multiple network pharmacies. However, the pass-through prices paid to the pharmacy may differ across network pharmacies. Some plan sponsors may perceive value in the use of lock-in prices to define negotiated prices, so that beneficiaries may pay a uniform price across different network pharmacies. However, we believe that beneficiaries receive no value from paying more for drugs in return for always paying a uniform stable price. Therefore, we believe that beneficiaries who utilize their Part D benefits are almost always better off paying pass-through prices under our proposed approach.

We would acknowledge that lower premiums at the expense of higher out-of-pocket costs would advantage some Part D beneficiaries who are non- or very low utilizers of the benefit. However, from a public policy perspective, lowering premiums at the expense of higher cost sharing for those individuals who most need the benefit dilutes the insurance principle. The drug purchases of those beneficiaries who utilize their Part D benefits are subsidized in part by those who do not need the benefit. Shifting costs from premiums to cost sharing would reduce the sharing of risk and drug costs across beneficiaries by shifting a greater percentage of the drug costs to those beneficiaries who use more prescription drugs and, therefore, pay more cost sharing. Those beneficiaries who use fewer prescription drugs are more likely to enroll in those plans with lower premiums and higher cost sharing (for example, plans that utilize lock-in prices). Less healthy beneficiaries who use more prescription drugs are more likely to enroll in those plans with higher premiums and lower cost sharing (for example, plans that use pass-through prices). This would distort the risk pool for those plans using pass-through prices and drive their costs up as those enrollees who use fewer prescription drugs disenroll from these plans as the premiums increase to reflect the increased percentage of high utilizers in the plan. It is important to create and maintain the most robust risk pool possible under the Medicare Part D to maintain program stability.

In addition, as noted in the preamble to the final rule: ''[a]s required under section 1860D–11(e)(2)(D)(i) of the Act and in § 423.272(b)(2), the structure of the benefit design (including cost sharing provisions and formulary design) must not be discriminatory; that is, it must not discourage enrollment by any Part D enrollee on the basis of health status * * *''. (70 FR 4297) We could argue that a business model and resulting benefit structure that by design shifts costs from the premium (where they would be paid by all) to cost sharing (where they are paid only by benefit utilizers) is per se discriminatory. That is, knowledgeable beneficiaries who seek to minimize their costs, who must utilize numerous prescription drugs due to their health status, and who use a tool such as the Medicare Prescription Drug Plan Finder, will determine that their costs are never minimized in a plan that bases their costs on lock-in prices—despite the lower premiums—and they will elect not to join that plan. Only non- or low utilizers of drug benefits might find that this plan design minimizes their costs. We believe that Congress instructed CMS to review Part D benefits in order to prohibit just this sort of systematically discriminatory benefit design.

All other things being equal then, requiring that those amounts paid by sponsors to PBMs (or other intermediary contracting organizations) that exceed the amounts paid by PBMs (or other intermediary contracting organizations) to pharmacies be treated as administrative costs will increase the basic Part D bid for any plan sponsor that previously based its bid on lock-in prices, shifting the majority of the cost to the direct subsidy paid by the government. This increase in direct subsidy costs will be offset somewhat by other payment impacts on the government. Specifically, reinsurance payments will be lower because (1) reinsurance payments are based on drug costs which generally are lower using

pass-through prices, and (2) fewer beneficiaries will reach catastrophic coverage due to being advanced through the earlier phases of the benefit more slowly. Similarly, the government's payments for low-income subsidy cost sharing are lower, as these subsidies are based on the negotiated price, which as previously explained is generally lower when based on pass-through prices. Thus, overall, a change from lock-in to pass-through prices will result in a cost shift from the beneficiaries who need the benefit most to the government—a result that, as we have argued above, is more consistent with the insurance principle.

The second potential undesirable impact of lock-in prices being used for drug cost calculations and reporting under the Part D program is interference with market competition. Because the cost shift from the government to the beneficiary lowers the bid, it also causes the plan's bid to become relatively more competitive. In fact, utilizing lock-in prices would seem to provide a competitive advantage to plans relative to other comparable plans that use pass-through prices, since premium levels are tied to the relationship between the plan's bid and the national average bid amount. The lower the plan's bid, the lower the difference between the plan's bid and the national average bid amount, and therefore, the lower the plan's premium. Unlike sponsors who do not use PBMs or other intermediary contracting organizations and, therefore, must base their bids on pass-through prices, those using PBMs or other intermediary contracting organizations currently have the option of using either pass-through or lock-in prices as the basis for their bids. This greater flexibility may give the latter a competitive advantage over the former. For example, to the extent a sponsor believes a lower premium rather than lower cost-sharing makes its plan more marketable, a sponsor contracting with a PBM may decide to use lock-in prices in its bid in order to obtain a lower premium. In addition, a sponsor may use lock-in prices in its bid to increase the likelihood that its plan qualifies for auto-enrollment and facilitated enrollment of LIS eligible individuals. To qualify for auto-enrollment and facilitated enrollment, a plan's premium must be at or below the low-income premium subsidy amount. A sponsor that is trying to gain or retain enrollment of LIS eligible individuals may use lock-in prices to help ensure that its plan premium is below the low-income premium subsidy amount. Thus, CMS believes that allowing both pricing approaches creates an unlevel playing field among plan sponsors. We specifically solicit comments on the economic and public policy impacts of this differential and whether it does in fact create an undesirable unlevel playing field, as between Part D sponsors contracting with PBMs or other intermediary contracting organizations and those who do not. We also solicit comments on each of the potential undesirable results discussed above.

In the discussion above we assumed that all other things were equal, and that the shift from one pricing methodology to the other only resulted in a shift in costs between the government and the beneficiary. That is, that overall program costs remained the same under either policy. However, arguments can be made that costs, both administrative as well as drug costs, would not remain the same under our proposed single approach.

On the one hand, some proponents of the lock-in approach have expressed concerns that our proposal would increase drug costs over time by discouraging the risk premium inherent in the lock-in method. They assert that the resultant pressure for downward pricing from the Part D sponsor would create a disincentive for PBMs to enter into this type of payment arrangement with plan sponsors. They are concerned that the demise of the lock-in model would result in the PBMs' role being reduced to one of mere claims processing agents with less incentive to negotiate the lowest possible network pharmacy discounts. In contrast, they contend that the risk premium incentives inherent in the lock-in approach result in significantly lower drug costs for Part D sponsors than other contractual models, and that the loss of this model could potentially increase drug costs, bids, premiums, and Part D program costs.

On the other hand, however, in response to the contention that the risk premium payment results in lower drug prices in the long run, we could argue that in a competitive market any potential increase in administrative fees (from transferring the spread to administrative costs) would be negotiated away in whole or in part with more perfect information in a fully transparent environment. For instance, our proposed changes do not prohibit Part D sponsors from contracting with PBMs for drug utilization management services and paying administrative incentive fees for reducing costs through such services. In a transparent environment, plans would be negotiating on lowest possible drug prices, as well as minimizing administrative costs, and these would be more clearly comparable among PBMs (or other intermediaries). It is not clear to us why PBMs would compete any less vigorously for the same level of profits included in administrative fees, or for the lowest possible network pharmacy negotiated prices in order to earn those fees. Therefore, we are more persuaded by the counterargument that the PBM spread is in fact an additional profit earned due to asymmetry in market information that might well be reduced with more transparency in pricing. Under these assumptions, leaving the additional costs in administrative costs would reduce bids, premiums, and total Part D program costs over time.

Moreover, nothing in our proposed rule prohibits the payment of a risk premium to the PBM by the plan sponsor. Our proposed changes to the definition of negotiated prices do not interfere with the negotiations between Part D sponsors, pharmacy benefit managers, and pharmacies for covered Part D drugs. Rather, we propose that 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. We do not require a Part D sponsor to use a particular pricing approach in its contracting agreements with PBMs. Part D sponsors may 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 us are based on the price ultimately received by the pharmacy. To the extent that Part D sponsors believe that the lock-in pricing contracting approach reduces their total costs, we expect that they will continue to use it when contracting with a PBM. We solicit comments on whether Part D sponsors and PBMs would use the lock-in pricing contracting approach in certain cases if the proposed policy were finalized.

We solicit comments from plan sponsors, other industry contracting experts, benefit consultants, and market analysts on the impact of our proposed change on aggregate pricing exhibited between plans and PBMs, as well as on the prevalence of and trends in lock-in pricing arrangements between plan sponsors and PBMs. In particular, we are soliciting comments on whether lock-in pricing truly offers benefits to sponsors equal to the value of the risk premium, or whether the existence of the risk premium is in effect a higher

price exacted from sponsors without the leverage to negotiate lower costs or due to asymmetry in market information as between PBMs and sponsors. We also solicit comments on whether stakeholders consider the proposed definition of ''negotiated prices'' to represent strictly a change in reporting requirements for Part D plan sponsors. We solicit comments on how contractual relationships and requirements may change between and among Part D plan sponsors and their first-tier, downstream, and related entities.

Our third concern with lock-in pricing involves the confusion that may be caused for beneficiaries whenever they see the difference between the price paid to the pharmacy and the price charged to the plan sponsor. While we understand that the intent is for the beneficiary to see the same information on drug prices on the pharmacy's receipt, on the Medicare Prescription Drug Plan Finder, and on the plan's Explanation of Benefits (EOB), this does not always happen. Under lock-in pricing, the EOB which the beneficiary receives from the plan may currently reflect the price the plan sponsor pays its PBM (the lock-in price) instead of the price negotiated with the pharmacy. We understand that pharmacies generally do not customize receipts for payers, and those that print total amounts paid on their receipts will not always be able to alter those amounts to correspond to the prices the plan sponsor pays its PBM. Even for cases in which the pharmacy does not print out total amounts received on its receipt, the same issues may occur in the deductible or coverage gap when the patient pay amount may equal the lock-in price, which could be higher than the price paid to the pharmacy. Whenever the pharmacy receipt does display the pharmacy's price, the beneficiary may see the discrepancy in price between the receipt and the plan's EOB. Even when receipts display the plan's price, the beneficiary may see discrepancies between the price they pay and pharmacy advertised specials or prices offered to a friend and believe the price they paid was wrong. Beneficiaries may perceive these discrepancies in drug prices as fraud and place complaints or inquiries. Reviewing and addressing these types of inquiries serves to increase administrative costs for pharmacies, plan sponsors, and the government. Moreover, if pharmacies were to err and charge pass-through prices during the coverage gap instead of the lock-in prices, actual beneficiary true out-of-pocket (TrOOP) expenses might diverge from the amounts reported on the plan's EOB, possibly leading to an overstatement of TrOOP costs in plan (PBM) claims payment systems. We solicit comments, particularly from beneficiary advocates, on the extent to which they are hearing of beneficiary concerns around such discrepancies.

The fourth potential undesirable impact concerns difficulties that may be caused for pharmacies in explaining apparent price discrepancies to customers, as well as the additional administrative burden of managing the resulting cash transfers between the beneficiary and the PBM. If a beneficiary notices an apparent price discrepancy as described above, the beneficiary is likely to ask the pharmacy for an explanation. We believe the pharmacy must then expend scarce staff resources on explaining the discrepancy and managing the beneficiary's reaction. Moreover, whenever the additional amount that exceeds the price negotiated between the PBM and pharmacy has been collected from the beneficiary, the pharmacy must have in place and manage accounting processes to transfer the additional amounts to the PBM and support ongoing reconciliations. We solicit comments from both chain and independent pharmacies on the extent to which these or any other impacts from lock-in prices have been incurred.

We are not aware of any advantages to pharmacies from lock-in prices. We have heard the argument that the proposed changes would have a disproportionately negative impact on small independent pharmacies. Under the lock-in pricing approach, Part D sponsors negotiate a single rate with their contracted PBMs and, therefore, are generally not aware of the different rates paid by the PBMs to each pharmacy. This argument suggests that under the revised definition of negotiated prices, Part D sponsors would be made aware of the different rates paid to each pharmacy, and, in particular, Part D sponsors would become aware of higher-cost pharmacy providers, which are generally small independent pharmacies that are unable to offer the more aggressive drug prices provided by retail chain pharmacies. This argument presupposes that in their efforts to reduce drug costs, Part D sponsors would then remove these higher-cost pharmacies from their pharmacy networks, leading to a significant impact on the financial viability of these pharmacies.

We are not persuaded by this argument at this time. First, as discussed above, we believe that under the revised definition of negotiated prices Part D sponsors may still use either the pass-through or lock-in pricing approach in their contracts with PBMs if sponsors continue to place value on being shielded from price variations. Moreover, even under transparent pricing arrangements, we expect that Part D sponsors would continue to contract with small independent pharmacies in order to satisfy our pharmacy access standards as outlined in § 423.120. In order to meet these rigorous pharmacy access standards, Part D sponsors would have to continue to contract with many if not most of these independent pharmacies and include them in their pharmacy networks. Moreover, we expect that Part D sponsors likely will determine that the proportion of their utilization that comes through independent pharmacies with the leverage to negotiate significantly higher reimbursements is generally not sufficiently large to significantly affect aggregate drug costs. Therefore, we are unable to conclude at this time that these proposed changes would have any adverse effects on pharmacies, including small independent pharmacies, and we solicit comments from all pharmacies on this question.

The final potential undesirable impact we attribute to lock-in prices is the continued, and possibly increased, risk of government risk-sharing on costs that may be better treated as administrative expenses. The payment of risk-sharing on those portions of ''drug costs'' under the lock-in methodology that are retained by the PBM or other intermediary appears contrary to Congressional intent. For both reinsurance and risk-sharing payments CMS is required to exclude ''administrative costs'' from the calculations. In accordance with § 1860D–15(b)(2) of the statute, and as codified at § 423.308, ''allowable reinsurance costs'' are defined as a subset of ''gross covered prescription drug costs.'' ''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 * * *'' (§ 1860D–15(b)(3)). Similarly, definitions of ''allowable risk corridor costs'', at § 1860D–15(e)(1)(B) of the statute and § 423.308 of the regulations, exclude administrative costs. We believe that any ''risk premium'' paid to the PBM to smooth actual drug expenses should be considered an administrative contracting cost, or like a drug utilization management program cost to

the plan. Thus, in order to exclude those amounts from being included in the reinsurance and risk-sharing calculations, we believe CMS should treat these costs as administrative costs and not as drug costs.

While there is no question that reinsurance costs to the government increase with lock-in prices (since per claim drug costs are higher and a greater number of beneficiaries will reach catastrophic coverage), it is possible that there would be no significant difference between the lock-in and pass-through prices with respect to government risk sharing *under certain constraints*. Very simply stated, risk sharing involves comparing the sum of drug costs anticipated in the plan sponsor's bid and paid prospectively through government and beneficiary monthly premiums (the ''target amount'') to the drug costs actually incurred, with the government then paying or recouping a portion of the difference. As long as the drug costs reflected in the bid are calculated in precisely the same way as the drug costs submitted to CMS as allowable costs, the target amount and the allowable costs will rise together. However, if a plan were to submit bids based on one level of PBM spread, but then submit costs to CMS reflecting a higher level of spread, then the difference between prospective costs and incurred costs would be increased. In the long run we believe lack of transparency could allow plans to game risk sharing and include extra administrative costs in the allowable drug cost reporting. If this would happen, and the plans used lower drug costs in the bid but included additional administrative costs in the allowable costs submitted in reconciliation, then the government risk sharing costs would increase. We solicit comments on the issues identified above concerning government risk sharing on costs that may more appropriately be considered administrative expenses.

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

i. Actually Paid (§ 423.308)

In the April 2006 Call Letter, CMS stated that Part D sponsors must report 100 percent of the rebates and price concessions they receive, including the portion of manufacturer rebates retained by PBMs. In other words, in defining price concessions that must be netted from drug costs, CMS does not make a distinction between a price concession that is passed fully through to the plan sponsor by the PBM (or any other intermediary contracting organization) and a price concession that is partially passed on and partially retained by the PBM (or any other intermediary contracting organization). When a PBM retains rebate amounts associated with drugs being purchased for enrollees in a Part D plan with which the PBM contracts, this revenue permits the PBM to charge the Part D sponsor a lower amount in administrative fees and still make the same income on the transaction. When a rebate of x amount is paid to the PBM, the Part D sponsor benefits from that rebate whether it is passed on to the sponsor in its entirety, or it is available as revenue to the PBM.

Thus, regardless of whether the PBM passes through 100% of rebates and the Part D sponsor in turn writes a check for 100% of administrative fees owed the PBM, or whether the PBM retains a portion of rebates and the Part D sponsor benefits from the fact that this revenue permits the PBM to charge a lower administrative fee for the transaction—the result is the same. The total amount of rebates received by the PBM for the Part D drugs dispensed under the Part D sponsor's contract must be reported as a price concession through DIR reporting to CMS. If we did not adopt this approach, a PBM and a Part D sponsor would be able to manipulate the amount reported in amounts actually paid simply by recasting administrative fees, which must be excluded, as rebates retained by the PBM that would not have to be reported as rebates to the PDP sponsor that benefits from the PBM's receipt of this revenue.

Therefore, we are proposing to include language in the definition of ''actually paid'' that codifies and clarifies our previous guidance, and provides 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 the entire direct and indirect remuneration to the Part D sponsor. Similarly, we are clarifying that this definition of actually paid applies regardless of the terms of the contract between the plan sponsor and any intermediary contracting organization. We solicit comment on this proposed clarification.

We believe that the above analysis has equal applicability in the Retiree Drug Subsidy (RDS) context, when a qualified retiree prescription drug plan contracts with a PBM, and the PBM retains rebate amounts associated with drugs obtained for a qualifying covered retiree. Again, the qualified retiree prescription drug plan benefits from the fact that revenue attributable to drugs purchased for its retirees is available to the PBM, because the PBM would not need to charge the sponsor of the qualified retiree prescription drug plan as much in administrative fees to make the same revenue on the transaction. As in the case of a Part D sponsor, if rebate amounts retained by a PBM were not deducted from the qualified retiree prescription drug plan's costs, the plan and the PBM could ensure higher RDS payments simply by recasting administrative costs as retained rebates. Therefore, as discussed below, we are proposing to make similar amendments to the definitions in Subpart R that apply to the RDS program.

ii. Administrative Costs (§ 423.308)

The statute requires CMS to exclude administrative costs from the calculation of gross covered prescription drug costs and allowable risk corridor costs. However, administrative costs are not defined in either the statute or the January 28, 2005 final rule. Therefore, to explain this term and clarify which costs are included in administrative costs, we are proposing to add a definition for the term ''administrative costs''. We previously proposed to add this definition in the notice of proposed rule making, Policy and Technical Changes to the Medicare Prescription Drug Benefit (72 FR 29403 through 29423). However, we chose not to finalize this proposed definition in order to further examine the impact of this proposal and provide the public with an additional opportunity to comment on this proposed definition. We will consider the comments received on this definition from the previous proposed rule, as well as comments received on this proposed rule when finalizing this rule.

In this definition, we propose to define ''administrative costs'' as the Part D sponsor's costs other than those incurred to purchase or reimburse the purchase of Part D drugs under the Part D plan. Included in the definition of administrative costs are 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. As discussed above in the section

on Negotiated Prices, any net profit (or ''risk premium'') retained by a PBM that is added to the prices paid to pharmacies and billed to a Part D sponsor would be considered an administrative cost and not a drug cost. As discussed above, we believe this is because such amounts are more appropriately considered costs the plan chooses to incur to mitigate its market risk around the costs of drugs, rather than the cost of the drugs itself, and should be viewed as analogous to the cost of drug utilization management programs and similar services purchased from PBMs to manage drug costs. In order to create a level playing field around the treatment of all such related costs, we propose to clearly categorize this ''net profit'', ''risk premium'', or ''PBM spread'' as an administrative cost to the Part D plan sponsor.

The proposed policy would also refine our interpretation of the statutory and regulatory definitions of ''allowable reinsurance costs'' and ''allowable risk corridor costs,'' which in both cases exclude any administrative costs of the sponsor. By statute, ''allowable reinsurance costs'' are a subset of ''gross covered prescription drug costs,'' and Congress specifically defined these gross costs as ''not including administrative costs.'' (See sections 1860D–15(b)(2) and 1860D–15(b)(3) of the Act.) Similarly, Congress defined ''allowable risk corridor costs'' as ''not including administrative costs.'' (See section 1860D–15(e)(1)(B) of the Act.) In the January 28, 2005 final rule, we adopted these definitions. (70 FR 4547.) As noted above, we interpret administrative costs to include any net profit (or loss) incurred by an intermediary contracting organization (for example, a pharmacy benefit manager (PBM)) as a result of lock-in pricing. Therefore, this net profit or loss must not be included in the reinsurance and risk corridor payments made by the government, as these payments exclude administrative fees. Thus, the Ingredient Cost, Dispensing Fee, Sales Tax, Gross Drug Cost below the Out of Pocket Threshold, and Gross Drug Cost above the Out of Pocket Threshold fields on Prescription Drug Event (PDE) records submitted to CMS would need to reflect the final amount ultimately received by the pharmacy at the point of sale.

We are aware of concerns that the proposed definition of administrative costs would indirectly prohibit the purchase of drugs from certain entities such as PBMs. In addition, it has been argued that any costs incurred to buy drugs should be considered drug costs regardless of the party from whom the drug is purchased. However, the proposed definition for administrative costs would not directly or indirectly require Part D sponsors to purchase drugs from dispensing providers only. Part D sponsors would continue to have the option to contract or purchase drugs from other entities such as PBMs. However, to the extent that the amounts paid to a PBM for administrative services provided to a Part D sponsor are included in the cost of the drug under the lock-in pricing approach, Part D sponsors would be required to report this spread amount as an administrative cost. These administrative costs would be excluded from the Part D sponsor's allowable reinsurance and allowable risk corridor costs as required by statute.

The proposed definition of administrative cost does not include administrative fees or other remuneration that a PBM receives on behalf of a plan from pharmaceutical manufacturers or biotechnology companies. CMS considers these amounts price concessions which directly or indirectly reduce the Part D sponsor's costs under its Part D plan. Therefore, Part D sponsors would continue to report these administrative fees as DIR to ensure that they are excluded from allowable reinsurance costs and allowable risk corridor costs.

Again, this same analysis applies in the RDS context to amounts a PBM retains in connection with price concessions that reduce the qualified retiree prescription drug plan's drug costs.

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

Part D sponsors are required to report drug costs to CMS for the purposes of reconciliation and risk sharing. We are required by statute to calculate reinsurance payments using ''allowable reinsurance costs,'' a subset of ''gross covered prescription drug costs,'' which Congress specifically defined as ''not including administrative costs.'' (See sections 1860D–15(b)(2) and 1860D–15(b)(3)of the Act). Risk sharing payments are calculated using ''allowable risk corridor costs,'' which are also defined as ''not including administrative costs.'' (See section 1860D–15(e)(1)(B) of the Act.)

There have been several questions regarding the appropriate drug costs to report, particularly when a Part D sponsor has contracted with a PBM. The January 28, 2005 final rule defines ''gross covered prescription drug costs'' as ''those actually paid costs incurred under a Part D plan, excluding administrative costs * * * [equal to:] (1) All reimbursement paid by a Part D sponsor to a pharmacy (or other intermediary) * * * plus (2) 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 drugs covered under the Part D plan.'' (70 FR 4547)

The January 28, 2005 final rule definition of ''gross covered prescription drug costs'' specifically recognizes that reimbursement may be paid by a Part D sponsor ''to a pharmacy (or other intermediary).'' (70 FR 4547) Many interpreted the term ''intermediary'' to mean PBM (rather than an agent of the pharmacy or other dispensing provider). Using this definition, many plan sponsors reported as gross covered prescription drug costs the prices they negotiated with their PBMs, rather than the prices that were agreed upon as the amount to be received by the pharmacies.

We propose rectifying these conflicting definitions to require the plan sponsor to include the net profit or loss retained or incurred by a PBM as part of lock-in pricing to be part of the administrative costs of the plan sponsor. This would require the amount ultimately received by the pharmacy (minus any other point-of-sale price concessions) to be used in calculating cost sharing for plan years 2010 and beyond. We previously proposed to amend this definition in the notice of proposed rule making, Policy and Technical Changes to the Medicare Prescription Drug Benefit (72 FR 29403–29423). However, we chose not to finalize this proposed definition in the final rule (73 FR 20486–20509) in order to further examine the impact of this proposal and provide the public with an additional opportunity to comment on this proposed definition. We will consider the comments received on this definition from the previous proposed rule, as well as comments received on this proposed rule when determining whether to finalize this policy. Specifically, we are proposing to amend the definition of ''gross covered prescription drug costs'' to eliminate the parenthetical ''or other intermediary'' to require that all plan sponsors report the amount ultimately received by the pharmacy or other dispensing provider. We propose that the amount ultimately received by the pharmacy or other dispensing provider (whether directly or indirectly) for the particular drug will be the basis for accumulating gross covered drug costs and reporting drug costs on the Prescription Drug Event (PDE) records.

Similarly, we propose clarifying our definition of ''allowable risk corridor costs'' so that it is clear that these costs are only based upon the amounts received directly by the pharmacy or other dispensing provider. This is because we would consider any net profit (or loss) earned by a PBM or other entity negotiating contracts with pharmacies to constitute an administrative cost, and therefore, to be exempt from the definition of allowable risk corridor costs, as well as gross covered prescription drug costs. Thus, for example, if a Part D sponsor pays a PBM a certain amount for a particular drug, and then the PBM negotiates a different price with the pharmacy, any differential retained or lost by the PBM would be considered an administrative cost, and could not be reported as part of drug costs. As discussed above in the section on Negotiated Prices, the net profit or loss (or ''risk premium'') retained by a PBM that is added to the prices paid to pharmacies and billed to a Part D sponsor under the lock-in pricing approach would be considered an administrative cost. As argued above, such amounts are more appropriately considered costs that the plan chooses to incur to mitigate its market risk around the costs of drugs, rather than the cost of the drugs itself, and should be viewed as analogous to the cost of drug utilization management programs and similar services purchased from PBMs to manage drug costs. In order to create a level playing field around the treatment of all such related costs, we propose to clearly categorize this ''profit'', ''risk premium'', or ''PBM spread'' as an administrative cost to the Part D plan sponsor and to explicitly disallow it from gross covered prescription drug costs, allowable reinsurance costs (a subset of gross covered prescription drug costs), and allowable risk corridor costs.

We, therefore, propose 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 intermediary contracting organization) is the basis for drug cost that must be reported to CMS, and not the amount paid by the Part D sponsor to the PBM. Accordingly, we are revising § 423.308 to incorporate these changes.

We are aware of concerns that these proposed changes to the definitions of gross covered drug costs and allowable risk corridor costs may require Part D sponsors to depend heavily on information traditionally held exclusively by PBMs. For the sponsor's convenience, or for other reasons, such as to protect the privacy of beneficiary personal health information data, a Part D sponsor's contractor may submit drug cost data on the Part D sponsor's behalf to CMS directly rather than through the Part D sponsor. Therefore, some have argued, the Part D sponsor cannot attest to the validity of drug cost data it does not see. However, because we contract with Part D sponsors for the provision of the Medicare prescription drug benefit, Part D sponsors, and not their subcontractors, are ultimately responsible for the quality of data submitted to us. Part D sponsors that choose to contract with a PBM or any other third party administrator, therefore, must take reasonable steps to ensure that the data submitted to us on their behalf is accurate and timely. For example, the sponsor may engage an independent auditor to audit the data prior to its submission to us.

We also propose amending the definition of ''gross covered prescription drug costs'' and ''allowable risk corridor costs'' to ensure that when entities other than pharmacies dispense Part D drugs and receive payment for Part D drugs, these expenditures also are reflected in gross covered prescription drug costs and allowable reinsurance costs, as well as allowable risk corridor costs. For instance, reimbursement for a vaccine that must be administered in a physician's office and reimbursement made to a third party payer in accordance with our coordination of benefits (COB) requirements are both legitimate drug costs that have been incurred through the payments indicated. In addition, in accordance with § 423.464, the Part D sponsor must coordinate benefits with other Part D plans as the result of any reconciliation process developed by CMS under § 423.464, such as when another Part D plan mistakenly paid for a prescription drug on the beneficiary's behalf based on an erroneous belief that the beneficiary was actually enrolled in its plan. In these cases, when the enrollment error is corrected, the beneficiary's true plan generally will reconcile payments with the original payer. The drug costs paid by Part D plans (as well as by the beneficiary) under these reconciliation processes reflect drug costs incurred by the plan's enrollees that a payer other than the correct Part D plan of record paid as primary. As drug costs paid for Part D covered drugs under Part D plans, these costs are included in the calculations of reinsurance costs and risk corridor costs. Therefore, we have amended the definition of ''gross covered prescription drug costs'' and ''allowable risk corridor costs'' in § 423.308 to include all these drug costs.

We also propose amending the definition of ''gross covered prescription drug costs'' to ensure 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 spending. This is consistent with guidance released via Q&A 7944 (issued May 9, 2006 *http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_alp.php?p_sid=gIVVcxhi*.) For example, when an enrollee is in an applicable coverage gap or deductible phase of the Part D benefit, the enrollee may be able to obtain a better cash price for a covered Part D drug at a network pharmacy than the plan offers via its negotiated price. The enrollee may take advantage of a special cash price or discount being offered to all pharmacy customers for the covered Part D drug or, alternatively, use a discount card. In such cases, the enrollee purchases a covered Part D drug without using the membership card for his or her Part D plan. If that purchase price is lower than the Part D plan's negotiated price, it will count toward TrOOP and total drug spend balances, provided the Part D plan finds out about the purchase. When the enrollee chooses not to use his/her membership card at a network pharmacy, that enrollee must take responsibility for submitting the appropriate documentation to the enrollee's Part D plan, consistent with plan-established processes and instructions for submitting that information, in order to have that amount aggregated to the beneficiary's TrOOP and total drug spend balances. We are aware of concerns that it is overly burdensome to require beneficiaries to submit claims for these reduced price purchases. However, we cannot require in-network pharmacies to submit these claims to Part D sponsors electronically, because at this time the HIPAA standard for claims submission does not accommodate the electronic transmission of this claim information by network pharmacies. To the extent that a future revision of the HIPAA standard does accommodate such transactions, we would support minimizing the submission of paper claims by beneficiaries.

The applicability of beneficiary out-of-pocket expenditures made outside the Part D benefit to TrOOP and total drug spend also extends to any nominal copayments assessed by manufacturer patient assistance programs (PAPs) that provide assistance with covered Part D drug costs to Part D enrollees outside the Part D benefit. Consistent with guidance provided via Q&A 7942 (*http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_alp.php?p_sid=gIVVcxhi*), providing assistance with covered Part D drug costs to Part D enrollees outside the Part D benefit does not preclude a PAP sponsor from requiring its enrollees (including those enrolled in a Part D plan) from paying a nominal copayment when they fill a prescription for a covered Part D drug for which they provide assistance. We note that any copayments assessed by PAPs operating outside the Part D benefit should be nominal, since only nominal beneficiary cost-sharing is consistent with the concept of operating outside Part D. Moreover, given that copayments are typically assessed for purposes of minimizing drug over-utilization, the assessment of anything but nominal cost-sharing by PAPs is seemingly inconsistent with the mission of a charitable organization structured to provide assistance with prescription drug costs to low-income patients.

Although PAP payments made for covered Part D drugs outside the Part D benefit do not count toward enrollees' TrOOP or total drug spend balances, nominal PAP copayment amounts paid by affected Part D enrollees can be applied to their TrOOP and total drug spend balances, provided the enrollees submit the appropriate documentation to their plan consistent with plan-established processes and instructions for submitting the information. We are proposing to revise the definition of ''gross covered prescription drug costs'', as well as the definition of ''incurred costs'' in § 423.100, to include these drug costs and to reflect this sub-regulatory guidance.

We also note 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 part or a component of the definition of gross covered prescription drug costs, but is a separate definition of a different term, we are proposing to revise the current discussion of ''target amount'' and are providing an amendatory instruction to add the definition in § 423.308. We are proposing technical edits to this definition to ensure that the structure of the definition is similar to that of other definitions in this section. We are proposing no substantive changes to the definition.

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

Section 423.882 codifies existing guidance. Given the similarities between the statutory definitions of ''gross covered prescription drug costs'' under section 1860D–15(b)(3) of the Act and ''gross covered retiree plan-related prescription drug costs'' under section 1860D–22(a)(3)(C)(ii) of the Act, we have consistently stated our intent to determine gross covered retiree plan-related prescription drug costs in a manner corresponding to our determination of gross covered prescription drug costs. Additionally, given the similarities between the statutory definitions of ''allowable reinsurance costs'' under section 1860D–15(b)(2) of the Act and ''allowable retiree costs'' under section 1860D–22(a)(3)(C)(i) of the Act, we determine allowable retiree costs in a manner parallel to how we determine allowable reinsurance costs. For example, for terminology not specifically defined under § 423.882, we generally utilize the relevant Part D definitions to the extent that they are consistent with the statutory provisions under section 1860D–22 of the Act. In addition, our RDS guidance related to the calculation of gross covered retiree plan-related prescription drug costs (or ''gross retiree costs'') and allowable retiree costs generally corresponds with the Part D guidance on the calculation of gross covered prescription drug costs and allowable reinsurance costs.

In order to ensure continued consistency between the RDS program and Part D, and because, as noted above, we believe the same policy arguments in favor of the Part D definitions apply to similar arrangements under the RDS program, we believe that the regulatory definitions under § 423.882 applicable to the RDS program should mirror the corresponding Part D definitions under § 423.100 and § 423.308. Accordingly, we propose to make the following additions and revisions to § 423.882 to be consistent with the corresponding existing and proposed definitions under § 423.100 and § 423.308. The proposed definitions under § 423.882 include codification of existing CMS guidance.

- *Actually Paid:* We propose to add this definition to mirror the proposed revised definition under § 423.308, with the exception of technical changes and clarifications to reflect its application to the RDS program. Specifically, we propose 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 are also proposing to include language in this definition that provides 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 are clarifying 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.
- *Administrative costs:* We propose to add this definition to mirror the proposed revised definition under § 423.308 with the exception of minimal changes to reflect the RDS terminology. Specifically, we propose 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 are proposing 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.
- *Allowable Retiree Costs:* We propose to make changes to the existing definition to mirror the relevant portions of the existing definition of ''allowable reinsurance costs'' under

§ 423.308. Specifically, we propose 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.

• *Gross covered retiree plan-related prescription drug costs:* We propose to revise the existing definition of ''gross covered retiree plan-related prescription drug costs'' (or ''gross retiree costs'') to mirror the proposed definition of ''gross covered prescription drug costs'' under § 423.308, with the exception of minimal changes to reflect the RDS terminology. Specifically, we propose to revise our definition of gross retiree costs to clarify that these costs equate to the sum of the negotiated prices (as defined in the proposed 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 would exclude administrative costs from gross retiree costs.

• *Negotiated Prices:* We propose to add this definition to mirror the proposed definition of negotiated prices under § 423.100 with the exception of minimal changes to reflect RDS terminology. Specifically, we propose 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 are proposing that negotiated prices include any dispensing fees.

Under these proposed definitions, payments made to RDS plan sponsors of qualified retiree prescription drug plans (or ''RDS sponsors'') would be based upon ''pass-through'' prices and not ''lock-in'' prices that the RDS plan sponsor pays to a PBM or other intermediary contracting organization. We elaborate on our reasons for requiring ''pass-through'' versus ''lock-in'' prices for RDS plan drug costs further below, as well as solicit specific comments from stakeholders to ensure we are aware of all of the ramifications of this proposed policy.

The ''pass through'' vs. ''lock in'' approach is being proposed for RDS plan sponsors for many of the same policy considerations that, as discussed in section II.B.4 of this proposed rule, underlie our proposed modifications to the Part D definitions of ''negotiated prices,'' ''administrative costs,'' ''allowable risk corridor costs,'' and ''gross prescription drug costs'' under § 423.100 and § 423.308. Specifically, the RDS payment is calculated based on allowable retiree costs, which in turn is a subset of gross retiree costs. (See sections 1860D–22(a)(3)(A),(C)(i), and (C)(ii) of the Act.) The statute requires CMS to exclude administrative costs from the calculation of gross covered retiree plan-related prescription drug costs and subsidizing these costs would therefore be contrary to Congressional intent. (See section 1860D–22(a)(3)(C)(ii) of the Act.) As explained in section II.B.3.a.ii of this proposed rule, discussing the proposed Part D definition of Negotiated Prices, we believe any net profit (or ''risk premium'') retained by a PBM that is added to the prices paid to pharmacies and billed to a Part D sponsor should be considered an administrative cost and not a drug cost. This same principle equally applies to the RDS program. Because we believe any net profit or risk premium retained by a PBM or similar intermediary contracting organization should be considered administrative costs and not drugs costs, we believe including these costs in gross retiree costs and allowable retiree costs would be contrary to Congressional intent that the RDS payment not subsidize an RDS sponsor's administrative costs. To ensure that these amounts are excluded from gross and allowable retiree costs, we, therefore, propose to define administrative costs as including any profit or loss retained by an intermediary contracting organization contracting with an RDS sponsor that differs from the amount paid to a pharmacy or other entity that is the final dispenser for drugs dispensed to qualifying covered retirees. We solicit comments on all proposed definitions discussed above.

We note that our proposed definition of administrative costs would not directly or indirectly require RDS plan sponsors to purchase drugs from dispensing providers only, and RDS plan sponsors would continue to have the option to contract or purchase drugs from other entities such as PBMs. However, to the extent that the amounts paid to a PBM or similar intermediary contracting organization for administrative services provided to a RDS plan sponsor are included in the cost of the drug under the lock-in pricing approach, RDS plan sponsors would be required to treat this spread amount as an administrative cost and these administrative costs would be excluded from the RDS plan sponsor's allowable retiree costs.

Our proposal would not require an RDS plan sponsor to use a particular pricing approach in its contracting agreements with PBMs. RDS plan sponsors may continue to use either the pass-through or lock-in pricing approach when contracting with a PBM—provided that drug costs reported to us are based on the price ultimately received by the pharmacy.

There may be concerns that these proposed changes may require RDS plan sponsors to depend heavily on information traditionally held exclusively by PBMs. To protect the privacy of beneficiary personal health information data, an RDS sponsor's PBM or other intermediary contracting organization may submit drug cost data on the RDS sponsor's behalf to CMS directly rather than through the RDS sponsor. However, RDS plan sponsors, and not the intermediary contracting organizations, are ultimately responsible for the data submitted to us, and those that choose to contract with a PBM or other third party to submit data to CMS, therefore, must take reasonable steps to ensure that the data submitted to us on their behalf is accurate and timely.

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

Section 1860D–2(d)(1) of the Act requires Part D sponsors to offer their enrollees access to negotiated prices used for payment for covered Part D drugs. In previous operational guidance, Part D sponsors were advised that it was optional when administering a Part D plan's benefit to apply either a copayment (if the sponsor elected to charge a flat copayment in lieu of coinsurance) or the actual negotiated price of the drug when that amount was lower than the copayment as outlined in the plan benefit package. Although we expected that very few Part D sponsors would choose to impose a cost sharing charge higher than the negotiated price of the drug, we allowed the option consistent with commercial practices. In practice, CMS found that the majority of Part D sponsors administer the benefit in such a way that the lesser of a cost sharing charge or the negotiated price of

the drug is applied to the beneficiary at the point of sale.

Based on our experience in implementing the benefit, we believe that a policy where the plan sponsor charges the beneficiary the lesser of the cost sharing amount or the negotiated prices is more consistent with the intent of section 1860D–2(d) of the Act. Accordingly, we propose to revise our policy so that, for example, a beneficiary who is subject to a $5 copayment during the coverage gap cannot be required to pay more than the negotiated price of the covered Part D drug, if the negotiated price is less than $5. Specifically, we propose 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, its negotiated prices of covered Part D drugs when the covered Part D drugs' cost-share is more than the Part D sponsor's negotiated price. In other words, if 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.

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

In accordance with the requirements of section 1860D–4(a)(4) of the Act, § 423.128(e) of our final rule implementing the provisions of the Part D program (which appeared in the **Federal Register** on January 28, 2005, and the provisions of which became effective March 22, 2005), requires Part D sponsors to furnish to enrollees who receive covered Part D drugs an explanation of benefits (EOB) when prescription drug benefits are provided. As articulated in the preamble to our January 2005 final rule, our intent was to ensure that an EOB was provided to Part D enrollees at least monthly if they used their prescription drug benefits in a given month. Section 423.128(e)(6) specifically requires that an EOB be provided ''*during* any month when prescription drug benefits are provided * * *.''. This was an inadvertent error given that, operationally, it is not feasible for Part D sponsors to mail their members an EOB during the same month in which they used their prescription drug benefits.

Sponsors must build into their EOB mailing cycles sufficient time to not only process each member's EOB, but also to produce and mail an EOB to each member with activity in a given month. Since the implementation of the Part D program in January 2006, it has become clear that a more reasonable timeframe for the provision of an EOB is warranted given the operational impossibility of providing an EOB for a month in which a member used his or her benefits during that same month. We therefore propose a revision to § 423.128(e)(6) to require sponsors to provide an 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) strikes a reasonable balance between Part D sponsor production constraints and the timely provision of claims information to Part D enrollees.

6. Low-Income Subsidy Provisions

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

CMS currently makes 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. 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.

Section 1860D–14(c)(1)(C) of the Act, when providing for administration of the subsidy program, gives the Secretary flexibility in determining a process for payment of the LICS subsidies as long as plan sponsors are reimbursed ''periodically and on a timely basis.''

The Part D program regulations at 42 CFR 423.329(d)(2) state that payments of the LICS subsidy under this section are based on a method that CMS determines. However, in paragraph (d)(2)(i) we also stated that LICS interim payments are to be made based on the low-income cost-sharing assumptions submitted with plan bids under § 423.265(d)(2)(iv) and negotiated and approved under § 423.272.

The language of § 423.329(d)(2)(i) regarding interim payments of the LICS subsidies has proven overly restrictive and has had the unintended effect of requiring CMS to make payments to Part D plan sponsors that are subsequently determined to have been significantly different from their actual costs, and which will not be recovered until payment reconciliation is completed. In contrast, the regulation governing interim payment of Part D reinsurance affords greater flexibility to CMS to determine the most appropriate interim payment methodology. The regulation at § 423.329(c)(2)(i) states that, ''CMS establishes a payment method by which payments of [reinsurance] are made on a monthly basis during the year, based on either estimated or incurred allowable reinsurance costs.'' Therefore, we propose to add to the end of § 423.329(d)(2)(i) the following qualifying statement: ''or by an alternative method that CMS determines.'' This proposed revision would afford CMS additional flexibility to make mid-year LICS payment adjustments or other modifications to the LICS interim payment methodology, as appropriate.

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

Section 1860D–14 of the Act establishes the low-income subsidy program available to Part D sponsors to provide low-income individuals assistance with their Part D plan cost-sharing amounts and premiums. The amount of a Part D sponsor's low-income cost-sharing subsidy is based upon the difference between the amount the non-subsidized beneficiary pays for his/her Part D covered drug under the plan's benefit package and the maximum cost-sharing amounts established in statute at section 1860D–14(a) of the Act. For calendar year 2008, full subsidy eligible individuals (as defined in the current regulation at 42 CFR 423.773(b)) are not subject to any deductible and cannot be charged cost sharing above the maximum cost sharing amounts of $1.05/$2.25 for generics and preferred multi-source brand name drugs; and $3.10/$5.60 for other brand name drugs in 2008. Other low-income subsidy eligible individuals, as defined at 42 CFR 423.780(d), cannot be charged more than $56 towards a Part D sponsor's deductible, and cannot be charged more per prescription than an amount equal to 15 percent coinsurance.

When we originally drafted the regulations, we assumed that the Part D sponsor benefit packages would routinely result in higher cost sharing amounts for non-subsidized beneficiaries than the maximum low-income subsidy deductible and cost sharing amounts. However, when Part D sponsors offer benefit packages that already provide beneficiaries with a deductible and cost sharing less than the low-income deductible and cost sharing maximum amounts established

in statute (such as for zero dollar generics), this turns out not to always be the case. There are also instances when the Part D sponsor's negotiated prices used for payment for covered Part D drugs are less than the low-income cost sharing amounts. In these cases, our operational guidance (Prescription Drug Event or PDE training guide *http://www.medicaretraining.net/federalemployees/ParticipantGuide.pdf*) has instructed that Part D sponsors charge low-income beneficiaries the lesser of (1) its plan benefit package's prescribed cost-sharing, (2) the sponsor's negotiated rate for the drug, or (3) the LIS cost sharing amount established in statute. If the Part D sponsor's plan deductible was either less than the maximum low-income subsidy deductible amount or zero, the beneficiary should not be charged more than the plan's actual deductible.

The basis of our PDE guidance is found both in regulation and in statute. Section 1860D–14(a) of the Act provides that a beneficiary is eligible for a ''*reduction* in the annual deductible'' and ''*reduction* in cost-sharing [above or below] the out-of-pocket threshold.'' We believe the statute does not require that the low-income subsidy beneficiary be charged the statutorily-defined cost-sharing amounts if the approved cost sharing for a specific drug under a plan is less than that amount. Nor does the statute require that the low-income subsidy beneficiary be subject to a defined deductible when a Part D sponsor's plan benefit structure does not include a deductible. Thus, our previously issued guidance is consistent with the statutory parameters outlining the reductions in beneficiary out-of-pocket cost sharing amounts. The statute at 1860D–2(d)(1) of the Act also requires Part D sponsors to offer their enrollees access to negotiated prices used for payment for covered Part D drugs. We believe a Part D sponsor that imposes the statutory low-income cost sharing amounts on low-income subsidy beneficiaries when the PDP sponsor's negotiated prices are less than the low-income cost sharing amounts, violates 1860D–2(d) of the Act with regard to an enrollee's access to negotiated drug prices.

Furthermore, our current regulations at 42 CFR 423.104(b) sets forth the requirement that Part D sponsors must offer the same drug plan to all Part D eligible beneficiaries residing in their plan service area. We commonly refer to this section of the regulation as the uniform benefit rule. This section prohibits Part D sponsors from varying plan benefits to beneficiaries in a service region and further supports the policy that low-income subsidy beneficiaries not be charged more than what they, or other non-LIS beneficiaries would be charged under the Part D sponsor's plan benefit package. For an extensive discussion of the statutory basis for 42 CFR 423.104(b), see 70 FR 4245 of the preamble to the final Medicare Prescription Drug Benefit Rule published January 28, 2005.

To ensure low-income subsidy eligible beneficiaries are not harmed when the statutory low-income subsidy cost-sharing amounts are in excess of cost-sharing imposed under their plan's benefit package, we propose to codify our existing guidance in regulation. We propose 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).

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

Section 1860D–14(a)(3)(B)(v) of the Act requires the Secretary to treat Part D eligible individuals who are full-benefit dual eligible individuals (as defined under 1935(c)(6)) or recipients of supplemental security income under title XVI as full low-income subsidy eligible individuals. Section 1860D–14(c)(1) of the Act further requires that the Secretary provide for a process under which (1) the Secretary notifies the PDP sponsor that an individual is eligible for a low income subsidy, and (2) the PDP sponsor is required to reduce the premiums and cost sharing for such individuals to the amount a low-income subsidy eligible individual is required to pay.

The primary process CMS has employed to implement these requirements is for CMS to identify low-income subsidy-eligible individuals based upon information from the States on Medicaid eligibility and Social Security on SSI eligibility and the eligibility of LIS applicants. Because we do not always have timely or up-to-date information from these sources, however, we developed a process under which sponsors accept and use reliable documentation, known as ''best available evidence,'' to establish a beneficiary's low-income subsidy eligibility status and communicate this information to the Secretary.

This ''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 CMS attempts to identify all subsidy eligible individuals to the full extent possible, experience has shown that this does not necessarily result in every such individual being successfully identified. CMS believes, therefore, that the Sponsors have an obligation to take reasonable steps to respond to documentation that identifies such individuals when they have not been identified by CMS, in order to fulfill their statutory obligation to reduce premiums and cost-sharing for such individuals.

Given the importance of this policy, we propose to codify it in § 423.800(b) and (d). Specifically, we propose to include in regulations text 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*) we have issued to Part D sponsors concerning our best available evidence (BAE) policy.

These revisions to § 423.800 reflect our current policy that Part D sponsors must accept and use BAE in those instances when this evidence, submitted by the beneficiary or another person on the beneficiary's behalf, substantiates that the beneficiary's information in CMS systems is not accurate. To ensure the appropriateness of corrections based on BAE, CMS policy requires sponsors to maintain for 10 years the original documentation used to substantiate requests for manual updating of the CMS system to accommodate subsequent periodic government audits. In addition, we plan to establish a feedback mechanism to the States to confirm the LIS corrections based on BAE and identify and address any problems in State to CMS reporting.

As noted above, this policy is necessary because the monthly files from the States and Social Security CMS uses to establish an individual's low-income subsidy eligibility pursuant to section 1860D–14(c)(1)(A) of the Act do not always accurately reflect an individual's true eligibility status. In certain cases, for example, the State has not yet reported the individual as Medicaid eligible, or has not reported him/her as institutionalized. As a result, CMS systems do not reflect a beneficiary's correct low-income subsidy (LIS) status at that point in

time. As a result, accurate subsidy information on these individuals has not been communicated to the Part D plan.

In these circumstances, beneficiaries, advocates or pharmacies have brought such errors to the Part D sponsor's attention. CMS believes that the Part D sponsor is in the best position to address such errors and appropriately apply the subsidy as it is required by statute to do under section 1860D–14(c)(1)(B) of the Act. This led to CMS's development of the best available evidence (BAE) policy that we are proposing to incorporate in this proposed rule.

Specifically, we are proposing to amend 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 propose to incorporate in this proposed rule, 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 when the change has not occurred as a result of the routine reporting.

CMS continues to work to improve low-income subsidy data reporting. Such improvements would include, for example, permitting more frequent State submission of data files to CMS, more frequent CMS processing of data files and improved communication of the information to Part D sponsors.

Nevertheless, we anticipate that the BAE policy will remain in place for the indefinite future. As a result, we are proposing 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. By adding this provision to the regulation, we are ensuring that our best available evidence policy and its requirements are clear to all parties and, in so doing, that the administration of the low-income subsidy program takes advantage of all data currently available to the Part D sponsors to ensure low-income beneficiaries are not burdened by unnecessary cost sharing at the point of sale. We also believe we will be in a stronger position from a compliance perspective, as it will strengthen our ability to take action against plans that fail to implement our best available evidence process.

We expect that CMS guidance implementing the BAE policy will be updated as necessary to reflect appropriate process modifications as they become warranted, based on changes in technology and the types of documents that could in the future prove to reliably verify a beneficiary's status as an individual eligible for a full low-income subsidy.

We propose to define best available evidence 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 are not proposing 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.

Currently, however, evidence sufficient to make a change to a beneficiary's low-income status includes any one of the following:

- A copy of the member's Medicaid card which includes the member's name and an eligibility date during the discrepant period or no later than July of the preceding year.
- A report of contact including the date a verification call was made to the State Medicaid Agency and the name, title and telephone number of the state staff person who verified the Medicaid status during the discrepant period;
- A copy of a state document that confirms active Medicaid status during the discrepant period;
- A print out from the State electronic enrollment file showing Medicaid status during the discrepant period;
- A screen print from the State's Medicaid systems showing Medicaid status during the discrepant period; or
- Other documentation provided by the State showing Medicaid status during the discrepant period.

In addition, evidence to establish that a beneficiary is institutionalized and qualifies for zero cost-sharing includes any one of the following:

- A remittance from the facility showing Medicaid payment for a full calendar month for that individual during the discrepant period;
- A copy of a state document that confirms Medicaid payment to the facility for a full calendar month on behalf of the individual; or
- 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 the discrepant period.

Again, the proposed changes described in this portion of the proposed rule would not change current BAE policy. Rather they would codify existing operational processes and reflect our historic policy that Part D sponsors use BAE when this evidence substantiates that the beneficiary's information in CMS systems is not accurate. We invite comment on methods by which we can improve this policy in the future.

7. Certification of Allowable Costs (§ 423.505)

We propose, by revising § 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.

8. Change of Ownership Provisions (§ 423.551)

We propose to amend the change of ownership provisions in 42 CFR 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.

This proposed restriction on the sale of beneficiaries is based on two CMS determinations. First, in the preamble to the current Part D rule that published in the **Federal Register** January 28, 2005 (70 FR 4341), CMS stated that we would recognize the sale of PDP lines of business as asset transfers that constitute a change ownership which CMS may recognize through the execution of an agreement to novate the selling sponsor's PDP sponsor contract to a second qualified sponsor. Using a

common understanding of the phrase ''line of business'' as referring to a company's set of products or services, CMS maintains that a ''PDP line of business'' includes a PBP as well as the beneficiaries enrolled in that PBP. Therefore, there can be no sale of a line of business consisting solely of a set of beneficiaries without the accompanying transfer to the succeeding sponsor of the obligation to continue to provide the PBP services the beneficiaries have already elected.

Second, the sale of individual beneficiaries would allow PDP sponsors effectively to make enrollment elections on behalf of beneficiaries when the Part D statute grants that authority exclusively to beneficiaries (see section 1860D–1(a)(1)(A) of the Act) and, in the case of full-benefit dual eligible beneficiaries, CMS (see section 1860D–1(b)(1)(C) of the Act). The change of ownership provisions of subpart L may not be read as a grant of enrollment election authority to PDP sponsors.

We propose to add § 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 CMS approval of transactions involving the sale of beneficiaries. This clarification will minimize the number of sponsors that mistakenly begin negotiations on such sale agreements.

C. Proposed Changes to the MA and Prescription Drug Benefit Programs

In order to assist readers in understanding how the proposed provisions we discuss in this section would apply to both programs, we are including Table 1, which highlights the provisions affecting both programs and the pertinent Part 422 and Part 423 CFR sections.

TABLE 1.—PROVISIONS AFFECTING BOTH THE PART C AND PART D PROGRAMS

Provision	Part 422 Subpart	Part 422 CFR section	Part 423 Subpart	Part 423 CFR section
Passive enrollment procedures	Subpart B	422.60	Subpart B	423.32
Involuntary disenrollment and non-payment of premium.	Subpart B	422.74	Subpart B	423.44
Disclosure of plan information	Subpart C	422.111	Subpart C	423.128
Retroactive premium collection and beneficiary repayment options.	Subpart F	422.262	Subpart F	423.293
Prohibiting improper billing of monthly premiums	Subpart F	422.262	Subpart F	423.293
Non-renewal notification timelines	Subpart K	422.506	Subpart K	423.507
Reconsiderations	Subpart M	422.578, 422.582	Subpart M	423.560, 423.580, 423.582
Civil money penalties	Subpart O	422.760	Subpart O	423.760
Marketing: Definitions	Subpart V (all marketing sections).	422.2260	Subpart V (all marketing sections.	423.2260
Marketing: Review and distribution of marketing materials.		422.2262		423.2262
Marketing: Guidelines for CMS review		422.2264		423.2264
Marketing: Deemed approval		422.2266		423.2266
Marketing: Standards for MA/Part D marketing		422.2268		423.2268
Marketing: Licensing of marketing representatives and confirmation of marketing resources.		422.2272		423.2272
Marketing: Broker and agent commissions		422.2274		423.2274
Marketing: Employer and group retiree marketing (MA provision only).		422.2276		423.2276

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

Section 1851(c)(1) of the Act directs the Secretary to establish a process through which an individual makes an ''election'' to receive Medicare coverage through an MA plan or original Medicare, or to change from one MA plan to another, including the form and manner in which such elections are made. Section 1860D–1(b)(1)(A) of the Act similarly directs the Secretary to establish a process for enrolling in or disenrolling from a PDP, or changing enrollment from one PDP to another. This authority is implemented for MA plans in §§ 422.60, 422.62, 422.66, and 422.74, and for Medicare prescription drug plans in §§ 423.32 and 423.36, as well as in CMS manuals.

In rare instances, CMS is faced with situations in which organizations become insolvent, or are determined to have such serious compliance issues that immediate plan terminations may become necessary. Normally, an organization that elects to non-renew its contract for the following year is required to notify CMS in July of the contract year, several months before the non-renewal takes effect. All beneficiaries enrolled in that plan are required to be notified in early October, providing individuals at least 3 months to evaluate other plan options, and make a plan election for the subsequent year. Consistent with existing regulations and guidance, such elections would normally entail ''active'' measures, such as signing an enrollment form, submitting an on-line enrollment request or calling a plan to enroll.

However, when CMS identifies a situation that requires an immediate plan termination, or other situations in which CMS determines plan members might be harmed by remaining in their current plan, CMS believes that it is in the best interests of beneficiaries to protect those that may not have adequate time to elect a plan due to emergency terminations as well as those unable to, or who otherwise do not, focus on their plan options. In these circumstances, our primary goal is to ensure that minimal harm comes to the beneficiary who fails to act on his or her election options. To achieve this goal, we have determined that it is sometimes appropriate to use ''passive'' enrollment procedures under which an individual is notified that he or she can make an enrollment ''election'' by taking no action. Under these procedures, we strive, when possible, to select plans for individuals that will maintain a level of coverage equal to or better than their current coverage, without incurring

additional costs. We also generally assume that individuals who are currently enrolled in a particular type of coverage, such as prescription drug coverage, would want to maintain this type of coverage. Similarly, we assume that LIS-eligible individuals would prefer a plan where their premiums and deductibles were fully subsidized.

In addition to termination situations, we have provided for ''passive'' enrollment in cases in which a failure to elect the enrollment in question would harm the beneficiary. For example, we have employed passive enrollment in the case of employer group members who would lose employer benefits if they were not passively enrolled. We also have provided for passive enrollment in which the particular plan in which the beneficiary is enrolled was being terminated by CMS due to compliance and insolvency issues, as well as instances when a beneficiary was enrolled in a terminating plan but a similar plan was offered by the same organization with which the beneficiary had already chosen to enroll.

We are proposing to incorporate our current passive enrollment policies in the regulations in a new § 422.60(g) and § 423.32(g). These new provisions would set forth in the regulations that CMS may authorize plans to carry out ''passive'' enrollment procedures in situations involving immediate plan terminations or potential beneficiary harm from remaining enrolled in the beneficiary's current plan. Under these enrollment procedures, individuals will be notified that they will be deemed to have elected the MA or PDP plan selected for them by CMS if they take no action to cancel such enrollment. In conjunction with these provisions, we would set forth several key beneficiary protections that would be required any time such an enrollment would occur. Such protections would include requiring that the organization that is receiving the enrollment notify all prospective enrollees of the passive enrollment prior to the effective date of the passive enrollment or as soon as possible after the enrollment effective date if prior notification is not possible under the circumstances. The notices to the enrollees would be approved by CMS and would explain their right to choose another plan, and describe the costs and benefits of the new plan and how to access care under the plan, as well and any other conditions of enrollment established by CMS.

We would also specify that affected individuals would be entitled to a special enrollment period after their new enrollment took effect, as permitted under §§ 422.62(b)(4) and 423.38(c)(8)(ii).

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

The MMA provides individuals with the option to choose to have their premiums for either MA or PDP membership withheld from their Social Security benefit, as described in 42 CFR 422.262(f) and 423.293, respectively. Section 1851(g)(3)(A) of the Act provides Medicare Advantage organizations the option to disenroll members who fail to pay basic and supplemental monthly premiums, as set forth at 42 CFR 422.74(d)(1). Section 1860D–1(b)(1)(B)(v) of the Act makes this provision applicable to PDP sponsors. See 42 CFR 423.44(d)(1).

Although MA organizations and PDP sponsors may disenroll individuals for failing to pay premiums in a timely manner, we believe that such disenrollments should be an option only in cases where individuals pay their required premiums directly to the plan, as opposed to individuals who have chosen to have their premiums automatically withheld from their Social Security benefits. In cases where MA organizations or PDP sponsors are not receiving premiums on a timely basis from members who have chosen the premium withhold option, the member is clearly not at fault if the premium for some reason is not being deducted or paid to the plan properly. Thus, we do not believe that the organization or sponsor should have the option to disenroll a member in that situation. Similarly, individuals who have elected the premium withhold option also should not be subject to disenrollment during the time needed to initially establish premium withhold status on an individual account.

Therefore, we are revising the MA and Part D regulations in § 422.74(d)(1) and § 423.44(d)(1) by adding the cross reference to paragraph (d)(1)(iv) to prohibit plans from disenrolling individuals for failure to pay premiums if they have either 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.

3. Disclosure of Plan Information (§§ 422.111 and 423.128)

As provided in section 1852(c)(1) of the Act, MA organizations and prescription drug benefit plan (PDP) sponsors must disclose detailed information about the plans they offer to their enrollees. This detailed information is specified in section 1852(c)(1) of the Act and §§ 422.111(b) and 423.128(b) of the Part C and Part D program regulations, respectively. Sections 422.111(a)(3) and 423.128(a)(3), as well as our Marketing Guidelines require that this information be disclosed at the time of enrollment and at least annually thereafter. In addition, the Marketing Guidelines specify that current enrollees must receive the annual notice of change (ANOC) by October 31 and the evidence of coverage (EOC) annually.

We propose clarifying in §§ 422.111(a)(3) and 423.128(a)(3) that plans must disclose the information specified in §§ 422.111(b) and 423.128(b) of the MA and Part D program regulations, respectively, both at the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period. Making this clarification is essential to ensuring that current enrollees receive comprehensive information necessary for making an informed decision regarding their health care options prior to the annual coordinated election period.

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

Routine changes in a beneficiary's plan status (for example, plan switching) or systems issues can result in a need for retroactive premium collections. Many beneficiaries can be financially harmed when required to pay the full amount of a retroactively-due premium in addition to their current month's premium in a single lump sum. Section 1860D–13(c)(1) of the Act states that ''the provisions of § 1854(d) shall apply to PDP sponsors and premiums (and any late enrollment penalty) under this part in the same manner as they apply to MA organizations and beneficiary premiums under Part C.'' Section 1854(d)(1) and (2) of the Act direct MA organizations to permit the payment of MA ''monthly basic, prescription drug, and supplemental beneficiary premiums on a monthly basis'' and ''in accordance with regulations, an MA organization shall permit each enrollee, at the enrollee's option, to make payment of premiums (if any) under this part to the

organization through'' withholding, electronic funds transfer, or ''such other means as the Secretary may specify.''

We believe it would be consistent with these provisions to provide beneficiaries with the option of prorating 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. Specifically, we believe that beneficiaries should be able to spread out their obligation over at least the same period for which the premiums were due. That is, if 7 months of premiums are due, the member should have at least 7 months to repay. Accordingly, we propose 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 this option.

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

Under some circumstances operational failures cause CMS payment delays with respect to premiums collected by Social Security withholding. When this has happened, some PDP sponsors and MA organizations have erroneously opted to directly bill members for premiums that the members have requested be withheld from their Social Security payments. Sections 1860D–13(a) (for Part D) and 1854(b) (for Part C) of the Act establish specific formulas (based on annual bidding) for calculation of monthly premiums. 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 have the right to have their premiums taken only out of their Social Security payments. Therefore, it is impermissible to bill a member for such premiums. Accordingly, we are proposing to revise 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 such improper billing. Note that under circumstances when CMS cannot effectuate the premium withhold option for beneficiaries, we will set beneficiaries back to direct bill. In those cases, plans will be able to directly bill beneficiaries for premium amounts owed.

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

Non-renewals of MA or prescription drug plan contracts require the MA organization, the Part D sponsor, or CMS to notify both the enrollees of the organization or sponsor and the general public of the non-renewal. Existing regulations require notification 90 days prior to the effective date of the non-renewal for notification to enrollees and 90 days prior to the end of the calendar year to the general public. The effective date of contract non-renewals in the MA and prescription drug plan programs is January 1st of each calendar year.

Currently, CMS regulations concerning contract non-renewals require that CMS notify an MA organization or a prescription drug plan sponsor (PDP sponsor) of a non-renewal by August 1 of the current contract calendar year. In cases where CMS announces its intention to non-renew an MA organization or a PDP sponsor, the MA organization or PDP sponsor has certain contract appeal rights. Note that in instances where an MA organization or PDP sponsor announces its intent to non-renew its contract with CMS, there is no similar contract appeals process available. Should an MA organization or PDP sponsor decide to pursue an appeal of CMS' decision to non-renew the organization or sponsor's contract, we believe it is appropriate that the appeals process be concluded in time for there to be a final decision on the non-renewal, and for there to be sufficient time for the enrollees and the general public to be notified of a contract non-renewal prior to January 1 of the following year. Presently, the 90 day notice requirement requires contract non-renewal appeals process to be completed in only 60 days (from August 1st which is the date of notification of non-renewal, until October 1st,in order for the notice period to have run prior to January 1st). Our experience is that the contract non-renewal appeals process is likely to extend beyond 60 days. For this reason, we propose 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, while still allowing for a sufficient beneficiary notice period, prior to January 1st. This change will help ensure that all termination decisions are final, prior to the start of marketing and enrollment activities.

CMS also believes that a 60 day notification requirement better aligns itself with other important CMS notification and election requirements. For example, CMS currently requires that all MA organizations and PDP sponsors provide annual notice of change (ANOC) documents to enrollees of Medicare private health plans by October 31st of each year. As mentioned previously, the annual election period runs from November 15th to December 31st of each year. By changing the enrollee notification timeframe from 90 to 60 days, beneficiaries will receive notice of a pending contract non-renewal during the same time period when beneficiaries are making important Medicare coverage decisions for the upcoming calendar year. A 60 day notification period is a sufficient amount of time for enrollees to review other plan options and to make an election for enrollment into a plan for the following calendar year.

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

We are proposing changes to the reconsideration process for both the MA and prescription drug benefit programs. The overall changes to the first level appeal process will be the same for both programs. However, we discuss the proposed revisions for each program separately because the proposed revisions would vary slightly due to program differences.

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

Under section 1852(g)(3)(A)(ii) of the Act and §§ 422.578 and 422.584 of the regulations, a physician, without regard as to whether the physician is treating the enrollee, is permitted to request an expedited plan reconsideration on behalf of an enrollee without having to be appointed by the enrollee as his or her representative. However, in order to request a standard pre-service plan reconsideration under §§ 422.578 and 422.582, a physician must have been appointed as the enrollee's representative, or be authorized by State law or other applicable law to act on behalf of the enrollee. We are proposing to revise § 422.578 and 422.582 to permit an enrollee's treating physician to request a standard plan reconsideration of a pre-service request on an enrollee's behalf without having been appointed by the enrollee as his or her representative.

Section 1852(g)(2) of the Act states that an MA organization ''shall provide for reconsideration of a determination described in paragraph (1)(B) upon request by the enrollee involved.'' Although the statute does not expressly give any individual other than the enrollee the right to request a standard plan reconsideration, we have long permitted an enrollee to appoint a representative (for example, an attorney or family member) to file a request on

behalf of an enrollee. In addition, when an individual is authorized under State law or other applicable law to act on the beneficiary's behalf, such an individual is also permitted to request a plan reconsideration on the enrollee's behalf.

With respect to a physician's request for a standard plan reconsideration, the current regulations draw a distinction between a physician who is requesting an organization determination on behalf of an enrollee regarding coverage of services that have not been provided, and a request involving services that the physician has furnished. In the latter case, under § 422.574(b), if the physician has furnished a service to an enrollee and formally waives any right to payment from the enrollee for that service, he or she becomes a ''party'' to the organization determination, and may, under § 422.578, request a standard plan reconsideration (1st level appeal) without being appointed by the enrollee as a representative. This is a third instance in which someone other than the enrollee can request a standard plan reconsideration.

After a number of years experience with the Part C program, we believe it is appropriate to revise the regulations to add a fourth circumstance under which an individual other than an enrollee can request a standard plan reconsideration on the enrollee's behalf. Specifically, we propose to allow the enrollee's physician, who the enrollee has already selected to provide treatment, to request standard plan reconsiderations on his or her patient's behalf without having been appointed as the enrollee's representative. We believe that an enrollee's treating physician already has been selected by the enrollee and occupies a position of trust. We also believe that as a treating physician, he or she is in a good position to know whether a request for plan reconsideration is warranted, and in the enrollee's interests. We have found that in some cases, requiring that the physician take the step of being appointed by the enrollee is a burden that does not serve the enrollee's interests.

We are proposing that the physician must be able to demonstrate that he or she is treating the enrollee in question in order to request a plan reconsideration on the enrollee's behalf, and would be required to notify the enrollee that he or she is taking this action.

We are not proposing to allow physicians who are not acting as an enrollee's representative to request appeals on behalf of enrollees beyond the plan level, as we believe that the enrollee should be directly involved in a decision to disclose his or her private health information to appeals adjudicators beyond the plan level of appeal because those adjudicators do not have the same relationship with the enrollee that the plan has.

b. Prescription Drug Benefit Program

i. Definitions (§ 423.560)

We propose to revise the regulation text of § 423.560 by adding a new definition for ''other prescriber.'' This term 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 this proposed new definition, we propose 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.

Sections 1860D–4(g) and (h) of the Act establish the role of the ''prescribing physician'' in the coverage determination and appeals processes. Specifically, under section 1860D–4(g) of the Act, an enrollee may request an exception to a tiered cost-sharing structure such that a non-preferred drug could be treated as a preferred drug if the prescribing physician ''determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual, or both.'' Section 1860D–4(h) of the Act provides that an enrollee may appeal a determination not to provide coverage for a Part D covered drug that is not on the plan's formulary ''only if the prescribing physician determines 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 nonformulary drug, would have adverse effects for the individual, or both.'' However, sections 1860D–4(g) and (h) of the Act are silent on the role of other health care professionals who have prescribing authority under State law or other applicable law.

As the statute reflects, the Congress recognized the important role a prescribing physician plays in the coverage determination and appeals processes. In particular, a prescribing physician is especially well qualified to assist Part D enrollees with certain aspects of the coverage determination and appeals processes. Because sections 1860D–4(g) and (h) of the Act are silent on the role of other health professionals who have prescribing authority under State law or other applicable law, an enrollee who has his or her prescription written by a non-physician prescriber arguably does not currently have the same protections and assistance in the coverage determination and appeals processes as an enrollee whose prescription is written by a physician. Based on program experience gained since the inception of the Part D program, and recognizing that there are other categories of health care providers who are authorized under State law or other applicable law to prescribe drugs for Part D enrollees, we are proposing to allow non-physician prescribers to perform the same functions as physicians for purposes of subpart M of part 423.

This proposed change would ensure that enrollees who have prescriptions written by non-physician prescribers are afforded all of the same protections and assistance in the coverage and appeals processes that are currently available to enrollees whose prescriptions are written by a physician. For example, under § 423.566(c), an enrollee's prescribing physician is permitted to request an expedited or a standard coverage determination on the enrollee's behalf without being his or her representative. Under this proposal, a nurse practitioner or other health care professional who is authorized under State law or other applicable law to write prescriptions would be able to request an expedited or standard coverage determination on behalf of the enrollee. We believe this proposal would ensure that all Part D enrollees have the same protections and access to assistance in the coverage determination and appeals processes, notwithstanding the type of health care professional who writes their prescription.

ii. Right to a Redetermination (§ 423.580)

We propose 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.

Section 1860D–4(g) of the Act requires Part D plan sponsors to ''meet the requirements of paragraphs (1) through (3) of section 1852(g) with respect to covered benefits under the prescription drug plan it offers under this part in the same manner as such requirements apply to an MA organization with respect to benefits it offers under an MA plan under Part C.''

Sections 1852(g)(1) through (g)(3) discuss the requirements for standard and expedited organization determinations and plan reconsiderations by MA organizations.

Under current §§ 423.580–423.584, an enrollee's prescribing physician is permitted to file an expedited redetermination on the enrollee's behalf without being his or her representative, but cannot request a standard redetermination without being the enrollee's representative. In accordance with section 1860D–4(g) of the Act, this limitation was carried over from §§ 422.578 and 422.582 of the Medicare Advantage regulations. However, as discussed above, in this proposed rule, we are proposing to revise §§ 422.578 and 422.582 of the regulations to allow non-representative physicians to request standard plan reconsiderations of pre-service requests on behalf of enrollees in MA appeals. In conjunction with that proposed change, and consistent with the requirement under section 1860D–4(g) of the Act that plan redeterminations under Part D be provided in the same manner as plan reconsiderations under Part C, we propose to revise §§ 423.580 and 423.582 to be consistent with our proposed changes to §§ 422.578 and 422.582. However, under Part D, we are not carrying over the limitation from proposed § 422.578 that would prevent a prescribing physician from requesting a standard plan-level appeal for payment. Unlike under Part C, prescribing physicians do not have a financial interest in the payment of Part D claims. Thus, we believe prescribing physicians may make requests for payment on behalf of enrollees under Part D. In addition, consistent with our proposal to afford non-physician prescribers the same authority to assist beneficiaries in the coverage determination process as prescribing physicians, we also propose to allow other prescribers to request plan redeterminations on behalf of enrollees.

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

CMS may impose civil money penalties (CMPs) on MA organizations and Part D sponsors for certain regulatory offenses, as described in subpart O of both 42 CFR 422 and 42 CFR 423. Section 1857(g)(3)(A) and section 1860D–12(b)(3)(E) of the Act provides CMS with the ability to impose CMPs of up to $25,000 per determination (determinations are those which could otherwise support contract termination, pursuant to §§ 422.509 or 423.510) when the deficiency on which the determination is based adversely affects or has the substantial likelihood of adversely affecting an individual covered under the organization's contract. The current regulations essentially echo the Act's wording with respect to the amount of the penalty that CMS may impose. However, the statute and the existing regulations shed little light on how to determine whether a series of incidents or events, or a single event that individually impacts multiple enrollees, constitutes a single determination or multiple determinations which could justify the calculation of a larger total penalty.

It is possible that one incident could negatively affect multiple enrollees, which would provide a justification for the CMP amount to potentially be greater than a CMP based on an event that only affects a few beneficiaries. For example, the failure of an organization or sponsor to timely issue annual notice of change (ANOC) documents would be a one-time incident that has the potential to have adverse consequences for a large number of enrollees. CMS believes it is appropriate for the specific factors to be considered in calculating a total CMP, such as the number of enrollees affected or potentially affected, whether the ANOCs were significantly delayed (resulting in a substantial decrease in the amount of time an enrollee had to determine whether or not to stay in their plan), or an additional factor was involved that further adversely affected the enrollees.

Similarly, one or a small group of marketing agents perpetrating similar misrepresentations over a period of time could constitute a series of incidents or events that CMS believes should be considered in calculating a total CMP. If one agent or several agents are misrepresenting plan benefits, the agent(s) may be repeating the same misrepresentation on multiple occasions and to multiple enrollees. Each time an agent misrepresents the plan's benefits and the enrollee is adversely affected or potentially adversely affected by such inaccurate statements, a determination justifying a CMP could be made based on each enrollee affected by the agent's actions.

Given that the Act requires that the deficiency on which the determination is based must have adversely affected or have the substantial likelihood of adversely affecting an individual covered under the organization's contract, CMS believes that a CMP may be calculated based on each enrollee covered under the organization's contract adversely affected or potentially adversely affected by the organization's conduct. The statute clearly specifies that CMPs may be levied at amounts up to but not exceeding $25,000 per determination. We propose to clarify our regulations relating to CMPs in both 42 CFR 422.760 and 42 CFR 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. These factors combined will assist us in determining the amount per affected beneficiary that the organization should be penalized.

CMS believes this clarification is necessary for both MA organizations and Part D sponsors to fully appreciate the consequences of noncompliance with applicable program requirements. An MA organization or Part D sponsor's conduct that adversely affects a significant number of Medicare beneficiaries may have a significant financial impact on the organization. Our proposed change is aimed at protecting enrollees by clarifying that penalties can be substantial for noncompliance.

Adding the option of assessing CMPs at the level of each enrollee covered under the organization's contract—to CMS' existing authority, which enables the Agency to continue to levy CMPs at the ''per contract'' level—provides necessary flexibility for CMS to better match CMP amounts to the specific nature of the determination that warrants 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. We therefore seek 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 is in violation of CMS requirements. We also seek comment as to the appropriate

monetary range for CMPs imposed on MA organizations and Part D sponsors and as to 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.

9. Medicare Advantage and Prescription Drug Program Marketing Requirements (Proposed New Subparts V)

a. General

Section 1851 of the Act sets forth provisions relating to beneficiaries making choices as to how they want to receive their Medicare benefits. Specifically, it addresses the provision of information to beneficiaries on their Medicare health care options, the marketing of such health care options, and the timing and method for making a choice among health care options, and enrollment in, disenrollment from, or a change in, the health care option of the beneficiary's choice.

Sections 1851(h)(1) through (5) of the Act govern the marketing of MA plans to Medicare beneficiaries by MA organizations. Section 1851(h)(1) of the Act requires that marketing material be submitted to CMS for approval before it is used, and provides for deemed approval after 45 days (or 10 days in certain cases) if CMS does not disapprove the material. Section 1851(h)(2) provides for CMS to establish ''standards'' for the review of marketing material, and requires that material be disapproved if it ''is materially inaccurate or misleading or otherwise makes a material misrepresentation.''

Section 1851(h)(3) of the Act provides that material approved for use in one geographic area is deemed approved in other areas except with respect to material specific to the area involved, and section 1851(h)(5) of the Act provides that if model language approved by CMS is used, it can be used only 10 days after submitting it to CMS for approval. Finally, section 1851(h)(4) of the Act requires that MA organizations conform to ''fair marketing standards,'' including those established by CMS by regulation, and requires that such standards prohibit an MA organization from providing for cash or rebates as an inducement to enroll, or otherwise, and may include a prohibition on an MA organization or its agent filling out an enrollment form for individuals. With respect to marketing by PDP sponsors, section 1860D–1(B)(1)(vi) of the Act requires CMS to use rules ''similar to (and coordinated with)'' the foregoing marketing rules set forth in section 1851(h). Regulations at §§ 422.80 and 423.50 and detailed operational guidance found in ''*The Medicare Marketing Guidelines for Medicare Advantage plans, Medicare Advantage prescription drug plans, prescription drug plans, and 1876 cost plans*,'' second revision dated July 25, 2006 (hereinafter referred to as ''Marketing Guidelines''), are the current standards by which MA organizations and Part D sponsors must meet in their marketing to eligible individuals regarding their plan choices. In developing these standards, CMS recognized that establishing fair marketing standards encompasses more than CMS approval of marketing materials. It also includes the development of standards related to the dissemination of information through a wide variety of media forms (for example, advertisements and Web sites) and MA organization or Part D sponsor (or their agents') conduct when attempting to persuade a beneficiary to enroll in a particular plan. Both the regulations and the Medicare Marketing Guidelines prohibit organizations from conducting marketing activities that would result in generating misleading information to Medicare beneficiaries.

In order to implement standards consistent with ''fair marketing'' practices in accordance with sections 1851(h) and 1860D–1(b)(1)(B)(vi) of the Act, and to ensure beneficiaries receive the necessary information to make informed choices during the annual election period, we propose to amend and expand our marketing regulations for both the MA and the Part D programs. Moreover, due to the proposed addition of new marketing provisions and the need to clarify current marketing regulations, we propose to remove §§ 422.80 and 423.50 of subpart B, which currently specify the requirements related to the approval of marketing materials and instead include this core of our marketing requirements in a new subpart V of 42 CFR 422 and 423 specific to the marketing regulations for each program.

b. Marketing Materials and Marketing Requirements

i. Definitions Concerning Marketing Materials (§§ 422.2260, 423.2260)

We are making an organizational change for this section consistent with our proposal to create a new subpart V of 42 CFR 422 and 423 specific to marketing. We are moving the definition of marketing materials to §§ 422.2260 and 423.2260 of the Part C and D program regulations, respectively.

ii. Review and Distribution of Marketing Materials: File and Use (§§ 422.2262, 423.2262)

In addition to moving our requirements concerning the approval of marketing materials and election forms to §§ 422.2262 and 423.2262 of the Part C and D program regulations, respectively, we are proposing to modify the ''file and use'' review process.

While the statute requires the submission of marketing materials to CMS for a 45-day period of CMS review, based on years of program experience CMS recognized that some MA organizations consistently met all marketing standards, and that their marketing materials warranted less scrutiny. CMS accordingly established a file and use policy that was designed to streamline the marketing materials approval process for these MA plans. Under this file and use policy, Medicare health plans that demonstrated to the satisfaction of CMS that they continually met a particular high standard of performance were able to publish and distribute certain marketing materials within 5 days of submission to CMS under section 1851(h)(1), without waiting for a response from CMS.

In effect, these materials were deemed approved by CMS after 5 days based on CMS's prior review of earlier materials. The criteria in order to be eligible for the original file and use policy were that a contracting entity had to have submitted at least eighteen months of marketing materials for CMS review, and at least ninety percent of the materials submitted within the past six months had to meet applicable marketing standards.

In the regulations implementing the MMA, CMS adopted a separate file and use policy that was based on the nature of the marketing materials in question, rather than the track record of the MA organization or PDP sponsor. Under this policy, an MA organization or PDP sponsor certifies that it is using either model language already reviewed and approved by CMS, or types of marketing materials that CMS has identified as not containing substantive content. As with the original policy that focused on the organization, the materials covered by this new file and use certification policy could be used 5 days after submission, without any explicit approval from CMS. In the case of MA organizations, this certification is made at the time of submission, while PDP sponsors are permitted to so certify in their contracts.

In order to level the playing field among contractors, eliminate redundancies, and focus resources on

materials that have content that warrants CMS scrutiny, we are proposing to eliminate file and use status based on an organization's track record, and apply a uniform policy of applying the file and use policy to marketing materials that either use model language without substantive modification, or materials that are identified by CMS as not containing substantive content warranting CMS review. The same approach to certifying that these types of materials are being used would apply for both Part C and Part D contractors. We would include the proposed file and use provision in § 422.2262(b) and § 423.2262 (b) of the MA and Part D programs, respectively.

iii. Guidelines for CMS (§§ 422.2264, 423.2264)

We are making an organizational change for this section consistent with our proposal to create a new subpart V of 42 CFR 422 and 423 specific to marketing regulations. We are moving §§ 422.80(c) and 423.50(d), which describe specific guidelines for CMS review of marketing materials and election forms, to §§ 422.2264 and 423.2264, respectively.

iv. Deemed Approval (§§ 422.2266, 423.2266)

Consistent with our proposal to create a new subpart V of 42 CFR 422 and 423 specific to marketing regulations, we are making an organizational change for this section. We are removing §§ 422.80(d) and 423.50(e) and creating §§ 422.2266 and 423.2266, respectively. The provision concerns CMS' deemed approval of the distribution of marketing materials.

v. Standards for MA and PDP Marketing (§§ 422.2268, 423.2268)

We are making an organizational change for this section consistent with our proposal to create a new subpart V of 42 CFR 422 and 423 specific to marketing regulations. We are removing §§ 422.80(e) and 423.50(f) and creating §§ 422.2268 and 423.2268, respectively.

vi. Licensing of Marketing Representatives and Confirmation of Marketing Resources (§§ 422.2272, 423.2272)

In response to questions from the Part D industry regarding state licensure of marketing representatives, CMS adopted in its Marketing Guidelines the requirement that MA organizations and Part D sponsors that conduct marketing through independent agents use state-licensed, certified, or registered individuals to do so, if a state licenses such agents. The use of only state-licensed marketing representatives helps ensure that the marketing representatives meet minimum standards of integrity and professionalism in order to market to Medicare-eligible beneficiaries. This Medicare requirement permits Medicare to benefit from State efforts to deny licensure to under-educated, unscrupulous or otherwise substandard individuals, and helps ensure that Medicare beneficiaries are not the victims of substandard or inappropriate marketing activities.

Based on the experience we have gained since the start of the Part D program, and continued experience with the Medicare Advantage program, we propose to codify in the regulation our existing requirement that MA organizations and Part D sponsors utilize only State-licensed marketing representatives to do marketing where they use independent agents in the States that license such agents.

We further propose to add a regulatory requirement to §§ 422.2272 and 423.2272 that MA organizations and PDP sponsors that market through independent agents not only be required to use licensed agents, but would be required to report to States that they are using such agents, in a manner consistent with State appointment laws. State appointment laws require MA and PDP sponsors to appoint marketing representatives before the agent can market a plan's product. Appointment laws may require an insurance plan to maintain a registry of marketers who sell their plans, including maintaining a list of license numbers, dates the individual began selling policies for the insurance company, and stopped selling plans for the insurance company. While we previously required only that licensed agents be used, and did not require that the appointment of such agents be reported to the State agency that regulates agents, we believe this latter requirement would enable States to monitor the agents' activities in connection with their Medicare marketing for the purpose of monitoring the agent's fitness to engage in marketing in the State. We believe Medicare beneficiaries would benefit from this State monitoring.

More specifically, we recognize that, under the preemption provisions in section 1856(b)(3) of the Act (incorporated for PDPs under section 1860D–12(g)), States do not have the authority to regulate the marketing of Medicare Part C and D plans. However, as noted, any abuses by an agent in marketing such plans would have direct relevance to the State's oversight of the agent generally, and implications for the agent's marketing of products over which the state has jurisdiction, and Medicare beneficiaries would benefit from having the agents who engage in Medicare marketing subject to this state oversight. Because State laws requiring compliance with an appointment law with respect to Medicare Part C and Part D marketing are pre-empted, however, we do not believe that any fees that would be charged in connection with a State appointment law would apply. Rather, we would limit the requirement to complying with only those aspects of State appointment laws that provide for giving the state information about which agents are marketing the Part C and D plans.

In the context of the requirement that MA organizations and Part D sponsors utilize only State-licensed marketing representatives, and report the appointment of such agents to States consistent with the procedures under State appointment laws, it is important to discuss the activities that would not trigger the need for using State-licensed marketing representatives. As standard practice, MA organizations and Part D sponsors employ customer service representatives who answer questions and accept enrollments on behalf of enrollees who have decided to enroll in a particular plan offered by the organization. We recognize that plan customer service representatives play an important role in disseminating information by answering factual questions posed by beneficiaries, and that such an activity is distinguishable from the act of steering to a plan (''marketing,'' as defined in the Medicare Marketing Guidelines).

Additionally, taking demographic information from someone who has decided to enroll in the plan, in order to complete an application, is not steering in that the beneficiary has already made a choice to enroll in a plan. Accordingly, we believe providing factual information, fulfilling a request for materials, and taking demographic information in order to complete an enrollment application at the initiative of the enrollee by a customer service representative, are legitimate customer service activities that would not trigger the need for using State-licensed marketing representatives.

In addition, we also propose to clarify in §§ 422.2268 and 423.2268 several standards for MA and PDP organization marketing. In §§ 422.2268(d) and 423.2268(d) we clarify that the prohibition on door-to-door solicitation includes other unsolicited instances of direct contact, such as outbound calling without the beneficiary initiating contact. We believe this clarification

would help prevent inappropriate conduct on the part of agents in aggressively pursuing the marketing of Part C and D plans to beneficiaries (for example, approaching beneficiaries directly in parking lots) outside of approved common areas that may be used for marketing displays and presentations. We would also clarify in §§ 422.2268(l) and 423.2268(l) that plans may not engage in sales activities, including the distribution or collection of plan applications, at educational events. These events may be sponsored by plan(s) or by outside entities, and are events that are promoted to be educational in nature and have multiple vendors, such as health information fairs, conference expositions, state-or community-sponsored events, etc. In §§ 422.2268(k) and 423.2268(k) we clarify that sales activities are only permitted in common areas of health care settings (for example, hospital cafeterias or conference rooms), and would be prohibited in areas where patients primarily intend to receive health care services (for example, waiting rooms and pharmacy counter areas). The term ''health care setting'' refers to all settings where providers operate, including but not limited to pharmacies, physicians offices, hospitals, and long-term care facilities.

We further propose several regulatory requirements in §§ 422.2268 and 423.2268, providing additional protections to ensure beneficiaries are not the victims of inappropriate marketing techniques. These include a new requirement in §§ 422.2268(b) and 423.2268(b) under which organizations would be required to limit the types of promotional items offered to potential enrollees (examples of acceptable items include pens, pill boxes and jar openers) and the value of such items to a nominal amount, established by CMS in operational guidance, and may not provide meals, regardless of value. (Refreshments are allowed, such as coffee, soft drinks, and snacks.) In §§ 422.2268(f) and 423.2268(f), we also propose to prohibit the cross-selling, in any MA or Part D sales activity or presentation, of non-health care-related products to a prospective enrollee. Marketing to current plan members of health care and non-health care-related products would also remain subject to HIPAA rules. In §§ 422.2268(g) and 423.2268(g), we are proposing to limit any appointment with a beneficiary involving marketing of health care-related products (for example, whether Medicare supplement, Medicare Advantage, stand-alone PDP will be discussed) to the scope agreed upon by the beneficiary. In advance of any marketing appointment, the beneficiary must have the opportunity to agree to the range of choices that will be discussed, and that agreement must be documented by the plan. Under proposed §§ 422.2268(h) and 423.2268(h), additional lines of plan business not identified prior to the in-home appointment would require a separate appointment that could not be re-scheduled until 48 hours after the initial appointment. An additional beneficiary protection, proposed in §§ 422.2268(n) and 423.2268(n), would limit the use of names and/or logos of co-branded network providers on plan membership and marketing materials. This proposed requirement will reduce the tendency of members to mistakenly believe they must use the co-branded network provider in order to obtain plan benefits.

vii. Broker and Agent Requirements (§§ 422.2274, 423.2274)

Section 1851(h)(2) of the Act requires us to establish marketing standards for Medicare Advantage (MA) plans and under section 1860D–1(b)(1)(B)(vi) of the Act, Medicare prescription drug benefit plans (PDP), to ensure that beneficiaries are not misled or provided inaccurate information. Since the passage of the MMA, CMS has not specified standards in the regulation pertaining to the way brokers or agents (herein after referred to as ''agents'') who are used to market MA plans and PDPs are compensated. Currently, the Marketing Guidelines allow agent compensation to vary based on the level of effort and the plan product type.

Agents selling MA and PDP products play a significant role in providing guidance and advice to beneficiaries when selecting health plan options. This unique position allows them to influence beneficiary choices. The current compensation structure in the Marketing Guidelines has the potential to create a financial incentive for agents to only market and enroll beneficiaries in some plan products and not others. Based on our experience since the passage of MMA, this compensation structure has lead some agents to encourage beneficiaries to enroll in products that may not meet the beneficiaries' health needs but pays the agents the highest commission. In addition, there is a potential financial incentive for agents to encourage beneficiaries to change plans each year. Therefore, in order to prevent agents from unnecessarily moving beneficiaries from plan to plan and to ensure that beneficiaries are receiving the information and counseling necessary to select the best plan based on their needs, CMS intends to establish guidelines for agent compensation.

We propose to add §§ 422.2274(a)(1) and (a)(2) and 423.2274(a)(1) and (a)(2) to include these requirements. Specifically CMS would require MA organizations and PDP sponsors to adopt a commission structure in which:

- The commission or other compensation (collectively referred to as ''commission'') to an agent or representative in the first year may not exceed the commission the agent would receive for selling or servicing the policy in all subsequent years.
- The commission must be the same for all plans and all plan product types offered by the organization's or sponsor's parent. Each organization offering MA and MA–PD products must establish a single commission that may not vary based on the premium of the plan or any other measure and apply this flat fee commission to all products. Each sponsor offering PDP products must establish a single commission that may not vary based on the premium of the plan or any other measure and apply this flat fee commission to all products.

Additionally, to ensure beneficiaries are getting the information necessary to make informed decisions, it is critical that agents are trained on Medicare rules, regulations and compliance-related information on the plan products they intend to sell. In addition to the training, we propose to require that agents pass a written test to demonstrate their knowledge of the Medicare program and the plan specific products they intend to sell. We expect MA organizations and PDP sponsors to develop training modules and written or electronic tests based on CMS guidelines. MA organizations and PDP sponsors may also use or accept the training modules and written or electronic tests of third parties or other MA organizations or PDP sponsors. CMS has reviewed sophisticated training and testing software of two major entities offering third party testing. The testing software included important controls to ensure the integrity of the testing. The testing software includes questions developed by test development experts. In addition the software has the ability to generate new questions for agents that require re-testing. CMS will review the training modules and tests during routine or focused monitoring visits. This will ensure that agents fully understand the products they are marketing and selling, that they are providing accurate plan information and are able to provide the best plan recommendations to beneficiaries.

We propose to establish guidelines for agent training and testing and require, at CMS request, the reporting of marketing related information. We propose to include these requirements at §§ 422.2274 and 423.2274. Specifically CMS would—

- In 422.2274(b) and 423.2274(b), require MA organizations and PDP sponsors to train all agents selling Medicare products on Medicare rules, regulations and compliance-related information.
- In 422.2274(c) and 423.2274(c), require agents selling Medicare products to pass written or electronic tests on Medicare rules, regulations and information on the plan products they intend to sell.
- In 422.2274(d) and 423.2274(d), require MA organizations and PDP sponsors to provide to CMS the information designated by CMS as necessary to conduct oversight of marketing activities.
- In 422.2274(e) and 423.2274(e), require MA organizations and PDP sponsors to comply with State requests for information about the performance of licensed agents or brokers as part of a State investigation into the individual's conduct. CMS will establish and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

We believe these proposed changes would enable beneficiaries to receive up-to-date information to help them select the best plan. In addition, the proposed changes would ensure that agents receive adequate training to market Medicare products, create a standard agent compensation structure and eliminate the financial incentives to encourage beneficiaries to enroll in a plan that may not be in the beneficiaries' best interest.

viii. Employer Group Retiree (§§ 422.2276, 423.2276)

We are making an organizational change for this section consistent with our proposal to create a new subpart V of 42 CFR 422 and 423 specific to marketing regulations. We are removing §§ 422.80(f) and creating §§ 422.2276 and, because the provision applies as well to the Part D program, adding new § 423.2276 to Part 423.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

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

Section 422.4 Types of MA Plans

Section 422.4(a)(1)(iv)(B) states that MA organizations offering disproportionate percentage SNPs must limit new enrollment of non-special needs members to no more than 10 percent of new enrollees, and that at least 90 percent of new enrollees must be special needs individuals as defined in § 422.2.

The burden associated with this requirement is the time and effort put forth by the MA organization to monitor the percentage of non-special needs individuals in the SNP and ensure that this level remains below the established threshold. It will take one MA organization an initial burden of 2 hours to comply with this requirement. Therefore, with 176 disproportionate percentage SNPs in the market, the initial burden associated with this requirement is 352 hours.

We estimate it would take one MA organization an additional burden of 1 hour/week to comply with this requirement on an ongoing basis for a total annual burden of 52 hours/year. We estimate 176 MA organizations would be affected annually by this requirement; therefore, the total annual burden associated with this requirement is 9152 hours.

Section 422.52 Eligibility To Elect an MA Plan for Special Needs Individuals

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. 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 776 SNPs; therefore, the total annual burden is estimated to be 60,000 hours.

Section 422.60 Election Process

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 (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.

Section 422.101 Requirements Relating to Basic Benefits

Section 422.101(f)(1) states that MA organizations offering special needs plans must have a model of care plan specifying how the plan will coordinate and deliver care designed for the plan's enrollees. The model of care plan would be developed by the deliberations of the appropriate staff of the MA organization and maintained in a written document.

The burden associated with this requirement is the time and effort put forth by the special needs plans to establish a model that meets the requirements specified under Section 422.101(f)(1). We estimate it would take one special needs plan 24 hours for six months to meet this requirement. We estimate 335 special needs plans would be affected by this requirement annually; therefore, the total annual burden associated with the requirement is 8,040 hours.

Section 422.103 Benefits Under an MA MSA Plan

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 that 20 MA plans may wish to participate as MSAs in 2009, which would be double the number participating in 2008.

We estimate the burden associated with this requirement in term of time and effort necessary for the plan to develop the information and to submit this information to CMS as a start-up cost of 100 hours per plan to develop this information for a total of 2,000 hours in the first year the plan participates as an MSA plan, with half of that cost occurring in subsequent years for plans to maintain and update this information. In addition, expected additional entry by plans in future years would add start-up costs in the initial year that plans enter.

Section 422.107 Special Needs Plans and Dual Eligibles: Arrangements With States

Section 422.107(a) states that an MA organization seeking to offer or currently offering a special needs plan primarily serving beneficiaries eligible for both Medicare and Medicaid (dual eligible SNPs) must have a documented relationship with the State Medicaid agency for the State in which the SNP is operating. At a minimum, documented arrangements must include the means to (1) verify enrollees' eligibility for both Medicare and Medicaid, identify and share information on Medicaid provider participation, and (3) identify Medicaid benefits which are not covered by Medicare. Medicare Advantage organizations and the respective states may choose to document their relationship in a variety of ways, such as a memorandum of agreement (MOA), a memorandum of understanding (MOU), or a contract.

The burden associated with this requirement is the time and effort put forth by each special needs plan to have a documented relationship. We estimate it would take one special needs plan 18 hours for 6 months to comply with this requirement. We estimate 460 special needs plans would be affected annually by this requirement; therefore, the total annual burden associated with this requirement is 8,280 hours.

Section 422.504 Contract Provisions

Section 422.504(g)(1) states that each MA organization must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability for payment of fees that are the legal obligation of the MA organization. This may be done by the establishment of identified liaison staff of the MA plan and the State Medicaid agency, and by conducting regular meetings for the purpose of enrollee review.

The burden associated with this requirement is the time and effort put forth by the MA plan to adopt and maintain arrangements. We estimate it would take one MA plan 208 hours to comply with this requirement. We estimate 3400 plans would be affected annually by this requirement; therefore, the total annual burden associated with this requirement is 707,200 hours.

Section 422.2260 Definitions

Section 422.2260 defines the marketing materials that an MA organization must provide to Medicare beneficiaries. 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(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

422.2262 Review and Distribution of Marketing Materials

Section 422.2262(a)(1)(i) states that at least 45 days before the date of distribution the MA organization submits the material or form to CMS for review under guidelines in Section 422.2264 of this Part. This may require the development of written marketing materials used to promote an organization, provide enrollment information, and explain benefits, rules or various membership operational policies.

The burden associated with this is the time and effort put forth by the MA organization to submit the material to CMS for review. We estimate it would take one MA organization 720 minutes/12 hours to comply with this requirement. We estimate 670 MA organizations would be affected annually by this requirement; therefore, the total annual burden associated with this requirement is 8,040 hours.

Section 422.2262(b) requires the MA organization to certify that in the case of these certain marketing materials designated by CMS, it followed all applicable marketing guidelines when applicable or used model language specified by CMS without modification.

The burden associated with this requirement is the time and effort put forth by the MA organization to provide such certification. 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).

Section 422.2264 Guidelines for CMS Review and Notification

Section 422.2264 states that in reviewing marketing material or election forms under § 422.2262 of this Part, CMS determines that the marketing materials provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling:

(a) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges.

(b) Adequate written description of any supplemental benefits and services.

(c) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each.

(d) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(e) Notify the general Public of its enrollment period in an appropriate manner, through appropriate media, throughout its service and if applicable, continuation areas.

(f) Includes in the written materials notice that the MA organization is authorized by law to refuse to renew its contract with CMS, that CMS also may

refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the plan.

(g) Are not materially inaccurate or misleading or otherwise make material misrepresentations.

(h) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

The burden with these guidelines is the time and effort put forth by the MA organization to provide adequate written descriptions of rules, of any supplemental benefits and services, explanation of the grievance and appeals process, and any other information necessary to enable beneficiaries to make an informed decision about enrollment. It also requires the MA organization to notify the general public of its enrollment period in an appropriate manner and include in the written materials notice that the MA organization is authorized by law to refuse to renew its contract with CMS. 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(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 422.2268 Standards for MA Organization Marketing

Section 422.2268(g) states MA organizations cannot market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

The burden associated with this requirement is the time and effort put forth by the MA organization to document a beneficiary's signed acknowledgement confirming the specific types of choices that the marketing representative is authorized to discuss. 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(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 422.2272 Licensing of Marketing Representatives and Confirmation of Marketing Resources

Section 422.2272(b) states that an MA organization must establish and maintain a system for confirming that enrolled beneficiaries have, in fact, enrolled in the MA plan and understand the rules applicable under the plan.

The burden associated with this requirement is the time and effort put forth by the MA organization to establish and maintain such a system. 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(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 422.2274 Broker and Agent Commissions and Training of Sales Agents

Section 422.2274(b) states that if a MA organization markets through independent brokers or agents, they must train and test agents selling Medicare products concerning Medicare rules and regulations specific to the plan products they intend to sell.

The burden associated with this requirement is the time and effort put forth by the MA organization to provide training and test agents. 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(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 422.2274(d) states that upon CMS's request, the MA organization must provide CMS the information necessary for it to conduct oversight of marketing activities. This may require producing information for CMS on marketing materials submitted for review or file and use of training and testing modules.

The burden associated with this requirement is the time and effort put forth by the MA organization to produce the information requested by CMS. We estimate it would take one MA organization (480 minutes/8 hours) to comply with this requirement. We estimate 670 MA organizations would be affected annually by this requirement; therefore, the total annual burden associated with this requirement is 5,360 hours.

Section 422.2274(e) states that MA organizations must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct.

The burden associated with this requirement is the time and effort put forth by the MA organization to comply with the State requests for information. 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(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 423.34 Enrollment of Full-benefit Dual Eligible Individuals

Section 423.34(g)(2) states that 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 their ability to decline the enrollment or choose another plan. Such notification must be provided to all potential enrollees prior to the enrollment effective date, in a form and manner determined by CMS.

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 8700 hours.

Section 423.46 Late Enrollment Penalty

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.

Section 423.505 Contract Provisions

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).

Section 423.580 Right to a Redetermination

Section 423.580 provides information on the ways for an enrollee to seek a redetermination. The burden associated with a reconsideration is exempt from the PRA as stipulated under 5 CFR 1320.4.

Section 423.2262 Review and Distribution of Marketing Materials

Section 423.2262(a)(1)(i) requires the Part D sponsor to submit the marketing material or form to CMS for review under the guidelines in § 423.2264. This may require the development of written marketing materials used to promote an organization, provide enrollment information, and explain benefits, rules or various membership operational policies.

The burden associated with these requirements is the time and effort put forth by the Part D sponsor to submit the marketing materials to CMS and to provide certification. We estimate it would take one Part D sponsor (720 minutes/12 hours) to comply with this requirement. We estimate 87 Part D sponsors would be affected annually by this requirement; therefore, the total annual burden associated with this requirement is 1044 hours.

Section 423.2264 Guidelines for CMS Review and Notification

Section 423.2264 reads that in reviewing marketing material or enrollment forms under § 423.2262, CMS determines (unless otherwise specified in additional guidance) that the marketing materials provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling must consist of:

(a) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges.

(b) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each.

(c) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(d) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area.

(e) Include in the written materials notice that the Part D plan is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the Part D plan. In addition, the Part D plan may reduce its service area and no longer be offered in the area where a beneficiary resides.

(f) Are not materially inaccurate or misleading or otherwise make material misrepresentations.

(g) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

The burden with these guidelines is the time and effort put forth by the Part D plan to provide adequate written descriptions of rules, of the grievance and appeals process, and any other information necessary to enable beneficiaries to make an informed decision about enrollment. It also requires the Part D plan to notify the general public of its enrollment period in an appropriate manner and include in the written materials notice that the Part D plan is authorized by law to refuse to renew its contract with CMS. 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(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 423.2272 Licensing of Marketing Representatives and Confirmation of Marketing Resources

Section 423.2272(b) requires the Part D organization to establish and maintain a system for confirming that enrolled beneficiaries have in fact enrolled in the PDP and understand the rules applicable under the plan.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor to establish and maintain such a system. 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(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 423.2268 Standards for Part D Marketing

Section 423.2268(g) states Part D organizations cannot market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

The burden associated with this requirement is the time and effort put forth by the Part D organization to document a beneficiary's signed acknowledgement confirming the specific types of choices that the marketing representative is authorized to discuss. 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(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 423.2274 Broker and Agent Commissions and Training of Sales Agents

Section 423.2274(b) requires the Part D sponsor to train and test agents selling Medicare products concerning Medicare rules and regulations specific to the plan products they intend to sell.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor to provide training and test agents. 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(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 423.2274(d) states that upon CMS's request, the Part D sponsor must provide CMS the information necessary for it to conduct oversight of marketing activities. This may require producing information for CMS on marketing materials submitted for review or file and use and training and testing modules.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor to produce the information requested by CMS. We estimate it would take one Part D sponsor (480 minutes/8 hours) to comply with this requirement. We estimate 87 Part D sponsors would be affected annually by this requirement; therefore, the total annual burden associated with this requirement is 696 hours.

Section 423.2274(e) states that Part D organizations must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct.

The burden associated with this requirement is the time and effort put forth by the Part D organization to comply with the State requests for information. 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(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Please note, CMS will revise the currently OMB approved PRA packages that contain Part 422—Medicare Advantage Program and Part 423—Voluntary Medicare Prescription Drug Benefit to include any new and/or revised burden requirements. The OMB approval numbers for those PRA packages are 0938–0753 and 0938–0964.

As reflected in the table that follows, the aggregate annual burden associated with the collection of information section for this proposed rule totals 985,527.5 hours.

OMB No.	Requirements	Number of respondents	Burden hours	Total annual burden (in hours)
	422.4(a)	176	54	9,504
0938–0753	422.52(g)	776	78	60,000
0938–0753	422.60(g)(2)	5	.5	2.5
0938–0753	422.101(f)(1)	335	24	8,040
0938–0753	422.103(e)	20	100	2,000
0938–0753	422.107(a)	460	18	8,280
0938–0753	422.504(g)(1)	3400	208	707,200
None/Exempt	422.2260	N/A	N/A	N/A
0938–0753	422.2262(a)(1)(i)	670	12	8,040
0938–0753	422.2262(b)	N/A	N/A	N/A
0938–0753	422.2264(a–e)	N/A	N/A	N/A
0938–0753	422.2268(g)	N/A	N/A	N/A
0938–0753	422.2272(b)	N/A	N/A	N/A
0938–0753	422.2274(b)(e)	N/A	N/A	N/A
0938–0753	422.2274(d)	670	8	5,360
0938–0964	423.34(g)(2)	42	207	8,694
0938–0964	423.46(b)	500,000	([1])15	125,000
0938–0964	423.46(d)	500,000	([1])5	41,667
None/Exempt	423.505(k)(5)	N/A	N/A	N/A
None/Exempt	423.580	N/A	N/A	N/A
0938–0964	423.2262(a)(1)(i)	87	12	1,044
0938–0964	423.2264(a–e)	N/A	N/A	N/A
0938–0964	423.2268(g)	N/A	N/A	N/A
0938–0964	423.2272(b)	N/A	N/A	N/A
0938–0964	423.2274(b)(e)	N/A	N/A	N/A
0938–0964	423.2274(d)	87	8	696
Total aggregate burden				985,527.5

[1] In minutes.

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

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

2. Mail copies to the address specified in the **ADDRESSES** section of this proposed 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:* Carolyn Lovett, CMS Desk Officer, CMS–4131–P *carolyn_lovett@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. Regulatory Impact Analysis

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). We estimate that this proposed rule is ''economically significant'' as measured by the $100 million threshold, and hence a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis. The provisions in this proposed rule would require MA organizations and Part D sponsors to spend a total of approximately 985,527.5 additional hours on the functions addressed, reflecting a cost of $45,940,906. In addition, the provisions associated with our proposed revision to the beneficiary cost sharing and reinsurance subsidy payments are estimated to cost $30 million for FY 2010 and $530 million for FYs 2010 through 2018. The provisions impacting which drug costs are reported to CMS under the Retiree Drug Subsidy (RDS) program and used as the basis for calculating RDS payments to RDS plan sponsors would result in estimated savings of $30 million for FY 2010 and $510 million for FYs 2010 through 2018. We solicit public comment on the regulatory impact analysis of this proposed rule.

We use, 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) [3] 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 for the provisions discussed in this proposed rule with comment period. (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 total net cost of our proposals would be approximately $45,940,906. This cost would be spread more or less evenly across participating plans, and hence would impose negligible burden on any plan in relation to existing administrative costs.

In the Regulatory Impact Analysis of the January 28, 2005 final rule (70 FR 4695) revising the Medicare Advantage program, we noted that costs associated with the MA program would be approximately $18.3 billion from 2004 through 2009, 10 percent of which we estimated would be administrative costs. The rule establishing the prescription drug benefit program published on January 28, 2005 (70 FR 4194) made a similar calculation in its Regulatory Impact Statement. Accordingly, the estimated cost of this proposed rule adds negligibly to the total administrative costs of the MA or Part D programs.

With respect to economic benefits, we have no reliable basis for estimating the effects of these proposals. Many of the proposed 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 these proposals, they are difficult to gauge at this time.

Because there are costs to plans and sponsors associated with several provisions of this proposed rule, however, we indicate general areas affected and specify the costs associated with these. For specific burden associated with the proposed requirements and the bases for our estimates, see section III, Collection of Information Requirements, of this rule. Note that we discuss separately, at the end of this section, provisions associated with our proposed revision to the Part D definitions (discussed in section II.B.3 of this proposed rule).

[3] 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).

Special Needs Plans

Several of our proposed provisions concern special needs plans and strengthening coordination between plans and States to better coordinate care, verify that individuals in dual eligible SNPs are eligible for Medicare, and to ensure that enrollees are not charged for costs that are the responsibility of the State. In addition, we are proposing that MA plans develop models of care that are specifically targeted to the special needs individuals served by their plans. We estimate the total cost of these provisions as $2,718,104. Costs for each provision are as follows:

- Verification of Medicaid eligibility or SNP status prior to beneficiary enrolling ($21.73 × 60,000 hours = $1,303,800).
- Developing models of care ($54.98 × 8,040 hours = $442,039).
- Documenting arrangements with States ($54.98 × 8,280 hours = $455,234).
- Monitoring enrollment to meet disproportionate share thresholds ($54.98 × 9,404 hours = $517,031).

Medicare Medical Savings Accounts (MSAs)

Costs associated with this proposed provision are for reporting cost and quality information about the plans to enrollees. We estimate the total cost of these provisions as $109,960 ($54.98 × 2,000 hours) for the first year a plan provides such information, and half that cost in subsequent years to maintain and update the information.

Enrollment

We are proposing requirements concerning Part D sponsor notification of full benefit dual eligible beneficiaries about enrollment options in addition to automatic enrollment, and would require 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 $42,692,449. The 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).

• Ensuring through provider contracts that dual eligible beneficiaries are not held liable for costs that are not their responsibility ($54.98 × 707,200 hours = $38,881,856).

Marketing

We are proposing several marketing provisions that would enhance our efforts to ensure that plans comply with all marketing requirements. The proposed provisions include requiring plans to submit marketing materials to CMS for review, and provide, for CMS oversight purpose, information to CMS concerning marketing activities. We estimate the total costs (MA and Part D programs) of these provisions as $530,353. Costs for each provision, in the context of each program, are as follows:

• Submission of marketing materials, MA program ($21.73 × 8,040 hours = $174,709).

• Training and testing of agents selling Medicare products, MA program ($54.98 × 5,360 hours = $294,692).

• Submission of marketing materials, Part D ($21.73 × 1,044 hours = $22,686).

• Training and testing of agents selling Medicare products, Part D ($54.98 × 696 hours = $38,266).

The RFA requires that we discuss any alternatives considered. Many of the proposed provisions would clarify or codify current policy which we discuss in section II, Provisions of the Proposed Regulations. 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 would be minimal and outweighed the minimal costs to implement these.

With respect to our proposed provisions concerning Medicare medical savings account plans, we considered the costs to plans of providing cost and quality information. As we discuss in more detail in section II, we believe that such information is readily available to most MSA plans and that, as a result, it would not be an undue burden on plans to provide such information. We would like more information on this subject, however, and have specifically asked for comments on this proposed provision.

The RFA requires agencies to analyze options for regulatory relief of small businesses. 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 $6.5 million to $31.5 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 would be affected by the proposed provisions, 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 generally are above the revenue threshold required for analysis. 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, 3–5 percent of their revenue would have to be affected by the proposed provisions. We do not believe that any of these provisions rise to that threshold. Many of the provisions we are proposing, for example, are clarifications of existing policy or require minimal costs. Because MA organizations and Part D sponsors are the only entities that would be affected by the proposed provisions and because of the minimal costs necessary to implement the proposed provisions, we are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities.

With respect to the proposed revision 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 proposed rule. These changes would primarily impact which drug costs are reported to us and how plans calculate beneficiary cost sharing. Moreover, we assume they would require minimal, if any, changes in health plan, PBM and pharmacy operational systems. We solicit comments on this assumption. 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 would 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 would increase Part D bids and Federal Government payments such that the total impact for FY 2010 through 2018 is $530 million. However, we do not expect these changes to significantly increase health plan costs. Table 1 presents the costs associated with the change in the beneficiary costs for FYs 2010–2018.

TABLE 1.—INCREASE IN SUBSIDY PAYMENTS FOR FY 2010–2018

	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FYs 2010–18
Increase in Subsidy Payments (millions)	$30	$40	$50	$50	$60	$60	$70	$80	$90	$530

With respect to the proposed 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 would be minimal, as the total compensation received by pharmacies should remain unaffected. However, Part D plans would need to include administrative costs paid to PBMs, which were previously included as drug costs, as administrative cost in their bids. They would also need to factor reductions in beneficiary cost sharing and reinsurance subsidy payments into their bids. The reductions in beneficiary cost sharing are expected to outweigh the estimated increase in costs to the Federal Government. The changes in beneficiary cost sharing and reinsurance subsidy payments are expected to increase Part D bids due to increased plan liability and therefore, would increase the direct subsidy payments made by the Federal Government to health plans. The proposed changes regarding which 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. We estimate the net cost of these changes to be $30 million for FY 2010 and $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 reductions in Federal reinsurance payments and low-income cost sharing subsidy payments. These estimated costs are based on the assumption that overall program costs would 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 proposed 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 would be unaffected by the changes in the reporting drug costs reported and the calculation of beneficiary cost sharing. Thus, we expect that the financial impact of the proposed rule on PBMs would be minimal.

With respect to the proposed changes impacting which drug costs are reported to CMS under the Retiree Drug Subsidy (RDS) program and used as the basis for calculating RDS payments to RDS plan sponsors, this will result in savings to the RDS program since gross costs and allowable retiree costs may, until this proposed regulation becomes effective, include amounts paid by the plan to a PBM for Part D drugs that differ from the amounts paid by the PBM to pharmacies for these drugs (typically called a ''risk premium'' or ''PBM spread''). The proposed revised definitions of administrative costs, gross retiree costs and allowable retiree costs would exclude these risk premium payments from the calculation of RDS payments.

The estimated impact of applying the proposed changes is a savings of $510 million for fiscal years 2010 through 2018, as detailed in Table 2. To calculate these savings estimates, we multiplied our assumption for the number of affected beneficiaries in RDS by an estimated per capita drug cost impact and the statutorily-required 28 percent RDS subsidy percentage. Our estimate for the number of affected beneficiaries in RDS is based on the number of RDS beneficiaries assumed to be enrolled in affected RDS plans. In addition, this estimate assumes that only those RDS beneficiaries with drug spending between the cost threshold and the cost limit would be impacted by the proposed change. The proposed change would not affect Plan Sponsors with regard to those individuals below the threshold. With regard to those above the cost limit, a Plan Sponsor generally is eligible for a set amount of subsidy based on the amount of drug costs between the threshold and the limit, regardless of how much above the limit the individual's drug costs are, and regardless of whether pass through or lock in is used. Therefore, the proposed change generally would not affect Plan Sponsors with regard to individuals above the cost limit. We estimated the drug cost impact of switching from lock-in pricing to pass through pricing based on current estimates for 2006 Part D plans. We used the estimated impact for Part D plans because RDS specific information is not currently available to develop this estimate. We welcome comments on the assumptions used to develop the savings estimates from applying the revised definitions to the RDS program. In addition, we expect that the proposed rule's clarifications may result in some plan sponsors incurring nominal additional administrative costs in revising cost reporting methods.

TABLE 2.—DECREASE IN RDS PAYMENTS FOR FY 2010–2018

	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FYs 2010–2018
Decrease in RDS Payments by the Federal Government (in millions)	$30	$40	$50	$50	$60	$60	$70	$70	$80	$510

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

Section 202 of the Unfunded Mandates Reform Act of 1995 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 would have no consequential effect on State, local, or tribal governments or on the private sector.

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

Alternatives Considered

As discussed earlier, many of the proposed provisions would clarify or codify current policy which we discuss in section II, Provisions of the Proposed Regulations. 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 would be minimal and outweighed the minimal costs to implement these provisions.

With respect to our proposed provisions concerning Medicare medical savings account plans, we considered the costs to plans of providing cost and quality information. As we discuss in more detail in section II, we believe that the information is readily available to most MSA plans and that, as a result, it would not be an undue burden on plans to provide the information. We would like more information on this subject, however, and have specifically asked for comments on this proposed provision.

With respect to the proposed changes to the drug cost-related definitions in the Part D and Retiree Drug Subsidy (RDS) programs, we have discussed the two alternatives at length in the preamble section. The two alternatives are (1) the current approach of allowing both pass-through and lock-in prices, and (2) the proposed approach of permitting only pass-through prices as the basis for Part D and RDS 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 propose to allow only the single ''pass-through'' pricing approach as originally intended in the final rule establishing the Part D prescription drug benefit.

Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/index.html*), in Table D1 below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. This table provides our best estimate of the increase in costs as a result of the proposed changes. The costs are classified as either transfers by the Federal Government to Part D plans, or transfers from RDS sponsors to the Federal Government.

TABLE 3.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers ($ millions)
Increase in Federal Payments, FYs 2010–2018	
Annualized Monetized Transfers Using 7% Discount Rate	$55.8.
Annualized Monetized Transfers Using 3% Discount Rate	$57.5.
From Whom to Whom	Federal Government to Part D Plans.
Decrease in RDS Payments for FY 2010–2018	
Annualized Monetized Transfers Using 7% Discount Rate	$54.1.
Annualized Monetized Transfers Using 3% Discount Rate	$55.5.
From Whom to Whom	RDS Sponsors to Federal Government.
Cost for all Other Provisions Not Related to the Part D Definitions for FY 2010	
Undiscounted Annualized Monetized Transfers	$45.94.
Who Is Affected	MAOs/Part D Sponsors.

Conclusion

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 (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping.

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

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

§ 422.4 Types of MA plans.

(a) * * *

(1) * * *

(iv) * * *

(B) Enrolls plan membership that consists of 90 percent or more special needs individuals as defined in § 422.2.

(*1*) For purposes of meeting the 90 percent threshold, the plan may not disenroll a member who does not meet the special needs individual definition in § 422.2 of this part.

(*2*) Those enrollees deemed continuously eligible per § 422.52(d) of this part, are considered special needs individuals for the purpose of determining the 90 percent threshold.

* * * * *

Subpart B—Eligibility, Election, and Enrollment

3. Amend § 422.52 by adding paragraph (g) to read as follows:

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

* * * * *

(g) *Establishing eligibility prior to enrollment.* A SNP must employ a process approved by CMS to verify the Medicaid eligibility or special needs status of an individual prior to enrolling the individual.

4. 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 their 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).

5. Amend § 422.74 by revising paragraph (d)(1) introductory text and adding paragraph (d)(1)(iv) to 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 has requested to have monthly premiums withheld per § 422.262(f)(1) or who is in premium withhold status.

* * * * *

6. Remove § 422.80.

Subpart C—Benefits and Beneficiary Protections

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

§ 422.101 Requirements relating to basic benefits.

* * * * *

(f) *Special needs plan model of care* (1) MA organizations offering special needs plans must have a model of care plan specifying how the plan will coordinate and deliver care designed for the plan's enrollees. The model of care plan must provide for the following:

(i) Coordinate care for eligible beneficiaries.

(ii) Include a network of providers/services having relevant clinical expertise.

(iii) Target a special needs population.

(iv) Deliver care based on appropriate protocol for the target enrollees.

(v) Deliver care to frail/disabled enrollees.

(vi) Deliver care to enrollees who are at the end of life.

(vii) Apply performance measures to evaluate processes and outcomes of the model.

(2) [Reserved]

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.

9. Add new § 422.107 to read as follows:

§ 422.107 Special needs plans and dual eligibles: arrangements with States.

(a) *General rule.* An MA organization seeking to offer or currently offering a special needs plan primarily serving beneficiaries eligible for both Medicare and Medicaid (dual eligible SNPs) must have a documented relationship with the State Medicaid agency for the State in which the SNP is operating. At a minimum, documented arrangements must include the means to—

(1) Verify enrollees' eligibility for both Medicare and Medicaid,

(2) Identify and share information on Medicaid provider participation, and

(3) Identify Medicaid benefits which are not covered by Medicare.

(b) *Date of Compliance.* Current SNPs must be in compliance with § 422.107(a) within 3 years after the effective date of the final rule.

10. Amend § 422.111 by revising paragraph (a)(3) to read as follows:

§ 422.111 Disclosure requirements.

(a) * * *

(3) At the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period.

* * * * *

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

11. Amend § 422.262 by—

A. Adding paragraph (g).

B. Adding paragraph (h).

The additions 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 requested that premiums be withheld from his or her Social Security benefit.

(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 or by equal monthly installment spread out over at least the same period for which the premiums were due. That is, 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

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

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

§ 422.504 Contract provisions.

* * * * *

(g) * * *

(1) 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 contracts must state that providers will—

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

(B) Bill the appropriate State source.

* * * * *

14. Amend § 422.506 by—

A. Revising paragraph (a)(2)(ii) and (a)(2)(iii).

B. Revising paragraph (b)(2)(ii) and (b)(2)(iii).

The revisions 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

15. 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.

16. 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

17. 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.

* * * * *

Subpart U—[Added and Reserved]

18. Subpart U is added and reserved.

19. New subpart V is added to read as follows:

Subpart V—Medicare Advantage Marketing Requirements

Sec.

Subpart V—Medicare Advantage Marketing Requirements

§ 422.2260 Definitions concerning marketing materials.

As used in this subpart—

Marketing materials. (1) Marketing materials include any informational materials targeted to Medicare beneficiaries which:

(i) Promote the MA organization, or any MA plan offered by the MA organization.

(ii) Inform Medicare beneficiaries that they may enroll, or remain enrolled in, an MA plan offered by the MA organization.

(iii) Explain the benefits of enrollment in an MA plan, or rules that apply to enrollees.

(iv) Explain how Medicare services are covered under an MA plan, including conditions that apply to such coverage.

(2) Examples of marketing materials include, but are not limited to, the following:

(i) General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the Internet.

(ii) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(iii) Presentation materials such as slides and charts.

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

(v) Membership communication materials such as membership rules, subscriber agreements, member handbooks and wallet card instructions to enrollees.

(vi) Letters to members about contractual changes; changes in

providers, premiums, benefits, plan procedures etc.

(vii) Membership or claims processing activities (for example, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or annual notification information).

§ 422.2262 Review and distribution of marketing materials.

(a) *CMS review of marketing materials.* (1) Except as provided in paragraph (b) of this section an MA organization may not distribute any marketing materials (as defined in § 422.2260 of this part), or election forms, or make such materials or forms available to individuals eligible to elect an MA organization unless—

(i) At least 45 days (or 10 days if using marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution the MA organization has submitted the material or form to CMS for review under the guidelines in § 422.2264 of this Part; and

(ii) CMS does not disapprove the distribution of new material or form.

(2) [Reserved]

(b) *File and use.* The MA organization may distribute certain types of marketing materials, designated by CMS, 5 days following their submission to CMS if the MA organization certifies that in the case of these designated marketing materials it followed all applicable marketing guidelines and, when applicable, used model language specified by CMS without modification.

§ 422.2264 Guidelines for CMS review.

In reviewing marketing material or election forms under § 422.2262 of this part, CMS determines that the marketing materials—

(a) Provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling:

(1) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges.

(2) Adequate written description of any supplemental benefits and services.

(3) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each and

(4) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(b) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service and if applicable, continuation areas.

(c) Include in written materials notice that the MA organization is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the plan.

(d) Ensure that materials are not materially inaccurate or misleading or otherwise make material misrepresentations.

(e) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

§ 422.2266 Deemed approval.

If CMS has not disapproved the distribution of marketing materials or forms submitted by an MA organization with respect to an MA plan in an area, CMS is deemed not to have disapproved the distribution in all other areas covered by the MA plan and organization except with regard to any portion of the material or form that is specific to the particular area.

§ 422.2268 Standards for MA organization marketing.

In conducting marketing activities, MA organizations may not—

(a) Provide for cash or other monetary rebates as an inducement for enrollment or otherwise. This does not prohibit explanation of any legitimate benefits the beneficiary might obtain as an enrollee of the MA plan, such as eligibility to enroll in a supplemental benefit plan that covers deductibles and coinsurance, or preventive services.

(b) Offer gifts to potential enrollees, unless the gifts are of nominal (as defined in the CMS Marketing Guidelines) value, are offered to all eligible members without discrimination, and are not in the form of cash or other monetary rebates. Providing meals for potential enrollees is prohibited, regardless of value.

(c) Engage in any discriminatory activity such as, for example, attempts to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(d) Solicit door-to-door for Medicare beneficiaries or through other unsolicited means of direct contact, including calling a beneficiary without the beneficiary initiating the contact.

(e) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the MA organization. The MA organization may not claim that it is recommended or endorsed by CMS or Medicare or that CMS or Medicare recommends that the beneficiary enroll in the MA plan. It may, however, explain that the organization is approved for participation in Medicare.

(f) Market non-health care related products to prospective enrollees during any MA or Part D sales activity or presentation. This is considered cross-selling and is prohibited.

(g) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

(h) Market additional health related lines of plan business not identified prior to an in-home appointment without a separate appointment that may not be scheduled until 48 hours after the initial appointment.

(i) Distribute marketing materials for which, before expiration of the 45-day period, the MA organization receives from CMS written notice of disapproval because it is inaccurate or misleading, or misrepresents the MA organization, its marketing representatives, or CMS.

(j) Use providers or provider groups to distribute printed information comparing the benefits of different health plans unless the materials have the concurrence of all MA organizations involved.

(k) Conduct sales presentations or distribute and accept plan applications in provider offices or other places where health care is delivered.

(l) Conduct sales presentations or distribute and accept plan applications at educational events.

(m) Employ MA plan names that suggest that a plan is not available to all Medicare beneficiaries. This prohibition shall not apply to MA plan names in effect on July 31, 2000.

(n) Display the names and/or logos of co-branded network providers on the organization's member identification card. Other marketing materials that include names and/or logos of provider co-branding partners must clearly indicate that other providers are available in the network.

(o) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

§ 422.2272 Licensing of marketing representatives and confirmation of marketing resources.

In its marketing the MA organization must—

(a) Demonstrate to CMS' satisfaction that marketing resources are allocated to marketing to disabled Medicare

population as well as beneficiaries age 65 and over.

(b) Establish and maintain a system for confirming that enrolled beneficiaries have, in fact, enrolled in the MA plan and understand the rules applicable under the plan.

(c) Employ as marketing representatives only individuals who are licensed by the State to conduct marketing activities (as defined in the Medicare Marketing Guidelines) in that State, and whom the organization has informed that State it has appointed, consistent with the appointment process provided for under State law, except that any fees required under such appointment process do not apply.

§ 422.2274 Broker and agent commissions.

If a Medicare Advantage organization markets through independent brokers or agents—

(a)(1) In paying a commission or other compensation (collectively referred to as ''commission'') to such agent or representative, the commission the agent would receive for selling or servicing the policy in the first year could not exceed the commission the agent receives for selling or servicing the policy in all subsequent years.

(2) The commission must be the same for all plans and plan product types offered by the MA plan's parent organization.

(b) It must ensure agents selling Medicare products are trained on Medicare rules and regulations specific to the plan products they intend to sell.

(c) It must ensure agents selling Medicare products are tested, as specified in CMS guidance.

(d) Upon CMS's request, the organization must provide to CMS the information necessary for it to conduct oversight of marketing activities.

(e) It must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct. CMS will establish and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

§ 422.2276 Employer group retiree marketing.

MA organizations may develop marketing materials designed for members of an employer group who are eligible for employer-sponsored benefits through the MA organization, and furnish these materials only to the group members. These materials are not subject to CMS prior review and approval.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

20. 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

21. 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), 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).

22. 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 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)). 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.* Full-benefit dual eligible individuals who are qualifying covered retirees as defined in § 423.882 also are automatically enrolled in a part D plan, consistent with this paragraph, unless they elect to decline that enrollment. 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.

* * * * *

23. 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 has requested to have monthly premiums withheld per § 423.293(a) or who is in premium withhold status, as defined by CMS.

* * * * *

24. 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). 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 subpart K, § 423.505(e)(1)(iii).

§ 423.50 [Removed]

25. Remove § 423.50.

Subpart C—Benefits and Beneficiary Protections

26. 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.

* * * * *

27. 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.

* * * * *

28. Amend § 423.128 as follows:

A. Revise paragraph (a)(3).

B. Revise paragraph (e)(6).

§ 423.128 Dissemination of Part D Plan information.

(a) * * *

(3) At the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period.

* * * * *

(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

29. Amend § 423.293 by—

A. Revising paragraph (a).

B. Adding paragraph (e).

The revision and addition read as follows:

§ 423.293 Collection of monthly beneficiary premium.

(a) *General rule.* Part D sponsors must charge enrollees a consolidated monthly Part D premium equal to the sum of the Part D monthly premium for basic prescription drug coverage (if any) and the premium for supplemental coverage (if any and if the beneficiary has enrolled in such supplemental coverage). Part D sponsors must also permit each enrollee, at the enrollee's option, to make payment of premiums (if any) under this part to the sponsor using any of the methods listed in § 422.262(f) of this chapter. In circumstances where retroactive collection of premium is necessary and where the member is without fault in creating the premium arrearage, the Part D sponsor shall offer the member the option of payment either by lump sum or by equal monthly installment spread out over the same period for which the premiums were due, that is, 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 requested that premiums be withheld from his or her Social Security benefit.

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

30. Section 423.308 is amended by—

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

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

C. Revising the definition of ''allowable risk corridor costs.''

D. Revising the definition of ''gross covered prescription drug costs.''

E. Revising the definition of ''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, 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 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 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 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) 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 chapter) 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) 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 chapter.

(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, 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), less the administrative expenses (including return on investment) assumed in the standardized bids.

31. 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) and negotiated and approved under § 423.272, or by an alternative method that CMS determines.

* * * * *

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

32. 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, 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 and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

* * * * *

33. Amend § 423.507 by—

A. Revising paragraphs (a)(2)(ii) and (a)(2)(iii).

B. Revising paragraphs (b)(2)(ii) and (b)(2)(iii).

The revisions read as follows:

§ 423.507 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 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

34. 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.

Subpart M—Grievances, Coverage Determinations, and Appeals

35. Amend § 423.560 by adding, in alphabetical order, the definition for ''Other prescriber'' 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.

* * * * *

36. 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.

37. 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 drug benefits.* When a party makes a request for a drug benefit, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request, or, for an exceptions request, the physician's or other prescriber's supporting statement.

* * * * *

38. 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). 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

* * * * *

39. 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.

* * * * *

40. Amend § 423.578 by—

A. Revising paragraph (a) introductory text.

B. Revising paragraph (a)(2) introductory text.

C. Revising paragraph (a)(2)(i).

D. Revising paragraph (a)(3).

E. Revising paragraph (a)(4) introductory text.

F. Revising paragraph (a)(5).

G. Revising paragraph (b) introductory text.

H. Revising paragraph (b)(2) introductory text.

I. Revising paragraph (b)(2)(i), (b)(4), (b)(5) introductory text, and (b)(6).

J. Revising paragraph (c)(3)(i), (c)(4)(i) introductory text, and (c)(4)(i)(A).

K. 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.

* * * * *

(3) 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.

41. 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.

42. 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 timeframe 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.

43. Amend § 423.584 by—

A. Revising paragraph (a).

B. Revising paragraph (b).

C. Revising paragraph (c)(2)(ii).

D. Revising paragraph (d)(2)(iii).

The revisions 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

* * * * *

44. Revise § 423.586 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.

45. 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.

* * * * *

46. 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

47. 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

48. Amend § 423.772 by adding the definition for ''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 authoritative sources 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.

* * * * *

49. 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.

50. Amend § 423.800 by revising paragraph (b) and adding a new paragraph (d) to 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 accept best available evidence as defined in § 423.772 of this part, and update the subsidy eligible individual's LIS status in accordance with a process established by CMS, and within a reasonable timeframe as determined by CMS.

Subpart R—Payment to Sponsors of Retiree Prescription Drug Plans

51. Section 423.882 is amended by—

A. Adding the definition of ''actually paid''.

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

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''.

E. Adding the definition of ''negotiated prices''.

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, 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 offered to some or all purchasers) 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. 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 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 and regardless of the terms of the contract between the plan sponsor and the intermediary contracting organization.

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. Administrative costs include amounts paid by the sponsor of a qualified retiree prescription drug plan to an intermediary contracting organization for Part D drugs dispensed to qualifying covered retirees in the sponsor's 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 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 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 actually paid 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 negotiated prices (as defined in this section) actually paid by the qualified retiree prescription drug plan that is received as reimbursement by the pharmacy or other dispensing entity, 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.

* * * * *

Negotiated prices means prices for Part D drugs that—

(1) 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;

(2) Are reduced by those 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; and

(3) Includes any dispensing fees.

* * * * *

52. Add new subpart V to read as follows:

Subpart V—Part D Marketing Requirements

Sec.

Subpart V—Part D Marketing Requirements

§ 423.2260 Definitions concerning marketing materials.

As used in this subpart—

Marketing Materials. (1) Marketing Materials include any informational materials targeted to Medicare beneficiaries which—

(i) Promote the Part D plan.

(ii) Inform Medicare beneficiaries that they may enroll, or remain enrolled in a Part D plan.

(iii) Explain the benefits of enrollment in a Part D plan, or rules that apply to enrollees.

(iv) Explain how Medicare services are covered under a Part D plan, including conditions that apply to such coverage.

(2) Examples of marketing materials include, but are not limited to—

(i) General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the Internet.

(ii) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(iii) Presentation materials such as slides and charts.

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

(v) Membership communication materials such as membership rules, subscriber agreements, member handbooks and wallet card instructions to enrollees.

(vi) Letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures etc.

(vii) Membership or claims processing activities.

§ 423.2262 Review and distribution of marketing materials.

(a) *CMS review of marketing materials.* (1) Except as provided in paragraph (a)(2) of this section a Part D plan may not distribute any marketing materials (as defined in § 423.2260 of this Part), or enrollment forms, or make such materials or forms available to Part D eligible individuals unless—

(i) At least 45 days (or 10 days if using certain types of marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution, the Part D sponsor submits the material or form to CMS for review under the guidelines in § 423.2264; and

(ii) CMS does not disapprove the distribution of new material or form.

(2) [Reserved]

(b) *File and use.* The Part D sponsor may distribute certain types of marketing materials, designated by CMS, 5 days following their submission to CMS if the Part D sponsor certifies that in the case of these marketing materials, it followed all applicable marketing guidelines and, when applicable, used model language specified by CMS without modification.

§ 423.2264 Guidelines for CMS review.

In reviewing marketing material or enrollment forms under § 423.2262, CMS determines (unless otherwise specified in additional guidance) that the marketing materials—

(a) Provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling must consist of:

(1) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges.

(2) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each.

(3) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(b) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area.

(c) Include in the written materials notice that the Part D plan is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the Part D plan. In addition, the Part D plan may reduce its service area and no longer be offered in the area where a beneficiary resides.

(d) Ensure that materials are not materially inaccurate or misleading or otherwise make material misrepresentations.

(e) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

§ 423.2266 Deemed approval.

If CMS has not disapproved the distribution of marketing materials or a form submitted by a Part D sponsor for a Part D plan in a Part D region, CMS is deemed to not have disapproved the distribution of the marketing material or form in all other Part D regions covered by the Part D plan, with the exception of any portion of the material or form that is specific to the Part D region.

§ 423.2268 Standards for Part D marketing.

In conducting marketing activities, a Part D plan may not—

(a) Provide for cash or other remuneration as an inducement for enrollment or otherwise. This does not prohibit explanation of any legitimate benefits the beneficiary might obtain as an enrollee of the Part D plan.

(b) Offer gifts to potential enrollees, unless the gifts are of nominal (as defined in the CMS Marketing Guidelines) value, are offered to all eligible members without discrimination, and are not in the form of cash or other monetary rebates. Providing meals for potential enrollees is prohibited, regardless of value.

(c) Engage in any discriminatory activity such as, including targeted marketing to Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(d) Solicit door-to-door for Medicare beneficiaries or through other unsolicited means of direct contact, including calling a beneficiary without the beneficiary initiating the contact.

(e) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the Part D sponsor or its Part D plan. The Part D organization may not claim that it is recommended or endorsed by CMS or Medicare or the Department of Health and Human Services or that CMS or Medicare or the Department of Health and Human Services recommends that the beneficiary enroll in the Part D plan. The Part D organization may explain that the organization is approved for participation in Medicare.

(f) Market non-health care related products to prospective enrollees during any Part D sales activity or presentation. This is considered cross-selling and is prohibited.

(g) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

(h) Market additional health related lines of plan business not identified prior to an in-home appointment without a separate appointment that may not be scheduled until 48 hours after the initial appointment.

(i) Distribute marketing materials for which, before expiration of the 45-day period, the PDP Sponsor receives from CMS written notice of disapproval because it is inaccurate or misleading, or misrepresents the PDP Sponsor, its marketing representatives, or CMS.

(j) Use providers, provider groups, or pharmacies to distribute printed information comparing the benefits of different Part D plans unless providers, provider groups or pharmacies accept and display materials from all Part D plan sponsors.

(k) Conduct sales presentations or distribute and accept Part D plan enrollment forms in provider offices, pharmacies or other places where health care is delivered.

(l) Conduct sales presentations or distribute and accept plan applications at educational events.

(m) Employ Part D plan names that suggest that a plan is not available to all Medicare beneficiaries.

(n) Display the names and/or logos of co-branded network providers on the organization's member identification card. Other marketing materials that include names and/or logos of provider co-branding partners must clearly indicate that other providers are available in the network.

(o) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

§ 423.2272 Licensing of marketing representatives and confirmation of marketing resources.

In its marketing, the Part D organization must—

(a) Demonstrate to CMS's satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(b) Establish and maintain a system for confirming that enrolled beneficiaries have in fact enrolled in the PDP and understand the rules applicable under the plan.

(c) Employ as marketing representatives only individuals who are licensed by the State to conduct direct marketing activities (as defined in the Medicare Marketing Guidelines) in that State, and whom the sponsor has informed that State it has appointed, consistent with the appointment process provided for under State law, except that any fees required under such appointment process do not apply.

§ 423.2274 Broker and agent commissions.

If a Part D sponsor markets through independent brokers or agents—

(a)(1) In paying a commission or other compensation (collectively referred to as ''commission'') to such agent or representative, the commission the agent would receive for selling or servicing the policy in the first year could not exceed the commission the agent receives for selling or servicing the policy in all subsequent years.

(2) The commission must be the same for all plans and all plan product types offered by the sponsor's parent organization.

(b) It must ensure agents selling Medicare products are trained on Medicare rules and regulations specific to the plan products they intend to sell.

(c) It must ensure agents selling Medicare products are tested, as specified in CMS guidance.

(d) Upon CMS's request, a sponsor must provide to CMS the information necessary for it to conduct oversight of marketing activities.

(e) It must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct. CMS will establish and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

§ 423.2276 Employer group retiree marketing.

Part D sponsors may develop marketing materials designed for members of an employer group who are eligible for employer-sponsored benefits through the Part D sponsor, and furnish these materials only to the group members. These materials are not subject to CMS prior review and approval.

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: January 17, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: February 19, 2008.

Michael O. Leavitt,

Secretary.

[FR Doc. 08–1244 Filed 5–8–08; 8:45 am]

BILLING CODE 4120–01–P