

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Parts 403, 411, 417, and 423**

[CMS-4068-P]

RIN 0938-AN08**Medicare Program; Medicare Prescription Drug Benefit****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Proposed rule.

SUMMARY: This proposed rule would implement the new Medicare Prescription Drug Benefit. This new voluntary prescription drug benefit program was enacted into law on December 8, 2003, in section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The addition of a prescription drug benefit to Medicare represents a landmark change to the Medicare program that will significantly improve the health care coverage available to millions of Medicare beneficiaries. The MMA specifies that the prescription drug benefit program will become available to beneficiaries beginning on January 1, 2006. Please see the executive summary in the

SUPPLEMENTARY INFORMATION section for further synopsis of this rule.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 4, 2004.

ADDRESSES: In commenting, please refer to file code CMS-4068-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments to <http://www.cms.hhs.gov/regulations/ecomments> (attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).

2. *By 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-4068-P, P.O. Box 8014, Baltimore, MD 21244-8014.

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

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original

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(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.)

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Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided 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:

Lynn Orlosky (410) 786-9064 or Randy Brauer (410) 786-1618 (for issues related to eligibility, elections, enrollment, including auto-enrollment of dual eligible beneficiaries, and creditable coverage).

Wendy Burger (410) 786-1566 (for issues related to marketing and user fees).

Vanessa Duran-Scirri (214) 767-6435 (for issues related to benefits and beneficiary protections, including Part D benefit packages, Part D covered drugs, coordination of benefits in claims processing and tracking of true-out-of-pocket costs, pharmacy network access standards, plan information dissemination requirements, and privacy of records).

Craig Miner, RPh. (410) 786-1889 or Tony Hausner (410) 786-1093 (for issues of pharmacy benefit cost and utilization management, formulary development, quality assurance, medication therapy management, and electronic prescribing).

Mark Newsom (410) 786-3198 (for issues of submission, review, negotiation, and approval of risk and limited risk bids for PDPs and MA-PD plans; the calculation of the national average bid amount; determination and collection of enrollee premiums; calculation and payment of direct and

reinsurance subsidies and risk-sharing; and retroactive adjustments and reconciliations.)

Jim Owens (410) 786-1582 (for issues of licensing and waiver of licensure, the assumption of financial risk for unsubsidized coverage, and solvency requirements for unlicensed sponsors or sponsors who are not licensed in all States in the region in which it wants to offer a PDP.)

Terese Klitenic (410) 786-5942 (for issues of coordination of Part D plans with providers of other prescription drug coverage including Medicare Advantage plans, state pharmaceutical assistance programs (SPAPs), Medicaid, and other retiree prescription drug plans; also for issues related to eligibility for and payment of subsidies for assistance with premium and cost-sharing amounts for Part D eligible individuals with lower income and resources; for rules for states on eligibility determinations for low-income subsidies and general state payment provisions including the phased-down state contribution to drug benefit costs assumed by Medicare).

Frank Szeplinski (303) 844-7119 (for issues related to conditions necessary to contract with Medicare as a PDP sponsor, as well as contract requirements, intermediate sanctions, termination procedures and change of ownership requirements; employer group waivers and options; also for issues related to cost-based HMOs and CMPS offering Part D coverage.)

John Scott (410) 786-3636 (for issues related to the procedures PDP sponsors must follow with regard to grievances, coverage determinations, and appeals.)

Tracey McCutcheon (410) 786-6715 (for issues related to solicitation, review and approval of fallback prescription drug plan proposals; fallback contract requirements; and enrollee premiums and plan payments specific to fallback plans.)

Jim Mayhew (410) 786-9244 (for issues related to the alternative retiree drug subsidy.)

Joanne Sinsheimer (410) 786-4620 (for issues related to physician self-referral prohibitions.)

Brenda Hudson (410) 786-4085 (for issues related to PACE organizations offering Part D coverage.)

Julie Walton (410) 786-4622 or Kathryn McCann (410) 786-7623 (for issues related to provisions on Medicare supplemental (Medigap) policies.)

For general questions: Please call (410) 786-1296.

SUPPLEMENTARY INFORMATION:

Executive Summary. Generally, coverage for the prescription drug

benefit will be provided under private prescription drug plans (PDPs), which will offer only prescription drug coverage, or through Medicare Advantage prescription drug plans (MA-PDs), which will offer prescription drug coverage that is integrated with the health care coverage they provide to Medicare beneficiaries under Part C of Medicare. PDPs must offer a basic prescription drug benefit. MA-PDs must offer either a basic benefit or broader coverage for no additional cost. If this required level of coverage is offered, the PDP or MA-PD plan may also offer supplemental benefits through enhanced alternative coverage for an additional premium. All organizations offering drug plans will have flexibility in the design of the prescription drug benefit. Consistent with the MMA, this proposed rule provides for subsidy payments to sponsors of qualified retiree prescription drug plans.

We intend to implement the drug benefit to permit and encourage a range of options for Medicare beneficiaries to augment the standard Medicare coverage for drug costs above the initial coverage limit (\$2250 in 2006) and below the annual out-of-pocket threshold (\$5100 in 2006). In addition to the coverage established by the statute for low-income beneficiaries, we seek comments on the best way to support options for expanding beneficiaries' drug coverage. Potential options include facilitating coverage through employer plans, MA-PD plans and/or high-option PDPs, as well as through charity organizations and State pharmaceutical assistance programs. We specifically seek comments on ways to maximize the continued use of non-Medicare resources (private contributions, employer/union contributions, state contributions, health plan contributions, and other sources) that currently provide at least partial coverage for three-fourths of Medicare beneficiaries. See sections II.C, II.J, and II.P, and II.R of this preamble for further details on these issues. We are also considering establishing a CMS demonstration to evaluate possible ways of achieving such extended coverage, and we welcome all suggestions in this regard.

Throughout the preamble, we identify options and alternatives to the provisions we propose. We strongly encourage comments and ideas on our approach and on alternatives to help us design the Medicare Prescription Drug Benefit Program to operate as effectively and efficiently as possible in meeting the needs of Medicare beneficiaries.

Although this proposed rule specifies most of the requirements for implementing the new prescription drug

program, readers should note that we are also issuing a closely related proposed rule that concerns Medicare Advantage plans, which will usually combine medical and prescription drug coverage. In addition, although this proposed rule specifies requirements related to PDP regions it does not designate those regions. Regional boundary decisions will be made through a separate process. Additional non-regulatory guidance on this and other topics will also be forthcoming.

We have considered and, in some places, have identified how this proposed rule intersects with other Federal laws, such as the Health Insurance Portability and Accountability Act (HIPAA) of 1996 Certification of Creditable Coverage and the HIPAA Privacy Rule. We are interested in learning how this proposed rule may interact with other legal obligations to which the PDP sponsors and MA-PD plans may be subject and intend to make appropriate changes in the final rule to address such issues.

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. Comments will be most useful if they are organized by the section of the proposed rule to which they apply. You can assist us by referencing the file code [CMS-4068-P] and the specific "issue identifier" that precedes the section on which you choose to comment.

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. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its public Web site. Comments received timely will 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 410-786-7197.

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I. Background

(If you choose to comment on issues in this section, please include the caption "Background" at the beginning of your comments.)

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

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) amended Title XVIII of the Social Security Act (the Act) by redesignating Part D as Part E and inserting a new Part D, which establishes the Voluntary Prescription Drug Benefit Program. (For ease of reference, we will refer to the new prescription drug benefit program as Part D of Medicare and the Medicare Advantage Program as Part C of Medicare.) We believe that the new Part D benefit constitutes the most significant change to the Medicare program since its inception in 1965. The addition of outpatient prescription drugs to the Medicare program reflects Congress' recognition of the fundamental change in recent years in how medical care is delivered in the U.S. It recognizes the vital role of prescription drugs in our health care delivery system, and the need to modernize Medicare to assure their availability to Medicare beneficiaries. This proposed rule is designed to ensure broad participation in the new benefit both by organizations that offer prescription drug coverage and by eligible beneficiaries. In conjunction with complementary improvements to the Medicare Advantage program, these changes should significantly increase the coverage and choices available to Medicare beneficiaries. Effective January 1, 2006, the new program

establishes an optional prescription drug benefit for individuals who are entitled to or enrolled in Medicare benefits under Part A and/or Part B. Beneficiaries who qualify for both Medicare and Medicaid (full-benefit dual eligibles) will automatically receive the Medicare drug benefit. The statute also provides for assistance with premiums and cost sharing to eligible low-income beneficiaries.

In general, coverage for the new prescription drug benefit will be provided through private prescription drug plans (PDPs) that offer drug-only coverage, or through Medicare Advantage (MA) (formerly known as Medicare+Choice) plans that offer integrated prescription drug and health care coverage (MA-PD plans). PDPs must offer a basic drug benefit. MA-PDs must offer either a basic benefit or broader coverage for no additional cost. If this required level of coverage is offered, the PDP or MA-PD plan may also offer supplemental benefits through enhanced alternative coverage for an additional premium.

All organizations offering drug plans will have flexibility in terms of benefit design, including the authority to establish a formulary to designate specific drugs that will be available within each therapeutic class of drugs, and the ability to have a cost-sharing structure other than the statutorily defined structure, subject to certain actuarial tests. The plans also may include supplemental drug coverage such that the total value of the coverage offered exceeds the value of basic prescription drug coverage. The specific sections of the Act that address the prescription drug benefit program are the following:

- 1860D-1 Eligibility, enrollment, and information.
- 1860D-2 Prescription drug benefits.
- 1860D-3 Access to a choice of qualified prescription drug coverage.
- 1860D-4 Beneficiary protections for qualified prescription drug coverage.
- 1860D-11 PDP regions; submission of bids; plan approval.
- 1860D-12 Requirements for and contracts with prescription drug plan (PDP) sponsors.
- 1860D-13 Premiums; late enrollment penalty.
- 1860D-14 Premium and cost-sharing subsidies for low-income individuals.
- 1860D-15 Subsidies for Part D eligible individuals for qualified prescription drug coverage.
- 1860D-16 Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

1860D-21 Application to Medicare Advantage program and related managed care programs.

1860D-22 Special rules for employer-sponsored programs.

1860D-23 State pharmaceutical assistance programs.

1860D-24 Coordination requirements for plans providing prescription drug coverage.

1860D-41 Definitions; treatment of references to provisions in Part C.

1860D-42 Miscellaneous provisions.

Specific sections of the MMA that also relate to the prescription drug benefit program are the following:

Sec. 102 Medicare Advantage Conforming Amendments

Sec. 103 Medicaid Amendments

Sec. 104 Medigap

Sec. 109 Expanding the work of Medicare Quality Improvement Organizations to include Parts C and D.

B. Organizational Overview of Part 423

The regulations set forth in this proposed rule will be codified in the new 42 CFR part 423—Prescription Drug Benefit Program. There are a number of places in which statutory provisions in Part D incorporate by reference specific sections in Part C of Medicare (the Medicare Advantage program). The MA regulations appear at 42 CFR part 422. Since the same organizations that offer MA coordinated care plans will also be required to offer MA-PD plans, we believe it is appropriate to adopt the same organizational structure as part 422. MA coordinated care plans (defined in § 1851(a)(2)(A)) are a type of Medicare Advantage plan. For example, requirements relating to eligibility, election, and enrollment would be set forth in subpart B of new part 423, just as they now are set forth in subpart B of part 422. Therefore, wherever possible, we have modeled the proposed prescription drug regulations on the parallel provisions of the part 422 regulations.

The major subjects covered in each subpart of part 423 are as follows:

Subpart A, General Provisions: Basis and scope of the new part 423. Definitions and discussion of important concepts used throughout part 423, and sponsor cost-sharing in beneficiary education and enrollment-related costs (user fees).

Subpart B, Eligibility, Election, and Enrollment: Eligibility for enrollment in the Part D benefit, enrollment periods, disenrollment, application of the late enrollment penalty, approval of marketing materials and enrollment

forms, and the meaning and documentation of creditable coverage. (Please note that other, related topics, are discussed in the following subparts: Subpart P, eligibility and enrollment for low-income individuals; Subpart S, provisions relating to the phase-down of state contributions for dual-eligible drug expenditures; Subpart F, calculation and collection of late enrollment fees; Subpart C, plan disclosure; Subpart Q, eligibility and enrollment for fallback plans; and Subpart T, the definition of a Medicare supplemental (Medigap) policy.)

Subpart C, Benefits and Beneficiary Protections: Prescription drug benefit coverage, service areas, network and out-of-network access, formulary requirements, dissemination of plan information to beneficiaries, and confidentiality of enrollee records. (Please note that actuarial valuation of the coverage offered by plans, as well as the submission of the bid, is discussed in subpart F. Access to negotiated prices is discussed in subpart C, while the reporting of negotiated prices is discussed in subpart G. Formularies are discussed in subpart C, while the appeals of formularies are discussed in subpart M. Incurred costs toward true out-of-pocket (TrOOP expenditures) are discussed in subpart C, while the procedures for determining whether a beneficiary's Part D out-of-pocket costs are actually reimbursed by insurance or another third-party arrangement are discussed in subpart J. Information that plans must disseminate to beneficiaries is discussed in subpart C, while Part D information that CMS must disseminate to beneficiaries is discussed in subpart B.)

Subpart D, Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans: Utilization controls, quality assurance, medication therapy, and fraud, waste and abuse, as well as rules related to identifying enrollees for whom medication therapy management is appropriate, consumer satisfaction surveys, and accreditation as a basis for deeming compliance.

Subpart E, Reserved.

Subpart F, Submission Of Bids and Monthly Beneficiary Premiums; Plan Approval: Bid submission, the actuarial value of bid components, review and approval of plans, and the calculation and collection of Part D premiums.

Subpart G, Payments To PDP Sponsors and MA Organizations Offering MA-PD Plans for All Medicare Beneficiaries for Qualified Prescription Drug Coverage: Data submission, payments and reconciliations for direct

subsidies, risk adjustment, reinsurance, and risk-sharing arrangements.

Subpart H, Reserved.

Subpart I, Organization Compliance With State Law and Preemption By Federal Law: Licensure, assumption of financial risk, solvency, and State premium taxes.

Subpart J, Coordination Under Part D With Other Prescription Drug Coverage: Applicability of Part D rules to the Medicare Advantage program, waivers available to facilitate the offering of employer group plans, and procedures to facilitate calculation of true out-of-pocket expenses and coordination of benefits with State pharmaceutical assistance programs and other entities that provide prescription drug coverage. (Please note that subpart C discusses, in more detail, coordination of benefits and the determination of which incurred beneficiary costs will be counted as TrOOP expenditures. Provisions relating to disenrollment for material misrepresentation by a beneficiary are discussed in subpart J and also referenced in subpart B.)

Subpart K, Application Procedures and Contracts With PDP Sponsors: Application procedures and requirements; contract terms; procedures for termination of contracts; reporting by PDP sponsors.

Subpart L, Effect of Change of Ownership or Leasing of Facilities During Term of Contract: Change of ownership of a PDP sponsor; novation agreements; leasing of a PDP sponsor's facilities.

Subpart M, Grievances, Coverage Determinations and Appeals: Coverage determinations by sponsors, exceptions procedures, and all levels of appeals by beneficiaries.

Subpart N, Medicare Contract Determinations and Appeals: Notification by CMS about unfavorable contracting decisions, such as nonrenewals or terminations; reconsiderations; appeals.

Subpart O, Intermediate Sanctions: Provisions concerning available sanctions for participating organizations.

Subpart P, Premiums and Cost-Sharing Subsidies for Low-Income Individuals: Eligibility determinations and payment calculations for low-income subsidies.

Subpart Q, Guaranteeing Access to a Choice of Coverage (Fallback Plans): Definitions; access requirements; bidding process; contract requirements.

Subpart R, Payments to Sponsors of Retiree Prescription Drug Plans: Provisions for making retiree drug payments to sponsors of qualified retiree prescription drug plans.

Subpart S, Special Rules for States—Eligibility Determinations for Subsidies and General Payment Provisions: State/Medicaid program's role in determining eligibility for low-income subsidy and other issues related to the Part D benefit.

In addition, in subpart T, this proposed rule also provides changes to: Part 403 relating to Medicare supplemental policies (Medigap), part 411 relating to exclusions from Medicare and limitations on Medicare payment (the physician self-referral rules), part 417 relating to cost-based HMOs, part 460 relating to PACE organizations, and part 442 relating to Medicaid amendments.

II. Provisions of the Proposed Rule

A. General Provisions

(If you choose to comment on issues in this section, please include the caption "General Provisions" at the beginning of your comments.)

1. Overview

Section 423.1 of subpart A specifies the general statutory authority for the ensuing regulations and indicates that the scope of part 423 is to establish requirements for the Medicare prescription drug benefit program. Section 423.4 of subpart A provides definitions for terms that appear in multiple sections of part 423 and whose meaning we believe should be featured prominently in order to aid the reader.

Consistent with the MMA statute, we are in many cases proposing procedures that parallel those now in effect under the Medicare Advantage program (for example the regulations concerning PDP and MA-PD plan contract and appeal requirements). We anticipate receiving at least two categories of comments on such provisions: (1) Recommendations for changes that would impact only the proposed Part D provisions (based for example on underlying differences between the MA and Part D programs); and (2) recommendations for changes that would impact both the MA and Part D provisions. Our goal is to maintain consistency between these two programs wherever possible; thus we will evaluate the need for parallel changes in the MA final rule when we receive comments on provisions that affect both programs.

2. Discussion of Important Concepts and Key Definitions (§ 423.4)

a. Introduction

For the most part, the definitions in the proposed rule are taken directly from section 1860D-41 of the Act. The definitions set forth in subpart A apply to all of part 423 unless otherwise

indicated, and are applicable only for the purposes of part 423. For example, "insurance risk" applies only to pharmacies that contract with PDP sponsors under part 423. Definitions that have a more limited application are not included in subpart A, but instead are set forth within the relevant subpart of the regulations. For example, in subpart F, we have included all the definitions related to bids and premiums. The detailed definitions and requirements related to prescription drug coverage are included in subpart C, but because of their direct relevance to the bidding process they are also referenced in subpart F.

Following our discussion of important concepts, we provide brief definitions of terms that occur in multiple sections of this preamble and part 423. We believe that it is helpful to define these frequently occurring terms to aid the reader but that these terms do not require the extended discussion necessary in our section on important concepts.

b. Discussion of Actuarial Equivalence, Creditable Prescription Drug Coverage, PDP Plan Regions, Service Area, and User Fees

i. Discussion of the Meaning of Actuarial Equivalence

The concept of actuarial equivalence is applied in different contexts in Title I of the MMA, including: Determinations related to creditable coverage (subpart B), determinations related to the value of drug coverage and bid components (subpart F); and determinations related to subsidy payments for employer or union sponsors of qualified retiree health plans that include prescription drugs (subpart R). In very general terms, actuarial equivalence refers to a determination that, in the aggregate, the dollar value of drug coverage for a set of beneficiaries under one plan can be shown to be equal to the dollar value for those same beneficiaries under another plan. Given the various uses for this term in the Part D context, we propose the following relatively general definition:

"Actuarial equivalence" means a state of equivalent values demonstrated through the use of generally accepted actuarial principles and in accordance with section 1860D-11(c) of the Act and § 423.265(c)(3) of this part.

This concept is discussed in further detail below and in those sections of this preamble, such as section II.F, where actuarial equivalence comes into play.

According to section 1860D-11(c) of the Act, we will develop processes and methods using generally accepted actuarial principles and methodologies for determining the actuarial valuation of prescription drug coverage. Although the statute sets forth specific requirements for actuarial equivalence and valuation, there is no formal definition of actuarial equivalence. Also, in each of the contexts described above, we must address the question of whether actuarial equivalence is determined from the perspective of the plan, or the beneficiary.

In the sections dealing with actuarial equivalence throughout this proposed rule, we have tried to avoid being overly prescriptive, in order to maintain flexibility to adjust and refine the needed valuation processes as we gain more experience with the administration of the new benefit. Thus, we fully expect to provide additional guidance in the future on these provisions.

ii. Discussion of the Meaning of Creditable Prescription Drug Coverage

The types of coverage considered creditable prescription drug coverage in proposed 42 CFR 423.4 are discussed in the preamble to subpart B.

In the preamble to subpart T, we discuss in more detail the effect of Part D on Medigap policies, one of the forms of drug coverage that may be creditable if it meets the actuarial equivalence test.

iii. Prescription Drug Plan Regions

Prescription drug plan regions are areas in which a contracting PDP plan must provide access to covered Part D drugs. Although we have included specifications for regions in § 423.112, the regions themselves are not set forth in this proposed rule. To the extent feasible, we intend that the PDP regions will be consistent with the regions established for the MA program (see § 422.455 of the MA proposed rule). In establishing the regions for both programs, we will use the results of a market survey that includes the examination of current insurance markets. MMA specifically states that there will be no fewer than 10 regions and no more than 50 regions, not including the territories. For a further discussion of the PDP regions, see section II.C of this preamble.

iv. Service Area

Medicare beneficiaries are eligible to enroll in a PDP or an MA-PD plan only if they reside in the PDP's or MA-PD plan's "Service Area." As noted above, for PDPs, this is the Region established by CMS pursuant to proposed § 423.112,

within which the PDP is responsible for providing access to the Part D drug benefit in accordance with the access standards in proposed § 423.120. Under the MA program, an MA plan's Service Area is defined in § 422.2. For coordinated care plans, the definition of "service area" expressly includes the condition that the service area is an area in which access is provided in accordance with access standards in § 422.112.

Prior to this rulemaking, we had not considered how this access requirement in the MA plan Service Area definition would apply to a jail or prison within the boundaries of a plan Service Area. Beneficiaries incarcerated there clearly would not have access to services as required under § 422.112. Such an area thus would not meet the coordinated care plan definition of "Service Area," which requires that such access standards be met. This issue never arose under the MA program because there would be no reason for an individual to enroll in an MA plan while incarcerated, since services typically are all covered by the jail or prison and the prisoner could always enroll in an MA plan without penalty upon being released.

We have however, considered this issue in the context of Part D benefits. If a prison or jail is located within the boundaries of a PDP region, or an MA PDP-plan Service Area, a Medicare-eligible individual incarcerated there technically would reside within the service area, and be eligible to enroll to receive Part D benefits. Under this scenario, such an individual then would have to pay a penalty for not enrolling while in prison if he or she enrolled in Part D upon being released.

We do not believe this to be an equitable result, as the beneficiary would face the choice of paying for services he or she would not be receiving, or paying a penalty at a later time. We also do not believe that it would be appropriate for a PDP or MA-PD plan to receive monthly Part D payments for such an individual, since drugs typically would be covered for the individual by the prison or jail. Such payments would represent an unwarranted "windfall" for services the PDP or MA-PD would not have to deliver.

In focusing on this situation, we have decided to propose that for purposes of enrolling in Part D with a PDP, or under an MA-PD plan, the definition of Service Area that governs eligibility to enroll is the area within which the Part D access standards under § 423.120 are met.

Beneficiaries in jail or prison do not have access to pharmacies available as required under § 423.120. Therefore, such beneficiaries would not be considered to be in a PDP or MA-PD plan's Service Area for purposes of enrolling in Part D. Incarcerated individuals accordingly would not be assessed a late penalty when they enroll in Part D (either with a PDP or MA-PD plan) upon being released.

We note that the analysis above would apply equally to a beneficiary who lives abroad, and does not reside within the boundaries of any PDP Region or MA-PD Service Area.

v. Sponsor Cost-Sharing in Beneficiary Education and Enrollment Related Costs—User Fees (§ 423.6)

The last section of subpart A proposes regulations implementing the user fees provided for in section 1857(e)(2) of the Act, as incorporated by section 1869D-12(b)(3)(D) of the Act. These fees are currently required of MA plans for the purpose of defraying part of the ongoing costs of the national beneficiary education campaign that includes developing and disseminating print materials, the 1-800 telephone line, community based outreach to support State health insurance assistance programs (SHIPs), and other enrollment and information activities required under section 1851 of the Act and counseling assistance under section 4360 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 103-66).

The MMA expands the user fee to apply to PDP sponsors as well as MA plans. The expansion of the application of user fees recognizes the increased Medicare beneficiary education activities that we would require as part of the new prescription drug benefit. In 2006 and beyond, user fees would help to offset the costs of educating over 41 million beneficiaries about the drug benefit through written materials such as a publication describing the drug benefit, internet sites, and other media.

In fiscal year 2006 and thereafter, the MMA authorizes up to \$200,000,000 to be spent on beneficiary education and enrollment activities reduced by the fees collected from MA organizations and PDP sponsors in that fiscal year. In each year, the total amount of collected user fees could not exceed the estimated costs in the fiscal year for carrying out the enrollment and dissemination of information activities in the MA and Part D prescription drug programs or the applicable portions (described below) of \$200,000,000, whichever is less.

Finally, these user fee provisions would establish the applicable aggregate

contribution portions for PDP sponsors and MA organizations. There are two calculations. First, we calculate the PDP sponsors' applicable portion as a group; their portion is the estimate of the total proportion of expenditures under Title 18 that are attributable to expenditures made to PDP sponsors for prescription drugs under Part D. The applicable portion of the user fee for MA organizations would be equal to the total expenditures for Medicare Part C, as well as for payments under Part D that are made to MA organizations, as a percent of Title 18 expenditures. Then, we calculate the fees charged to individual PDP sponsors and MA plans.

c. Definitions of Frequently Occurring Terms

Full-benefit dual eligible beneficiary means an individual who meets the criteria established in § 423.772 (subpart P), regarding coverage under both Part D and Medicaid.

Insurance risk means, for a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitutions, nor does it include elements potentially in the control of the pharmacy (for example, labor costs or productivity).

MA means Medicare Advantage, which refers to the program authorized under Part C of the Act.

MA-PD plan means an MA plan that provides qualified prescription drug coverage.

Medicare prescription drug account means the account created within the Federal Supplementary Medical Insurance Trust Fund for purposes of Medicare Part D.

Part D eligible individual means an individual who is entitled to or enrolled in Medicare benefits under Part A and/or Part B.

Prescription drug plan or PDP means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in § 423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the contract requirements under subpart K.

PDP region means a prescription drug plan region as determined by CMS under § 423.112.

PDP sponsor means a nongovernmental entity that is certified under this part as meeting the requirements and standards of this part for that sponsor.

d. Financial Relationships Between PDP Sponsors, Health Care Professionals and Pharmaceutical Manufacturers

The financial relationships that exist between or among PDP sponsors, health care professionals (including physicians and pharmacists), and/or pharmaceutical manufacturers may be subject to the anti-kickback statute and, if the relationship involves a physician, the Stark statute. These financial relationships could potentially implicate the anti-kickback and physician self-referral statutes, therefore, they should be structured appropriately to comply with legal requirements. Nothing in this regulation should be construed as implying that financial relationships described in the regulations meet the requirements of the anti-kickback statute or physician self-referral statute or any other applicable Federal or State law or regulation. All such relationships must comply with these laws. Therefore, PDPs are not prevented from paying pharmacists, for instance, for medication therapy management, provided that the PDPs do not violate anti-kickback and physician self-referral laws.

B. Eligibility and Enrollment

1. Eligibility To Enroll (§ 423.30)

The MMA established section 1860D-1 of the Act, which includes the eligibility criteria an individual must meet in order to obtain prescription drug coverage by enrolling in a PDP plan or an MA-PD plan. In accordance with section 1860D-1(a)(3) of the Act, a "Part D eligible individual" is defined as an individual who is entitled to or enrolled in Medicare benefits under Part A or enrolled in Part B. In order to enroll in a PDP plan, the individual must reside in the plan's service area, and cannot be enrolled in an MA plan, other than an MSA plan or private fee-for-service plan that does not provide qualified prescription drug coverage. This residency requirement flows from the statute's direction for us to use enrollment rules similar to MA (which has such a requirement) and the drug benefit's basic structure, which designates regions within which PDPs are to provide services.

Section 1860D-1(b)(1)(B)(i) requires that we adopt a residency requirement similar to the Part C residency requirements under section 1851(b)(1)(A) of the Act, which stipulates that a beneficiary is eligible to enroll in a plan only if the beneficiary resides in the plan's service area. Because a PDP's service area may consist only of one or more PDP regions, individuals who reside outside of the

United States would be ineligible to enroll in a PDP or MA-PD plan. Consequently, these individuals are ineligible to enroll in Part D.

Under section 1860D-1(b)(1)(B)(i) of the Act, which incorporates into Part D section 1851(b)(1)(A) of the Act, the Secretary may provide exceptions to the general rule that an individual is eligible to enroll in a PDP serving the geographic area in which the individual resides. We note also that section 1860D-1(b)(1)(B) of the Act directs us to adopt enrollment rules "similar to," but not necessarily identical to, those under Part C, giving us some flexibility to modify the Part C enrollment rules as appropriate. We believe that incarcerated individuals should be ineligible to enroll in a PDP. We therefore provide in § 423.4 of the proposed rule that a PDP's service area would exclude areas in which incarcerated individuals reside (that is, a correctional facility).

Were we not to adopt these rules, individuals who are incarcerated or who live outside of the U.S. and who fail to enroll in a PDP or MA-PD when first eligible, or remain enrolled thereafter, would face a late enrollment penalty if they later decide to enroll in Part D. In accordance with section 1860D-13(b) of the Act and § 423.46 of the proposed rule, individuals are subject to a late penalty if there is a continuous period of eligibility of at least 63 days, beginning after the termination of the individual's initial enrollment period, during which the individual was not enrolled in a PDP or MA-PD plan. Thus, in order to avoid such a penalty, these individuals would have to enroll in a PDP or MA-PD, but would not be able to avail themselves of the plan's services while they are incarcerated or outside of the plan's service area. Under our proposed rule, individuals residing outside the U.S. and incarcerated individuals would be ineligible to enroll in a PDP. Thus, there would not be a continuous period of eligibility of at least 63 days during the time of the individuals' residency abroad or incarceration. Consequently, these individuals would not need to enroll in Part D in which they would not be able to receive services or benefits in order to avoid the late penalty.

Generally, a Part D eligible individual enrolled in an MA plan that does not provide qualified prescription drug coverage (that is, an MA-PD plan) may not enroll in a PDP; however, there are two exceptions. Section 1860D-1(a)(1)(B) of the Act permits a Part D eligible individual who is enrolled in either a MA private fee-for-service plan (as defined in section 1859(b)(2) of the

Act) that does not provide qualified prescription drug coverage or an MSA plan (as defined in section 1859(b)(3) of the Act) to enroll in a PDP. We have provided for these exceptions in § 423.30(b) of the proposed rule.

Except as provided above, in accordance with section 1860D–1(a)(B)(i) of the Act and as provided in 423.30(c) of the proposed rule, a Part D eligible individual who is enrolled in an MA–PD plan must obtain prescription drug coverage through that plan. In order to enroll in an MA–PD plan, a Part D eligible individual must also meet the eligibility and enrollment requirements of the MA–PD plan as provided in 42 CFR 422.50 through 422.68 of proposed regulations.

As discussed in § 423.859, section 1860D–3(a)(1) of the Act requires the Secretary to ensure that each Part D eligible individual will have available a choice of enrollment in at least two qualifying plans, at least one of which must be a PDP. If this choice is not available, in accordance with section 1860D–2(b) of the Act, a fallback prescription drug plan will be made available and individuals will be eligible to enroll in that fallback plan if eligible for Part D. As discussed in § 423.855 of the proposed rule, a fallback prescription drug plan is a prescription drug plan offered by an eligible fallback entity that provides only standard prescription drug coverage (without supplemental benefits), provides access to negotiated prices, and meets the requirements for PDP sponsors (except as otherwise indicated), and other requirements specified by CMS.

2. Part D Enrollment Process (§ 423.34)

Section 1860D–1(b)(1) of the Act requires that we establish a process for the enrollment, disenrollment, termination, and change of enrollment of Part D eligible individuals in prescription drug plans. The statute further requires that this process use rules similar to, and coordinated with, the enrollment, disenrollment, termination, and change of enrollment rule for MA–PD plans under certain provisions of section 1851 of the Act. As such, we have incorporated, where possible, the MA enrollment and disenrollment requirements provided under 42 CFR 422.50–422.80. In accordance with section 1860D–1(b)(1)(C) of the Act, we would establish a process to automatically enroll a full benefit dual-eligible individual (as defined under section 1935(c)(6) of the Act) who has failed to enroll in a PDP or MA–PD plan by either the end of the individual's initial enrollment period or

upon becoming dual eligible after his/her initial enrollment period. Prior to this automatic enrollment process, a widespread education and information campaign (described later in this subpart at § 423.48) will equip full benefit dual eligible individuals with information designed to explain options and encourage these individuals to take an active role in their enrollment rather than wait to be automatically enrolled.

An full benefit dual eligible individual who fails to enroll in a PDP or MA–PD would be automatically enrolled into a prescription drug plan that has a monthly beneficiary premium equal to or below the subsidy amount available to low-income beneficiaries in accordance with section 1860D–14(a)(1)(A) of the Act. This premium may not exceed the low-income benchmark premium amount established under section 1860D–14(b)(2) of the Act. The calculation of the low-income benchmark premium is further described in § 423.780(a) of the proposed rule.

Section 1860D–1(b)(1)(C) of the Act also directs us to enroll full benefit dual eligible individuals who fail to elect a PDP or MA–PD plan on a random basis if more than one PDP within an area has a monthly beneficiary premium equal to or below the low-income benchmark premium. To ensure that each full benefit dual eligible individual will have access to at least one PDP in each region, section 1860D–14(b)(3) of the Act provides that the premium subsidy amount for eligible individuals (including full benefit dual eligible individuals) cannot be less than the lowest monthly beneficiary premium for a PDP in a region. A more detailed discussion of the premium subsidy is found at § 423.780 of the proposed rule.

Two major issues require resolution because the statutory provisions are inherently contradictory in their requirements. The first is how to provide qualified prescription drug coverage to those full benefit dual eligible individuals who are in an MA–only plan and who have failed to enroll in a PDP or MA–PD plan. The second issue is how to provide qualified prescription drug coverage to a full benefit dual eligible enrolled in the Medicare Advantage program when the premium for the MA–PD plan(s) offered by an individual's MA organization exceeds the low income benchmark premium. We discuss each of these issues below and request comments on how best to reconcile these conflicting provisions.

A literal reading of section 1860D–1(b)(1)(C) of the Act would seem to preclude automatic enrollment of full

benefit dual eligible individuals into MA–PD plans. The language requires automatic enrollment into a "prescription drug plan" whose premium meets the aforementioned requirements. However, section 1860D–1(a)(1)(B)(ii) of the Act precludes Part D eligible individuals enrolled in MA (not MA–PD) plans (other than those in some private fee-for-service or MSA plans) from enrolling in PDPs. To reconcile this apparent conflict, we propose that the reference in section 1860D–1(b)(1)(C) of the Act to "prescription drug plans" be interpreted as including both PDPs and MA–PD plans, thereby allowing automatic enrollment of an MA full benefit dual eligible into a MA–PD plan offered by the same MA organization offering his or her MA plan if the basic premium for such plan does not exceed the low-income benchmark premium amount.

General principles of statutory interpretation require us to reconcile two seemingly conflicting statutory provisions whenever possible, rather than allowing one provision to effectively nullify the other provision. Consequently, when a statutory provision may reasonably be interpreted in two ways, we have an obligation to adopt the interpretation that harmonizes and gives full effect to competing provisions of the statute. The rationale for automatic enrollment is to ensure that full-benefit dual eligible individuals receive outpatient drug coverage under Part D because Medicaid will no longer provide medical assistance for covered Part D drugs to such individuals. For full benefit dual eligible individuals enrolled in MA plans, we believe this objective is best accomplished by enrolling them in one of the MA–PD plans offered by their MA organization.

To the extent that the MA–only portion of the MA–PD plan parallels the coverage under a full benefit dual eligible individual's MA plan, enrolling the individual in the MA–PD plan would be similar to permitting the individual to remain enrolled in the MA plan while simultaneously enrolling the individual in a PDP. In other words, enrolling the individual in a MA–PD plan offered by the same MA organization is, in effect, simply adding qualified prescription drug coverage to the individual's MA benefits. For this reason, we believe the reference to "prescription drug plans" in section 1860D–1(b)(1)(C) of the Act should be interpreted as requiring enrollment of a full benefit dual-eligible into a plan that will provide the individual with Part D drug benefits in addition to any other benefits the individual receives under

Medicare, whether through Medicare Part A and/or Part B, or through enrollment in the Medicare Advantage program under Part C. We believe this interpretation promotes the policies underlying sections 1860D-1(b)(1)(C) and 1860D-1(a)(1)(B)(ii) of the Act, giving full effect to both statutory provisions. However, in the above situation, if the basic premium for the MA-PD plan exceeds the low-income benchmark premium amount, under section 1860D-1(b)(1)(C) of the Act, we could not permit automatic enrollment of a full-benefit dual eligible into that MA-PD plan.

One possible solution for an MA full benefit dual eligible enrolled in an MA organization in which all of its MA-PD premiums exceed the allowable amount might be to allow that individual to remain in the MA plan and to automatically enroll him or her into a PDP that meets the premium requirements. However, according to section 1860D-1(a)(1)(A) of the Act, only a part D eligible individual who is not enrolled in an MA plan may enroll in a PDP, thereby precluding this option.

Another possibility would be to involuntarily withdraw MA full benefit dual eligible individuals from their MA plan, which would default them to Original Medicare and then automatically enroll them into a PDP. However, there is no statutory authority to involuntarily disenroll the individual from his or her MA plan. In fact, we believe doing so would violate section 1851(c)(3)(B) of the Act, which provides that an individual who makes an MA election is considered to have continued to have made this election until he or she voluntarily changes the election, or the plan is discontinued or no longer serves the individual's service area.

Enrolling an MA full dual eligible individual whose MA organization's MA-PD plan premiums exceed the benchmark amount into a MA-PD plan offered by another MA organization whose premiums are equal to or below the benchmark would be problematic as well since this would violate section 1851(c)(3)(B) of the Act. In addition, this would not be possible if the monthly premium amount of any available MA-PD plan is greater than the low-income benchmark premium amount. Similarly, we believe that requiring these full

benefit dual eligibles to disenroll from the Medicare Advantage program so that we may automatically enroll them into less expensive PDPs would violate section 1851(c)(3)(B) of the Act.

One last option would be to allow the beneficiary to go without outpatient prescription drug coverage unless the beneficiary chooses a MA-PD plan on his or her own accord. We do not see this as a reasonable option because it appears to violate section 1860D-1(b)(1)(C) of the Act and would leave a vulnerable beneficiary without outpatient drug coverage. While the statute prescribes an automatic enrollment process for full benefit dual eligibles who fail to elect a PDP or MA-PD plan, it is important to note that such full benefit dual eligible individuals may decline the enrollment or change the enrollment if they so choose. One option for such a process could be to provide notice to the individual to allow him or her to choose another option. Since the statute affords full benefit dual eligible individuals a special election period, they would be able to make a change in their election of PDP or MA-PD plans. Furthermore, while automatic enrollment of these individuals could be restricted to plans with premiums at or below the low-income benchmark premium, these dual eligible individuals would not be restricted to electing only such plans. However, if they select a high premium plan, they would be responsible for paying the difference between the premium and the low-income subsidy amount.

In implementing the automatic enrollment process for full benefit dual eligible individuals, we are considering which entity is best suited to perform the automatic and random enrollment function. The options include CMS or the State performing this function, or a contracted entity or entities on their behalf. If we (or a contractor on our behalf) performed the auto assignment, we would expect consistent, clear oversight of the process, thus making the process uniform nationally; this might also reduce the need to transmit data from CMS to the States. However, this would be highly dependent on receiving timely, accurate Medicaid eligibility data from States and would also make us responsible for a new national workload of indeterminate size.

An alternative is for States (or their contracted entities) to be responsible for performing the automatic enrollment. This approach may be appropriate because States have experience with random assignments through their Medicaid programs and have more immediate access to changes in Medicaid eligibility. We would define random assignment, establish standards for notification, and so forth, to ensure consistency. If we were to pursue this option, we could consider this function as necessary for the proper and efficient administration of the State plan. We would need to provide States with accurate and timely Part D data. States could be compensated for this effort through Federal financial participation (FFP) in their administrative expenses or through contractual or other arrangements. We invite comment on the most appropriate method of performing automatic assignment of dual eligibles and the appropriate entity to do so.

3. Part D Enrollment Periods (§ 423.36)

a. General Enrollment Periods

The MMA directs us to establish three coverage enrollment periods: (1) The initial enrollment period; (2) the annual coordinated election period; and (3) special enrollment periods (SEPs). Generally, in accordance with section 1860D-1(b)(2)(B) of the Act, the initial enrollment period for Part D is the same as the initial enrollment period established for Part B. Specifically, this period is the seven-month period that begins three months before the month an individual first meets the eligibility requirements for Part B and ends three months after that first month of eligibility. However, if an individual's initial enrollment period for Part B ends prior to May 15, 2006, his or her initial enrollment period under Part D will be extended to May 15, 2006. In addition, as part of the implementation of the Part D program, and in accordance with section 1860D-1(b)(2)(A) of the Act, we would establish an initial enrollment period for Part D from November 15, 2005, until May 15, 2006, for those individuals who are already eligible to enroll in a Part D plan as of November 15, 2005.

Examples:

Month individual first entitled to part A or enrolls in part B	Initial enrollment period for part D
June 1, 2005	November 15, 2005–May 15, 2006.
November 1, 2005	November 15, 2005–May 15, 2006.
December 1, 2005	November 15, 2005–May 15, 2006.

Month individual first entitled to part A or enrolls in part B	Initial enrollment period for part D
January 1, 2006	November 15, 2005–May 15, 2006.
February 1, 2006	November 15, 2005–May 31, 2006.
May 1, 2006	February 1, 2006–August 31, 2006.
June 1, 2006	March 1, 2006–September 30, 2006.

In accordance with section 1860D–1(b)(1)(B)(iii) of the Act, the annual coordinated election period for Part D is concurrent with the annual coordinated election period for the Medicare Advantage program under section 1851(e) of the Act. It is during this annual period in which all PDP plans must open enrollment to Medicare beneficiaries. For coverage beginning in 2006, the annual coordinated election period begins on November 15, 2005, and ends on May 15, 2006. As a result, the initial enrollment period for individuals who are eligible to enroll in a Part D plan as of November 15, 2005 and the annual coordinated election period will run concurrently during this time frame. The annual coordinated election period for MA and MA–PD plans will also occur during this time. In accordance with section 1851(e)(3)(B)(iv) of the Act, § 423.36(b)(2) of our proposed rule provides that, for 2007 and subsequent years, the annual coordinated election period would be November 15 through December 31 for coverage beginning on January 1 of the following year.

b. Special Enrollment Periods

The MMA also establishes special enrollment periods (SEPs). Special enrollment periods allow an individual to disenroll from one PDP and enroll in another PDP. Special enrollment periods are available as follows:

(i) Involuntary Loss, Reduction, or Non-notification of Creditable Coverage

As discussed below in § 423.56, Part D eligible individuals who fail to enroll in Part D during their initial enrollment period will not be subject to late penalties if they had creditable prescription drug coverage during the time they were not enrolled in Part D. Part D eligible individuals who involuntarily lose creditable prescription drug coverage, such as the loss of employment and associated health benefits, or the loss of coverage due to the death of a spouse, would have an SEP to enroll in a Part D plan, in accordance with section 1860D–1(b)(3)(A) of the Act. Pursuant to section 1860D–1(b)(3)(A)(iii) of the Act, this SEP does not apply when the individual loses creditable coverage because of his

or her failure to pay premiums for that coverage, since this would be considered a voluntary loss of coverage for purposes of this section.

The SEP would also apply if the individual was never informed that the coverage that he or she had was not creditable or if current creditable coverage was reduced so that it was no longer creditable coverage under this part. In cases where the coverage is reduced, the SEP applies only when the current creditable coverage is reduced by the issuer or group through which the individual has such coverage. Therefore, if the covered individual voluntarily reduces the coverage, for example, to reduce his or her premium costs, this SEP would not apply because that action is voluntary.

(ii) Erroneous Enrollment

Section 1860D–1(3)(B) of the Act provides for an SEP for an individual who has been subject to enrollment errors, similar to those provided for both Part A and Part B under section 1837(h) of the Act. We are using the same language provided for this SEP at § 423.36(c)(3) of the proposed rule as provided under § 407.32, which establishes a special enrollment period for enrollment errors for Part B. Specifically, § 407.32 refers to misrepresentation, inaction, or error by the Federal government that affects an individual's enrollment rights.

(iii) Individuals With Medicaid Coverage

Section 1860D–1(b)(3)(D) of the Act provides an SEP for an individual who is eligible for both Medicare and full benefits under a State's Medicaid program, as those individuals are described in section 1935(c)(6) of the Act. This would be available to individuals who are determined full benefit dual eligible after the initial enrollment period. This would also provide these individuals who have been automatically assigned to a plan the opportunity to change PDPs or MA–PDs at any time.

(iv) Individuals Age 65

During the Part D eligible individual's initial enrollment period, the individual has several options available, including

remaining in original Medicare and enrolling in a PDP or enrolling in an MA–PD plan. Section 1860D–1(b)(3)(E) of the Act provides an SEP to an individual who enrolls in a MA–PD plan upon first becoming eligible for benefits under Part A at age 65 and then discontinues that enrollment and elects coverage under original Medicare and a PDP at any time during the 12-month period beginning on the effective date of the MA–PD plan election. This specific provision applies only to an individual who elects an MA–PD plan during his or her initial enrollment period, as defined under section 1837(d) of the Act, which surrounds his or her 65th birthday. This SEP will only apply to individuals who elect an MA–PD plan, and does not pertain to individuals who elect an MA-only plan.

(v) Exceptional Circumstances

Finally, in addition to providing for special enrollment periods as mentioned above, section 1860D–1(b)(3)(C) of the Act authorizes us to establish SEPs in exceptional circumstances. CMS has historically included in regulation those SEPs that have been specifically named in the statute and established the SEPs for exceptional circumstances in our manual instructions rather than through regulation. While we intend to continue establishing these exceptional SEPs through this process, we seek public input on other SEPs that should be considered through our manual process.

In addition to those SEPs established by the MMA, we intend to apply certain SEPs established under the MA program. The SEPs that will be included from the MA program under this section will include the following conditions—

- (1) The PDP terminates its service area or is terminated in the area in which the individual resides;
- (2) The individual moves out of the plan's service area; or
- (3) The individual demonstrates to us, in accordance with guidelines that we establish, that the PDP offering the plan substantially violated a material provision of its contract with regard to the individual or the organization, its agent, representative, or the PDP materially misrepresented the plan's

provisions in marketing the plan to the individual.

There is a disconnect issue between the enrollment period provided for individuals eligible to enroll in a Part D plan at section 1860D-1(b)(1)(iii) of the Act and the open enrollment periods provided for MA eligible individuals under section 1851(e)(2) of the Act that we believe can be addressed through a special election period. Section 1851(e)(2) of the Act provides for an open enrollment period for MA eligible individuals in which they may change their election once. Beginning in 2006, this period is limited to 6 months from January through June and in 2007, to 3 months, from January through March. The MMA, at Section 102 (a)(6), further limits individuals' elections during this open enrollment period to a specific "type" of plan. Specifically, an individual who is enrolled in an MA-PD plan may elect another MA-PD plan or elect original Medicare and a PDP, but cannot elect an MA-only plan. However, there is no corresponding enrollment period that would allow the individual to elect a PDP during this time. We propose to remedy this situation by establishing an SEP for these individuals under our aforementioned authority to establish SEPs for exceptional circumstances.

In addition, section 1851(e)(2)(D) of the Act provides for a continuous open enrollment period for institutionalized individuals throughout the year. We also propose establishing an SEP for this through our exceptional circumstance authority in our manual instructions.

4. Effective Dates of Coverage and Change of Coverage (§ 423.38)

Section 1860D-1(b)(1)(B)(iv) of the Act authorizes us to apply the effective date requirements provided under the MA program at section 1851(f) of the Act. The three enrollment periods provided under Part D are the initial enrollment period, the annual coordinated election period, and special enrollment periods. The effective dates for these enrollment periods are as follows:

a. Initial Enrollment Period

In accordance with section 1851(f)(1) of the Act, as incorporated into Part D under section 1860D-1(b)(1)(B)(iv) of the Act, an enrollment made during the initial enrollment period will generally be effective the first day of the calendar month following the month in which the individual enrolled in Part D. An enrollment made prior to the month of entitlement to or enrollment in Medicare benefits under Part A and/or Part B is effective the first day of the

month the individual is entitled to or enrolled in Part A or Part B. Since the Part D provisions are not effective until January 1, 2006, we would clarify that in no case may enrollment in Part D be effective prior to this date. We are also clarifying that initial enrollments made between November 15 and December 31, 2005, will be effective January 1, 2006. An enrollment made during or after the month of entitlement to or enrollment in Medicare benefits under Part A and/or Part B is effective the first day of the calendar month following the month in which the enrollment in Part D is made. We have reflected these provisions in § 423.38(a) of our proposed rule.

b. Annual Coordinated Election Period

In accordance with section 1851(f)(2) of the Act, as incorporated into Part D under section 1860D-1(b)(1)(B)(iv) of the Act, an enrollment made during the annual coordinated election period is effective as of the first day of the following calendar year, that is, January 1st. We have reflected this provision in § 423.38(b) of the proposed rule.

c. Special Enrollment Period

A special enrollment period is effective in a manner that we determine to ensure continuity of health benefits coverage. We have reflected this provision in § 423.38(c) of the proposed rule.

5. Coordination of Beneficiary Enrollment and Disenrollment Through PDPs (§ 423.42)

Section 1860D-1(b)(1)(A) of the Act authorizes us to establish a process for enrollment in and disenrollment from prescription drug plans. We have outlined the coordination of enrollment and disenrollment through PDP organizations in the regulations at § 423.42. A Part D eligible individual who wishes to make, change, or discontinue an enrollment during applicable enrollment periods may do so by filing an enrollment with the PDP directly. We envision a paper enrollment form process and recognize the opportunity for other possible mechanisms that may prove secure, convenient for beneficiaries, and valuable to the efficient administration of the program. We request comments on other possible enrollment mechanisms that address data security and integrity, privacy and confidentiality, authentication, and other pertinent issues.

We have added a provision at § 423.42(e) of the proposed rule that would ensure that beneficiaries are not disenrolled from their PDP at the end of

the calendar year. We are including this provision to clarify that beneficiaries will remain enrolled in their PDP without having to actively re-enroll in that PDP at the beginning of the calendar year.

6. Disenrollment by the PDP (§ 423.44)

Section 1860D-1(b)(1)(B) of the Act generally directs us to use disenrollment rules similar to those established under section 1851 of the Act. We are applying the provisions of section 1851(g)(3) of the Act that provide authority for the basis of terminations for MA plans. We codify these in 42 CFR 422.74. The disenrollment provisions for PDPs are outlined in § 423.44 of our proposed rules, including the basis for disenrollment—both optional and required—and guidance for notice requirements.

Specifically, a PDP is required to disenroll an individual who dies, who no longer resides in the PDP's service area, loses entitlement or enrollment to Medicare benefits under Part A and is no longer enrolled in Part B, or who knowingly misrepresents to the PDP that he or she has received or expects to receive reimbursement for covered Part D drugs through third-party coverage. A PDP is also required to disenroll an individual if the PDP's contract is terminating.

We are particularly interested in receiving comments about the requirement to disenroll individuals from a PDP if they no longer reside in the service area. Under the MA rules at 42 CFR 422.74, individuals who are out of the service area for more than 6 months will be disenrolled, unless the MA plan offers visitor or traveler benefits. We recognize the inherent difference between PDPs and MA plans (in particular, the range of services each provides) and that it may not be reasonable to apply the disenrollment requirements established under MA in the same way for PDPs. For example, while we have a limit on the length of time an MA enrollee may be out of the service area, this limit may not be necessary as long as there are specific assurances from the PDP that individuals will have access to PDP benefits while out of the area (provided the individual remains in the United States). For example, a regional PDP may either have a corporate or other relationship with a PDP in another region or have a network of pharmacies in other regions (or nationwide) that would provide access to prescription drugs outside of the region on the same basis as in-network pharmacies within the enrollee's region of residence. We

would appreciate any comments on this area.

In addition to providing requirements for disenrollments that are required by the PDP, we also provide under § 423.44(d) of our proposed rule that PDPs may disenroll individuals who do not pay monthly premiums or whose behavior is disruptive. However, we believe there are important beneficiary implications for those PDPs who disenroll individuals for these reasons. An individual who is disenrolled for failure to pay monthly PDP premiums, disruptive behavior, or misrepresentation of third party reimbursement will not be provided an SEP permitting him or her to enroll in another PDP. Since the individual generally will not be able to enroll in either a PDP or an MA-PD until the next annual coordinated election period, he or she may be subject to late enrollment penalties under § 423.46 of the proposed rule.

We plan to establish re-enrollment guidelines under the MA program for optional disenrollment for nonpayment of premium and disruptive behavior. We recognize, however, that this policy may not be appropriate for PDPs. If the individual is prohibited from re-enrolling in each of the MA plans available in an area, original Medicare is always available to provide and deliver services to that individual. Under the PDP infrastructure, if the individual was prohibited from re-enrolling in each PDP available, there is no other option available. We would appreciate comments regarding the applicability of prohibiting re-enrollment in a PDP.

As with the MA program, PDP sponsors will be required to provide proper notice to the beneficiary and afford him or her due process in accordance with the procedures outlined in our manual instructions. For example, a PDP that wishes to disenroll a beneficiary for disruptive behavior must receive prior approval from CMS and must demonstrate to CMS' satisfaction that it has made a good faith effort to resolve the issue prior to requesting the disenrollment. CMS reviews these requests on a case-by-case basis, taking into account all of the facts and circumstances of a particular case, prior to making its decision. PDP sponsors must apply their policies for optional disenrollment for failure to pay premiums and disruptive behavior consistently among individuals enrolled in their plans, unless we permit otherwise, and must do so consistent with applicable laws regarding discrimination on the basis of disability.

7. Late Enrollment Penalty (§ 423.46)

Section 1860D-13(b) of the Act establishes late enrollment penalties for beneficiaries who fail to maintain creditable prescription drug coverage for a period of 63 days following the last day of an individual's initial enrollment period and ending on the effective date of enrollment in a PDP or MA-PD. The calculation of the amount of the penalty is described in § 423.286(d)(3) of our proposed rule. Specifically, the penalty amount for a Part D eligible individual for a continuous period of eligibility is the greater of an amount that CMS determines is actuarially sound for each uncovered month in the same continuous period of eligibility that is subject to this penalty; or 1 percent of the base beneficiary premium for each uncovered month in the period. An uncovered month is any month in which individual does not have creditable coverage at any time during that month. Because Part D is a voluntary benefit, it is susceptible to selection bias, where predominantly sicker beneficiaries, with higher than average prescription drug expenses enroll, and healthier, less expensive beneficiaries defer participation. Such a dynamic would make the initial premium levels higher than Congress expected at the time of MMA's enactment. Left unchecked, the selection bias would be exacerbated, potentially resulting in what has been called an insurance "death spiral." To ensure the affordability of the Part D benefit and the stability of the associated premium, we believe there is a strong public policy value in creating an incentive for immediate, widespread enrollment in this new, heavily subsidized benefit.

The process for documenting creditable coverage is discussed in § 423.56 of the proposed rule.

8. Part D Information That CMS Provides to Beneficiaries (§ 423.48)

As provided under section 1860D-1(c)(1) of the Act, we would conduct activities designed to broadly disseminate information about Part D coverage to individuals who were either eligible or prospectively eligible for Part D benefits. This information would be made available to beneficiaries at least 30 days prior to their initial enrollment period as provided under § 423.38 of our proposed rule. The information dissemination activities for Part D would be similar to, and coordinated with, the information dissemination activities that we currently perform for Medicare beneficiaries under sections 1851(d) and 1804 of the Act.

As required under section 1860D-1(c)(3) of the Act, we would include the following comparative information with respect to qualified prescription drug coverage provided by PDPs and MA-PD plans as part of our dissemination of Part D information and our efforts to promote informed beneficiary decisions—

- Benefits and prescription drug formularies;
- Monthly beneficiary premium;
- Quality and performance;
- Beneficiary cost-sharing; and
- Results of consumer satisfaction surveys.

We would not provide information on quality and performance or consumer satisfaction surveys during—

- (1) The first plan year; or
- (2) The next plan year if it were impracticable to obtain that information, or if the information were not available.

As stated in section 1860D-1(c)(4) of the Act, we would also provide information to beneficiaries regarding the methodology we will use for determining late enrollment penalties, as provided in § 423.286(d) of our proposed rule.

In carrying out the annual dissemination of Part D information, we anticipate conducting a significant public information campaign to educate beneficiaries about the new Medicare drug benefit and to ensure the broad dissemination of accurate and timely information. We would place an emphasis on ensuring that low-income individuals eligible for or currently enrolled in Part D benefits were aware of the additional benefits available to them and how to receive those benefits. In order to maximize the enrollment of Part D eligible individuals, this public information campaign would include outreach, information, mailings, and enrollment assistance with and through appropriate State and Federal agencies—including State health insurance assistance programs (SHIPs)—and would coordinate with other Federal programs providing assistance to low-income individuals. In addition, we would undertake special outreach efforts to disadvantaged and hard-to-reach populations, including targeted efforts among historically underserved populations, and coordinate with a broad array of public, voluntary, and private community organizations serving Medicare beneficiaries. Materials and information would be made available in languages other than English, where appropriate.

We would require, as described in § 423.48 of our proposed rule, that each organization offering a prescription drug plan or MA-PD plan provide us

annually with the information to disseminate to individuals who are currently or prospectively eligible for Part D benefits. This information would enable beneficiaries to make informed decisions regarding their Part D coverage options. Organizations offering a prescription drug plan or MA-PD plan would be required to provide this information in a format and to use standard terminology that we would specify in further operational guidance.

Under the recently implemented Medicare Prescription Drug Discount Card and Transitional Assistance Program (42 CFR parts 403 and 408), we took the unprecedented step of establishing a price comparison Web site available through <http://www.medicare.gov> to provide beneficiaries with information about drug card sponsors' negotiated drug prices in actual dollars—including dispensing fee information—for the purpose of comparing negotiated prices across approved card programs. The prices and fees on the price comparison Web site reflect an estimate of the maximum prices beneficiaries will experience at the point of sale. The Web site also includes information about generic substitutes. In the interest of broadly disseminating information that promotes informed decision-making among Part D enrollees and prospective Part D enrollees, as required under section 1860D-1(c) of the Act, we propose extending the price comparison requirements to PDP sponsors and MA organizations offering MA-PD plans and making comparative information about Part D plans' negotiated prices available to beneficiaries through <http://www.medicare.gov>. Our drug card experience shows that providing drug price information can significantly reduce prices and we believe that information about negotiated drug prices will assist beneficiaries in deciding which Part D plan will offer them the greatest financial advantage. We propose building on our experience in implementing the drug discount card price comparison Web site as we develop requirements for the Part D price comparison Web site, and we are seeking comments on how to provide information in the drug benefit to help achieve maximum drug savings.

Since the introduction of <http://www.medicare.gov> in 1998, CMS has substantially increased the amount of personalized information available to Medicare beneficiaries, making it one of the government's most comprehensive and customer-oriented sites available to the public. The Web site hosts twelve separate database applications to help individuals make their own health care

decisions. The most significant ones are: the Medicare Personal Plan Finder (which contains costs, benefits, quality, satisfaction and disenrollment measures), Nursing Home Compare (which contains basic characteristics, staffing information and inspection results), the Prescription Drug and Other Assistance Programs application (which contains the most extensive, nationally complete listing of the Medicare-approved discount drug cards, including price comparisons, as well as other government and private programs designed to help with prescription drug costs), and the Medicare Eligibility Tool (which assists users in determining when they are eligible, how to enroll and what they need to consider when joining Medicare). Other tools providing customized results include: the Participating Physician and Supplier Directories, Home Health and Dialysis Facility Compare, Your Medicare Coverage, Helpful Contacts, Publications, and Frequently Asked Questions. By updating all information on the Web site at least once a month, the information provided to Medicare beneficiaries via <http://www.medicare.gov> is the most reliable and consistent information available.

Much of the information available through <http://www.medicare.gov> is also available via the 1-800-MEDICARE helpline. 1-800-MEDICARE is a major information channel for providing the most personalized and reliable information to people with Medicare. As a result of the Medicare Modernization Act (MMA), we are receiving the largest call volume ever for 1-800-MEDICARE. The beneficiary can call 1-800-MEDICARE to find out the most reliable information on public and private programs that offer discounted or free medication, programs that provide help with other health care costs, and Medicare health plans that include prescription coverage. The caller can always talk to a live person at 1-800-MEDICARE to get the facts they need. When a beneficiary calls 1-800-MEDICARE, we can send them a personalized brochure that allows them to look at discount cards based on their drug needs and their preferences about how to get their medicines, and their enrollment forms. We can also give the beneficiary personalized brochures containing information on their health plan choices, nursing homes and Medicare participating physicians in their area. 1-800-MEDICARE is available 24 hours a day, 7 days a week, to provide the one-on-one service that our Medicare beneficiaries need to make appropriate health care decisions.

9. Approval of Marketing Materials and Enrollment Forms (§ 423.50)

Section 1860D-1(b)(1)(B)(vi) of the Act directs CMS to use rules similar to those established under section 1851 of the Act to review PDP's marketing materials and application forms. While all entities with which CMS does business with are required to adhere to all Federal laws, with regard to marketing, it is important to refer here to section 1140 of the Act, prohibiting the misuse of symbols, emblems, or names in reference to Social Security or Medicare. While we have not reiterated this provision in our proposed rule, we believe that it is important to provide such reference in this discussion.

We are generally replicating the marketing provisions established under § 422.80 for MA plans as appropriate for PDPs. Therefore, § 423.50(a) of our proposed rule would provide guidance for our review of marketing materials, definition of marketing materials, deemed approval, and standards for PDP marketing.

While we generally replicated MA provisions, we recognize that the differences between PDPs and MA plans may require different marketing requirements. For example, while we prohibit enrollment forms from being accepted in provider offices or other places where health care is delivered under the MA rules at 42 CFR 422.80, this may not be appropriate to extend to relationships between PDP sponsors and pharmacies with respect to marketing a PDP. We invite comment regarding the applicability of the MA marketing requirements to PDPs.

We are proposing to add § 423.50(a)(3) in order to establish a program that recognizes consistent compliance with marketing guidelines by providing for streamlined approval of marketing materials submitted by PDP sponsors that have demonstrated such compliance. Called the "File and Use" program, organizations that have demonstrated to us that they continually meet a specified standard of performance will have certain types of marketing materials (such as advertising materials or other materials that do not describe plan benefits) deemed to be approved by us if they are not disapproved within five days of submission to us for prior approval. Thus, under these circumstances, organizations only need submit material for our approval five days prior to their distribution.

The advantages of File & Use are that the organization can decrease the time it takes to begin using certain marketing materials and improve planning and

budgeting for publication of these materials. Since PDPs will be new to the CMS marketing review process, we intend to not allow PDPs to qualify for the File & Use program until they have been in the program for a specified period of time, as determined by us, and establish consistent compliance with marketing guidelines.

We are also aware that the ability to provide additional products (for example, financial services) to Medicare beneficiaries could provide additional tools to help beneficiaries manage their expenses and financial security, and could be a strong incentive for potential PDP sponsors to participate in Part D. We ask for comments on the advisability of allowing such products to be provided in conjunction with PDP services and the appropriate limitations on such activities. We note that in accordance with HIPAA privacy rules, the PDP sponsor may have to obtain beneficiary authorization to market certain products.

10. Information Provided to PDP Sponsors and MA Organizations

Section 1860D-1(b)(4)(A) of the Act authorizes us to provide PDP sponsors and MA organizations with information about Part D eligible individuals so that their organizations may facilitate the marketing and enrollment of beneficiaries in their PDP and MA-PD plans and is intended solely for these purposes. That information is intended to assist in the outreach to individuals to ensure participation in the Part D program, as well as to reduce costs to those plans.

While the statute provides us with broad authority to share information with PDPs and MA organizations, we have operational questions, especially regarding any potential adverse impact on beneficiaries. To the extent we were to share such information with PDP sponsors and MA organizations, should beneficiaries be given the ability to choose not to have their information shared with these entities? To the extent that such information is shared for purposes of marketing, should PDP sponsors and MA organizations be able to use this information to contact beneficiaries only through written communications, or should telephone contacts be permitted, and, if so, under what circumstances? We also have questions as to whether such information should be provided by CMS upon request, or only at specific, scheduled times during the year (for example, just prior to the Annual Coordinated Election Period). Further, we would like to know what specific information we could provide to PDP or

MA organizations that would facilitate their marketing and enrollment activities. The new authority provided in section 1860D-1(b)(4)(A) of the Act gives us the ability to permit plans to interact with prospective enrollees on a different basis. At the extreme, plans would be permitted to market directly to Medicare beneficiaries, based on contact information we provide, using approved materials, but otherwise bypassing CMS. At the other extreme, current rules regarding the marketing activities of MA plans would remain unchanged. Because Part D is an entirely new, voluntary benefit that would not otherwise be available to beneficiaries absent positive enrollment, there arguably exists a compelling difference in beneficiary interests relative to marketing under Part D (including both PDP and MA-PDs) versus under Part C (for purposes of MA only). We therefore encourage input from the public on these specific concerns and the provision in general.

While this section and discussion may appear to raise HIPAA Privacy rule issues with regards to disclosure of information between CMS and PDPs sponsors or MA-PD organizations, the statute explicitly provides for these activities. Therefore, the Privacy Rule, including the disclosure of protected health information, does not apply to the uses provided for by this section.

11. Procedures To Determine and Document Creditable Status of Prescription Drug Coverage (§ 423.56)

Section 1860D-13(b)(6) of the Act identifies certain entities, which we describe in this section of our proposed rule, that must disclose whether the prescription drug coverage that they provide to their members who are Part D eligible is creditable coverage.

Section 1860D-13(b)(4)(A)-(G) of the Act lists seven forms of creditable coverage: Coverage under a PDP or under an MA-PD; Medicaid; a group health plan (including coverage provided by a federal or a nonfederal government plan and by a church plan for its employees); a State pharmaceutical assistance program; veterans' coverage of prescription drugs; prescription drug coverage under a Medigap policy; and military coverage (including Tricare). Many of these terms are defined elsewhere in Federal regulations; some of them are under the jurisdiction of other Federal agencies. However, the definition of a Medicare supplemental (Medigap) policy, is under CMS' jurisdiction. This term is being clarified in subpart T of this regulation to coordinate with

implementation of the Medicare prescription drug benefit.

In addition to the forms of creditable coverage identified in section 1860D-13(b)(4)(A)-(G) of the Act, section 1860D-13(b)(4)(H) of the Act provides the Secretary with the flexibility to identify "other coverage" that could be considered to be creditable coverage. In 42 CFR 423.56, we propose expanding the list of types of creditable coverage to include health insurance policies sold in the individual market (with the exception of policies that meet the definition of excepted benefits under section 2791 of the Public Health Service (PHS) Act, 42 U.S.C. 300gg-91). This category would include any policies that included prescription drug coverage, whether as part of a more comprehensive policy or as an independent "stand-alone" drug policy, that may have been sold to Medicare beneficiaries. Such stand-alone policies do not meet the definition of an excepted benefit under the Federal statute, even though States may regulate them as "limited" or "supplemental" benefit plans. It would also include comprehensive individual market policies with drug coverage that may have been sold to individuals before they became eligible for Medicare.

It is important to include these policies as creditable coverage. There are a variety of reasons why Medicare beneficiaries may have had individual market coverage, instead of Medigap coverage, after becoming eligible for Medicare. For example, as discussed in the preamble for subpart T, certain policies which will be regulated as Medigap policies after January 1, 2006, do not meet the definition of a Medigap policy prior to that date. Therefore they do not come within the scope of the statutory list of types of creditable coverage. Similarly, if an individual purchased a policy with prescription drug coverage before becoming eligible for Medicare, under title XXVII of the PHS Act, 42 U.S.C. 300gg, *et seq.*, the individual has a guaranteed right to continue to renew the policy. Again, while the policy might have met the definition of a Medigap policy had it been marketed and sold to Medicare beneficiaries, it does not meet those criteria, and does not come within the scope of the statutory list.

We believe it is appropriate to give beneficiaries credit for this coverage, which does not fall within the scope of any of the types of creditable coverage listed in the statute, but which clearly fits within Congress' intent to provide credit for prior prescription drug coverage, and require that the individuals be informed of whether

their drug coverage is creditable and of the choices they will need to make relative to Part D enrollment.

We are also adding coverage provided by the medical care program of the Indian Health Service, Tribe or Tribal organization, or Urban Indian organization (I/T/U) which is described under the Indian Health Improvement Act, 25 U.S.C. 1601 *et seq.* As a result of adding individual market and Indian Health Service coverage to the list of creditable coverage, beneficiaries with both of these types of drug coverage would receive notice of whether this coverage is creditable. We invite comments as to whether there are still more forms of coverage that we should consider creditable coverage.

As discussed above in § 423.46 of the proposed rule, upon becoming eligible for Part D, beneficiaries must decide whether to enroll in Part D, or forego that opportunity and face a possible financial penalty should they later decide to enroll. Beneficiaries who decide not to enroll in Part D because they have creditable prescription drug coverage would not face such a penalty if they later decide to enroll in Part D. According to section 1860D-13(b)(5) of the Act, an enrollee who would otherwise be subject to a late enrollment penalty may avoid the penalty if his or her previous coverage met the standards of "creditable prescription drug coverage". Under section 1860D-13(b)(5) of the Act, previous coverage will only meet those standards *** if the coverage is determined (in a manner specified by the Secretary) to provide coverage of the cost of prescription drugs the actuarial value of which (as defined by the Secretary) to the individual equals or exceeds the actuarial value of standard prescription drug coverage ***.

We are interpreting "to the individual" in this case as being to the average individual under the plan, as opposed to the sponsor of the plan. We believe that the relevant concern in this case is whether the beneficiary has been in a risk pool that on average provided benefits of equal value to Part D. Consequently, for purposes of determining creditable coverage, we are proposing to evaluate the actuarial value of the alternative coverage by means of a single test applied to all coverage: Will the expected plan payout on average under the coverage be at least equal to the expected plan payout under the standard benefit? For example, we propose to require sponsors of group health plans to determine the actuarial equivalency of each group health plan to the standard if, on average, the actuarial value of enrollee drug coverage

under the plan as a whole is at least equal to the actuarial value of standard prescription drug coverage under Part D. (This approach set forth in Subpart R of this proposed rule concerning payments to sponsors of retiree prescription drug plans.) In other words, the calculation of actuarial equivalence would be based on the average plan payout across all benefit packages and all participants and beneficiaries receiving coverage under the sponsor's group health plan. We seek comments on our assumption that this approach is both familiar to employers (and unions) and imposes minimum burden on sponsors.

We are also proposing that any entity seeking to offer creditable prescription drug coverage must attest to this actuarial equivalence (or non-equivalence) in their notice to Medicare beneficiaries and in a submission to CMS, and must maintain documentation of the actuarial analysis and assumptions supporting the attestation. In other words, we would not require CMS approval of this analysis, but would require that it be submitted to CMS and made available to participants upon request.

In coordination with the provisions regarding the late enrollment penalty in § 423.46 of our proposed rule, we would establish a process under which these entities would disclose the creditable status of their prescription drug coverage to us and to each part D eligible beneficiary enrolled in such coverage.

We intend to describe the process for providing this disclosure, including guidance on the content, placement, and timing of the disclosure. The content of this notice and its timely receipt will be important components in the decision making process for beneficiaries, as the creditable status of the beneficiary's drug coverage will have a direct impact on the assessment of late enrollment penalties associated with Part D premiums. Equally important is the notification to the beneficiary of any subsequent changes in the creditable status of his or her coverage. Because beneficiaries have a limited time in which to make decisions about their Part D coverage without facing a penalty, it is important that the notice of creditable status be provided in a timely and conspicuous manner. However, we are also concerned about the potential administrative burden imposed by this requirement and are therefore soliciting comments on the format, placement, and timing of such a notice.

There are several approaches we will consider. One approach would be to incorporate the required disclosure into

materials these entities routinely disseminate to their Part D eligible beneficiaries. We could provide standard language to be inserted into such materials. We would benefit from comments regarding the types of materials that could provide an appropriate vehicle for this purpose and ways to ensure that the notice is conspicuous and readily identified by recipients, particularly in those instances where the coverage is not creditable. Another approach would be to require each entity to issue a separate notice to each Part D eligible enrollee. This type of notice would be most conspicuous and would therefore increase the likelihood that beneficiaries would become aware of the creditable status of their prescription drug coverage. Because beneficiaries are subject to financial penalties for the failure to maintain creditable coverage when they enroll in Part D, a separate notice may better inform beneficiaries and ensure that they take appropriate action to avoid such penalties.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 101-93, requires that certain entities that offer health coverage provide covered individuals with a document, called a "certificate of creditable coverage," that establishes the time period during which the coverage was in effect. Implementing regulations provide a model "Certification of Creditable Coverage." Those regulations require that a certificate be produced and disseminated to individuals when their coverage ends. We have considered requiring that information about the creditable status of prescription drug coverage be included in this certification. However, since the certification required under HIPAA is not required to be provided until after such coverage has ended (or upon request), it would arrive too late to assist beneficiaries in deciding whether to enroll in Part D. However, the HIPAA certification may serve as a useful model and we invite comments about the administrative burden associated with producing and disseminating a similar notice of creditable status to beneficiaries.

The timing and frequency of these notices is also a key consideration. The initial notice of creditable status could be coordinated with the first Annual Coordinated Enrollment Period for Part D, which begins November 15, 2005, to ensure that beneficiaries have this information when making decisions regarding their Part D coverage. Another option would be to coordinate this disclosure with the end of the first Part

D initial enrollment periods and the annual coordinated election period, both of which end May 15, 2006. Beneficiaries would also need to know about any change in the creditable status of existing coverage before such a change becomes effective so that they have sufficient time to decide whether to obtain Part D coverage. If a beneficiary's creditable drug coverage ends or is changed to the extent that it is no longer creditable, the beneficiary has a Special Enrollment Period (SEP) during which the beneficiary can enroll in Part D without financial penalty. Thus, we believe that such notice should be provided, at a minimum, at these two important times, as well as upon the beneficiary's request.

We invite comments on how best to ensure that beneficiaries receive timely and adequate notice of the creditable status of their prescription drug coverage without imposing a significant administrative burden on entities that provide such coverage. We also note that the statute requires entities to disclose the creditable status of this coverage to us, and we invite comments on the possible methods of providing such disclosure. Given the importance of knowing whether coverage constitutes "creditable coverage," we would like to receive feedback regarding whether it would be a significant administrative burden for group health plans and other sponsors to include in disclosures an indication of the value of their drug benefit, the total amount of the annual premium for their drug benefit, and the amount of the annual drug benefit premium that the beneficiary will be required to pay.

Section 1860D-13(b)(6)(C) of the Act provides that an individual who was not adequately informed that his or her prescription drug coverage was not creditable may apply to CMS to have such coverage treated as creditable coverage for purposes of not having the late penalty imposed. We envision establishing a process in which an individual could apply for reconsideration of the late enrollment penalty based upon not being adequately informed. In this process, we would instruct beneficiaries as to the type of information that should be submitted as well as where the beneficiaries should submit the information. The process could also include CMS, or an entity with which CMS may contract, receiving and reviewing information related to the reconsideration, including validating that the entity in which the individual had previously been covered had provided the required disclosure. We appreciate comment on this process.

C. Voluntary Prescription Drug Benefit and Beneficiary Protections

1. Overview and Definitions (§ 423.100)

Subpart C of part 423 implements sections 1860D-2, 1860D-4(a), 1860D-4(b), 1860D-4(i), 1860D-4(k), 1860D-11(a), 1860D-21(a), 1860D-21(c)(3), and 1860D-21(d)(2) of the Social Security Act. This subpart sets forth requirements regarding—

- The benefits offered by PDP sponsors and MA organizations that offer qualified prescription drug coverage.
- The establishment of prescription drug plan service areas.
- Access standards with regard to covered Part D drugs.
- Information dissemination by PDP sponsors and MA Organizations offering qualified prescription drug coverage.
- Disclosure to beneficiaries of pricing information for generic versions of covered Part D drugs.
- Privacy, confidentiality, and accuracy of PDP sponsors' beneficiary records.

Section 423.100 of our proposed rule also includes definitions for terms that are frequently used in this subpart. Generally, we clarify the definitions in § 423.100 in the relevant parts of section II.C of this preamble. However, we believe that additional clarification is needed with regard to the terms "covered Part D drug" and "dispensing fee" in order to provide necessary context for the Part D benefit requirements in this subpart. We are providing that clarification below.

a. Covered Part D Drug

The definition of a covered Part D drug in § 423.100 of our proposed rule closely follows the statutory definition in section 1860D-2(e) of the Act. According to this definition, a covered Part D drug must be available only by prescription, approved by the Food and Drug Administration (FDA), used and sold in the United States, and used for a medically accepted indication (as defined in section 1927(k)(6) of the Act). A covered Part D drug would include prescription drugs, biological products, and insulin as described in specified paragraphs of section 1927(k) of the Act and vaccines licensed under section 351 of the Public Health Service Act. The definition also includes "medical supplies associated with the injection of insulin (as defined in regulations of the Secretary)." We propose to define those medical supplies to include syringes, needles, alcohol swabs, and gauze.

In accordance with section 1860D-2(e)(2) of the Act, the definition of a covered Part D drug would specifically

exclude drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid, with the exception of smoking cessation agents. In accordance with section 1927(d)(2) of the Act, the drugs or classes of drugs that may currently be excluded or otherwise restricted under Medicaid include—(1) Agents when used for anorexia, weight loss, or weight gain; (2) agents when used to promote fertility; (3) agents when used for cosmetic purposes or hair growth; (4) agents when used for the symptomatic relief of cough and colds; (5) prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations; (6) nonprescription drugs; (7) outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale; (8) barbiturates; and (9) benzodiazepines. We are concerned that the aforementioned exclusion of outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer (or its designee) as a condition of sale (item 7 above) may prove too narrow to address inappropriate tying arrangements. We may consider expanding this exclusion and solicit public comments on how to reduce the risk of abusive tying arrangements.

The definition of a covered Part D drug would also exclude any drug for which, as prescribed and dispensed or administered to an individual, payment would be available under Parts A or B of Medicare for that individual (even though a deductible may apply). By including the language "as so prescribed and dispensed or administered," section 1860D-2(e)(B) makes a distinction between what would be paid for under Part D as opposed to Part B. This language indicates that Congress was aware that some covered Part D drugs could qualify for payment under Part B in some circumstances and Part D in other circumstances, depending on the way those drugs were dispensed or administered. Dispensation or administration should be interpreted to include the setting, personnel, and method involved, and not simply the route of administration.

One goal of Part D is to fill any gaps in existing Part B coverage of drugs. Part B has a limited and specific drug benefit covering drugs furnished "incident to" a physician's service (for example, certain injectable drugs that are not usually self-administered and furnished incident to

a physician office visit); drugs furnished as a supply to covered items of durable medical equipment; certain oral drugs (immunosuppressive, and certain oral anti-cancer and anti-emetic drugs); certain immunizations; and several other drugs and biologicals. Part D cannot pay for these drugs because payment is available under Part B.

Section 1860D-2(e)(2)(B) of the Act that specifies that a drug prescribed to a Part D eligible individual that would otherwise qualify as a Part D drug cannot be considered a covered Part D drug if payment for such drug “* * * is available (or would be available but for the application of a deductible) under part A or B for that individual.” We interpret this to mean that if payment could be available under Part A or B to the individual for such drug, then it will not be covered under Part D. This will be the case even if a beneficiary has Part A, but not Part B or vice versa, since, as we explain in section F of this preamble and at § 423.265(c) of the Act, PDP sponsors must offer a uniform benefit package in order to carry out Congress’s intent in section 1860D-13(a)(1)(F) of the Act. If Part B covered drugs were included in the Part D benefit package only for those enrollees without Part B, but not for others, it would not be possible for PDP sponsors to offer uniform benefit packages for a uniform premium to all enrollees. In addition, we believe that payment for a drug under Part A or B is *available* to any individual who *could* sign up for Parts A or B, regardless of whether they actually enrolled. All individuals who are entitled to premium-free Part A are eligible to enroll in Part B. This includes individuals who are entitled to Part A based on age, disability, and ESRD. All individuals who are entitled to Part B only are age 65 or older and, in almost all instances, not eligible for premium-free Part A. However, they are eligible to buy into Part A for a premium. Thus, for all Part D eligible individuals, drugs covered under Parts A and B are available if they choose to pay the appropriate premiums.

We believe that the phrase “for that individual” in 1860D-2(e)(2)(B) of the Act is intended to capture the fact that under local medical review policies (LMRPs), a drug that might be covered under Part B for an individual in one area of the country might not be covered in another area of the country. Thus, what is covered “under Part B for that individual” may be, as discussed earlier, different in different geographic regions. Under this reading, in a region where a drug is covered under Part B, it would be considered “available” to

“that individual” whether he or she had elected to enroll in Part B or not.

The Part D drug coverage described in this proposed rule does not alter the coverage or associated rules for drugs that are currently covered by Medicare prior to the MMA, such as those included in the following list, which offers examples but is not meant to be exhaustive—

1. Drugs furnished incident to a physician’s service that are not usually self-administered by the patient.

2. Drugs used in immunosuppressive therapy furnished to a beneficiary who receives an organ transplant for which Medicare makes payment.

3. Drugs administered to ESRD patients and separately billed by dialysis facilities. These would include erythropoietin (EPO), both when administered in the dialysis facility or furnished to an ESRD patient for self-administration.

4. Drugs taken orally during cancer chemotherapy provided that they have the same active ingredients as chemotherapy drugs and are used for the same indications as chemotherapy drugs which would be covered if they were not self-administered and were administered as incident to a physician’s professional service, and certain oral drugs prescribed for use as an acute antiemetic as part of an anticancer chemotherapeutic regimen if the drug is administered by a physician.

5. Blood clotting factors for hemophilia patients competent to use such factors to control bleeding without medical supervision, and items related to the administration of those factors.

6. Supplies (including drugs) necessary for the effective use of covered durable medical equipment, including those which must be put directly into the equipment and furnished to a beneficiary via the equipment (for example, amphotericin B, an anti-fungal agent, administered with an infusion pump, or inhalation drugs furnished to a beneficiary via a nebulizer).

7. Pneumococcal pneumonia vaccines, hepatitis B vaccines, and influenza virus vaccines.

We intend to ensure that the Part D benefit “wraps around” Part B drug benefits to the greatest extent possible. For example, Part D would cover immunosuppressive drugs furnished to Medicare beneficiaries who did not have their transplant paid for by Medicare (e.g., a beneficiary who had his or her transplant paid for by a private insurer when he or was employed, and the beneficiary has now enrolled in Part B). Part D could pay for these immunosuppressive drugs for

these beneficiaries since Part B is prohibited by statute from paying for them. Therefore, we are soliciting comments concerning any drugs that may require specific guidance with regard to their coverage under Part D, and any gaps that may exist in the combined “Part D & B” coverage package.

b. Dispensing Fees

The Medicare Modernization Act (MMA) does not define the term “dispensing fee,” although the terms “dispensing fee” and “dispense” appear several times throughout the Act. Section 1860D-2(d)(1)(B) states that negotiated prices available under Part D, “shall take into account negotiated price concessions * * * and include any dispensing fees for such drugs.” Sections 1860D-15(b)(3) and (e)(1)(b) of the Act provide that reinsurance and risk corridor payments will be based on allowable costs that include “costs directly related to the dispensing of covered part D drugs during the year.” The costs used in calculating the retiree drug subsidy also include the “costs directly related to the dispensing of covered part D drugs during the year,” as provided in section 1860D-22(a)(3)(C)(ii) of the Act. Section 1860D-2(e)(1)(B) of the Act specifically includes the medical supplies associated with the injection of insulin (as defined in our proposed rule); this is the only reference to supplies associated with drug administration in the Part D drug benefit provisions of the MMA.

Because the statute is ambiguous on the meaning of “dispensing fee,” in this proposed rule we are not proposing a specific definition of “dispensing fee,” but instead are offering three different options we believe would be reasonable, permissible definitions of the term. We invite comments on each of the definitions proposed below.

Option 1: The dispensing fee would include only those activities related to the transfer of possession of the covered Part D drug from the pharmacy to the beneficiary, including charges associated with mixing drugs, delivery, and overhead. The dispensing fee would not include any activities beyond the point of sale (that is, pharmacy follow-up phone calls) or any activities for entities other than the pharmacy.

Option 2: The dispensing fee would differentiate between “dispensing” a covered Part D drug and “administering” one in order to restrict the scope of these fees to include only those charges for pharmacy services related to the preparation and delivery of a covered Part D drug. Under option 1, the dispensing fee could not include

any charges associated with administering the drug once the drug has already been transferred to the beneficiary. Thus, for example, the fee would not include any professional fees (such as skilled nursing services), durable medical equipment (such as an external infusion pump or an IV pole), supplies (such as tubes and dressings), or even follow-up telephone calls from the pharmacy to the patient to check on the patient's progress with the drug.

Option 2: The dispensing fee would include the activities included in Option 1, but in addition would include amounts for the supplies and equipment necessary for the drugs to be provided in a state in which they can be effectively administered.

Option 3: The dispensing fee would include the activities in Option 2, but in addition would include activities associated with ensuring proper ongoing administration of the drugs, such as the professional services of skilled nursing visits and ongoing monitoring by a clinical pharmacist.

Our proposed options 2 or 3 would also frame the definition so that supplies, equipment, and the professional services associated with administering the drug would be limited to cases where: (a) A typical patient with the condition at issue could not receive the benefit of the medication in the absence of the associated supplies, equipment or professional services, and (b) the patient is receiving home infusion therapy.

We believe that option 1 represents the best reading of the statute, since it would limit dispensing fees to a transfer of possession of the drug and would not include any fees associated with administering the drug. In addition, where Congress wished for CMS to include the cost of supplies under Part D, it specifically directed CMS to do so (by requiring that the supplies associated with the injection of insulin be included in the definition of covered Part D drug).

However, we also recognize that options 2 or 3 would eliminate current gaps in coverage relative to home infused drugs. We have limited options 2 and 3 to cases of home infusion because this is the only circumstance we know of where the additional services associated with administering the drug would not already be covered under Medicare Part A or B and would be necessary to ensure effective delivery of the drug. (For example, infusion therapy provided in a hospital outpatient setting or in a physician office could be covered under Part B. Infusion therapy by a hospice could be covered as part of the hospice benefit,

if a patient meets the conditions for hospice care.) However, there may be related issues with respect to the administration of other drugs (for example, vaccines and injectable long-acting antipsychotic drugs), and we solicit comments regarding any implications for our proposed options for defining dispensing fees.

Home infusion therapy equipment, supplies, and services typically are used in order to administer medications to patients using intravenous, subcutaneous, and epidural routes. Drug therapies commonly administered via infusion include antibiotics, chemotherapy, pain management, parenteral nutrition and immune globulin. Generally, home infusion therapy includes coordinating the varied services a patient might need in order to receive infusion in the home. For example, a home infusion company might provide, or facilitate the provision of, skilled nursing services, durable medical equipment (such as an external infusion pump or an IV pole), supplies (such as tubes and dressings), education of the patient, pharmacy services (including mixing the drugs if necessary), and delivery services. A home infusion company might also call the patient periodically to monitor care. Based on our research, home infusion is covered under the medical benefits of most commercial insurers and MA plans as a cost-effective alternative to inpatient care for administering drugs that cannot be self-administered for treatment of acute or chronic medical conditions in patients who are sufficiently ill to be unable to visit an outpatient clinic or physician's office to receive the necessary therapy. Home infusion providers generally bill private insurance plans for these services by billing separately for the drug, and also charging a per diem for other services. The per diem charge represents the average daily expense associated with non-pharmaceutical expenses (including nursing services), such as equipment, supplies, labor, and non-nurse clinical services involved in the compounding, preparation, delivery, administration, and monitoring for a given drug therapy.

While Parts A and B pay for some home infusion therapies (through, for example, the drugs and supplies that are provided incident to the provision of a home infusion pump), in other cases home infusion therapies would not be covered by Medicare Parts A and B (for example, when the drug is administered in the home through an intravenous drip and not a pump). In addition, infusion therapy policies may vary from

region to region based on local DMERC coverage policies.

Options 2 and 3 would therefore allow us to include in the Part D dispensing fee items and services that might be considered essential in order to effectively utilize the drug benefit. However, it would also extend the definition of dispensing fee beyond the mere transfer of possession of the drug. Also, to the extent that professional services are included in the definition of dispensing fees, we are concerned about double billing with regard to some of the skilled nursing costs associated with home infusion. In many cases these skilled nursing costs are separately billable to Part A, Medicaid, or supplemental insurance, and we are concerned about Part D supplanting these other sources of payment. In addition, as discussed in subpart D of this preamble, PDP sponsors and MA organizations offering MA-PD plans will be required to offer quality assurance and medication therapy management programs. These programs could be used for pharmacies to follow up with patients and ensure that patients are properly administering their drugs or adhering to their drug regimens. We are concerned about beneficiaries being charged for quality assurance services as part of the dispensing fee, when such charges might have already been included in the cost of the premium.

Finally, we note that any definition we adopt for purposes of Part D would not carry over to Part B of the Medicare program. Section 1842(o)(2) of the Act gives the Secretary discretionary authority to pay a dispensing fee to a licensed pharmacy that furnishes certain covered Part B drugs and biologicals to Medicare beneficiaries. While the term "dispensing fee" is not defined in section 1842(o)(2) of the Act, the considerations under Medicare Part B, a more comprehensive health insurance product that has separate payment mechanisms for durable medical equipment and professional services, are different from those under Part D. In addition, the Secretary is not required to pay any dispensing fee under section 1842(o)(2) of the Act, while in Part D, the dispensing fee is included in the negotiated price of a drug.

c. Long-Term Care Facility

We request comments regarding our definition of the term long-term care facility in § 423.100, which we have interpreted to mean a skilled nursing facility, as defined in section 1819(a) of the Act, or a nursing facility, as defined in section 1919(a) of the Act. We are

particularly interested in whether intermediate care facilities for the mentally retarded or related conditions (ICF/MRs), described in § 440.150, should explicitly be included in this definition given Medicare's special coverage related to mentally retarded individuals. It is our understanding that there may be individuals residing in these facilities who are dually eligible for Medicaid and Medicare. Given that payment for covered Part D drugs formerly covered by Medicaid will shift to Part D of Medicare, individuals at these facilities will need to be assured access to covered Part D drugs. Our proposed definition limits our definition to skilled nursing and nursing facilities because it is our understanding that only those facilities are bound to Medicare conditions of participation that result in exclusive contracts between long-term care facilities and long-term care pharmacies. However, to the extent that ICF/MRs and other types of facilities exclusively contract with long-term care pharmacies in a manner similar to skilled nursing and nursing facilities, we would consider modifying this definition.

2. Requirements Related to Qualified Prescription Drug Coverage (§ 423.104)

Under section 1860D–11(e)(2)(A) of the Act, we may approve as PDP sponsors or MA organizations offering MA–PD plans only those entities proposing to offer qualified prescription drug coverage in accordance with our requirements. As provided in section 1860D–2(a)(1) of the Act and § 423.104(d) of our proposed rule, qualified prescription drug coverage may consist of either standard prescription drug coverage or alternative prescription drug coverage. Alternative prescription drug coverage may include supplemental benefits, and this coverage is referred to as "enhanced alternative coverage" (these concepts are discussed in detail below).

We would review and approve current and potential PDP sponsors' proposed prescription drug plans and current and potential MA organizations' proposed MA–PD plans consistent with the rules described in section II.F.6 of this preamble. We will further articulate requirements regarding the approval of qualified prescription drug coverage in written policy guidelines and other CMS instructions.

Section 1860D–1(b)(1) of the Act provides that we establish an enrollment process for prescription drug plans that uses rules similar to, with limited exceptions, those governing enrollment in an MA plan under various subsections of 1851 of the Act,

including portions of 1851(g). Section 1851(g)(1) of the Act provides that an MA organization must accept without restrictions individuals who are eligible to elect enrollment in its MA plan. Accordingly, section § 423.104(b) of our proposed rule provides that a PDP sponsor offering qualified prescription drug coverage would be required to offer its plan to all Part D eligible individuals residing in the plan's service area. We note that, unlike a local MA–PD plan, a prescription drug plan is not eligible for a capacity waiver as described in 42 CFR 422.60(b) of our proposed rule.

a. Standard Prescription Drug Coverage

As provided under section 1860D–2(b) of the Act and codified in § 423.104(e) of our proposed rule, "standard prescription drug coverage" would consist of coverage of covered Part D drugs subject to an annual deductible; 25 percent coinsurance (or an actuarially equivalent structure) up to an initial coverage limit; and catastrophic coverage after an individual incurs out-of-pocket expenses above a certain threshold. In 2006, the annual deductible would be \$250, the initial coverage limit would be \$2,250, and the out-of-pocket threshold would be \$3600. Once a Part D enrollee reached the annual out-of-pocket threshold, his or her nominal cost-sharing would be equal to the greater of: (1) 5 percent coinsurance, or (2) a copayment of \$2 for a generic drug or a preferred multiple source drug and \$5 for any other drug, or an actuarially equivalent structure. (See Table C–1 for a summary version of standard prescription drug coverage benefits for 2006.)

A multiple source drug is defined under section 1927(k)(7)(A)(i) of the Act as a drug for which there are two or more drug products that are (1) rated as therapeutically equivalent by the Food and Drug Administration (FDA), (2) are pharmaceutically equivalent and bioequivalent, as defined in section 1927(k)(7)(C) of the Act, and as determined by the FDA, and (3) are sold or marketed in a State during the relevant time period. Section 423.100 of our proposed rule provides definitions for therapeutically equivalent and bioequivalent drugs based on the definitions provided in sections 1927(k)(7)(A) of the Act and section 505(j)(8) of the Food, Drug, and Cosmetic Act, respectively. The term therapeutically equivalent refers to drugs that are rated as therapeutic equivalents under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence

Evaluations." Section 423.4 of our proposed rule defines a generic drug as a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act is approved. To clarify, generic drugs are both bioequivalent and therapeutically equivalent to an innovator drug. Section 423.100 of our proposed rule also clarifies that a preferred drug refers to a covered Part D drug on a prescription drug plan or MA–PD plan's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug on the formulary.

According to section 1860D–2(b)(4)(C) of the Act, and as defined in § 423.100 of the proposed rule, beneficiary costs for covered Part D drugs are only considered incurred (for purposes of applicability toward beneficiary spending against the annual out-of-pocket limit) if they are—

1. Incurred against any annual deductible, any applicable cost-sharing for costs above the annual deductible and up to the initial coverage limit, and any applicable cost-sharing for costs above the initial coverage limit and up to the out-of-pocket threshold;

2. Incurred by the Part D enrollee (or by another person on behalf of that individual); paid on behalf of a low-income individual under the Part D subsidy provisions described in § 423.782 of the proposed rule; or paid on behalf of the enrollee under a State Pharmaceutical Assistance Program (SPAP) described in § 423.454 of the proposed rule; and

3. Incurred with respect to covered Part D drugs that are either included in a prescription drug plan or MA–PD plan's formulary or treated as being included in a plan's formulary as a result of a coverage determination, redetermination, or appeal under §§ 423.566, 423.580, and 423.600 of our proposed rule.

As a point of clarification, we also propose that beneficiary costs incurred under the following circumstances count as incurred costs consistent with the definition of that term in § 423.100 of our proposed rule (with plans explicitly accounting for such price differentials in the actuarial valuation of their coinsurance in their bids):

- Any differential between a network retail pharmacy's negotiated price and a network mail-order pharmacy's negotiated price for an extended (for example, 90-day) supply of a covered Part D drug purchased at a retail pharmacy, as described in section II.C.4.a of this preamble, and
- Any differential between an out-of-network pharmacy's usual and customary price for a covered Part D

drug purchased in accordance with the out-of-network access rules described in section II.C.5 of this preamble and the plan allowance for that covered Part D drug.

Section 1860D-2(b)(4)(C)(ii) of the Act provides that any costs for which a Part D individual is reimbursed by insurance or otherwise, a group health plan, or another third-party payment arrangement do not count toward incurred costs; only costs paid by a Part D enrollee, or on behalf of a Part D enrollee by another person, would count as incurred costs. This provision thus creates a distinction between all enrollee out-of-pocket expenditures and those that are counted toward the out-of-pocket threshold (incurred costs).

In § 423.100 of our proposed rule, we define the terms "person," "insurance or otherwise," "group health plan," and "third-party payment arrangement" in such a way as to strike what we believe to be an appropriate balance between: (1) allowing certain individuals or charitable organizations to provide financial assistance to Part D enrollees that would be counted toward those enrollees' incurred costs, and (2) reducing incentives for current employers, other insurers, and government programs to reduce their current levels of coverage and replace that coverage with Part D wrap-around benefits, thereby requiring Medicare to pay for drug costs that were previously borne by other payers. We propose defining "person" in such a way that other individuals, such as family members, could pay for covered Part D drug cost-sharing on behalf of Part D enrollees. The term "person" is also defined more broadly than a human being based on legal definitions of the term that include corporate entities or organizations. This definition of "person" is consistent with other statutory definitions of the term "person," including 1 U.S.C. 1, which provides that in interpreting an Act of Congress, unless the context indicates otherwise, the term "person" includes corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals.

We believe that *bona fide* charities unaffiliated with employers or insurers could not be excluded from financially assisting Part D enrollees with covered Part D drug expenditures and having those expenditures count toward enrollees' incurred costs. Although allowing such financial contributions to count toward incurred costs could increase Medicare expenditures by allowing more beneficiaries to qualify, and to qualify sooner, for coverage above the out-of-pocket threshold, we

expect that the number of people who are both assisted by charitable organizations and have expenditures high enough to qualify for protection against high out-of-pocket expenditures would be small. Since there will be many Part D eligible beneficiaries with incomes higher than the low-income subsidy eligibility limits described in § 423.782 of our proposed rule, we believe it is a desirable goal to allow appropriate charitable assistance to count toward enrollees' incurred costs. This interpretation is consistent with (1) our interpretation of the term "person" and (2) our interpretation of the terms "insurance or otherwise," "group health plan," and "third-party payment arrangement" (as discussed subsequently in this preamble section). In addition, we note that any arrangements pursuant to which a charitable organization pays a Medicare beneficiary's cost-sharing obligations must comply with the Federal fraud and abuse laws, including the anti-kickback statute, section 1128B(b) of the Act, as well as the civil monetary penalty provision at section 1128A(a)(5) of the Act. We are considering whether assistance in paying enrollees' out-of-pocket cost-sharing obligations provided through prescription drug patient assistance program sponsored by pharmaceutical manufacturers would be allowed under the aforementioned Federal fraud and abuse laws.

We have defined the term "insurance or otherwise" consistent with our policy goal of reducing incentives for current employers, other insurers, and government programs to reduce their current levels of coverage and replace that coverage with Part D wrap-around benefits. The use of the term "insurance or otherwise" in section 1860D-2(b)(4)(C)(ii) of the Act suggests that the Congress understood that programs other than insurance programs would be helping beneficiaries pay for covered Part D drugs.

Section 1860D-24 of the Act, which extends the coordination of benefits provisions required for SPAPs to other types of plans—including Medicaid programs, Section 1115 waiver demonstrations, group health plans, FEHBP, military coverage (including TRICARE), and "such other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of Part D eligible individuals as the Secretary may specify"—appears to support our proposed definition of "insurance or otherwise," in § 423.100 of our proposed rule, as a plan (other than a group health plan) or program that

provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the Public Health Service Act). We note that our definition of "insurance or otherwise" does not modify the definition of "health plan" at 45 CFR 160.103 of the HIPAA Administrative Simplification Regulations, or any interpretation thereof issued by the Department of Health and Human Services.

Therefore, "insurance or otherwise" would include the following programs and entities:

- Government programs and entities (for example, Department of Veterans Affairs (VA), Department of Labor Federal Workers' Compensation Program, and Federally Qualified Health Centers (FQHCs);
- Government insurers (for example, Medicaid 1115 demonstrations and the State Children's Health Insurance Program (SCHIP); and
- Government-sponsored funds (for example, black lung benefits, Ryan White CARE Act funds, and State special funds that assist certain individuals with their medical costs, such as a special fund for AIDS patients).

Because costs for covered Part D drugs paid by insurance or otherwise on behalf of a Part D enrollee do not, as previously discussed, count as incurred costs, any Part D wrap-around coverage provided to beneficiaries by these entities would not count toward incurred costs. Wrap-around coverage provided to Part D enrollees by group health plans and other third-party payment arrangements would also not count as incurred costs. We have defined the term "group health plan" to have the same meaning as in 42 CFR 411.101. In addition, we have defined the term "third party payment arrangements" to mean any contractual or similar arrangement under which a person has a legal obligation to pay for covered Part D drugs.

We request comments regarding the treatment of health savings account (HSAs) vis-à-vis our definition of "group health plan," "insurance or otherwise," and "third party payment arrangements." Our strong preference is not to treat HSAs as group health plans, insurance or otherwise, or third party payment arrangements and therefore to allow HSA contributions to count toward incurred costs, since we see these funds as essentially analogous to a beneficiary's bank account. We also seek comments on how to treat FSAs, health reimbursement accounts (HRAs), and Medicare savings accounts (MSAs), relative to our definitions of group

health plan, insurance or otherwise, and third party payment arrangements.

In proposing this policy, an assessment was made of the need for coordination of the Part D benefit with the Department of Health and Human Services' programs, including the Indian Health Service (IHS) and AIDS drug assistance programs. The IHS is the agency that fulfills the Secretary's unique relationship to provide health services to American Indians and Alaska Natives (AI/ANs) based on the government-to-government relationship between the United States and tribes. The Department has a long history of recognizing AI/AN beneficiaries' dual eligibility for services both from the IHS and from other Department programs. We expect many AI/AN beneficiaries will qualify for full and partial low-income subsidies under Part D. For those not receiving a full or partial subsidy, the IHS may wish to pay for premiums to eliminate any barriers to Part D benefits.

For AI/ANs not eligible for the low-income subsidies and enrolled in a prescription drug plan or MA-PD plan, the costs of covered Part D drugs obtained at an I/T/U pharmacy or a non-IHS retail pharmacy (through an appropriate IHS contract health services referral) will be applied to meet the beneficiary's deductible under qualified prescription drug coverage. These payments will not count as incurred costs towards meeting the out-of-pocket threshold, however. This will ensure that an IHS beneficiary receives a benefit for IHS expenditures between the deductible and the out-of-pocket limit. Once the deductible is met, the IHS will benefit from Part D coverage because the I/T/U pharmacy will be reimbursed for 75 percent of spending (on average) between the deductible and the initial coverage limit. We seek comments on how I/T/U pharmacies and IHS beneficiaries will achieve maximized participation in Part D benefits.

We also assessed the role of the Ryan White CARE Act, and in particular the AIDS Drug Assistance Program (ADAP), which addresses the pharmaceutical needs of the neediest HIV/AIDS population. The implementation of Part D will enable approximately one-half of the ADAP enrollees who are potentially eligible for Part D to qualify for full Medicare low-income subsidies, and an additional 30 percent may qualify for partial low-income subsidies. In addition, for those not receiving a full or partial subsidy, the Part D benefit would pay—depending on the cost-sharing structure employed by the particular prescription drug plan or

MA-PD plan—75 percent, on average, of an enrollee's covered Part D drug expenditures between the deductible and initial coverage limit. Although ADAP may realize savings with the implementation of Part D, these may be offset by the increased costs of picking up expenses no longer covered by Medicaid for the dual eligible population.

To ensure coordination of benefits for the HIV/AIDS population, the ADAP program may wish to pay for this population's premiums to eliminate any barriers to Part D benefits. ADAP may also subsidize costs incurred toward a Part D plan's deductible or cost-sharing for those patients unable to afford these costs. It should be noted, however, that when ADAP does subsidize these costs, they would not count as incurred costs and thus may make it less likely that an eligible person would incur costs above the annual out-of-pocket threshold and thus qualify for catastrophic cost-sharing.

ADAPs and other Ryan White "titled" programs are eligible to participate in what is known as the 340B Drug Pricing program and are encouraged to do so. Under Section 340B of the Public Health Service Act, discounted outpatient drugs are available to certain Federally-funded grantees, such as Federally qualified health centers (FQHCs), AIDS drug assistance programs, and certain disproportionate (DSH) hospitals. Upon successful registration, these covered entities are eligible to purchase outpatient prescription medications from drug wholesalers and pharmaceutical manufacturers at significantly reduced prices. All but three ADAPs, which have State-based programs, participate in 340B. About one-half of these States purchase their drugs directly and receive an upfront discount. The other half operate under the rebate model and receive a rebate from manufacturers. Studies have indicated that the States receiving an upfront discount benefit more fully from the 340B program than those States receiving a rebate. States are encouraged to move toward the model of purchasing their drugs directly, as they can realize more savings than States using the rebate model.

We welcome comments on how to maximize the savings for people in need of HIV/AIDS medications under the 340B program. In particular, is it feasible for ADAP programs to participate with prescription drug plans so that the drugs offered to individuals with HIV/AIDS can be offered at 340B prices? In addition, because it is of critical importance for Medicare beneficiaries with HIV/AIDS to comply

with their drug regimens, we are soliciting comments regarding the coordination of ADAP and Medicare Part D benefits.

We note that nothing precludes an insurer, group health plan, or other third party arrangement from paying for a Part D enrollee's deductible costs; while these payments will not count as incurred costs vis-à-vis the out-of-pocket threshold, they will not prevent a Part D enrollee from receiving a benefit for expenditures between the deductible and the out-of-pocket limit. In addition, these entities are not precluded from paying for a Part D enrollee's cost-sharing above the out-of-pocket threshold once a beneficiary has accumulated incurred costs in excess of the out-of-pocket threshold. Please refer to section II.J of this preamble for a detailed discussion regarding the collection of information regarding third-party reimbursement for covered Part D drugs for the purpose of determining enrollees' incurred costs.

Section 1860D-2(b) of the Act provides that, beginning in 2007, the annual deductible, initial coverage limit, out-of-pocket threshold, and beneficiary cost-sharing after the out-of-pocket threshold is met are to be adjusted annually. In accordance with section 1860D-2(b)(6) of the Act and as provided in § 423.104(e)(5)(iv) of our proposed rule, these amounts would be increased over the previous year's amounts by the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs for the 12-month period ending in July of the previous year. The amounts for the annual deductible, initial coverage limit, out-of-pocket threshold, and catastrophic cost-sharing amounts would be rounded to the nearest \$5, \$10, \$50, and \$0.05, respectively, as required by sections 1860D-2(b)(1)(B), (b)(3)(B), (b)(4)(B)(ii), and (b)(4)(A)(ii) of the Act, and codified in §§ 423.104(e)(1)(ii), (e)(3)(ii), (e)(5)(iii)(B), and (e)(5)(i)(A)(2) of our proposed rule.

We anticipate that in the first several years after the implementation of Part D, determining the annual percentage increase will be difficult and will require the use of alternative sources of data. We request comments regarding possible alternative data sources we could use to determine the annual percentage increase in the first several years of the Part D program. We will provide further detail regarding the methods and data sources we would use to determine this annual percentage increase in operational guidance to PDP sponsors and MA organizations offering

MA-PD plans prior to the deadline for bid submissions.

TABLE C-1.—STANDARD PRESCRIPTION DRUG COVERAGE BENEFITS FOR 2006

	Cost-sharing percentage	Beneficiary out-of-pocket costs	Plan payment percentage	Plan payment
Annual Deductible (\$0–\$250 in spending on covered Part D drugs covered under the plan).	100	\$250	0	\$0
Initial Benefit (\$251–\$2,250 in spending on covered Part D drugs covered under the plan).	25 ¹	500 ²	75 ¹	1,500
No coverage of costs (\$2,251–\$5,100 ³ in spending on covered Part D drugs covered under the plan).	100	2,850	0	0
Catastrophic Coverage (after the enrollee has incurred out-of-pocket costs on covered Part D drugs covered by the plan greater than \$3,600; this is generally equivalent to \$5,100 ³ in covered spending).	The greater of: (1) 5; or (2) \$2 for a generic or preferred multiple source drug/\$5 for other drugs ¹	95

¹ Entities have the option of substituting a cost-sharing structure that is actuarially equivalent.

² \$500 is the maximum out-of-pocket costs if coverage is based on 25 percent coinsurance. Under an actuarially equivalent cost-sharing structure, the maximum out-of-pocket costs and the maximum plan payment for any Part D enrollee could be higher or lower.

³ This figure may, in fact, be higher to the extent that a Part D enrollee is reimbursed for out-of-pocket costs for covered Part D drugs covered under his/her plan by a group health plan, insurance or otherwise, or other third party arrangement.

We have interpreted the provisions of section 1860D–2(b) of the Act to provide for two distinct types of standard prescription drug coverage—“defined standard coverage” and “actuarially equivalent standard coverage.” Defined standard coverage basically constitutes standard prescription drug coverage as defined in the statute—with 25 percent coinsurance for costs above the deductible but below the initial coverage limit and cost-sharing for costs above the annual out-of-pocket limit equal to the greater of: (1) A copayment (for 2006, and adjusted annually as specified earlier in this preamble) of \$2 for a generic or preferred multi-source covered Part D drug, or \$5 for other drugs; or (2) 5 percent coinsurance. Actuarially equivalent standard coverage is used to describe standard coverage with actuarially equivalent alternatives to these cost-sharing requirements and consistent with section 1860D–2(b) of the Act.

Section 1860D–2(b)(2)(A)(ii) of the Act provides that PDP sponsors and MA organizations offering actuarially equivalent standard prescription drug coverage would be permitted to substitute cost-sharing requirements (including tiered structures tied to plan formularies or particular pharmacies in a plan’s network) for costs above the annual deductible and up to the initial coverage limit, provided that those alternative cost-sharing requirements were actuarially equivalent to an average expected coinsurance of 25 percent for costs above the annual deductible and up to the initial coverage

limit. Alternative cost-sharing arrangements under actuarially equivalent standard coverage could include reducing cost-sharing to \$0 for generic or preferred covered Part D drugs, as provided under section 1860D–2(b)(5) of the Act, as long as the cost-sharing structure is actuarially equivalent to an average expected coinsurance of 25 percent for costs above the annual deductible and up to the initial coverage limit. Plans with cost-sharing arrangements that are actuarially more generous than standard prescription drug coverage would be considered enhanced alternative coverage, as defined in section II.C.2.b.ii of this preamble. (Section II.F.2 of this preamble explains the methodology for determining actuarial equivalence).

Based on our interpretation of section 1860D–2(b)(5) of the Act, we also propose allowing plans offering actuarially equivalent standard coverage to establish cost-sharing of an amount that is actuarially equivalent to the expected cost-sharing under § 423.104(e)(5)(i) (taking into account both 5 percent coinsurance and \$2/\$5 copayments for costs above the out-of-pocket threshold required under defined standard coverage). As previously discussed, section 1860D–2(b)(5) of the Act indicates that plans cannot be prevented from reducing to \$0 the cost sharing applicable to preferred or generic drugs. While this provision only references reductions based on the need to retain a standard benefit, we propose requiring that any alternative cost-sharing structure for costs in the

catastrophic range (whether under actuarially equivalent standard coverage or enhanced alternative coverage) be actuarially equivalent to standard prescription drug coverage’s structure of 5 percent coinsurance or \$2/\$5 copayments. Our proposed requirement would function in the same manner as the requirement for actuarial equivalence to alternatives to the 25 percent coinsurance structure for costs above the deductible and below the initial coverage limit, as discussed in further detail in section II.F.4.b of this preamble. Any such alternative cost-sharing arrangements would be reviewed, along with the rest of a plan’s benefit design, to ensure that they do not discriminate against certain Part D eligible individuals.

b. Alternative Prescription Drug Coverage

Section 1860D–2(c) of the Act and § 423.104(f) provide that a PDP sponsor offering a prescription drug plan or an MA organization offering an MA-PD plan may offer an alternative prescription drug benefit design, provided that the PDP sponsor or MA organization applies for and receives our approval for the proposed alternative. In order to receive approval to offer an alternative prescription drug benefit design, a PDP sponsor offering a prescription drug plan or an MA organization offering an MA-PD plan would have to meet the requirements related to actuarial equivalence described in section 1860D–2(c)(1) of the Act and discussed in further detail

below (as well as in section II.F.3 of this preamble). It is important to note that, in modifying the standard coverage design to offer alternative prescription drug coverage per the following requirements, plans would have to use defined standard coverage (and not actuarially equivalent standard coverage) as a fixed point of comparison. Because numerous variants of actuarially equivalent standard coverage are possible, it would not be feasible to use actuarially equivalent standard coverage as a point of comparison for alternative prescription drug coverage.

As provided under section 1860D-2(c)(2) of the Act and codified in § 423.104(f)(1) of our proposed rule, any alternative prescription drug benefit design would be required to include a deductible that was no greater than the deductible offered under standard prescription drug coverage. Section 1860D-2(c)(3) of the Act requires that alternative coverage provide the coverage required under section 1860D-2(b)(4), which specifies the requirements for coverage to protect beneficiaries against high out-of-pocket expenditures. As provided in § 423.104(f)(2) of our proposed rule, we are interpreting this requirement to mean that prescription drug plans and MA-PD plans must provide coverage above the out-of-pocket threshold that is at least as generous as that provided under defined standard coverage. In other words, plans could—at their option—reduce cost-sharing below that included under defined standard coverage (the greater of 5 percent coinsurance or \$2/\$5 copayments).

In addition, section 1860D-2(c)(1)(B) of the Act and § 423.104(f)(3) of our proposed rule would require that the actuarial value of alternative prescription drug coverage's unsubsidized coverage is at least equal to the actuarial value of unsubsidized defined standard coverage. Section 1860D-2(c)(1)(C) of the Act and § 423.104(f)(4) of our proposed rule would require that, under alternative prescription drug coverage, the plan payout at the dollar value of the initial coverage limit under standard coverage, for an individual whose total spending exceeds that limit, is at least equal to that provided under defined standard coverage.

i. Basic Alternative Coverage

Beyond the required parameters for alternative coverage discussed above, we are interpreting the provisions of section 1860D-2(c) of the Act, together with section 1860D-2(a)(1) of the Act, as providing for two forms of alternative

coverage—either “basic alternative coverage” or “enhanced alternative coverage.” Basic alternative coverage would refer to alternative coverage that is actuarially equivalent to defined standard prescription drug coverage, as described in section II.C.2.a of this preamble. Enhanced alternative coverage would refer to alternative coverage that exceeds defined standard coverage by offering supplemental benefits and is discussed in section II.C.2.b.ii of this preamble.

Within the parameters for alternative prescription drug coverage described above, a PDP sponsor offering a prescription drug plan or an MA organization offering an MA-PD plan with a basic alternative prescription drug benefit design could theoretically—by combining features such as a reduction in the deductible, changes in cost-sharing (for example, benefit designs that use tiered copayments or coinsurance in an actuarially equivalent manner to the 25 percent cost-sharing above the deductible and below the initial coverage limit under defined standard coverage), and a modification of the initial coverage limit—still be able to maintain an actuarial value of coverage equal to defined standard prescription drug coverage.

Although basic alternative prescription drug coverage within the parameters described above is allowed, it is unclear because of utilization effects whether PDP sponsors and MA organizations could, in fact, offer coverage that meets the statutory requirements other than by modifying cost-sharing as already allowed under actuarially equivalent standard coverage. We invite comments on whether there are basic alternative benefit designs that go beyond actuarially equivalent standard coverage.

ii. Enhanced Alternative Coverage

Section 423.104(g) of our proposed rule would permit PDP sponsors and MA organizations offering an MA-PD plan to provide qualified prescription drug coverage that includes supplemental benefits. Because the actuarial value of any prescription drug coverage benefit package that includes supplemental benefits would exceed that of standard coverage, such coverage must always be alternative drug coverage as described in section II.C.2.b of this preamble. Thus, we refer to any Part D benefit package that includes supplemental benefits as “enhanced alternative coverage.”

Enhanced alternative coverage would include basic prescription drug coverage

and supplemental benefits. The requirements for the supplemental benefits that may be included in enhanced alternative coverage are found in section 1860D-2(a)(2) of the Act and § 423.104(g)(1)(ii) of our proposed rule. These supplemental benefits would supplement basic prescription drug coverage, providing for a package of benefits that exceeds the actuarial value of defined standard coverage.

Supplemental benefits could consist of:

- Reductions in cost-sharing (for example, a reduction in the deductible, a reduction in the coinsurance percentage or copayments applicable to covered Part D drugs obtained between the annual deductible and the initial coverage limit, or an increase in the initial coverage limit described in § 423.104(e)(2), provided these reductions in cost-sharing increase the actuarial value of the benefits provided above the actuarial value of basic prescription drug coverage); and/or
- Coverage of drugs that are specifically excluded as covered Part D drugs under section 1860D-2(e)(2)(A) of the Act and § 423.100 of our proposed rule.

We propose interpreting “value” to mean the total value as described in section 1860D-2(c)(1)(A) of the Act. We request comments on this interpretation.

Under section 1860D-2(a)(2)(B) of the Act, and proposed in § 423.104(g)(2), a PDP sponsor would not be permitted to offer a prescription drug plan that provided enhanced alternative coverage in a particular service area unless it also offered a plan that provided only basic prescription drug coverage in that same area. Section 1860D-2(a)(3) of the Act defines basic prescription drug coverage as either—

(a) Standard prescription drug coverage (as described in proposed § 423.104(e) and in section II.C.2.a of this preamble) with access to negotiated prices; or

(b) Basic alternative drug coverage (as described in § 423.100 and section II.C.2.b.i of this preamble) with access to negotiated prices.

Similarly, as provided under section 1860D-21(a)(1)(A) and codified in § 423.104(g)(3)(i) of our proposed rule, beginning on January 1, 2006, an MA organization could not offer an MA coordinated care plan, as defined in 42 CFR 422.4 of our proposed rule and section 1851(a)(2)(A) of the Act, in a service area unless that plan, or another MA plan offered by the same organization in the same service area, includes required prescription drug coverage. As defined in § 423.100, required prescription drug coverage, for the purposes of an MA organization

offering an MA–PD plan, would include either: (1) Basic prescription drug coverage, or (2) enhanced alternative coverage, provided there is no MA monthly supplemental beneficiary premium applied under the plan. Such enhanced alternative coverage could be provided without a monthly supplemental beneficiary premium only if a plan applied a credit against the otherwise applicable premium of rebate dollars available under section 1854(b)(1)(C) of the Act. Rebate dollars represent the dollars available for supplemental (and other) benefits when an MA plan's risk-adjusted non-drug bid is under the risk-adjusted non-drug monthly benchmark amount. In other words, to the extent that an MA–PD plan chose to provide enhanced alternative coverage for no additional premium through the application of rebate dollars, such enhanced alternative coverage would constitute required coverage for the purposes of meeting the requirement in section 1860D–21(a)(1)(A) of the Act.

This provision is similar in intent to the restrictions on the offering of enhanced alternative coverage by PDP sponsors found in § 423.104(g)(2) of our proposed rule. As previously mentioned, PDP sponsors are required to offer at least one plan offering basic prescription drug coverage in all areas they serve in order to offer any plan that enhances or supplements that basic coverage. The objective of both of these requirements is to assure that PDP sponsors and MA PD organizations offer at least one option for Part D coverage for a premium at the cost of basic prescription drug coverage.

As a note of clarification, provided a PDP sponsor offers at least one plan in a service area that provides basic prescription drug coverage only, it can offer as many plans that offer enhanced alternative coverage as it wishes. Similarly, an MA organization that offers at least one MA–PD plan that meets the aforementioned test of providing required prescription drug coverage is free to offer plans that provide other types of enhanced alternative coverage for which they can charge a monthly supplemental beneficiary premium, as well as plans that offer no qualified prescription drug coverage.

As provided under section 1860D–21(a)(1)(B)(i) of the Act and codified in our proposed rule at § 423.104(g)(3)(ii)(A), an MA organization could not offer prescription drug coverage (other than that required under Parts A and B of Medicare) to enrollees of an MSA plan. Under section 1860D–21(a)(1)(B)(ii) and

§ 423.104(g)(3)(ii)(B) of our proposed rule, an MA organization also could not offer prescription drug coverage (other than that required under Parts A and B of Medicare) under another type of MA plan—including a private fee-for-service plan—unless the drug coverage it provided under that MA plan consisted of qualified prescription drug coverage and met our requirements regarding required prescription drug coverage as articulated previously in this preamble section.

c. Negotiated Prices

Section 1860D–2(d)(1) of the Act requires, as implemented under § 423.104(h) of our proposed rule, that a PDP sponsor or MA organization offering an MA–PD plan provide beneficiaries with access to negotiated prices for covered Part D drugs. As required by section 1860D–2(d)(1)(B) of the Act, negotiated prices would have to take into account negotiated price concessions for covered Part D drugs such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, and would include any applicable dispensing fees. Access to negotiated prices would have to be provided even when no benefits would otherwise be payable on behalf of an enrollee due to the application of a deductible, the initial coverage limit, or other cost-sharing. We are interpreting the reference to the lack of payable benefits due to the application of the initial coverage limit as referring to that portion of covered Part D drug expenditures between the initial coverage limit and the out-of-pocket threshold. In that expenditure range, a beneficiary enrolled in standard prescription drug coverage would be responsible for 100 percent cost-sharing, and the plan would pay no benefits. We are also interpreting the phrase "or other cost-sharing" as a reference to plan designs that may include, as a part of their formulary design, access to negotiated prices on certain drugs but at a tier within their formulary in which the plan would pay no benefits and the beneficiary would be responsible for 100 percent cost-sharing (in other words, a negotiated price would be available and the drug would be on the plan's formulary, but the beneficiary would be responsible for 100 percent of that drug's negotiated price).

As required under section 1860D–2(d)(1)(C) of the Act, prices negotiated with manufacturers for: (1) Covered Part D drugs by either a prescription drug plan or an MA–PD plan; or (2) a qualified retiree prescription drug plan, as described in § 423.882 of our proposed regulation on the Medicare

retiree drug subsidy program, with respect to covered Part D drugs provided on behalf of part D eligible individuals would not be taken into account in making "best price" determinations under the Medicaid program. Under current Medicaid best price policy, the largest discount a pharmaceutical manufacturer negotiates in the private market must be passed along to the Medicaid program; however, prices negotiated with manufacturers for covered Part D drugs would not be factored into these calculations as provided under § 423.104(h)(2) of our proposed rule.

Section 423.104(h)(3) would require, as stated in the provisions of section 1860D–2(d)(2) of the Act, that PDP sponsors offering a prescription drug plan and MA organizations offering an MA–PD plan disclose to us all aggregate negotiated price concessions—including discounts, direct or indirect subsidies, and direct or indirect remunerations—they obtain from each pharmaceutical manufacturer that are passed through to the Medicare program in the form of lower subsidies or to beneficiaries in the form of: (1) Lower monthly beneficiary premiums, and/or (2) lower covered Part D drug prices at the point of sale. We note that plans may fulfill this requirement through the data submission requirements articulated in proposed § 423.336(c)(1) and § 423.343(c)(1) and discussed in further detail in section II.G.4 of this preamble. In other words, we should be able to determine the proportion of total aggregate price concessions that are passed through to either the Medicare program or to beneficiaries based on the cost data plans would be required to submit to CMS.

As provided under section 1860D–2(d)(2) of the Act and § 423.104(h)(3)(ii) of our proposed rule, information on negotiated prices reported to CMS for the purposes of ascertaining the level of pass-through would be protected under the confidentiality provisions applicable to Medicaid pricing data under section 1927(b)(3)(D) of the Act. We note, however, that these confidentiality protections would not preclude audit and evaluation of negotiated price concession information by the HHS Office of the Inspector General (OIG) and, in fact, that such audits and evaluations may be necessary for carrying out the requirements of section 1860D–4(d)(1) of the Act.

We would specify in operational guidance the format and frequency of these reports. As discussed in section II.G.4 of this preamble, we are proposing to require plans to ensure that price concessions are accounted for separately

from any fair market value administrative fees pharmaceutical manufacturers may pay PDP sponsors or MA organizations. For a more detailed discussion of data submission requirements, please refer to section II.G.4 of this preamble.

As provided under section 1860D–2(d)(3) of the Act and codified in § 423.104(h)(4) of our proposed rule, we would be authorized to conduct periodic audits—either directly or through contracts with other organizations—of the financial statements and records of PDP sponsors and MA organizations pertaining to the prescription drug plans and MA–PD plans they offer. As required in section 1860D–2(d)(3) of the Act, this auditing would be performed with the ultimate goal of protecting the Medicare program against fraud and abuse, as well as ensuring proper disclosures and accounting under Part D. Section 423.504(d) of our proposed rule includes additional requirements with respect to auditing of PDP sponsors as a safeguard against fraud and abuse. These fraud and abuse protections incorporate those protections applicable to MA organizations under section 1857(d)(2)(B) of the Act and are discussed in detail in section II.K.6.a of this preamble.

3. Establishment of Prescription Drug Plan Service Areas (§ 423.112)

Section 1860D–11(a)(1) of the Act requires that a prescription drug plan's service area encompass an entire PDP region, as established by us under § 423.112(b), and § 423.112(a) of our proposed rule codifies that requirement. However, as provided under § 423.112(e) of our proposed rule, a prescription drug plan can be offered in more than one PDP region (provided the plan encompasses the entire PDP region for each region where offered), as well as nationally.

Section 1860D–11(a)(2) of the Act provides us with the authority to establish PDP regions, and such PDP regions must be established in a manner that is consistent with the establishment of MA regions under 42 CFR 422.445 of our proposed rule. Section 1860D–11(a)(2)(B) stipulates that PDP regions must be, to the extent practicable, consistent with MA regions as established under section 1858(a)(2) of the Act. As provided under § 423.112(b)(2), however, if we determine that access to Part D benefits would be improved by establishing PDP regions that are different than MA regions, we may establish PDP regions that vary from MA regions. Section 423.112(d) of our proposed rule would

allow us to revise the PDP regions we establish as necessary.

In accordance with section 1860D–14(a)(3)(F) of the Act, residents of United States territories are not eligible for the Part D subsidies otherwise provided to low-income individuals. Such territorial residents, however, would be eligible for financial assistance for prescription drug expenses under section 1935(e) of the Act. Note that a new section 1935 of the Act was added by section 103 of the Medicare Modernization Act (MMA) through a redesignation of the current section 1935 as section 1936. The U.S. territories, unlike the 50 United States and the District of Columbia, may continue to receive federal Medicaid grants under section 1108 of the Act to compensate them for drug coverage provided to Part D eligible individuals under specific conditions. For this reason, section 1860D–11(a)(2)(C) of the Act and § 423.112(c) of our proposed rule stipulate that CMS designate a separate PDP region (or regions) for the U.S. territories.

We intend to initially designate both PDP and MA regions by January 1, 2005. In accordance with section 1858(a)(2)(C)(i) of the Act, there will be between 10 and 50 PDP regions within the 50 States and the District of Columbia and at least one PDP region covering the United States territories. The PDP regions, like the MA regions, will become operational in January 2006.

We conducted a public meeting on July 21, 2004, in order to obtain broad public comment on the methodology we should use in establishing both the PDP regions and MA regions for MA regional plans, which would operate as preferred provider organizations (PPOs). The information on that meeting is available at <https://www.cms.hhs.gov/medicarereform/mmaregions>. Using the feedback from that meeting and other research, we are considering a number of issues, including: how we should design PDP regions in order to ensure that all beneficiaries have access to prescription drug plans; how best to ensure access to prescription drug plans through the design of PDP regions that are the same as (or, if necessary, different than) MA regions; how to design a PDP region (or regions) in the U.S. territories; and how we can best discuss with the public the development of both the PDP and MA regions. Separate guidance on the designation of regions will be forthcoming.

Whereas § 423.112 provides that a prescription drug plan's service area must encompass one or more PDP

regions, an MA–PD plan's service area would consist of either: (1) one or more MA regions (for a regional MA plan), or (2) one or more MA local areas (for a local MA plan). “MA region” is defined in 42 CFR 422.455(b) of our proposed rule as a region within the 50 States and the District of Columbia as established by CMS. As provided in § 423.112(b)(2) of our proposed rule, we will attempt to establish PDP regions that coincide with MA regions to the extent practicable. “Local MA area” is defined in 42 CFR 422.252 of our proposed rule as a payment area consisting of county or equivalent area that we specify.

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

a. Pharmacy Access Standards

As required by section 1860D–4(b)(1)(C) of the Act, prescription drug plans and MA–PD plans would be required to secure the participation in their pharmacy networks of a sufficient number of pharmacies that dispense drugs directly to patients (other than by mail order) to ensure convenient access to covered Part D drugs by plan enrollees. To achieve that goal, we are authorized to establish access rules that are no less favorable to enrollees than rules for convenient access established in the statement of work solicitation (#MDA906–03–R–0002) by the Department of Defense (DoD) on March 13, 2003, for purposes of the TRICARE Retail Pharmacy program. Consistent with the TRICARE standards, § 423.120(a)(1) of our proposed rule would require that prescription drug plans and MA–PD plans establish pharmacy networks in which:

- In urban areas, at least 90 percent of Medicare beneficiaries in the plan's service area, on average, live within 2 miles of a retail pharmacy participating in the prescription drug plan's or MA–PD plan's network;
- In suburban areas, at least 90 percent of Medicare beneficiaries in the plan's service areas, on average, live within 5 miles of a retail pharmacy participating in the prescription drug plan's or MA–PD plan's network; and
- In rural areas, at least 70 percent of Medicare beneficiaries in the plan's service area, on average, live within 15 miles of a retail pharmacy participating in the prescription drug plan's or MA–PD plan's network.

For the purposes of meeting these access standards, as also provided in DoD's statement of work of solicitation #MDA906–03–R–0002—

- Urban would be defined as a five-digit ZIP Code in which the population

density is greater than 3,000 persons per square mile;

- Suburban would be defined as a five-digit ZIP Code in which the population density is between 1,000 and 3,000 persons per square mile; and
- Rural would be defined as a five-digit ZIP Code in which the population density is less than 1,000 persons per square mile.

We are interpreting the access standard under § 423.120(a)(1) such that a prescription drug plan or regional MA–PD plan would have to meet or exceed the access standards across each region in which it operates, and a local MA–PD plan would have to meet or exceed the access standards in its local service area. In other words, a prescription drug plan or regional MA–PD that operates in a multi-region or national service area could not meet the access standards proposed in § 423.120(a)(1) by applying them across the entire geographic area serviced by the plan; instead, it would have to meet the standards in each region of its multi-region or national service area. We believe that such an interpretation maximizes plan flexibility while assuring the best possible access to pharmacies for Part D enrollees, and we request comments on our proposed approach.

While prescription drug plans and MA–PD plans would not be precluded from including non-retail pharmacies (for example, institution-based pharmacies) in their networks under our proposed rule, we interpret the access requirements in section 1860D–4(b)(1)(C) of the Act as requiring prescription drug plans and MA–PD plans to count only retail pharmacies as part of their networks for the purpose of meeting the access standard in § 423.120(a)(1). We would consider a retail pharmacy to be any licensed pharmacy from which covered Part D enrollees could purchase a covered Part D drug without being required to receive medical services related to that particular covered Part D drug from a provider or institution affiliated with that pharmacy. In other words, prescription drug plans and MA–PD plans could—and would be encouraged to—include non-retail pharmacies (for example, hospital and clinic pharmacies) in their networks; however, given the limited populations served by such non-retail pharmacies, plans could not count these pharmacies toward our pharmacy access requirements.

We recognize, however, that prescription drug plans and MA–PD plans operating in rural areas with high concentrations of American Indian/Alaska Native (AI/AN) individuals may

have a difficult time meeting our access standards if they cannot count pharmacies that are operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (hereinafter referred to as “I/T/U pharmacies”) toward their pharmacy access requirements. We are considering allowing prescription drug plans and MA–PD plans to count I/T/U pharmacies toward their network access requirements, provided: (1) Such pharmacies are under contract with the plan; and (2) it would be impossible or impracticable for the plan to meet the access standard in rural areas of its service area without the inclusion of an I/T/U pharmacy (or pharmacies) in that count because there is not a sufficient number of non-I/T/U pharmacies in those areas willing or able to contract with the PDP sponsor or MA organization in accordance with its terms and conditions. We invite comments on this proposed exception to our pharmacy access rules, including any impact it might have on pharmacy access for non-AI/AN Part D enrollees residing in those areas.

Section 423.120(a)(1) of our proposed rule would not in any way preclude PDP sponsors or MA organizations offering an MA–PD plan from contracting with pharmacies outside their plans’ service areas, provided that the plans meet the pharmacy access requirements within their service areas. Such a feature would be of particular benefit to beneficiaries who spend significant amounts of time outside their prescription drug plan’s or MA–PD plan’s service area (for example, “snowbirds”) and could make a particular prescription drug plan or MA–PD plan more attractive to them. In addition, the fact that beneficiaries would have access to network pharmacies outside their plan’s service area would obviate the need for out-of-network access (discussed in greater detail in section II.C.5 of this preamble) to covered Part D drugs in many cases. Thus, contracting with pharmacies outside a plan’s service area could ultimately represent a cost-savings both to plans and beneficiaries, particularly if a plan enrolls a high proportion of beneficiaries who regularly travel outside the plan’s service area.

Section 1860D–4(b)(1)(C)(iv) of the Act provides that, in establishing rules for convenient access to network pharmacies, we may include standards with respect to access to long-term care pharmacies for Part D enrollees who reside in skilled nursing facilities and nursing facilities (hereinafter referred to as “long-term care facilities”), as well as for American Indian/Alaska Native (AI/

AN) Part D enrollees who obtain their prescription drugs at I/T/U pharmacies. We recognize that given their specialized missions and the narrowly defined subsets of beneficiaries they serve, access to long-term care and I/T/U pharmacies should be preserved. Such access would greatly enhance Part D benefits for enrollees in long-term care facilities, as well as for AI/AN enrollees.

As discussed in section II.C.5 of this preamble, we expect that the out-of-network access requirement articulated in § 423.124(a)(2) would assure access to covered Part D drugs provided by long-term care pharmacies for Part D enrollees residing in long-term care institutions that do not contract with their prescription drug plans or MA–PD plans. Since it is generally the case that long-term care facilities contract with a single long-term care pharmacy, Part D enrollees residing in a long-term care facility could not reasonably be expected to access their covered Part D drugs at another pharmacy if their facility’s long-term care pharmacy is not part of their plan’s network.

However, we are also considering whether to use the authority provided under section 1860D–4(b)(1)(C)(iv) of the Act to require prescription drug plans and MA–PD plans to approach some or all long-term care pharmacies in their service areas with at least the same terms available under their plans’ standard pharmacy contracts. Given Federal nursing home regulations, nursing facilities contract with a long-term care pharmacy to provide prescription drugs and services to their residents. In the absence of direct collaboration between a plan and a Part D enrollee’s long-term care pharmacy, it would be difficult for nursing facilities to meet Federal pharmacy management standards.

We are concerned, however, that to the extent that we require plans to solicit long-term care pharmacies in their service areas to join their networks, plans may be forced to negotiate preferential contracting terms and conditions (relative to the terms they would offer any other pharmacy willing to participate in its network) with a number of long-term care pharmacies in order to meet our requirement.

We also expect that long-term care pharmacies will be concerned about appropriate reimbursement for services (for example, clinical consultations, emergency medication access with 24-hour-a-day deliveries, specialized packaging, and IV and infusion therapies) that they currently provide long-term care facility residents. It is

possible that recognition of appropriate services would be addressed by provisions arranged by prescription drug plans and MA–PD plans and network pharmacies, with any resulting dispensing charges reflected in permissible dispensing fees. Section II.C.1 of this preamble discusses several options for defining the term “dispensing fees.” However, it is our goal to balance convenient access to long-term care pharmacies with appropriate payment for dispensing fees of efficient facilities. To the extent that we require plans to contract with long-term care pharmacies, it is our goal to assure that long-term care pharmacies charge reasonable dispensing fees to plans (and indirectly to CMS through the direct subsidy paid to prescription drug plans and MA–PD plans). We welcome comments regarding how to balance convenient access to long-term care pharmacies with appropriate payment to long-term care pharmacies under the provisions of the MMA.

Alternatively, we would not require that plans contract with long-term care pharmacies and would, instead, strongly encourage PDP sponsors and MA organizations offering MA–PD plans to negotiate with and include long-term care pharmacies in their plans’ pharmacy networks. We seek public comment regarding the advantages and disadvantages of these two approaches.

Similarly, we are considering two options for assuring access to I/T/U pharmacies by AI/AN Part D enrollees per the provisions of section 1860D–4(b)(1)(C)(iv) of the Act. There are currently 201 I/T/U pharmacies serving 107,000 senior and disabled AI/ANs in 27 States. In some areas, I/T/U pharmacies may be the only facilities capable of providing medication therapy management services to certain AI/AN beneficiaries due to language and cultural barriers. I/T/U pharmacies are unique in several different ways, including that they purchase drugs off the Federal Supply Schedule (FSS); can only serve AI/ANs; may have less experience than retail pharmacies (or none at all) with point-of-sale technology; are not typically well integrated into commercial pharmacy networks; generally stock a more limited range of drugs than would be required under a Part D formulary; and always waive co-pays.

One approach to assuring access to I/T/U pharmacies under Part D would be to use our authority under Section 1860D–4(b)(1)(C)(iv) of the Act to require that PDP sponsors and MA organizations approach any I/T/U pharmacies in their plan service areas with at least the same terms available

under the plan’s standard pharmacy contract. We are aware, however, that contracting with I/T/U pharmacies is potentially more complex than contracting with retail pharmacies given that there are a number of provisions in the standard contracts of commercial health plans that would likely need to be modified or deleted given statutory or regulatory restrictions to which I/T/U pharmacies are subject, as well as the particular circumstances of I/T/U pharmacies. Some examples of standard contract clauses that could be problematic for I/T/U pharmacies include:

- Prohibitions on waiving copays;
- Required provision of all drugs on a plan’s drug formulary;
- Requirements that providers bill and/or receive funds electronically to participate in the network;
- Requirements that claims be submitted within a specific timeframe;
- Requirements that plans serve all patients without discrimination;
- Requirements that providers carry private malpractice insurance;
- Requirements that providers be licensed in the state in which they provide services; and
- Requirements that binding arbitration be used in the event that any dispute arises with regard to performance or interpretation of any terms of the agreement and the parties are unable to resolve the dispute in an informal fashion.

We expect that, to the extent that we require plan inclusion of I/T/U pharmacies in plan networks, we would provide plans with a model addendum to their standard contracts (should we require them) that would take the special circumstances of I/T/U pharmacies into account. Such an addendum could also be useful for facilitating the inclusion in prescription drug plan or MA–PD plan pharmacy networks of other types of pharmacies (Federally Qualified Health Centers, for example, which are subject to some of the same limitations described above for I/T/U pharmacies that make many standard contract clauses impracticable).

A requirement that plans contract with I/T/U pharmacies could potentially expand plans’ market share in areas with high concentrations of AI/ANs. Plans may also benefit from cost-savings as a result of doing business with I/T/U pharmacies given I/T/U pharmacies’ heavy reliance on the dispensing of generic drugs. Also, given that IHS/tribal government subsidies of Part D cost-sharing on behalf of beneficiaries will not, as discussed in section II.C.2.a

of this preamble, count toward incurred costs, most IHS beneficiaries would almost never incur costs above the out-of-pocket limit; this would likely provide plans with additional cost-savings. On the other hand, we recognize that there is some potential for increased administrative costs for prescription drug plans and MA–PD plans given the need to modify standard contracts (should we require them) and, given the limited electronic capabilities of most I/T/U pharmacies, the processing of paper claims. In addition, the AI/AN population is one with which commercial health plans have little, if any, experience. Given these potential administrative costs, we are reluctant to require contracts with I/T/U facilities if that requirement discourages PDP sponsors and MA organizations from offering plans in service areas with large concentrations of AI/ANs.

Another option for assuring access to I/T/U pharmacies under Part D would be not to require that plans contract with I/T/U pharmacies and, instead, to strongly encourage PDP sponsors and MA organizations offering MA–PD plans to negotiate with and include I/T/U pharmacies in their plans’ pharmacy networks. We are concerned, however, that—in the absence of a contracting requirement—plans may make assumptions regarding the administrative costs (whether real or perceived) of contracting with I/T/U pharmacies and may not actively solicit the inclusion of these pharmacies in their networks. It is our understanding that I/T/U pharmacies are not currently well integrated in commercial pharmacy networks. The lack of I/T/U pharmacies in Part D plan networks would render enrollment in Part D of little use to AI/AN beneficiaries who rely primarily on I/T/U facilities for their health care. We encourage comments regarding these two approaches, their advantages and disadvantages, and their ramifications for AI/AN enrollees who are eligible to enroll in Part D.

As noted earlier, federally qualified health centers (FQHCs) and rural pharmacies face many of the same barriers to inclusion in commercial plan networks as do I/T/U pharmacies. Beneficiaries served by FQHCs and rural pharmacies are often served in those settings because of their financial and geographic circumstances. Plans may have to contract with these pharmacies in order to meet the access requirements in § 423.120(a)(1) of our proposed rule—particularly in rural areas. However, to the extent that they are able to meet the access requirements without doing so, we are concerned about compromised access to network pharmacies by low-

income beneficiaries who rely on FQHC and rural pharmacies for their health care. We solicit comments on permissible ways for us to assure Part D enrollees' access to FQHC and rural pharmacies, among others.

As stated above, we have proposed three options for defining "dispensing fees." Two of these options take into account some of the costs associated with administering infused covered Part D drugs to the beneficiary. Based on our research, most commercial health plans cover home infusion drugs and services under their medical benefits, given the cost-savings resulting from averted hospitalizations. However, because prescription drug plans do not offer a medical benefit under which to experience cost-savings, we do not believe that prescription drug plans would have an incentive to include home infusion pharmacies in their networks. We are considering using the authority in section 1860D-4(b)(1)(C) of the Act to require that both MA-PD plans and prescription drug plans contract with a sufficient number of home infusion pharmacies in their service area to provide reasonable access for Part D enrollees. Such a requirement would be allowed under Section 1860D-4(b)(1)(C) of the Act because the rules established with respect to convenient access to network pharmacies for Part D enrollees would be at least as favorable to enrollees as those used under the TRICARE Retail Pharmacy program. We seek public comment regarding the advantages and disadvantages of such an approach, how such a requirement could be structured, and any other issues we should consider.

We recognize that some beneficiaries may prefer to obtain their prescription drugs from mail-order pharmacies. While prescription drug plans and MA-PD plans could not offer a mail-order-only option to their beneficiaries or count mail-order pharmacies as part of their networks for the purpose of meeting the access standard in § 423.120(a)(1), prescription drug plans and MA-PD plans would be permitted, as provided under § 423.120(a)(2), to offer a home delivery option via a mail-order pharmacy. Any such home delivery option would be in addition to the retail pharmacies in a plan's network.

As provided under section 1860D-21(c)(3) of the Act and codified in § 423.120(a)(3)(i) of our proposed rule, we are authorized to waive the pharmacy access standards in § 423.120(a)(1) in the case of an MA-PD plan that provides access (other than via mail order) to qualified prescription

drug coverage through pharmacies owned and operated by the MA organization that offers the plan. However, in order for the pharmacy access standards to be waived, the MA-PD plan in question would be required to have a pharmacy network that, per our determination, provides comparable pharmacy access to its enrollees. We would evaluate whether such a plan's network provides comparable access to covered Part D drugs to its enrollees using the same considerations we currently use to evaluate MA plans' other provider networks under 42 CFR 422.112 of our proposed rule.

Similarly, § 423.120(a)(3)(ii) would codify section 1860D-21(d)(2) of the Act, which provides that if a private fee-for-service MA plan offering qualified prescription drug coverage provides coverage for drugs, including covered Part D drugs, purchased from all pharmacies—regardless of whether they are network pharmacies under contract with the MA plan, and provided that beneficiaries are not charged any cost-sharing above and beyond what they would be charged under standard prescription drug coverage—the pharmacy access requirements at § 423.120(a)(1) would also be waived.

As provided under section 1860D-4(b)(1)(A) of the Act and implemented in § 423.120(a)(4)(i), PDP sponsors and MA organizations offering an MA-PD plan would be required to permit the participation in their plan networks of any pharmacy that was willing to accept the plan's terms and conditions. However, it is unreasonable to assume that a PDP sponsor or MA organization could establish a network using a uniform set of terms and conditions throughout a service area. Modification of contracting terms and conditions might be necessary, for example, to assure access in remote rural areas or for beneficiaries who obtain their drugs from long-term care pharmacies. Varying terms and conditions might also be required in order for the sponsor to provide a cost effective benefit through rebates and price concessions. The cost estimates for Part D assume that PDP sponsors and MA organizations offering an MA-PD plan would be able to achieve savings from retail prices through formulary and network design. Thus, the requirement at § 423.120(a)(4)(i) of our proposed rule does not mandate a single set of terms and conditions for participation in a pharmacy network.

We seek comment on whether, in order to guarantee that any pharmacy willing to meet a PDP sponsor's or MA organization's contracting terms and conditions could participate in a plan's

pharmacy network, we should require that PDP sponsors and MA organizations offering an MA-PD plan make available to all pharmacies a standard contract for participation in their plans' networks. That requirement would not preclude PDP sponsors and MA organizations from negotiating terms and conditions different from those in the standard contract with a subset of pharmacies. These varying terms and conditions would therefore not have to be made available to all pharmacies. We note that, if required, it is our expectation that these standard contracts would require network pharmacies (except for pharmacies—long-term care, I/T/U, and rural pharmacies, for example—for which paper claims are the norm given technology access or coordination of benefits issues) to maintain systems to adjudicate drug claims at the point-of-sale.

As stipulated under section 1860D-4(b)(1)(E) of the Act and § 423.120(a)(4)(ii) of our proposed rule, pharmacies could not be required to accept insurance risk as a condition of participation in a PDP sponsor's or MA organization's pharmacy network. As defined in § 423.4, "insurance risk" in relation to a network pharmacy refers to risk of the type commonly assumed only by insurers licensed by a State. Insurance risk does not include payment variations designed to reflect performance-based measures of activities within the control of a pharmacy, such as formulary compliance and generic drug substitutions, nor does it include elements potentially in the control of the pharmacy (for example, labor costs, productivity).

Section 423.120(a)(5) of our proposed rule, based on section 1860D-4(b)(1)(B) of the Act, clarifies that a PDP sponsor or MA organization offering an MA-PD plan would have the option of reducing cost-sharing for its enrolled beneficiaries below the level that would otherwise apply for covered Part D drugs dispensed through network pharmacies. We interpret this provision as not restricting PDP sponsors and MA organizations offering MA-PD plans from varying cost-sharing not only based on type of drug or formulary tier, but also on a particular pharmacy's status within the plan's pharmacy network—in essence authorizing distinctions between "preferred" and "non-preferred" pharmacies. We believe that the statute allows these within network (preferred versus non-preferred pharmacy) distinctions to be made despite the "any willing provider"

provision at § 423.120(a)(4)(i) of our proposed rule.

While these within network distinctions are allowed, the statute also requires that any such tiered cost-sharing arrangements in no way increase our payments to PDP sponsors or MA organizations. We are therefore proposing that tiered cost-sharing arrangements based on within-network distinctions could be included in plans' benefits subject to the same actuarial tests that apply for tiered cost-sharing structures based on formulary. Thus, a reduction in cost-sharing for preferred pharmacies could be offered through higher cost-sharing for non-preferred pharmacies or as alternative prescription drug coverage. For further discussion of actuarial equivalence, please see section II.F.4 of this preamble.

We recognize the possibility that plans could effectively limit access in portions of their service areas by using the flexibility provided in § 423.120(a)(5) of our proposed rule to create a within-network subset of preferred pharmacies. In other words, in designing its network, a plan could establish a differential between cost-sharing at preferred versus non-preferred pharmacies—while still meeting the access standards in § 423.120(a)(1) of our proposed rule—that is so significant as to discourage enrollees in certain areas (rural areas or inner cities, for example) from enrolling in that plan. Our intent is to use the authority provided under section 1860D–11(e)(2)(D) of the Act to review, as part of the bid negotiation process described in § 423.272 of our proposed rule, the design of proposed prescription drug plan and MA–PD plan designs to ensure that they are not likely to substantially discourage enrollment by certain part D eligible individuals. Such a review would preclude the approval of bids submitted by plans that attempt to use strategies such as that outlined above to limit enrollment in portions of their service areas that are more difficult or costly to serve.

We recognize that some beneficiaries may prefer to purchase their prescription drugs at a community pharmacy rather than through a mail-order pharmacy and that community pharmacies typically dispense only 30-day supplies of prescription drugs at a time. Section 1860D–4(b)(1)(D) of the Act would require PDP sponsors and MA organizations offering an MA–PD plan to allow their enrollees to receive benefits at a network retail pharmacy instead of a network mail-order pharmacy, if they so choose. Such benefits could include an extended

supply (for example, 45-day, 60-day, 90-day supply) of covered Part D drugs that is typically available only through a network mail-order pharmacy. However, because mail-order pharmacies are often able to provide lower prices to individuals than retail pharmacies, it is possible that the negotiated price for an extended supply (for example, a 90-day supply) of a covered Part D drug would be more costly at a network retail pharmacy than through the network mail-order pharmacy assigned to the enrollee by their prescription drug plan or MA–PD plan. Thus, as provided under § 423.120(a)(6) of the proposed rule, a plan enrollee who chooses to obtain an extended supply of a covered Part D drug through a network retail pharmacy would be responsible for any differential between the network retail pharmacy's and the network mail-order pharmacy's negotiated price for that covered Part D drug. Since any such differential costs would be associated with benefits covered under a Part D plan, we seek comments on our proposal that this price differential be counted as an incurred cost against the annual out-of-pocket threshold consistent with the definition of "incurred cost" in § 423.100. Under this approach, plans would be required to explicitly account for such price differentials in the actuarial valuation of their coinsurance in their bids. In addition, any such differential would also count toward the deductible for covered Part D expenditures between \$0 and the plan's deductible.

b. Formulary Requirements

To the extent that a PDP sponsor or MA organization uses a formulary to provide qualified prescription drug coverage to Part D enrollees, it would be required to meet the requirements of § 423.120(b)(1) and section 1860D–4(b)(3)(A) of the Act to use a pharmaceutical and therapeutic (P&T) committee to develop and review that formulary. As a note of clarification, we interpret the requirement at section 1860D–4(b)(3)(A) of the Act that a formulary be "developed and reviewed" by a P&T committee as requiring that a P&T committee's decisions regarding the plan's formulary be binding on the plan. However, we request comments on this interpretation. In addition, it is our expectation that P&T committees will be involved in designing formulary tiers and any clinical programs implemented to encourage the use of preferred drugs (e.g., prior authorization, step therapy, generics programs).

The majority of members comprising the P&T committee would be required to be practicing physicians and/or

practicing pharmacists. In addition, at least one practicing pharmacist and one practicing physician member would have to be experts in the care of elderly and disabled individuals. However, we would also encourage that plans select P&T committee members representing various clinical specialties in order to ensure that all disease states are adequately considered in the development of plan formularies. Section 423.120(b)(1)(ii) of the proposed rule also provides that at least one practicing pharmacist and one practicing physician members on a plan's P&T committee be independent experts. We interpret the statutory language at section 1860D–4(b)(3)(A)(ii) of the Act requiring certain members of the P&T committee to be "independent and free of conflict with respect to the sponsor and plan" to mean that such P&T committee members must have no stake, financial or otherwise, in formulary determinations. In other words, these individuals would be required to be independent and free of conflict with respect not only to a PDP sponsor and its prescription drug plan or an MA organization and its MA–PD plan, but also with respect to pharmaceutical manufacturers. In addition, we solicit public comment with respect to the appropriateness of strengthening the statutory requirement in section 1860D–4(b)(3)(A)(ii) of the Act by requiring, in our final regulations, that more than just one pharmacist and one physician on the P&T committee be independent and free of conflict.

When developing and reviewing the formulary, the P&T committee would be required, under § 423.120(b)(1)(iii) and in accordance with section 1860D–4(b)(3)(B) of the Act, to base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature (for example, randomized clinical trials, pharmaco-economic studies, outcomes research data, and such other information as the committee determined appropriate). We note that the Public Health Service has developed guidelines for the treatment of HIV disease and related opportunistic infections that may also be useful to plan's P&T committees; these guidelines can be found at <http://www.aidsinfo.nih.gov/guidelines/>. Pharmaco-economic studies may be considered in clinical decision making by a P&T committee with respect to formulary development. It is our expectation, however, that any cost considerations will be balanced with

clinical considerations in the development and revision of a plan's formulary. The P&T committee would also take into account whether including a particular covered drug in the formulary (or in a particular formulary tier) had any therapeutic advantages in terms of safety and efficacy, per § 423.120(b)(1)(iv) of our proposed rule. Section 423.120(b)(1)(v) of our proposed rule would require that any decisions made by the P&T committee regarding development or revision of a plan's formulary be documented in writing.

As provided under section 1860D–4(b)(3)(C)(ii) of the Act, we will request the U.S. Pharmacopeia (USP) to develop a model set of guidelines that consists of a list of drug categories and classes that may be used by PDP sponsors and MA organizations to develop formularies for their qualified prescription drug coverage, including their therapeutic categories and classes. We expect that the model categories and classes developed by USP will be defined so that each includes at least one drug that is approved by the FDA for the indication(s) in the category or class. That is, no category or class would be created for which there is no FDA approved drug and which would therefore have to include a drug based on its "off label" indication. However, this would not preclude physicians and other prescribers from prescribing drugs for off label indications, though we strongly encourage prescribers to clearly document and justify off-label use in their Part D enrollees' clinical records. Additionally, the USP model guidelines would not preclude PDP sponsors or MA organizations from assigning an FDA approved drug to a category or class based on an off label use for that drug, provided the FDA has not made a determination that the drug is unsafe for that use. In addition to developing these initial model guidelines, the USP will revise its classification periodically to reflect changes in therapeutic uses of covered Part D drugs and any additions of new covered Part D drugs. As explained below, PDP sponsors and MA organizations will have some flexibility in developing formularies for prescription drug plans and MA–PD plans.

We expect that the development of these guidelines will require USP to conduct outreach to beneficiary groups and major industries affected by the development of model guidelines. We specifically envision USP conducting multiple consultations and a public meeting with related health care industries and providers (including national representatives of pharmacies);

Medicare physicians and other practitioners, including pharmacists; other provider groups, including long-term care providers; the managed care industry; the health insurance industry; pharmacy benefit managers (PBMs); and Medicare beneficiary advocacy groups). These consultations would be conducted with the goal of researching current best practices in formulary development and existing commercial and other standards (for example Medicaid, the Medicare Prescription Drug Discount Card), as well as obtaining informed recommendations concerning the development of the Part D model guidelines. The goal of the public meeting would be to solicit comments on a draft of the model guidelines, which would be developed on the basis of the aforementioned consultations, as well as USP's research and recommendations. As our work with USP gets underway, we will provide further detail on the USP classification in upcoming operational guidance to entities wishing to become PDP sponsors or MA organizations offering MA–PD plans. Also, we wish to make clear that any guidelines established by the USP are applicable only to Part D benefits. They do not require the Secretary to make any decisions or take any actions with regard to classifying or categorizing drugs for any purpose other than implementing the Part D benefit.

Although the USP will develop guidelines, under section 1860D–4(b)(3) of the Act PDP sponsors and MA organizations would have the flexibility to develop their own classification schemes. The USP listing would simply serve as a model set of guidelines. As specified in 1860D–11(e)(2)(D)(ii) of the Act, if the therapeutic classifications within a plan's formulary conform to the USP classification model, we could not determine, based on the formulary's therapeutic classifications, that the plan violates the provision at 1860D–11(e)(2)(d)(i) of the Act and § 423.272(b)(2) that prohibits the design of a plan and its benefits (including any formulary and tiered formulary structure) that substantially discourages enrollment by certain Part D eligible individuals. It is important to note, however, that even if a plan's formulary classifications conform to the USP classification model, its overall formulary design could still be found to substantially discourage enrollment by certain Part D individuals (for example, based on particular drugs selected for inclusion in the formulary and/or proposed cost-tiering structure). If, on the other hand, a PDP sponsor or MA

organization offering an MA–PD plan designs its formulary using therapeutic classes and categories that vary from the USP classification model, CMS would evaluate the submitted formulary design to ensure that the proposed therapeutic classification system does not substantially discourage enrollment by certain Part D eligible individuals. We invite comments regarding standards and criteria that we could use to determine that a PDP sponsor or MA organization's formulary classification system that is not based on the model classification system does not in fact discriminate against certain classes of Part D eligible beneficiaries.

Section 1860D–4(b)(3)(C) of the Act and § 423.120(b)(2) require the inclusion of "drugs" in each therapeutic category and class of covered Part D drugs in a plan's formulary, although not necessarily all drugs within such categories and classes. We interpret this requirement to mean that a PDP sponsor or MA organization's formulary would be required to include at least two drugs within each therapeutic category and class of covered Part D drugs within the PDP sponsor or MA organization's formulary (unless there is only one drug in a particular therapeutic class or category, in which case the inclusion of only one drug would be required). Section 423.120(b)(2) of our proposed rule would also require that the drugs included in each therapeutic class or category include a variety of strengths and doses to the extent this is feasible. We believe that the inclusion of at least two drugs in each therapeutic class or category (except for those classes or categories that include only one drug) strikes an appropriate balance between providing plans with the necessary leverage to negotiate with manufacturers for significant discounts on covered Part D drugs and ensuring sufficient drug choice for beneficiaries. We note, however, that it is our expectation that plans' formularies will provide Part D enrollees a comprehensive benefit—one that covers an amount and variety of drugs sufficient to treat all disease states. In addition, given that discounts on commonly used generic drugs are typically made available to enrollees under current industry practice and produce cost-savings both for plans and enrollees, we expect that prescription drug plan and MA–PD plan formularies will include a wide range of generic drugs.

As elaborated above, we will evaluate the formularies of plans using a classification system different from the USP model guidelines to ensure that the formulary does not discriminate against certain classes of beneficiaries. We also

intend to strictly enforce rules regarding plans' P&T committees, as described above, as well as coverage determination, reconsideration, and appeals processes, to ensure that Part D enrollees are able to access the drugs they need.

Within the aforementioned parameters, it is certainly possible that a prescription drug plan or MA-PD plan could develop a formulary that employs a number of strategies—for example, financial incentives to encourage use of generics, tiered cost-sharing and other mechanisms that create strong incentives for manufacturers to negotiate favorable prices for covered Part D drugs, prior authorization procedures, therapeutic interchange, step therapy, and use of mail order—to produce cost-savings both for plans and for Medicare. While we are open to these types of strategies as a way to minimize costs for enrollees and for the Medicare program, it is possible that certain vulnerable populations (enrollees in long-term care facilities or those suffering from mental illness or chronic diseases such as AIDS, for example) may be negatively impacted financially if they do not have access to a wide range of drugs in certain therapeutic classes and categories. We seek comments on ways to balance plans' flexibility to use some of the mechanisms described above to maximize covered Part D drug discounts and lower enrollee premiums with the needs of certain special populations of Part D enrollees.

One such population is Part D enrollees residing in long-term care facilities. Given the changes in Medicaid drug coverage introduced by the MMA, we believe it is particularly important to ensure that the drug needs of institutionalized Part D enrollees—most of whom are dually eligible for Medicare and Medicaid—are met. The institutionalized population is generally more sensitive to and less tolerant of many medications. Long-term care pharmacies typically provide an open formulary to prescribing physicians that allows immediate access to a wide variety of medications in many different dosages and delivery forms. We request comments regarding any special treatment (for example, offering certain classes of enrollees an alternative or open formulary that accounts for their unique medical needs, and/or special rules with respect to access to dosage forms that may be needed by these populations but not by other Part D enrollees), we should consider requiring of plans with respect to special populations, as well as suggestions regarding the particular special

populations for whom we may want to make allowances.

Under § 423.120(b)(3) of our proposed rule and in accordance with section 1860D-4(b)(3)(C)(iii) of the Act, PDP sponsors and MA organizations could not change therapeutic categories and classes in a formulary other than at the beginning of a plan year, except as we would permit to take into account new therapeutic uses and newly approved covered Part D drugs. Section 423.120(b)(4) of our proposed rule specifies that, in accordance with section 1860D-4(b)(3)(F) of the Act, PDP sponsors and MA organizations offering MA-PD plans would periodically be required to evaluate and analyze treatment protocols and procedures related to their formularies to ensure that their plan members were receiving the best possible care for conditions related to their use of covered Part D drugs. We invite comments as to minimum timeframes for periodic evaluation and analysis of protocols and procedures related to a plan's formulary by PDP plans and MA organizations offering MA-PD plans (for example, quarterly, annually).

In addition, section 1860D-4(b)(3)(E) of the Act requires that PDP sponsors and MA organizations provide "appropriate notice" to us, affected enrollees, authorized prescribers, pharmacists, and pharmacies regarding any decision to either: (1) Remove a drug from its formulary, or (2) make any change in the preferred or tiered cost-sharing status of a drug. Section 423.120(b)(5) would implement that requirement by defining appropriate notice as at least 30 days prior to such change taking effect during a given contract year. We interpret the statutory term "affected enrollee" as referring to a plan enrollee who is currently taking a covered Part D drug that is either being removed from a plan's formulary, or whose preferred or tiered cost-sharing status is changing. In other words, plans would not be required to notify all enrollees regarding formulary changes during a contract year—only those directly affected by changes with respect to a particular covered Part D drug. We note that plans would still be required to provide at least two drugs within each therapeutic category and class of covered Part D drugs within the PDP sponsor or MA organization's formulary (unless there is only one drug in a particular therapeutic class or category), even if they choose to remove a covered Part D drug from their formularies in the middle of a contract year. In addition, we refer the reader to section II.M.5 of this preamble, which discusses formulary exceptions

procedures and may be important for enrollees of plans whose formularies change mid-year.

We recognize that both current and prospective enrollees of a prescription drug plan or an MA-PD plan will need to have the most current formulary information by the time of the annual coordinated election period described in § 423.36(b) in order to enroll in the Part D plan that best suits their particular covered Part D drug needs. To this end, and as provided under § 423.120(b)(6) of our proposed rule, PDP sponsors and MA organizations would be prohibited from removing a covered Part D drug or from changing the preferred or tiered cost-sharing status of a covered Part D drug between the beginning of the annual coordinated election period described in § 423.36(b)(2) and 30 days subsequent to the beginning of the contract year associated with that annual coordinated election period. We believe this requirement will prevent situations in which prescription drug plans or MA-PD plans change their formulary early in the contract year, without providing appropriate notice, as described in § 423.120(b)(5), to new enrollees. Given that we are proposing that plans provide at least 30 days notice to affected enrollees prior to making formulary changes, it seems reasonable to require, as we propose doing in § 423.120(b)(6), that all marketing materials distributed during the annual coordinated election period reflect the formulary a plan will offer at the beginning of the contract year for which it is enrolling Part D eligible individuals.

As discussed in sections II.C.6.c and II.C.6.d of this preamble, PDP sponsors and MA organizations can get information regarding formulary changes to beneficiaries via an Internet Web site, as well as via explanations of benefits sent to enrollees who utilize their Part D benefits. However, other methods (for example, notification by mail) will have to be used to provide notice to CMS, all affected enrollees, authorized prescribers, pharmacists, and pharmacies about impending formulary changes.

Each PDP sponsor and MA organization offering qualified prescription drug coverage would also be required to establish policies and procedures to educate and inform health care providers and enrollees about its formulary, according to the provisions of § 423.120(b)(7) and section 1860D-4(b)(3)(D) of the Act. As required under section 1860D-4(b)(3) of the Act, the requirements regarding the development and application of formularies discussed in this preamble section may

be met by a PDP sponsor or MA organization directly, or through contracts or other arrangements between a PDP sponsor or MA organization and another entity or entities.

c. Use of Standardized Technology

In accordance with the requirements of section 1860D–4(b)(2)(A) of the Act, § 423.120(c) of our proposed rule would require that PDP sponsors and MA organizations issue (and reissue, as appropriate) a card or other technology that enrollees could use to access negotiated prices for covered part D drugs. Section 1860D–4(b)(2)(B)(i) of the Act mandates that we develop, adopt, or recognize standards relating to a standardized format for a card or other technology for accessing negotiated prices to covered Part D drugs. These standards would be compatible with the administrative simplification requirements of Title XI of the Act and could be based on standards developed by a standard setting organization.

As provided under section 1860D–4(b)(2)(B)(ii) of the Act, we will consult with the National Council for Prescription Drug Programs (NCPDP) and other standard setting organizations, as appropriate, to develop these standards. Given that NCPDP is recognized as the industry standard for current prescription drug programs, and we relied on its standards in developing requirements for discount card sponsors' cards under the Medicare Prescription Drug Discount Card and Transitional Assistance Program, we are proposing basing our card standards on NCPDP's "Pharmacy ID Card Standard." This standard is based on the American National Standards Institute ANSI INCITS 284–1997 standard titled *Identification Card—Health Care Identification Cards*, which may be ordered through the Internet at <http://www.ansi.org>. We will provide further operational guidance regarding our standards for a card (or other technology) to entities wishing to become PDP sponsors or MA organizations in time for these entities to use the standards (and have their cards approved for use by us) beginning January 1, 2006. It is our intent, however, that these standards require that plans use something other than an enrollee's social security number as an identifier on their cards.

5. Special Rules for Access to Covered Part D Drugs at Out-of-Network Pharmacies (§ 423.124)

Section 1860D–4(b)(1)(C)(iii) of the Act requires us to establish pharmacy access standards that include rules for adequate emergency access to covered

Part D drugs by Part D enrollees. We reviewed the definition of an "emergency medical condition" (see § 422.113(b)(1)(i) of our proposed rule) under the MA program to determine whether the "prudent layperson" standard was an appropriate standard for ascertaining whether the need for a covered Part D drug constitutes an emergency. However, we do not believe that the definition of an emergency medical condition, or a variation thereof, is entirely appropriate to prescription drugs. To the extent that a physician (or other prescriber) prescribes a covered Part D drug, we consider that covered Part D drug to likely be medically necessary. The issue of urgency or emergency is difficult to determine from a clinical perspective, however.

Given the inherent difficulties in establishing emergency access standards for covered Part D drugs, we propose to meet the requirements of section 1860D–4(b)(1)(C)(iii) by establishing a broader out-of-network access requirement. As provided in § 423.124(a) of our proposed rule, we would require that PDP sponsors and MA organizations offering MA–PD plans assure that their enrollees have adequate access to drugs dispensed at out-of-network pharmacies when they cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy. We expect that out-of-network access would be guaranteed under at least the following four scenarios:

- In cases in which a Part D enrollee meets all of the following: is traveling outside his or her plan's service area; runs out of or loses his or her covered Part D drug(s) or becomes ill and needs a covered Part D drug; and cannot access a network pharmacy;
- In cases in which a Part D enrollee cannot obtain a covered Part D drug in a timely manner within his or her service area because, for example, there is no network pharmacy within a reasonable driving distance that provides 24-hour-a-day/7-day-per-week service;
- In cases in which a Part D enrollee resides in a long-term care facility and the contracted long-term care pharmacy does not participate in his or her plan's pharmacy network; and
- In cases in which a Part D enrollee must fill a prescription for a covered Part D drug, and that particular covered Part D drug (for example, an orphan drug or other specialty pharmaceutical typically shipped directly from manufacturers or special vendors) is not regularly stocked at accessible network retail or mail-order pharmacies.

We believe that enrollees under the aforementioned circumstances could not reasonably be expected to access a network pharmacy and must therefore be assured access to an out-of-network pharmacy as provided under § 423.124(a) of our proposed rule. We request comments on our proposed out-of-network access requirements.

We are aware that routine access to out-of-network pharmacies by Part D enrollees may undermine a plan's cost-savings incentives. However, provided adequate access is assured under § 423.124(a), PDP sponsors and MA organizations offering MA–PD plans would have some flexibility to design their out-of-network coverage policies. PDP sponsors and MA organizations offering MA–PD plans may therefore establish reasonable rules to assure that enrollees use out-of-network pharmacies appropriately. For example, PDP sponsors and MA organizations offering MA–PD plans could limit the amount of covered Part D drugs dispensed at an out-of-network pharmacy, require the use of mail order pharmacies as appropriate for extended out-of-area travel, and/or require a plan notification process for individuals who fill their prescriptions at out-of-network pharmacies.

As a point of clarification, enrollees would not be permitted to access prescription drugs that were not considered covered Part D drugs due to application of the prescription drug plan's or MA–PD plan's formulary at an out-of-network pharmacy. Enrollees who require a covered Part D drug that is not on their prescription drug plan or MA–PD plan's formulary would be required to use the coverage determination process described in § 423.566 of our proposed rule.

Both the enrollee and his or her prescription drug plan or MA–PD plan would be financially responsible for covered Part D drugs obtained at an out-of-network pharmacy as described in § 423.124(a) of our proposed rule (in other words, when an enrollee cannot reasonably be expected to access his or her covered Part D drugs at a network pharmacy), though we note that paper claims may have to be filed and payment reconciled after the drug purchase instead of (as would be the case with most, if not all, network pharmacies), at the point of sale. Section 423.124(b)(1) of our proposed rule would require that the Part D enrollee be liable for any cost-sharing, including a deductible, that would have otherwise applied had the covered Part D drug been obtained at a network pharmacy. Such cost-sharing would be applied relative to the plan allowance for that

covered Part D drug, which we propose defining in § 423.100 as the amount prescription drug plans and MA–PD plans use to determine their payment and Part D enrollees' cost-sharing for covered Part D drugs purchased at out-of-network pharmacies in accordance with the requirements of proposed § 423.124(b). We request comments on how to further define the term "plan allowance." Our understanding is that it is current industry practice to define the plan allowance as the lowest of the contractual discount offered to pharmacies in a plan's standard contract (as described above, we are soliciting public comment regarding whether we should require PDP sponsors and MA organizations to offer a standard contract to all pharmacies), maximum allowable cost (MAC), or the pharmacy's usual and customary price (described below).

Thus, for example, if the beneficiary would have been liable for 25 percent coinsurance at a network pharmacy, he or she would pay 25 percent of the plan allowance for that covered Part D drug. If, on the other hand, the beneficiary would have been liable for a \$10 copay at a network pharmacy, he or she would still pay \$10 at the out-of-network pharmacy.

In addition to this cost-sharing, and as provided under proposed § 423.124(b)(2), the enrollee would be responsible for any difference in price between the out-of-network pharmacy's usual and customary (U&C) price and the plan allowance for that covered Part D drug. The term "usual and customary price" refers to the price that a pharmacy would charge a customer who does not have any form of prescription drug coverage. Thus, for example, if an out-of-network pharmacy's U&C price for a covered Part D drug were \$100, the plan's allowable cost (including beneficiary cost-sharing) for that covered Part D drug were \$90, and the negotiated price for the covered Part D drug at the beneficiary's network pharmacy were also \$90, a beneficiary obtaining a drug at the out-of-network pharmacy would pay the cost-sharing that would have otherwise applied at a network pharmacy (for example, 25 percent of the \$90 plan allowance), plus the \$10 difference—a total of \$32.50, in this case (compared to \$22.50 at the network pharmacy). We request public comments regarding our definition of usual and customary price. We are concerned that, given our proposed out-of-network access policy, pharmacies may increase their U&C prices to increase their total reimbursement. This would be prejudicial not only to beneficiaries in need of out-of-network

access, but also to uninsured individuals purchasing drugs at retail pharmacies, and we seek feedback on permissible ways to prevent such an outcome.

When an enrollee purchases a covered Part D drug at an out-of-network pharmacy consistent with § 423.124(a) of our proposed rule, the cost-sharing he or she pays relative to the plan allowance (\$22.50 in the example above) counts as an incurred cost against his or her annual out-of-pocket threshold because such out-of-network access to a covered part D drug is a covered benefit under those circumstances. As with the price differential that a beneficiary could incur by purchasing an extended supply (for example, 90-day) of covered Part D drugs purchased at a retail pharmacy rather than a mail-order pharmacy (discussed in section II.C.4.a of this preamble), the price differential between out-of-network pharmacies' U&C costs and the plan allowance would also be counted as an incurred cost against a beneficiary's annual out-of-pocket threshold. We seek comments on our proposal that this price differential be counted as an incurred cost against the out-of-pocket threshold consistent with the definition of "incurred cost" in § 423.100 of the proposed rule. Under this approach, plans would be required to explicitly account for such price differentials in the actuarial valuation of their coinsurance in their bids. In addition, any such differential would also count toward the deductible for covered Part D expenditures between \$0 and the plan's deductible.

The plan in the example above would be responsible for payment of the plan allowance for the covered Part D drug minus the applicable beneficiary cost-sharing—\$67.50, in this case—which is the same amount as the plan would have paid for that covered Part D drug at the network pharmacy. Given our proposed rules regarding financial responsibility for out-of-network access to covered Part D drugs, plans would in effect be financially held harmless for out-of-network use by their enrollees under § 423.124(a) of our proposed rule. We believe this is necessary in order to curb unnecessary use of out-of-network pharmacies and to ensure that plans can achieve cost-savings for both beneficiaries and the Medicare program. We welcome public comments regarding our proposed payment rules for covered Part D drugs obtained at out-of-network pharmacies when enrollees cannot reasonably obtain those drugs at a network pharmacy.

6. Dissemination of Plan Information (§ 423.128)

Section 423.128 of our proposed rule would establish beneficiary protection requirements concerning the dissemination of Part D information by PDP sponsors and MA organizations to enrollees in, and individuals eligible to enroll in, a prescription drug plan or MA–PD plan. Part D information disseminated by PDP sponsors and MA organizations to current or prospective Part D enrollees would constitute marketing materials, as described in § 423.50(b) of the proposed rule, and must be approved by us. For more information regarding the approval of marketing materials, please refer to section II.B.9 of this preamble).

As explained in greater detail below, we note that—with the exception of the drug-specific information dissemination requirements—many of the requirements of § 423.128 of the proposed rule duplicate information dissemination requirements contained in § 422.111 of our proposed rule that are applicable to all MA plans, including MA–PD plans. We have proposed applying the requirements of § 423.128 to MA–PD plans to ensure that Part D eligible enrollees have access to comparable drug-specific information from both prescription drug plans and MA–PD plans. We solicit comments on how best to coordinate the requirements of § 423.128 and § 422.111 of our proposed rule for MA–PD plans.

a. Content of Plan Description

Sections 423.128(a) and (b) of our proposed rule complies with the stipulation in section 1860D–4(a)(1) of the Act that requirements for the dissemination of Part D information be similar to the information dissemination requirements for MA organizations under section 1852(c)(1) of the Act and as interpreted in § 422.111(b) of our proposed rule.

In order to ensure that individuals who are either eligible for, or enrolled in, a plan offering qualified prescription drug coverage receive the information they need to make informed choices about their Part D coverage options, PDP sponsors and MA organizations offering an MA–PD plan would be required to disclose, to each enrollee in a plan offering qualified prescription drug coverage, a detailed description of that plan. This description would be provided in a clear, accurate, and standardized form at the time of enrollment and annually, at a minimum, after enrollment. The information provided would be similar to the information MA plans must disclose to

their enrollees under § 422.111(b) of our proposed rule. The plan description would include information about:

- The service area;
- Benefits offered, including information on cost-sharing requirements (for example, tiered or other copayment level applicable to a drug or class of drugs, deductibles, coinsurance), cost-sharing requirements for subsidy eligible individuals, and how a beneficiary may obtain further information about those cost-sharing requirements;
- How any formulary used by the plan works, the process for obtaining an exception to a prescription drug plan's or MA-PD plan's tiered cost-sharing structure, and how to obtain a copy of the formulary as well as information about formulary changes;
- Access to network pharmacies;
- Out-of-network coverage provided by the plan;
- Grievance, coverage determination, exceptions, reconsideration, and appeals procedures;
- A description of the plan's quality assurance program, including the medication therapy management program required under § 423.153(d) of our proposed rule; and
- Disenrollment rights and responsibilities.

b. Disclosure of Information Upon Request

In addition, according to section 1860D-4(a)(2) of the Act and as codified in § 423.128(c) of our proposed rule, a beneficiary who is eligible to enroll in a PDP sponsor's prescription drug plan or an MA organization's MA-PD plan would have the right to obtain, upon request, more detailed plan information. This information would be similar to that which MA organizations are required to disclose to their enrollees upon request under sections 1852(c)(2)(A), (B), and (C) of the Act and 42 CFR 422.111(c) and (f) of our proposed rule, and would include:

- General coverage information (for example, enrollment procedures; grievance, coverage determination, reconsideration, exceptions, and appeals procedural rights; the potential for the PDP sponsor or MA organization contract termination or service area reduction; benefits; premiums; formulary; service area; and quality and performance indicators);
- The procedures the organization would use to control utilization of services and expenditures;
- The number of disputes and their disposition in the aggregate; and
- The financial condition of the PDP sponsor or MA organization.

c. Provision of Specific Information

As required under section 1860D-4(a)(3) of the Act and § 423.128(d) of our proposed rule, PDP sponsors and MA organizations offering an MA-PD plan would be required to have in place a mechanism for providing, on a timely basis, specific information to current and prospective enrollees upon request. Such mechanisms would include:

- A toll-free customer call center;
- An Internet Web site; and
- Responses in writing upon beneficiary request.

As provided in § 423.128(d)(1)(i) and (ii) of our proposed rule, plans' customer call centers would be required to be open during usual business hours and provide customer telephone service, including to pharmacists, in accordance with standard business practices. We strongly recommend, however, that plans provide some sort of 24-hour-a-day/7 day-a-week access to their toll-free customer call centers in order to provide timely responses to time-sensitive questions (for example, on out-of-network pharmacy access) and request comments on whether we should require the more stringent 24-hour-a-day/7-day-a-week standard in our final regulations.

In addition, we are proposing requiring that plans maintain Web sites as one means of disseminating information to current and prospective Part D enrollees. The Internet has proved to be an inexpensive and widely available source of information on health plans. Almost all Federal Employees Health Benefits (FEHB) plans, most large employer plans, and almost all managed care organizations maintain websites for the convenience of enrollees. Such Web sites typically contain information on drug formularies, preferred providers, plan access and emergency procedures, claims procedures, and a wide array of other useful information. Health plans have found that up-to-date formulary and provider information can be conveyed to enrollees far more quickly, reliably, and inexpensively via Internet than through traditional paper processes. Survey evidence shows that roughly half of the elderly routinely use the Internet. Even those who do not have direct access usually have friends or family who can assist them in obtaining information from the Internet. Libraries and senior support and counseling groups are almost always able to provide Internet Assistance. Thus, a great number of Medicare beneficiaries could benefit from the existence of prescription drug plan and MA-PD plan Web sites.

As provided in § 423.128(d)(2)(i) of our proposed rule, PDP sponsors and MA organizations offering MA-PD plans would be required to include the detailed plan description information described in section II.C.6.a of this preamble. In addition, per §§ 423.128(d)(2)(ii) and (iii) of our proposed rule, plans would have to post current versions of their formularies, update those formularies at least weekly, and use the website as one mechanism to provide notice (at least 30 days in advance, as discussed in section C.4.b of this preamble) of upcoming formulary changes, including the removal of covered Part D drugs from a formulary or changes to the tiered or preferred status of covered Part D drugs. Plan websites would have to be available both to current and prospective Part D enrollees. We note that plans would continue to be required to make information available to Part D eligible individuals in written formats as is currently the case for MA plans, and the provision of plan information via the Internet would simply be one additional mechanism for plans to communicate with enrollees and potential enrollees.

Finally, prescription drug plans and MA-PD plans would be required to respond to beneficiary requests for specific information in writing, upon request. This requirement is codified in § 423.128(d)(3) of our proposed rule.

d. Claims Information

In accordance with the requirements of section 1860D-(4)(a)(4) of the Act, and as codified in § 423.128(e) of our proposed rule, PDP sponsors would furnish to enrollees who receive covered Part D drugs an explanation of benefits. Explanations of benefits would be required to be written in a form easily understandable to beneficiaries.

As provided in §§ 423.128(e)(1)–(5) of our proposed rule, plans' explanations of benefits would have to include:

- A listing of the item or service for which payment was made, as well as the amount of such payment for each item or service;
- A notice of the individual's right to request an itemized statement;
- Information regarding the cumulative, year-to-date amount of benefits provided relative to the deductible, the initial coverage limit, and the annual out-of-pocket threshold for that year;
- A beneficiary's cumulative, year-to-date total of incurred costs (to the extent practicable); and
- Information about any applicable formulary changes.

We would require, under § 423.128(e)(6) of our proposed rule, that an explanation of benefits be provided at least monthly for those utilizing their prescription drug benefits in a given month. This proposed requirement is consistent with our policy regarding the Medicare Summary Notice, which is provided monthly for beneficiaries with Part A or Part B utilization. It is also consistent with the standards followed by banking and other financial organizations, which provide their clients with monthly statements provided there is activity on their accounts.

A PDP sponsor or MA organization offering an MA–PD plan could provide the notice of benefits electronically in cases in which a beneficiary elected to receive notices in that form. If technically feasible, a PDP sponsor or MA organization could also provide the notice of benefits at the point of sale; this would allow the PDP sponsor or MA organization to provide enrollees with additional information (for example, this could facilitate the provision of information regarding the availability of lower-cost generic availability required under § 423.132 of the proposed rule).

7. Public Disclosure of Pharmaceutical Prices for Equivalent Drugs (§ 423.132)

Under § 423.132(a) of our proposed rule, which codifies the requirements of section 1860D–4(k)(1) of the Act, PDP sponsors offering a prescription drug plan and MA organizations offering an MA–PD plan would be required to ensure that pharmacies inform enrollees of any differential between the price of a covered Part D drug to an enrollee and the price of the lowest priced generic version of that drug and available under the plan at that pharmacy. Under § 423.132(b) of our proposed rule, this information would have to be provided at the time the plan enrollee purchases the drug, or in the case of drugs purchased by mail order, at the time of delivery of that drug. Disclosure of this information would not be necessary, however, if the particular covered Part D drug purchased by an enrollee was the lowest-priced generic version of that drug available at a particular pharmacy.

As provided under section 1860D–4(k)(2)(B) of the Act and § 423.132(c) of our proposed rule, we are permitted to waive the requirement that information on differential prices between a covered Part D drug and generic equivalent covered Part D drugs be made available to prescription drug plan enrollees at the point of sale (or at the time of delivery of a drug purchased through a mail-order pharmacy). Accordingly, we

are proposing waiving the requirement in § 423.132(a) that information on lowest-priced generic drug equivalents be provided to enrollees for covered Part D drugs purchased by prescription drug plan and MA–PD plan enrollees when those covered Part D drugs are purchased at:

- Any pharmacy, when the individual is enrolled in an MA private fee-for-service plan that offers qualified prescription drug coverage and provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies, and does not charge additional cost-sharing for access to covered Part D drugs dispensed at all pharmacies;
- Out-of-network pharmacies;
- I/T/U network pharmacies; and
- Network pharmacies located in any of the U.S. territories (American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands).

Section 1860D–21(d)(2) of the Act specifically requires us to waive the public disclosure requirement for private fee-for-service MA plans meeting the criteria described above. Section 423.132(c)(1) of our proposed rule implements this waiver for private fee-for-service MA plans that meet those criteria.

Our rationale for proposing waiver of the public disclosure requirement for out-of-network pharmacies, as provided under § 423.132(c)(2) of our proposed rule, is that such a requirement necessitates a contract between a PDP sponsor or MA organization and a pharmacy. Since, by definition, out-of-network pharmacies are not under contract with a PDP sponsor or an MA organization, complying with the public disclosure requirement would be impracticable.

We also propose waiving the requirement in § 423.132(a) when prescription drug plan enrollees obtain covered Part D drugs in I/T/U pharmacies, as provided under § 423.132(c)(3) of our proposed rule. Because I/T/U pharmacies do not charge American Indians/Alaska Natives (AI/ANs) for drugs obtained at I/T/U pharmacies, AI/ANs obtaining drugs from these pharmacies would not benefit from the provision of information about covered Part D drug price differentials. Furthermore, because I/T/U pharmacies generally only stock the generic versions of brand name drugs, AI/ANs obtaining drugs from these pharmacies would already be receiving a generic equivalent of any brand name part D drug prescribed to them.

We believe it is appropriate to waive the public disclosure requirement for PDP sponsors when covered Part D drugs are provided in network pharmacies located in the territories given that few PBMs and health plans currently have contractual relationships with retail pharmacies in the territories. Our goal in waiving this requirement, as provided in § 423.132(c)(4) of our proposed rule, would be to reduce the administrative complexity of PDP sponsors and MA organizations' contracts with participating retail pharmacies in the territories, which we believe would enhance organizations' willingness to offer qualified prescription drug coverage in the territories. However, mail order drugs sent to residents of the territories would be required to include information about the price differential between a covered Part D drug and its lowest-priced generic version in the same manner as such information would be provided to Part D enrollees in the 50 States and District of Columbia who obtain mail order drugs under Part D.

Finally, as provided in § 423.132(c)(5) of our proposed rule, we propose waiving the public disclosure requirement in § 423.132(a) under such circumstances as we deem to be impossible or impracticable. We request comments on the appropriateness of the circumstances we have proposed for waiver of the requirements in § 423.132(c), as well as any additional circumstances we may wish to consider. We note that a similar public disclosure requirement was waived for endorsed discount card sponsors under the Medicare Prescription Drug Discount Card (42 CFR 403 and 408) for covered discount card drugs dispensed under several of the same circumstances as those described above.

In § 423.132(d)(1) of our proposed rule, we propose waiving the requirement that information on differential prices between a covered Part D drug and generic equivalent covered Part D drugs be made available to prescription drug plan and MA–PD plan enrollees at the *point of sale* when prescription drug plan enrollees obtain covered Part D drugs in long-term care pharmacies. Long-term care pharmacies generally provide drugs directly to the skilled nursing facilities and nursing facilities where the patient resides, not directly to the patient, under a medical benefit. They also engage in a significant coordination of benefits effort that would require that at least some claims be processed off-line, and not in real time. Given the manner in which long-term care pharmacies provide prescription drugs to residents of long-

term care facilities, as well as the way in which they process claims, it would be impracticable for these pharmacies to provide beneficiaries with information regarding covered Part D drug price differentials at the point of sale.

Although long-term care network pharmacies would be exempt from the requirement that information about lower-priced generic alternatives be provided at the point of sale, they would not be exempt from the public disclosure requirement in § 423.132(a) altogether. We request comments regarding appropriate standards with regard to the timing of such disclosure by long-term care pharmacies to the institutionalized Part D enrollees they service. We note, as well, that under § 423.132(d)(2) of our proposed rule, we may modify the timing of the public disclosure requirement under such other circumstances as we deem compliance with that requirement to be impossible or impracticable.

8. Privacy, Confidentiality, and Accuracy of Enrollee Records (\$ 423.136)

To the extent that the prescription drug plan offered by a PDP sponsor maintains medical records or other health information regarding Part D enrollees, § 423.136 of our proposed rule would require the PDP sponsor to meet the same requirements regarding confidentiality and accuracy of enrollee records as MA organizations offering MA plans must currently meet under 42 CFR 422.118, according to the stipulations of section 1860D-4(i) of the Act. PDP sponsors would therefore be required to—

- Abide by all Federal and State laws regarding confidentiality and disclosure of medical records or other health and enrollment information, including the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the privacy rule promulgated under HIPAA;
- Ensure that medical information is released only in accordance with applicable Federal or State law;
- Maintain the records and information in an accurate and timely manner; and
- Ensure timely access by enrollees to records and information pertaining to them.

Prescription drug plans would be considered covered entities under the HIPAA Privacy Rule because they meet the definition of “health plan,” as described in 45 CFR 160.103. The HHS Office for Civil Rights (OCR) is responsible for implementing and enforcing the HIPAA Privacy Rule. OCR has authority to investigate complaints,

to conduct compliance reviews, and to impose civil money penalties for HIPAA Privacy Rules violations. Thus, any violations by an endorsed sponsor with respect to its obligations under the Privacy Rule as a covered entity are subject to such enforcement by OCR. OCR maintains a Web site with frequently asked questions and other compliance guidance at <http://hhs.gov/ocr/hipaa>.

D. Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans

1. Overview (§ 423.150)

Subpart D of part 423 implements provisions included in sections 1860D-4(c), 1860D-4(d), 1860D-4(e), 1860D-4(j), and 1860D-21(d)(3) of the Act and sections 102(b) and 109 of Title I of the MMA. This subpart sets forth the following requirements:

- Cost and Utilization Management Programs, Quality Assurance Programs, Medication Therapy Management Programs (MTMP), and Programs to control fraud, abuse, and waste for PDP sponsors and MA Organizations offering MA-PD plans that offer qualified prescription drug coverage;
- CMS consumer satisfaction surveys of PDP and MA-PD plan enrollees.
- Electronic prescription programs.
- Compliance deemed on the basis of accreditation.
- Accreditation organizations.
- Procedures for the approval of accreditation as a basis for deeming compliance.

2. Cost and Utilization Management, Quality Assurance, Medication Therapy Management, and Programs To Control Fraud, Abuse, and Waste (§ 423.153)

Section 423.153(a) of our proposed rule would require each PDP sponsor or MA Organization offering a MA-PD plan that provides qualified prescription drug coverage under a prescription drug plan to establish a cost-effective drug utilization management program, a quality assurance program, a MTMP, and a program to control fraud, abuse, and waste as described in §§ 423.153(b), 423.153(c), 423.153(d), and 423.153(e), respectively.

We have combined these requirements into one section of the proposed regulation because each of these requirements would impact the quality and cost of care provided to beneficiaries. Our intent is to ensure that the prescription drug benefit would be provided using state of the art cost management and quality assurance systems. We also understand the overlapping nature of these

requirements and that provisions under one requirement might complement another requirement. For example, drug utilization management early-refill edits used to prevent stockpiling of medications could also identify potential medication misuse by patients.

Although these requirements are similar in their underlying goals, they can also be quite different. For example, drug utilization management and quality assurance systems are generally considered to be population based, while medication therapy management involves targeted, direct patient care.

While we understand that some members of industry use various quality assurance measures and systems for controlling utilization and reducing medication errors, less information is available regarding medication therapy management. Medication therapy management has been used to describe a broad range of professional activities and responsibilities. We are familiar with state Medicaid programs (for example, Wisconsin, Mississippi) paying for cognitive services as part of their prescription drug benefit, but we have less information about current similar practices in the private sector. Therefore, our regulatory approach for utilization management, quality assurance, and controlling fraud, abuse, and waste will be different than our approach for medication therapy management. We particularly ask for comments on this section of the proposed regulation.

In general, and within the parameters described later in this preamble and in regulation, PDP sponsors and MA Organizations offering MA-PD plans would have flexibility to design drug utilization management programs, quality assurance measures and systems, MTMPs, and programs designed to control fraud, abuse, and waste.

a. Cost Effective Drug Utilization Management

Section 423.153(b) of our proposed rule would require each PDP sponsor or MA Organization offering a MA-PD plan that provides qualified prescription drug coverage under a prescription drug plan to provide a cost-effective drug utilization management program. The program would include incentives to reduce costs when medically appropriate, such as through the use of multiple source drugs as defined in section 1927(k)(7)(A)(i) of the Act. For example, plans could utilize different dispensing fees that would encourage the use of these multiple source drugs as opposed to more expensive single source drugs. This should not be

confused with the practice of "switching" one branded drug product with another similar branded drug product, commonly referred to as "therapeutic substitution." Therapeutic substitution would always require explicit prescriber notification and approval.

We believe that a cost-effective drug utilization management program could also employ the use of prior authorization, step therapy, tiered cost-sharing, and other tools to manage utilization. We are aware that these are tools commonly used today to manage pharmacy benefit costs for many commercial and State programs. We believe that the competitive bidding and premium setting processes, combined with the requirements for transparency and information availability, provide powerful incentives for plans to innovate and adopt the best techniques available. We invite comment on whether there are industry standards for cost effective drug utilization management and whether CMS should adopt any of these standards for PDPs and MA-PDs.

Although we have not included proposed regulations, we are considering for the final rule a requirement that these tools should be under the direction and oversight of a Pharmacy and Therapeutics Committee to ensure an appropriate balance between clinical efficacy and cost effectiveness. We seek comments on this issue. We also seek comments on requiring the direct involvement of a Pharmacy and Therapeutics Committee not only with cost containment measures, but also with other areas of quality assurance and medication therapy management. Again, although we have not included proposed regulations requiring this standard, we are considering this standard for our final rule.

In addition, appropriate drug utilization management programs would have policies and systems in place to assist in preventing overutilization and underutilization of prescribed medications. PDP sponsors and MA Organizations offering MA-PD plans must inform enrollees of program requirements and procedures in order to prevent unintended interruption in drug therapy. For example, enrollees would be made aware of how to proceed if special circumstances require their prescriptions to be refilled before the targeted refill date.

b. Quality Assurance

Section 423.153(c) of our proposed rule would require each PDP sponsor or MA Organization offering a MA-PD

plan that provides qualified prescription drug coverage under a prescription drug plan to provide a quality assurance program. That program would include quality assurance measures and systems for (1) reducing medication errors, (2) reducing adverse drug interactions, and (3) improving medication use.

We are proposing that quality assurance programs include requirements for drug utilization review, patient counseling, and patient information record-keeping. We believe these requirements would generally need to comply with section 4401 of the Omnibus Reconciliation Act of 1990 as codified in 42 CFR 456.705 and section 1927(g)(2)(A) of the Act, and we are considering such specific requirements for the final rule. Although these regulations were written specifically for the Medicaid population, we understand that they describe currently accepted standards for contemporary pharmacy practice and our intent is to require plans to continue to comply with contemporary standards. We solicit comment on whether the Medicaid standards are in fact industry standards, whether they are appropriate standards for part D, and if they are, how they should be adapted for use in part D. Therefore, we have chosen not to add further specification in the regulation text. We also understand that some members of industry use additional quality assurance measures and systems. We invite comments on whether there are industry standards, above and beyond those mentioned above, that we might adopt. Furthermore, PDP sponsors and MA Organizations offering MA-PD plans will be required to have systems and measures established to ensure that network pharmacy providers are complying with their quality assurance requirements. We are requesting comments on the costs and challenges associated with these systems and measures.

The elements that are currently viewed as desirable for quality assurance systems are—(1) electronic prescribing (which will become a requirement in the future as discussed later in this preamble); (2) clinical decision support systems; (3) educational interventions, which could be provided by QIOs or could rely on other mechanisms; (4) bar codes; (5) adverse event reporting systems; and (6) provider and patient education. We do not expect PDPs and MA-PD plans to adopt all of these elements. However, we expect substantial innovation and rapid development of improved quality assurance systems in the new competitive and transparent market

being created by the new Part D benefit. We invite comments on which, if any, elements of a quality assurance system should be contained in our program requirements. We are particularly interested in best practices in quality assurance, costs and benefits associated with each element, the challenges involved in implementing quality assurance measures and systems, types of data useful for reducing medication errors, associated costs and challenges with collecting this data, and how this data could be best communicated to providers and beneficiaries to improve medication use.

We note that the MMA does not define or explain the term "medication error." Nevertheless, we believe a common definition is important. In the future, we may require quality reporting that includes error rates. We could use this information to evaluate plans. In addition, we may publish this information for enrollees to use when comparing and choosing their individual plans. Therefore, we particularly invite comments on how we could evaluate PDPs and MA-PDs based on the types of quality assurance measures and systems they have in place, how error rates can be used to compare and evaluate plans, and how this information could best be provided to beneficiaries to assist them in making their choices among plans.

Medication error reduction programs and requirements have been discussed in many venues and various definitions of "medication error" have been used. For example, in its proposed rule requiring bar codes on most human drug products, the Food and Drug Administration adopted the following definition of a medication error:

Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice; healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. (See 68 FR 12500 (March 14, 2003)).

This definition of "medication error" is identical to that used by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). (See National Coordinating Council for Medication Error Reporting and Prevention, "What is a Medication Error?" (Undated)).

We are citing this definition in this preamble as one that we would use initially in interpretive guidance. We believe that this definition could be

applied to, and include, adverse drug events and interactions as they pertain to quality assurance. As the state of industry practice evolves, we may, from time to time, update this definition by manual issuance. We invite comments on this definition.

c. Medication Therapy Management Programs

Section 1860D–4(c)(1)(C) of the Act requires PDP sponsors and MA organizations offering MA–PD plans to establish a MTMP, and § 423.153(d) would codify that requirement. As stated earlier, neither we, nor many private insurers, have extensive experience requiring or reimbursing for MTMPs. As a result, we seek comments on what requirements and/or guidelines for MTMPs should be formulated in our regulation. In this section of the preamble, we are providing a broad overview of the types of activities that a PDP sponsor or MA organization offering a MA–PD plan could provide as part of a MTMP. We also discuss various options for determining which beneficiaries might qualify as “targeted individuals” and what types of clinicians might provide MTMP services. We plan to conduct further research and seek comments before establishing requirements with respect to MTMPs. We are interested in current MTMP best practices, essential components of MTMPs, and which quality assurance requirements, if any, should be included in MTMPs. We are also interested in measures and information on effective MTMP services that could be publicized and used by beneficiaries who wish to use these services. We are particularly interested in the most effective steps to make valuable, proven MTMP services available to beneficiaries to improve health care quality and reduce costs. We are mindful of the importance of stimulating the evolution of the most appropriate and efficient form of MTMPs, without stifling innovation or prematurely locking-in specific attributes.

The description of a MTMP in section 1860D–4(c)(2) of the Act would allow for plans to establish a broad range of additional services. The purpose of a MTMP is to provide services that will optimize therapeutic outcomes for targeted beneficiaries. Specific services to be provided under a MTMP would be distinct from those required for dispensing medication. Medication therapy management services would be reimbursable when adopted by a plan and only when provided to targeted beneficiaries as defined in § 423.153(2)

of our proposed rule and discussed later in this preamble.

Section 1860D(4)(c)(2)(B) of the Act states that MTMPs may include elements designed to promote (for targeted beneficiaries):

- Enhanced enrollee understanding through beneficiary education counseling, and other means—that promotes the appropriate use of medications and reduces the risk of potentially adverse events associated with the use of medications.
- Increased enrollee adherence to prescription medication regimens (for example, through medication refill reminders, special packaging, and other compliance programs and other appropriate means).
- Detection of adverse drug events and patterns of overuse and underuse of prescription drugs.

In order to promote these elements and optimize therapeutic outcomes for targeted beneficiaries, we envision MTMPs potentially spanning a range of services, from simple to complex. In addition to those mentioned in the statute, services could include, but not be limited to, performing patient health status assessments, formulating prescription drug treatment plans, managing high cost “specialty” medications, evaluating and monitoring patient response to drug therapy, providing education and training, coordinating medication therapy with other care management services, and participating in State-approved collaborative drug therapy management. We would also anticipate that these services could be offered as components of more coordinated disease management programs, but would not expect provision of these services to be limited to such programs.

In addition to MTMPs providing for different types of services, we would also anticipate the need for different levels of service based on the individual requirements of targeted beneficiaries. For example, one beneficiary may require only a fifteen-minute phone consultation, while another would be better served by a one-hour in-person visit with the pharmacist. The level of service should be determined by time and resources required to accommodate the specific needs of the individual beneficiary. Therefore, we would anticipate that a MTMP would include policies and procedures for ensuring targeted beneficiary access to the appropriate types and levels of service offered by the particular PDP or MA–PD plan.

Within this broad framework, we believe that PDP sponsors and MA Organizations offering MA–PD plans

can customize their MTMPs and that a competitive market supported by useful information on MTMP services will provide the best mechanism for establishing optimal MTMPs. We believe that MTMPs can lead to improved overall health for individuals, while at the same time decreasing overall healthcare costs resulting from improper medication use and adverse drug events. We may provide a mechanism for plans to demonstrate the types of services, levels of service, and quality outcomes associated with their MTMPs to further aid beneficiaries with choosing the plan that will best meet their needs.

In addition, as provided in § 423.153(d)(3), a MTMP, as adopted by a plan, would have to be developed in cooperation with licensed practicing pharmacists and physicians.

Beyond these broad parameters for a MTMP, there are several issues to consider as we provide additional guidance to PDP sponsors and MA organizations. First, we consider MTMPs to be administrative activities similar to quality assurance drug utilization review or measures to control fraud, abuse and waste. Like these other quality improvement services intrinsic to the drug plan, MTMP services would not involve direct beneficiary cost-sharing and Part D enrollees would not be required to pay separate fees for these services (although the cost could be reflected in the premium rate). The cost of a MTMP is considered an administrative cost incident to appropriate drug therapy and, therefore, not an additional benefit. Nevertheless, unlike the general quality assurance and fraud, abuse, and waste control requirements, MTMP services can be limited to targeted beneficiaries. To the extent that MTMPs reduce drug spending by more than their costs, they have the potential to lower overall Part D costs. To the extent that MTMP services lower overall medical costs for beneficiaries with chronic illnesses, we also seek comment on how to integrate MTMP services and financial incentives into the Medicare Chronic Care Improvement program (section 721 of the Act).

Second, section 1860D4(c)(2)(A)(ii) of the Act requires that MTMP services be provided only for targeted individuals. In other words, not all members of a plan would be entitled to receive these services. As provided under § 423.153(d)(2), “targeted beneficiaries” would be plan enrollees who have multiple chronic diseases, are taking multiple Part D covered drugs, and are likely to incur annual costs that exceed a certain level that we determine. We

invite comments on how we should provide guidance to drug plans in defining "multiple chronic diseases" and "multiple covered Part D drugs" for the purposes of determining which Part D enrollees would qualify for MTMP services, or whether such determinations are best left to the plans as part of their benefit design.

While the statute states that CMS sets the level of annual costs that must be incurred by a beneficiary to qualify for the receipt of MTMP services, our preferred policy is to delegate this function to the private drug plans, as they would be able to evaluate their patients with greater specificity and information. We request comments on this policy as both a policy and legal matter. We believe that, given current evidence, the level of annual costs that must be incurred by a beneficiary to qualify for the receipt of MTMP services should be determined by the drug plan. We do not think there is sufficient evidence at this point to specify a threshold of annual drug costs to be used for targeting these services to particular Part D enrollees. However, we seek comments on what guidance we could provide to plans to ensure these services are targeted in the most efficient manner and to the most appropriate beneficiaries.

In addition, we are concerned about the method that plans should use to determine the costs that enrollees are "likely to incur" to ascertain whether they qualify as targeted beneficiaries. Once plans have historical data on specific patients, determining how to target such services should become easier and more effective. For example, based on their previous experience with providing prescription drug services, plans could qualify enrollees for MTMP services based on whether the enrollees have multiple chronic diseases and whether they are using multiple drugs. As they develop more experience with their Medicare enrollees, past medication history might become another useful guide.

We believe that plans would benefit from additional guidance on interpreting the level above which a beneficiary's incurred costs would qualify him or her for MTMP services. We invite comments on all the disease, drug, and cost issues that we should consider in further refining the definition of a targeted beneficiary for receipt of MTMP services.

Another issue to be considered relates to which clinicians would be providing MTMP services and the method for providing those services. Section 1860D-4(c)(2)(A)(i) of the Act specifically states that a pharmacist may

furnish MTMP services. While we believe that pharmacists will be the primary providers of these services, MTMPs could also include other qualified health care professionals as providers of services. The individual needs of the targeted beneficiary should determine the appropriate provider and setting for MTMP services. For example, consultant pharmacists will likely provide services to beneficiaries in long-term care facilities; retail pharmacists could provide those same services to ambulatory beneficiaries.

Furthermore, we believe beneficiary choice and on-going beneficiary-provider relationships should play a role in determining the best provider for MTMP services. Improved therapeutic outcomes through MTMP services will frequently require active beneficiary, or caregiver, participation. While population based quality assurance and cost control measures might adequately be served by impersonal telephone services, we believe that telephone services are only one mode of providing medication therapy management services. Active beneficiary participation and consistent delivery of quality MTMP services will require developing and maintaining on-going beneficiary-provider relationships. Therefore, to the extent that these services are adopted by plans in their MTMPs, we would expect the range of services offered to reflect this important component and maximize beneficiary participation by considering beneficiary preference and existing beneficiary-provider relationships in determining the appropriate provider and setting for delivery of MTMP services.

Section 1860D-4(c)(2)(E) of the Act states that in establishing fees for pharmacists or others providing MTMP services, to the extent that these services are adopted by a plan in its MTMP, a PDP sponsor must take into account the resources and time associated with implementing the MTMP. Section 423.153(d)(5) codifies that requirement. We propose to implement this requirement as follows:

(1) First, we would expect potential PDP sponsors to describe, as part of their applications, their plan to consider the resources used and the time required to implement their MTMP in establishing fees for pharmacists and others providing services under the MTMPs.

(2) Second, in the event that we receive complaints that a PDP sponsor is not paying pharmacists or others in accordance with the fees discussed in the application for the MTMP it has elected to adopt, we would investigate further.

While section 1860D-4(c)(2)(E) of the Act specifies that the time and resources necessary to implement the MTMP must be taken into account when establishing fees, it does not specify how these fees should be paid. We believe that fees associated with provision of medication therapy management services are separate and distinct from dispensing fees discussed in section § 423.100 of the preamble for this proposed regulation. Although section 1860D-4(c)(2)(E) of the Act states that PDP sponsors must disclose to the Secretary the amount of "any such management or dispensing fees", it merely governs disclosure and does not require that MTMP be included in the dispensing fee (indeed the Act distinguishes management fees from dispensing fees that are part of individual prescriptions).

Therefore, costs associated with MTMPs, including these management fees, are included as part of the general administrative overhead costs in the plan bid. For purposes of evaluating the administrative component of a PDP's bid, we will ask a PDP sponsor or MA organization to disclose the fees it pays to pharmacists or others, including an explanation of those fees attributable to MTMP services. The fee information provided to us under this authority would be protected under the confidentiality provisions of section 1927(b)(3)(D) of the Act. Under those provisions, we would be prohibited from disclosing the specific fees in a manner that links the fees to the particular pharmacy or other provider providing the MTMP services—except to the extent necessary to administer the Part D program, to permit the Comptroller General to review the information, or to permit the Director of the Congressional Budget Office to review the information. If we were to discover situations in which plans systematically did not pay the fees described in their applications—and, if those errors were not corrected upon notification, we might, at our discretion, employ the broad ranges of intermediate sanctions or termination provisions available under subparts K and O of the regulations.

While we expect to perform the due diligence described above through application review and potentially following up on any complaints we do not believe we have the authority to mandate that PDP sponsors or MA organizations pay pharmacists or other providers a certain amount for MTMP services. We also would not adjudicate any specific disputes between PDP sponsors or MA organizations and pharmacists or other providers

regarding the specific fees due for MTMP services.

Finally, as specified in section 1860D-4(c)(2)(D) of the Act, we are required to establish guidelines that MTMPs operated by PDP sponsors are coordinated with the "chronic care improvement program" (CCIP) under section 1807 of the Act. The CCIP is a new program established by section 721 of the MMA, which added a new section, section 1807, to the Act. The new section 1807 creates a method for us to assist beneficiaries with multiple chronic conditions in managing their care. The program is targeted only to beneficiaries in original fee-for-service Medicare—not beneficiaries enrolled in MA plans. Therefore, we anticipate that our guidelines will be targeted toward PDP sponsors and not to MA organizations that offer MA-PD plans. As stated above, the CCIP is a new program. By statute, the first agreements under that program with chronic care improvement organizations should be entered into within 12 months of the MMA's date of enactment. On April 23, 2004, we published in the **Federal Register** (69 FR 22065-22079), the solicitation for the CCIP program. Because the program has not yet been established, however, we cannot provide a great deal of guidance at this time regarding how the MTMPs under Part D would coordinate with the CCIP. We are concerned with the possibility of beneficiaries receiving duplicative services. We seek comments on how MTMP services provided through CCIP can be effectively coordinated with MTMP services provided by PDPs. There are several different ways that communication could take place so that a beneficiary enrolled in both the CCIP and a PDP receives efficient assistance with managing their chronic diseases. For example, the CCIP might collect information at intake, obtain a beneficiary information release, and inform the PDP of enrollment. An alternate approach is for us to use the enrollment files from the two programs to communicate to the respective parties. We invite comments on this issue and these proposed options. We may provide further interpretive guidance on coordination with the CCIP once the section 1807 agreements are finalized and the new program is in place. We invite comments from interested parties relating to specific key issues that should be addressed in this guidance.

d. Fraud, Abuse and Waste

Section 423.153(e) of our proposed rule would require PDP sponsors and MA Organizations offering MA-PD

plans that provide qualified prescription drug coverage under a prescription drug plan to provide a program to control fraud, abuse, and waste. These requirements overlap to some extent with those in subpart K of this regulation, but cover somewhat different territory.

We would expect these plans, as prudent purchasers, to implement programs to control their expenditures. We would be interested in comments on the following discussion as to possible requirements in this area over and above the incentives operating in at risk plans. We would also like comments on the value added from requiring plans to develop comprehensive performance standards for use in evaluating internal processes that would appropriately and efficiently research, identify, monitor, and take immediate action to mitigate fraud, abuse, and waste. Fraud, abuse, and waste apply not only to both the PDPs and MA-PDs and their staffs, but also to the PBMs, pharmacies, physicians, and other providers that they deal with. For instance, PDPs and MA-PDs need to determine whether or not physicians are illegally prescribing narcotics. In addition to available appropriate data that might be supplied by us, the plans could develop and utilize methods such as data analysis, record audit of PBMs, pharmacies, physicians, and other providers, DUR (note these DURs overlap with those described previously, but these focus on those related to fraud, abuse, and waste), and methods used to consider and resolve disputes related to pharmacies, physicians', and other provider's dissatisfaction to ensure the integrity of all entities (government, beneficiary, PDP sponsor, PBMs, pharmacies, physicians, and other providers).

One area of concern is inappropriate switching of prescriptions by a PDP or MA-PD plan without consulting a prescribing physician. For instance, switching from brand to generic may be appropriate, but switching brands, e.g. Lipitor to Zocor, may not without consultation.

We also seek comments on the appropriateness, value and need for requiring the plans to test program integrity analytic tools for effectiveness, efficiency, and adaptability to the Medicare Benefit environment. For example, one approach could require the plans to provide any of the following in periodic reports: (1) Summary of data analysis activities, (2) resources, (3) tools, or (4) trend analysis. Alternatively, the plans could be required to develop their strategy and propose what each plan determines to

be the best approach for detecting and deterring fraud and abuse. Furthermore, the plans could be asked to demonstrate that the agreed upon activities and outcomes that the plans achieve are in relation to priorities established by us. We seek comments on the likely value of these requirements. We also seek comments on the implementation, scope, and operation of an effective and robust fraud, abuse, and waste control program for plan sponsors.

e. Exception for Private Fee for Service Plans

Section 423.153(f) of our proposed rule would implement section 1860D-421(d)(3) of the Act by exempting private fee-for-service MA plans that offer qualified prescription drug coverage from the requirement to establish a drug utilization management program and a MTMP; however, these private fee-for-service MA plans would still be required to establish a quality assurance program and program to control fraud, abuse and waste as described in § 423.153(c) and § 423.153(e), respectively.

3. Consumer Satisfaction Surveys (§ 423.156)

Under § 423.156, we would conduct consumer satisfaction surveys among enrollees of PDPs and MA Organizations offering MA-PD plans in order to provide comparative information about qualified prescription drug coverage to enrollees as part of our information dissemination efforts. Section 1860D-4(d) of the Act specifies that these surveys be conducted in a manner similar to that in which they are currently conducted under § 422.152(b) (that is, annually) for MA plans by using the Consumer Assessment of Health Plans (CAHPS). We believe a CAHPS-like instrument (or perhaps a modification of CAHPS for MA Organizations offering MA-PD plans) will most likely be the vehicle used to collect this information. As we have done in the past in developing surveys of Medicare beneficiaries in various settings, we will work with the Agency for Healthcare Research and Quality (AHRQ) to develop a survey measuring the experience of beneficiaries with their qualified prescription drug coverage, a sampling strategy, and an implementation strategy. We will provide further information regarding this survey as it is developed.

4. Electronic Prescription Program (§ 423.159)

Section 1860D-4(e) of the Act contains provisions for electronic prescription programs. The statute

contains specific provisions on when voluntary initial standards may be adopted (not later than September 1, 2005), and when final standards should be published (not later than April 1, 2008) and then effective (not later than 1 year after the date of promulgation of final standards).

The statute requires the National Committee on Vital and Health Statistics (NCVHS) to develop recommendations, in consultation with a specific group of constituencies, for possible adoption by the Secretary according to the schedule set forth above. Those constituencies include physicians, hospitals, pharmacists and pharmacies, PBMs, State boards of pharmacy and medicine, Federal agencies and other electronic prescribing experts for uniform standards. The law also requires a pilot project once the Secretary has adopted or announced the initial standards. The pilot will run from January 2006 through December of that year, and it will be completed prior to the promulgation of the final standards. The law further states that a pilot is not needed if there is already adequate industry experience with whatever standards the Secretary is planning to adopt.

To fulfill the statute's responsibilities, the NCVHS' Subcommittee on Standards and Security has already held two public hearings on issues related to e-prescribing. The hearings on March 30 and 31, 2004, and May 25, 26, and 27, 2004 included testimony from e-prescribing networks, providers, software vendors, and industry experts on patient safety and drug knowledge databases. National electronic prescribing studies were also presented. In order to further refine their recommendations to the Secretary, the NCVHS Subcommittee on Standards and Security will continue to hold additional hearings on the state-of-the-art of electronic prescribing including testimony from a broad representation of stakeholders in July, August and September 2004. Readers interested in the NCVHS' hearing schedule for e-prescribing standards, testimony presented at the hearings and standards recommendations should consult the NCVHS Web site at <http://www.ncvhs.hhs.gov/>.

Many in the industry urge us to move expeditiously to establish electronic prescribing standards. However, the statute intentionally provided for a deliberative process by directing the NCVHS to study, select and recommend electronic prescribing standards. Any comments received in response to this proposed rule will be considered along

with the NCVHS' recommendations in the development of the proposed rule on the electronic prescribing standards. We are particularly interested in comments that help us identify consensus or reach consensus on e-prescribing standards ahead of the statutory time frame, and to help us identify and evaluate industry experience based on pilot programs engaged in e-prescribing activities in 2004 and 2005.

To ensure that our regulations are as comprehensive as possible, we have included language at § 423.159(a) that would require PDP sponsors and MA Organizations offering MA-PD plans to have the capacity to support e-prescribing programs in accordance with the final e-prescribing standards established by the Secretary, including any standards that are established before the drug benefit begins in 2006. In addition, once final standards are set, any prescriptions that are transmitted electronically under the Part D drug benefit for Medicare beneficiaries will have to conform to those standards. Aside from PDP and MA-PD plans having the capacity to support final e-prescribing standards, there is, however, no requirement that prescriptions be written or transmitted electronically (by for example physicians or pharmacies). Until e-prescribing standards are effective, of course, our regulations at § 423.159(a) also will not be in effect.

Although there is no requirement that physicians write prescriptions electronically, our regulations state that PDP sponsors and MA Organizations offering MA-PD plans who participate in the Part D program must be able to support the final e-prescribing program as specified in section 1860D-4(e)(2) of the Act. The statutory language is quite specific that e-prescribing will not just be used for a physician to send a prescription to a pharmacy, but also will transmit data that can only be supported by the PDP sponsor or MA organization offering an MA-PD plan. For example, the e-prescribing program is intended to ensure that pharmacies receive electronic information on the drugs included on the PDP's or MA-PD's formulary, any tiering of the formulary, the patient's medical history, the possibility of any adverse drug-interactions (based on other prescriptions the patient is already taking) and the availability of lower-priced, alternative prescriptions. Since the PDP sponsor or MA organization offering an MA-PD plan will most likely be the warehouse for all this information, without participation of the PDP sponsors or MA Organizations offering MA-PD plans, the e-prescribing

program would not be able to provide the results the Congress intended. In addition, if plans do not have this program, beneficiaries participating in those plans would not benefit from the patient safety aspects of the program. Also, under section 1860D-12(b)(3)(D) of the Act, we have the authority to add additional contract terms to the PDP and MA-PD contracts.

While PDP sponsors and MA Organizations offering MA-PD plans will be required to support the final e-prescribing standards issued by us, they will not be required to support the pilot standards, which are voluntary under section 1860D 4(e)(4)(C) of the Act. Therefore, only those entities that participate in a pilot testing of certain e-prescribing standards will be required to implement an e-prescribing program using the initial standards adopted by the Secretary. Others in the health care industry will not be required to use the initial standards at the time they are issued, but will be encouraged to do so.

Finally, we note that the pilot test specified in the MMA is not required if there is adequate industry experience with the standards. In that case, the Secretary may propose them as final standards in a proposed rule, thereby expediting a portion of the standards adoptions process. Therefore, to the extent we determine, after consultation with affected standard setting organizations and industry users, that there already is adequate industry experience with certain standards, we may propose to finalize those standards through notice and comment rulemaking even if we have not completed the pilot testing of other standards so that a portion of the standards adoptions process could be expedited. We seek comments on the desirability of this strategy, including any concerns about potential unintended consequences.

In order to facilitate electronic prescribing by a PDP or MA-PD sponsor, we invite public comment on additional steps to spur adoption of electronic prescribing, overcome implementation challenges, and improve Medicare operations. For example, we have added regulations at § 423.159(b) of this proposed rule that would allow an MA-PD plan to provide a separate or differential payment to a participating physician who prescribes covered Part D drugs in accordance with electronic prescription standards. (Note that this provision only applies to MA-PD plans and not to PDPs.) Section 102(b) of the MMA makes it clear that this differential payment may occur when a participating physician prescribes drugs in accordance with an

electronic prescription drug program that meets standards established under section 1860D-4(e) of the Act. These differential payments are to reward physicians for using electronic prescriptions rather than handwritten ones. These payments would not be used to encourage physicians to prescribe more frequently or inappropriately steer their use of particular drugs. Since the standards established under section 1860D-4(e) of the Act include the initial, voluntary standards, which may be tested on a pilot basis as early as January 1, 2006, we believe the differential payments envisioned by section 102 of the MMA may occur as early as January 1, 2006 (for physicians who prescribe in accordance with the standards adopted by the Secretary in September 2005). We believe the fact that section 102 of MMA has an effective date of January 1, 2006, supports this determination. Differential payments, at the MA organization's discretion, could take into consideration the cost to the physician in implementing the program and could be increased for participating physicians who use e-prescribing to significantly increase—

- (1) Formulary compliance where medically appropriate;
- (2) Use of lower cost, therapeutically equivalent alternatives;
- (3) Reductions in adverse drug interactions as evidenced by appropriate use of drug interaction checking functions in electronic prescribing; and
- (4) Efficiencies in filling and refilling prescriptions through reduced administrative costs.

The additional or increased payments made to the physicians could be structured in the same manner as fees for services under § 423.153(d) of this proposed rule. We have not provided a great deal of specificity in our regulations regarding how the differential payments may be structured because we believe the MA Organizations offering MA-PD plans should have discretion in structuring these added payments, if any.

We note that any payments must be in compliance with other Federal and State laws, including "the physician self-referral prohibition at section 1877 of the Act" and the Federal anti-kickback provisions at section 1128B(b) of the Act. We are soliciting the public's view of the application of these legal authorities to the differential payments described in this section. We will share any comments regarding the anti-kickback statute with the Office of Inspector General.

We also seek comment on measures of MA-PD plan quality related to the use

of e-prescribing, and other MA-PD quality measures that reflect effective e-prescribing systems. The use of electronic prescribing shows promise for improving Medicare operations by reducing costs in the administration of the Part D drug benefit and in the use of prescription drugs, for example promoting generic drug use and creating timely interface with formularies supported by up-to-date evidence. Likewise, it has the potential to improve the quality of the care provided to Medicare beneficiaries through the therapeutic monitoring of allergies and adverse events. Yet, implementing electronic prescribing effectively poses a number of challenges. While electronic prescribing is gradually gaining acceptance by health care providers, fewer than 10 percent of U.S. doctors currently engage in the practice. The adoption rate is particularly low among solo practitioners, those in rural areas, and certain medical specialties. The electronic prescribing process and the technology that enables it must be cost effective, the systems must be fast and easy to use, and alerts and other data passed back to the prescriber must demonstrate value. We invite comments on these challenges and on possible Federal activities that would promote the effective use of e-prescribing by providers, including publishing best practices, and making technical information on e-prescribing products available. In addition receptivity to the use of electronic prescribing by consumers is not well understood especially among the elderly and disadvantaged populations. We seek additional information on how those populations may view electronic prescribing and what step may be taken to get them to use this modality and, thus, take advantage of the safety and quality benefits it offers.

We also invite comments on how to promote the use of electronic prescribing by providers, health plans and pharmacies and other entities involved in the provision and payment of health care to Medicare beneficiaries. Beyond the grants authorized in § 423.159(b) of this proposed rule, we invite comments on what incentives could be used to spur more widespread adoption, especially for early implementers. We also invite your comments on what educational efforts or data analyses might be undertaken to help health practitioners understand, or empirically confirm, and ultimately realize, the benefits of electronic prescribing. Lastly, we seek public input on the ways electronic prescribing can further reduce costs to the Medicare

program and promote quality of care to beneficiaries.

5. Quality Improvement Organizations (QIO) Activities (§ 423.162)

Section 109 of the MMA expands the work of QIOs to include Part C and Part D. This provision explicitly covers the full range of Part C organizations. QIOs are required to offer providers, practitioners, MA organizations, and PDP sponsors quality improvement assistance pertaining to health care services, including those related to prescription drug therapy. We plan to issue guidance on how QIOs can provide this assistance and would coordinate the activities of the QIOs with the quality related activities of other stakeholders.

To fulfill this responsibility, QIOs would need access to data from the transactions between pharmacies and PDPs and MA-PD plans providing the Part D benefit. This data would be extracted from the claims data submitted to us. Although the agency is still developing plans for the QIO activities related to the Part D benefit, we expect that this data primarily from the NCPDP telecommunications format between pharmacies and plans will be used. The data would include payment-related information (that is, plan identification, beneficiary HIC, date prescription filled, NDC, quantity dispensed, ingredient cost, dispensing fee, and pharmacy zipcode) and additional items such as prescriber identifiers, pharmacy identifiers, dose, days supply, and other dispensing information. Potentially, the information gathered will be aggregated in our data warehouse, and then distributed to QIOs to fulfill their requirements for quality improvement as specified in their contracts and in response to requests.

We have been consulting, on an individual, organization by organization basis, with representatives from pharmacy benefit managers, managed care organizations, programs that have monitored drug utilization, and others who have utilized pharmacy claims data. We welcome comments related to the collection and use of information for providing quality improvement assistance related to Part D.

We are proposing that any information collected by the QIOs would be subject to confidentiality requirements in Part 480 of our regulations. For purposes of applying these confidentiality regulations, we are also proposing that MA organizations offering MA-PD plans and PDP sponsors fall within the definition of health care facilities. This means that

the confidentiality provisions in Part 480 of our regulations would apply to PDP sponsors and MA-PD plans in the same manner as they apply to institutions.

6. Treatment of Accreditation (\$ 423.165, § 423.168, and § 423.171)

Section 1860D-4(j) of the Act requires that the provisions of section 1852(e)(4) of the Act relating to the treatment of accreditation will apply to PDP sponsors with respect to—(1) access to covered Part D drugs including the pharmacy access requirements and the use of standardized technology and formulary requirements; (2) quality assurance, drug utilization review, medication therapy management, and a program to control fraud, abuse and waste; and (3) confidentiality and accuracy of enrollee records. Thus, the requirements in § 423.165, § 423.168, and § 423.171 are similar to the requirements found in § 422.156, § 422.157, and § 422.158 for the MA program, except for subject areas that are deemed.

A PDP sponsor may be deemed to meet the requirements that relate to access to covered Part D drugs; quality assurance, drug utilization review, medication therapy management, and a program to control fraud, abuse, and waste; and confidentiality and accuracy of enrollee records, if it is accredited and periodically reaccredited by a private national accrediting organization under a process that we have determined meets a process and standards that are no less stringent than our applicable requirements. National accreditation organizations are those entities that offer accreditation services that are available in every State to every organization wishing to obtain accreditation status. The process that we would use to deem compliance with PDP requirements would mirror the process used for deeming compliance with fee-for-service requirements and the MA program.

Section 423.165 would provide the conditions under which a PDP sponsor may be deemed to meet our requirements permitted under paragraph (b) of this section. The first condition would be that the PDP plan be fully accredited (and periodically reaccredited) by a private, national accreditation organization that we approve. The second condition would be that the PDP organization be accredited using the standards that we approved for the purposes of assessing the PDP sponsors' compliance with Medicare requirements.

Consistent with our approach in the MA program, we would analyze on a

standard-by-standard basis whether an accreditation organization applies and enforces requirements no less stringent than those in part 422 with respect to the standard at issue. We would determine the scope of the accreditation organization's approval (and, thus, the extent to which PDP organizations accredited by the organization are deemed to meet our requirements) based on a comparison of the accreditation organization's standards and its procedures for assessing compliance with our deemable requirements and our own decision-making standards. We would make those determinations on the basis of the application materials submitted by accreditation organizations seeking our approval in accordance with § 423.168. We would also conduct surveys to validate the accreditation organization's enforcement on a standard-by-standard basis.

Section 423.165(d) would establish the obligations of deemed PDP sponsors. A PDP sponsor would have to submit to our surveys that are intended to validate an accreditation organization's process and authorize the accrediting organization to release to us a copy of its most current accreditation survey, together with any information related to the survey that we may require (including corrective action plans and summaries of our unmet requirements). These activities are part of our ongoing oversight strategy for ensuring that the accreditation organization applies and enforces its accreditation standards in a manner comparable to ours.

Section 423.165(e) would address removal of deemed status. We would remove part or all of a PDP sponsor's deemed status if—

(1) We determine, on the basis of our own survey or the results of the accreditation survey, that the PDP organization does not meet the Medicare requirements for which deemed status was granted.

(2) We withdraw our approval of the accreditation organization that accredited the PDP organization; or

(3) The PDP fails to meet the requirements of § 423.165(d).

Section 423.165(f), would explain that we retain the authority to initiate enforcement action against any PDP sponsor that we determine, on the basis of our own survey or the results of the accreditation survey, no longer meets the Medicare requirements for which deemed status was granted. We expect the accreditation organization to have a system in place for enforcing compliance with our standards (such as sanctions for motivating correction of deficiencies), but we cannot delegate to

the accreditation organization the authority to impose the intermediate sanctions established by section 1860D-12 of the Act or termination of the PDP contract.

Deeming applies only to our enforcement of this regulation, and neither our enforcement of this regulation nor accreditation by an accrediting body undercuts the Office for Civil Rights enforcement of the HIPAA privacy rule.

Section 423.168 would discuss the 3 conditions for our approval of an accreditation organization. We could approve an accreditation organization if the organization applies and enforces standards for PDP sponsors that are at least as stringent as Medicare requirements and, if the organization complies with the application and reapplication procedures proposed in § 423.171.

Section 423.168(c) of our proposed rule would establish ongoing accreditation organization responsibilities. These responsibilities largely parallel those currently imposed upon accreditors under original Medicare. One exception is the proposed requirement that an accreditation organization notify us in writing within 3 days of identifying, with respect to an accredited PDP sponsor, a deficiency that poses immediate jeopardy to the PDP sponsor's enrollees or to the general public.

Section 423.168(d) of our proposed rule would establish specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization. Oversight consists of equivalency review, validation review, and onsite observation.

We could withdraw our approval of an accreditation organization at any time if we determine that deeming based on accreditation no longer guarantees that the PDP organization meets the Medicare requirements, that failure to meet those requirements could jeopardize the health or safety of Medicare enrollees or constitute a significant hazard to the public health, or that the accreditation organization has failed to meet its obligations under § 423.165 through § 423.171.

Section 423.171 of our proposed rule would address the procedures for approval of accreditation as a basis for deeming compliance. As mentioned, the process that we would use to deem compliance with PDP requirements is virtually identical to the process that is being used for deeming compliance with fee-for-service requirements. One proposed requirement that would

appear in § 423.171, and which also appears in regulations governing MA plans at § 422.158(a)(11), but does not appear in regulations governing original Medicare, is the requirement that an accreditation organization applying for approval of deemed authority submit the name and address of each person with an ownership or control interest in the accreditation organization. This information would be used to determine whether the accreditation organization is controlled by the organizations it accredits for the purposes of § 423.168. Section 423.171 would further provide for reconsideration of adverse determinations of accreditation applications.

F. Submission of Bids and Monthly Beneficiary Premiums: Determining Actuarial Valuation

1. Overview

Subpart F would implement most of the provisions in sections 1860D–11 and 1860D–13 of the Act, as well as sections 1860D–12(b)(2) (on limitation on entities offering fallback plans), 1860D–15(c)(2) (on geographic adjustment of the national average monthly bid amount), 1860D–21(d) (on special rules for private fee-for-service (PFFS) plans), 1860D–21(e)(3) (on cost contractors), and 1860D–21(f)(3) (on PACE) of the Act. In this section we address submission, review, negotiation, and approval of bids for prescription drug plans and MA–PD plans; the calculation of the national average bid amount; and determination and collection of enrollee premiums. References to 42 CFR part 422 of our regulations are to the new MA rules.

As discussed in subpart C, the statute provides a framework for the provision of subsidized prescription drug coverage. Within this framework, PDP sponsors and MA organizations have some flexibility to design coverage that is different from defined standard coverage to meet the needs of Part D–eligible Medicare beneficiaries. This framework plays a critical role in bid submissions, and the actuarial evaluation and approval of bids.

As part of our discussion we specify the actuarial equivalency tests plan sponsors would have to meet when offering coverage other than defined standard coverage. Please note that the coverage definitions are discussed in detail in subpart C of the preamble. In order to determine actuarial equivalency, plan sponsors would compare their plans to the defined standard coverage baseline to assess the various tests of actuarial equivalency

that we discuss in detail in the sections below.

2. Requirements for Submission of Bids and Related Information

As provided under section 1860D–11(b) of the Act, each applicant to become a PDP sponsor or MA organization would be required to submit a bid for prescription drug coverage for each plan it intends to offer. Most bids would be expected to represent *full risk plans*, meaning that the prescription drug plan is not a limited risk plan or a fallback prescription drug plan, and is not asking for any modification of the statutory risk sharing arrangements. A bid from a full risk plan may be referred to as a full risk bid. PDP sponsors may choose to participate as *limited risk plans*, meaning that they provide basic prescription drug coverage and request a modification of risk level (as described in § 423.265(d)) in its bid submitted for the plan. A bid with a modified level of risk is referred to as a limited risk bid. This term does not include a fallback prescription drug plan. A risk bid (whether full risk or limited risk) could not be accepted from any entity applying to become a PDP sponsor or MA organization offering an MA–PD plan that—(1) also submits a bid for the same year to act as a fallback plan; (2) will be offering a fallback plan in any region for the upcoming year; or (3) currently offers a fallback plan in the region for which they are submitting the bid. In determining whether an entity is barred from submitting a risk bid according to these rules, we would use, as our reference point, the calendar year that they are submitting their bids. For example, the limitation would work as follows:

An applicant submitting a risk bid for sponsoring a PDP in 2009 would be excluded from the risk bidding if—it

(1) Also submits a bid to act as a fallback plan in 2009 (where 2009 is the first year of a multi-year fallback contract);

(2) Already is approved to act as a fallback in any PDP region for 2009; or

(3) Offers a fallback in 2008 for the same region for which they would be submitting their 2009 risk bid.

This fallback prohibition also applies if an applicant (or related entity) acted as, or will act as a subcontractor to an entity offering a fallback plan. In other words, an entity would be treated as having submitted a bid under the fallback contracting process, and thus not be an eligible risk bidder, if that entity was acting as a subcontractor for an integral part of the drug benefit management activities of an eligible

fallback entity. Thus, for example, if an applicant was a subcontractor to a fallback in 2008, it cannot submit a risk bid for the same region for 2009.

Similarly, an applicant for a 2009 risk bid cannot include as its subcontractor an entity already approved or applying to act as a fallback plan for 2009. Because awards for 2006 will not be known at the time the initial bids are due in 2005 (for contracts in 2006), any entity that bids as a fallback plan (or a subcontractor to a fallback plan) is barred from bidding as a non-fallback plan in any and all regions for that year.

Bids would be due to us no later than the first Monday in June for each plan to be offered in the subsequent calendar year. This date stems from the requirement in section 1860D–11(b) of the Act that bid data from potential PDP sponsors be submitted at the same time and in a similar manner as the information described in section 1854(a)(6) of the Act for MA plans. Since section 1854(a)(1) of the Act requires initial data to be submitted on the first Monday of June of each year after 2004, we have also incorporated this date into our regulations. In the case of MA–PD plans, the prescription drug bid would be a component of the unified MA bid described in § 422.254(b)(1) with benefits beyond basic coverage (if any) incorporated into the supplemental benefits portion of the prescription drug benefit bid.

We are clarifying that this bid would represent the expected monthly average cost (including reasonable administrative costs) to be incurred by the plan applicant for qualified prescription drug coverage in the applicable area for a Part D eligible individual with a national average risk profile for the factors described in section 1860D–15(c)(1)(A) of the Act and in § 423.329(b)(1) of this proposed rule. We plan to develop and publish the risk adjustment factors and identify the characteristics of an average individual no later than the date of the 45-day notice for the announcement of 2006 rates, which is February 18, 2005. Any modifications to these characteristics for subsequent years would be announced by the date of the annual 45-day notice. (For further discussion of prescription drug risk adjustment, see Subpart G of this preamble.) We are interested in providing information to potential bidders to help eliminate the uncertainty of drug trend for Medicare beneficiaries and in delaying the submission of pricing information as long as we can under the law and consistent with our need to inform beneficiaries. We solicit comment on

the nature of any additional information needed to prepare bids and suggestions for any other methods that the bid submission process could be structured to provide for later pricing data submission.

The costs represented in each plan bid should be those for which the plan would actually be responsible. Given the structure of qualified prescription drug coverage, these costs would not include payments made by the enrollee for deductible, coinsurance (including 100 percent coinsurance between the initial coverage limit and the out-of-pocket threshold), copayments, or payments for the difference between a plan's allowance and an out-of-network pharmacy's usual and customary charge (as discussed in § 423.124(b)). It also does not include costs reimbursed by us through the reinsurance subsidy. However, we require the separate identification, calculation, and reporting of costs assumed to be reimbursed by us through reinsurance. For standard coverage, defined or actuarial equivalent, these costs would include the plan's share of costs above the deductible and up to the initial coverage limit, as well as the plan's share of costs above the annual out-of-pocket limit. If enhanced alternative coverage is provided, the plan costs for supplemental benefits would be distinguished from those for basic coverage. The costs attributable only to basic coverage, once approved, are known as the standardized bid amount.

In § 423.265(c) we would require that, with the exception of potential employer group waivers under section 1860D-22(b) and 1857(i) of the Act, late enrollment penalties and low-income premium and cost sharing subsidies, the bid represents a uniform benefit package based upon a uniform level of premium and cost sharing among all beneficiaries enrolled in the plan. This means that all enrollees in a given PDP or MA-PD plan would be subject to the same cost sharing structure and would be charged the same premium for benefits the PDP sponsor or MA organization chose to offer.

We note that while benefits are required to be uniform for all enrollees under the drug benefit, this is not the case for enrollees under a prescription drug discount card program. To avoid any confusion between these related programs, we would like to make this distinction clear. Because of the limited low-income assistance under the card program, card sponsors have been permitted to negotiate lower prices for low-income members. Also, in some cases there may be reduced cost sharing sponsored by manufacturers for low-

income members after the \$600 in transitional assistance is used that does not apply to other card members. Under the Part D prescription drug program, however, both the negotiated prices and the benefit structure would be the same for all enrollees in a given PDP or MA-PD plan. While the low-income subsidies will result in low-income beneficiaries' actual out-of-pocket costs being lower than for beneficiaries who do not qualify for this assistance, the benefit structure to which the subsidies apply is the same for all enrollees in a plan.

3. General CMS Guidelines for Actuarial Valuation of Prescription Drug Coverage

As directed by section 1860D-11(c) of the Act, we would develop processes and methods using generally accepted actuarial principles and methodologies for determining the actuarial valuation of prescription drug coverage. Although we plan to provide additional information in the future in the form of interpretive guidance on these processes, we are currently considering the following processes and methods for calculating "actuarial valuation" and "actuarial equivalence" in the context of risk bids:

- Sponsors offering standard coverage with cost-sharing variants either to the 25 percent coinsurance (before the initial coverage limit) or the greater of 5 percent coinsurance or \$2 generic/preferred/\$5 any other drug (after the out-of-pocket threshold is met) would be required to demonstrate the actuarial equivalence of their variations.

- + Sponsors offering basic or enhanced alternative prescription drug coverage would be required to demonstrate that—

- + The actuarial value of total or gross plan coverage is at least equal to the actuarial value of total or gross coverage of the defined standard benefit.

- + The actuarial value of total coverage of their alternative is at least equal to the actuarial value of defined standard coverage;

- + The actuarial value of unsubsidized coverage of their alternative is at least equal to the actuarial value of the unsubsidized portion of defined standard coverage; and

- + The plan payout at the dollar value of the initial coverage limit under standard coverage, for individuals whose total spending exceeds that limit, is at least equal to that provided under defined standard coverage.

- All sponsors would determine the actuarial value of the defined standard benefit, either because it is—

- + Offered to the beneficiaries;

- + Used as a comparison for either of the following:

- Standard coverage with actuarially equivalent cost-sharing variants.

- Alternative coverage; or

- + Used to determine the basic component in enhanced alternative coverage.

- Sponsors that offer enhanced alternative coverage would also be required to determine the actuarial value of coverage beyond basic coverage.

- We anticipate that we would specify data sources, methodologies, assumptions, and other techniques in accordance with generally accepted actuarial principles as either recommended or required in further guidance. We would also specify the data elements (including format) to be sent to us for evaluation. We would then evaluate the analysis and assumptions for compliance and reasonableness. For example, we would evaluate the source, size, and timeframe of data on which assumptions are based, the demographic characteristics of enrollees, the distribution of risk levels, the average costs in each cost-sharing tier, and the update factors used, among other considerations.

- We would also have reported and separately identified administrative costs. Since the level of the bid will directly affect the premium paid by the beneficiary and the attractiveness of the plan, we expect that plans will have a strong incentive to keep administrative costs and return on investment at reasonable levels. Any review of administrative costs would likely focus primarily on outliers from the competitive range identified in the bids received. All proposals would contain a description of how certain costs (those related to appeals that result in payment for non-formulary drugs) are included in the calculations. Processes and methods for determining actuarial valuation would take into account the effect that providing actuarially equivalent standard coverage or alternative prescription drug coverage (rather than defined standard coverage) has on drug utilization. This includes utilization effects attributable to different benefit structures, such as from tiered cost sharing, as well as those attributable to supplemental benefits. The utilization effect of supplemental benefits on basic benefits would have to be loaded into the supplemental portion of the bid. In other words, since the existence of supplemental coverage would increase total average per capita spending, that increase over the average spending (if coverage were limited to basic coverage) would be included in the portion of the

bid attributable to supplemental coverage. Section 1860D–11(c)(1)(D) of the Act specifies “the use of generally accepted actuarial principles and methodologies.” We are interpreting this to require that a qualified actuary certify the plan’s actuarial valuation (which may be prepared by others under his or her direction or review). Actuarial certification would give better assurance that the actuarial values in the bid were prepared in conformance with actuarial standards and methodologies.

- Section 1860D–11(c)(3)(B) of the Act specifies that PDP sponsors or MA organizations offering MA–PD plans may use qualified independent actuaries in certifying the actuarial values in their bids. (The actuarial valuation may be prepared by others under the direction or review of a qualified actuary). We interpret this provision as encouraging PDP sponsors and MA organizations that do not employ qualified actuaries, to use outside actuaries in their processes. We propose to specify that a qualified actuary is an individual who is a member of the American Academy of Actuaries because members of the Academy must meet not only educational and experience requirements, but also a code of professional conduct and standards of practice. These standards create a common ground for actuarial analysis. Furthermore, a member of the Academy is subject to its disciplinary action for violations of the code and standards. This same requirement is specified in the SCHIP legislation at section 2103(c)(4)(A) of the Act. Moreover, the National Association of Insurance Commissioners (NAIC) imposes significantly stricter requirements on actuaries preparing the financial statements of insurance companies.

4. Determining Actuarial Equivalency for Variants of Standard Coverage and for Alternative Coverage

When considering the specific requirements for actuarial equivalence and valuation in the Act, we are aware that there is no official definition of actuarial equivalence. Moreover, the concept of actuarial equivalence is applied in multiple contexts. We must address actuarial equivalence requirements regarding cost sharing, expected benefits, and bid submissions. We plan to address the application of actuarial equivalence within these separate contexts in this discussion and in separate detailed guidance to the industry. Thus, we plan to use interpretive guidance to further explain the process and methodology for determining actuarial equivalence and valuation. The processes and methods

for determining actuarial equivalence and valuation would be in keeping with generally accepted actuarial principles. We would require prospective PDP sponsors and MA organizations wishing to offer MA–PD plans to include all of the requirements discussed in the following sections in the information submitted with the bid, when applicable. The MMA contains some specific requirements for actuarial equivalence or valuation. These actuarial equivalence tests are discussed below.

a. Actuarial Equivalence as Applied to Actuarially Equivalent Standard Coverage—Cost-Sharing

As required in section 1860D–2(b)(2)(A) of the Act, standard prescription drug coverage must have “coinsurance for costs above the annual deductible * * * and up to the initial coverage limit that is equal to 25 percent; or is actuarially equivalent * * * to an average expected payment of 25 percent of such costs.” We interpret this to mean that sponsors would be required to demonstrate that the actuarial value of their alternative cost-sharing as a percent of the actuarial value of both cost-sharing and plan payments for claims up to the initial coverage limit is the same percentage as for 25 percent coinsurance under defined standard coverage. In calculating these percentages, sponsors would reflect the utilization impacts of the two structures, but hold constant formulary (drug list), drug pricing (except to the extent that the plan incorporated differential pricing and cost sharing based on participation status within the plan’s network), and the group whose utilization is modeled. This would allow plans to have variable co-payments or coinsurance, including tiered structures for preferred and non-preferred drugs, in the initial coverage interval as long as the actuarial equivalence test is met. As a simple example, a plan could have a tiered coinsurance benefit with coinsurance higher than 25 percent for brand name drugs and lower than 25 percent for generics. Some beneficiaries with expenses between the deductible and the initial coverage limit would be expected to pay more than 25 percent, and others to pay less, depending on their usage of brand versus generic drugs. Overall, however, the total coinsurance would have to be actuarially equivalent to an average of 25 percent for all beneficiaries with expenses in this interval, even if the total expenditures beneath the initial coverage limit (\$2,250 in 2006) are lower than would be expected under

defined standard coverage (due to increased use of generics, for example).

If sponsors wanted to provide a variant on defined standard cost sharing after the out-of-pocket threshold is met, an actuarial test similar to that described above for variants on the 25 percent coinsurance would apply. In this case, based on the group of individuals projected to exceed the out-of-pocket threshold, the sponsor would compute total cost sharing once the true out-of-pocket (TROOP) threshold has been met as a percentage of the sum of that cost sharing plus the comparable plan payout. This percentage would have to equal the percentage computed in the same manner using the defined standard benefit (that is, the greater of \$2/\$5 or 5 percent). We note that any variant in cost sharing could not lead to discrimination against certain beneficiaries, for example, by increasing the cost sharing of a drug used for a particular illness well above the cost sharing for other drugs.

b. Tests for Alternative Coverage

As required by section 1860D–2(c) of the Act, sponsors offering alternative coverage, that is, benefit structures different from standard coverage, must satisfy five tests (three of the five are actuarial equivalency tests). As discussed in Subpart C, alternative coverage would include coverage actuarially equivalent to defined standard coverage (basic alternative coverage) or coverage that would include supplemental coverage (enhanced alternative coverage). All alternative coverage would have to meet all five of the coverage standards or tests discussed in section b.1–5 of this preamble. Tests one through three were established by the Congress to assure that alternative coverage would be at least actuarially equivalent to standard coverage. Tests four and five are additional tests imposed by the Congress through section 1860D–2(c) of the Act.

1. Test for Assuring at Least Equivalent Value of Total Coverage

As required in section 1860D–2(c)(1)(A) of the Act, a plan could offer alternative prescription drug coverage as long as the actuarial value of total or gross coverage is at least equal to total or gross coverage provided under standard coverage. Based on a typical distribution of enrollee utilization, the average plan payout (including costs reimbursed by Medicare through the reinsurance subsidy) would have to be at least equal to the sponsor’s estimate of the payout under defined standard coverage (holding various factors

constant as described above under section 4.a.).

Alternative benefit structures, such as a decrease in the deductible with an increase in coinsurance below the initial coverage limit, or a lower initial coverage limit with a corresponding decrease in coinsurance, or a lower initial coverage limit with a corresponding decrease in deductible, could be accommodated as basic alternative coverage as long as the actuarial value of this coverage equaled that of defined standard coverage. Alternative structures could not increase the deductible or provide less than the protection offered against high out-of-pocket expenditures described in section 1860D-2(b)(4) of the Act. To the extent that the alternative coverage exceeds the value of defined standard coverage, the plan would be offering enhanced alternative coverage, that is, alternative coverage that includes supplemental benefits (as discussed in subpart C).

2. Test for Assuring Equivalent Unsubsidized Value of Coverage

In section 1860D-2(c)(1)(B) of Act, a plan could offer alternative coverage as long as the unsubsidized value of coverage (the value of the coverage exceeding subsidy payments) is at least equal to the sponsor's estimate of unsubsidized value under defined standard coverage (holding various factors constant as described above section 4.a.). We interpret the unsubsidized value of coverage to mean the value of the benefit attributable to the beneficiary share of the premium.

There is a basic question about how this test could be applied during the plan review and approval process. In order to determine the unsubsidized value of coverage, one would have to know the projected reinsurance payments, and the value of the direct subsidy. While the projected reinsurance payments would be known at the time of the submission (since the actuarial value of the benefit is reduced by projected reinsurance payments to produce the bid), the value of the direct subsidy would not be known (since it would require computing the national weighted average bid and bids have not yet been approved). In the face of this problem, one approach could be to remove reinsurance payments as estimated by the sponsor and to use an estimate of the direct subsidy that we would provide. For instance, in the first year we might provide the estimate used for budgeting purposes, and in subsequent years, an estimate based on prior years' actual experience updated

for trend. We are requesting comments on this approach.

In trying to assess the impact of the test of total value (section 1860D-2(c)(1)(A) of the Act) and the test of unsubsidized value (section 1860D-2(c)(1)(B) of the Act), we have been unable to identify an example of a plan meeting the first test but not the second. We are seeking comment with regard to this question.

3. Test for Assuring Standard Payment for Costs at Initial Coverage Limit

Under section 1860D-2(c)(1)(C) of the Act, sponsors are to determine the average payout "with respect to costs incurred that are *equal* to the initial coverage limit" for "an actuarially representative pattern of utilization." This projected payout is compared to a dollar amount that is equal to what defined standard coverage would pay for someone with costs equal to the initial coverage limit. Given the comparison, this raises the question of what represents "an actuarially representative pattern of utilization." As with the other tests, we believe that it would be reasonable for plans to use either anticipated plan utilization or a typical utilization pattern based on the Medicare population. However, given the implicit comparison to payout under defined standard for someone with costs equal to the initial coverage limit, it would not be valid to include individuals with expenses below the value of the initial coverage limit. After excluding individuals with total expenses below the value of the initial coverage limit, the plan would compute the actuarial value of plan payout at the point where total expenses are equal to the initial coverage limit under standard coverage. Under this interpretation, a plan could offer alternative coverage as long as the coverage is designed to provide an actuarial value of plan payout that is equal to at least 75 percent of costs between the standard deductible and initial coverage limit (\$1,500 in 2006). In other words, considering only plan enrollees with expected expenses greater than or equal to the dollar value of the standard initial coverage limit, the plan would have to demonstrate that the expected plan payout associated with expenses equal to that dollar value would be at least 75 percent of benefit costs between the deductible and initial coverage limit (75 percent of \$2,000 per beneficiary in CY 2006) including taking into account their expected behavioral response to the different benefit structure. This test, combined with the prohibition on increasing the deductible under alternative coverage (described below),

would ensure that the benefit below the dollar level of the standard initial coverage limit is always actuarially equivalent to standard coverage. As a defined standard benefit it is not permissible to trade off benefits above the initial coverage limit for benefits below.

4. Test for Assuring the Deductible Does not Exceed the Standard Deductible.

In keeping with the requirements of section 1860D-2(c)(2) of the Act, alternative coverage could not be structured so that the deductible is any higher than what it is in standard coverage (\$250 in 2006).

5. Test for Assuring the Same Protection Against High Out-of-Pocket Costs

As specified by section 1860D-2(c)(3) of the Act, any alternative coverage must provide "the coverage" specified for costs above the catastrophic limit in standard coverage. We interpret this to mean that both enhanced and basic alternative coverage would have to offer at least the coverage available above the catastrophic limit through defined standard coverage. We would apply this test in the same way that we do for standard coverage with a variant of cost sharing above the catastrophic limit. That is, examining the group of individuals the sponsor projects would exceed the out-of-pocket threshold, total cost sharing once TROOP has been met, as a percentage of the sum of such cost sharing plus comparable plan payout, must be less than or equal to the percentage computed using the defined standard benefit (that is, the greater of \$2/\$5 or 5 percent). Again, we note that any variant in cost sharing could not lead to discrimination against certain beneficiaries, for example, by increasing the cost sharing of a drug used for a particular illness well above the cost sharing for other drugs.

c. Value of Qualified Coverage

In accordance with section 1860D-11(b)(2)(B) of the Act, with the bid, each PDP sponsor and MA organization offering an MA-PD plan must submit the actuarial value of qualified coverage in the region for the Part D eligible individual with a national average risk profile for the factors described in section 1860D-15(c)(1)(A) of the Act. We interpret this to mean that the weighted average of the plan's expected risk-standardized costs will represent the plan's cost for the theoretical national average-risk Part D individual. Any increase in costs attributable to increased utilization as the result of enhanced alternative coverage must be

excluded from this calculation. (Any alternative coverage that does not include supplemental coverage would be, by definition, actuarially equivalent to standard coverage. In this case, there is no need to make a further utilization adjustment since the test of actuarial equivalence for the 25 percent cost-sharing requirement has already taken into account utilization.) Any utilization effect that supplemental coverage has on the basic benefit should be priced into the supplemental portion of the bid.

5. Information Included With the Bid

a. Bid Format

We have not yet determined the exact format for the bid submission and we would provide future guidance on these requirements. We believe that we would develop a fully automated process that would include electronic signatures for certifications of the actuarial analysis and the plan benefit package. Section 1860D–11(c)(1)(D) of the Act specifies “the use of generally accepted actuarial principles and methodologies.” We would require that an actuary (a member of the American Academy of Actuaries) certify the actuarial valuation, which may be prepared by others under his or her direction or review. Actuarial certification would give better assurance that the actuarial values in the bid were prepared in conformance with actuarial standards and methodologies. Section 1860D–11(c)(3)(B) of the Act permits use of outside qualified independent actuaries. We expect that plans would use outside actuaries, especially if they did not have qualified in-house actuaries.

As provided in section 1860D–11(b)(3) of the Act, we would develop the bid submission format to facilitate the submission of bids for multiple regions and in all regions, and we would take this into account in process development. This approach would need to ensure that separate bids were provided for each region in order to calculate the national average monthly

bid amount and any geographic adjustment required. Our overall approach would be to increase our flexibility to develop appropriate methodologies in response to program changes, while minimizing burden, rather than codifying these processes in regulation. We believe that we would have the authority to develop these methodologies through interpretive guidance because our regulations state that sponsors provide the actuarial value of their plans in accordance with generally accepted actuarial principles and methodologies.

The information included with the bid should be sufficient for our review of the acceptability of a proposed plan based on actuarial principles and for negotiation of terms and conditions of an entity’s participation in the provision of Part D benefits. As provided in section 1860D–11(b)(2) of Act and § 423.265(d) of this proposed rule, the information that would accompany the bid submission would, at a minimum, include the following:

- Information on the prescription drug coverage to be provided, including the structure of the benefit, including deductibles, coinsurance (including any tiers), initial (or subsequent) coverage limits at which coinsurance levels change, and out-of-pocket thresholds. This would also include the plan’s formulary and any drugs, or types of drugs, excluded from coverage, and all documents provided to beneficiaries explaining the benefit, including the Evidence of Coverage, and would be certified by an officer of the plan. We solicit comments on the best way to obtain clear information on what drugs are included in the formulary.

- The actuarial value of the qualified prescription drug coverage in the region for a beneficiary with a national average risk profile certified by a qualified actuary.

- The portion of the bid attributable to basic benefits.
- The portion of the bid attributable to supplemental benefits, if applicable.

- The actuarial basis for the portion of the bid attributable to basic coverage and to supplemental benefits, if applicable, certified by a qualified actuary.

- The assumptions regarding reinsurance subsidy payments.

- The assumptions regarding administrative expenses.

- The plan’s service area and the plan’s network of pharmacies serving that service area.

- (For PDP sponsors only) the level of risk assumed in the bid, including whether the sponsor requires a modification of risk level (see discussion below) and, if so, the extent of the modification. Although our procedures may subsequently seek this information, we may only review it to the extent that the initial submission of bids does not yield the statutory minimum number of full risk bidders in each region and area. Our goal in designing the bidding process will be to maximize the level of risk borne by contracting plans and to minimize the need for fallback plans, and we would welcome comments on facilitating risk bidding; and

- Any other information that we would require.

b. Risk Adjustment of Supplemental Premium

The portion of the bid attributable to supplemental benefits represents the supplemental premium for a beneficiary with a national *average* risk profile. The payment process provided in section 1860D–15 of the Act would only address risk adjustment of the basic portion of the bid, and there are no other provisions for risk adjusting the supplemental benefit portion of the bid. If not addressed, this would result in plans with average risk scores above 1.0 being under-compensated by enrollees for supplemental benefits, and plans with average risk scores below 1.0 being over-compensated, as illustrated below.

TABLE F-1.—SUPPLEMENTAL PREMIUM RISK ADJUSTMENT

	Plan A	Plan B	Plan C
Plan Average Risk Profile	0.80	1.00	1.10
1.0 Supplemental Premium	100	100	100
Supplemental Premium if Risk-Adjusted	80	100	110
Over or (under) compensation	\$20.00	\$0.00	\$(10.00)

Table F-1 illustrates the case of three equally efficient plans that each estimate the cost of the same supplemental benefits at \$100. Plan B

has an average risk profile, that is, the arithmetic average of the risk scores of all of its enrollees is equal to 1.0. Plan A and Plan C, however, have healthier

and sicker than average risk pools, with enrollee risk scores averaging .80 and 1.10, respectively. Plan A only needs an average risk-adjusted premium of \$80 to

meet the revenue requirements of providing those supplemental benefits to its healthier enrollees, but would receive \$20 more on average from enrollees if it collects the whole \$100 unadjusted premium. In contrast, Plan C needs to collect \$10 more than it would receive from the unadjusted (1.0) premium to fully fund the expected needs of its sicker enrollees.

Consequently, we are proposing to require additional information on the projected risk profiles of its projected enrollees for accurate valuation of the supplemental portion of the bid with the bid submission. We intend, through the negotiation process, to reach agreement on a supplemental premium based on the bid submission that would account for the risk profile of enrollees and, thus, meet the plan's revenue requirements. Our goal is to maintain a level playing field that would facilitate the fair competition envisioned in the MMA. Review and approval of this information is discussed in section F.3. of this preamble.

c. Modification of Risk in PDP Bids

As provided under section 1860D–11(b)(2)(E) of Act and in § 423.265(d)(4), PDP sponsors may request a modification of certain risk sharing arrangements provided under section 1860D–15(e) of the Act, thus, becoming a limited risk plan. Modification of risk could include an increase in the Federal percentage assumed in the risk corridors or a decrease in the size of the risk corridors. Any modification of risk would have to apply to all PDP plans offered by a PDP sponsor in a region.

Section 1860D–11(b)(2)(E)(i) of the Act states that modification of risk will not be available to MA–PD plans. Therefore, in discussing the possibility of including in the bid a request for a modification of risk, we include only PDP sponsors. Limited risk plans would only be accepted if the access requirements in section 1860D–3(a) of the Act could not otherwise be met through the approval of a sufficient number of full risk plans. These requirements call for at least two qualifying plans offered by different entities, one of which must be a stand-alone prescription drug plan. If other bidders meet these requirements, a bid from a limited risk plan could not be approved and might not be reviewed.

6. Review and Negotiation of Bid and Approval of Plans

a. Authority To Review Bids

We would review the information filed by the PDP sponsor or MA organization in order to conduct

negotiations on the terms and conditions proposed in the bid. The MMA grants use the authority to negotiate bids and benefits "similar to" the statutory authority given the Office of Personnel Management (OPM) in negotiating health benefits plans under the FEHBP program. We believe that the Congress used "similar to" in the statute because of the differences between the two programs. For example, while the OPM authority applies to level of benefits, standard Part D drug coverage is defined. With regard to rates, in some cases the context for FEHBP negotiations is not applicable to Part D. For example, the rates for community-rated plans under FEHBP are related to the rate the entity provides to similarly sized groups, and there is no comparable concept in Part D. Arguably the degree of competition among plans, and price signaling through premium and benefits, might be significantly greater in Part D than in FEHBP. Although these differences do exist there are also similarities. OPM is concerned about trend factors used to establish the premium for experience-rated plans, and we would have similar concerns about the reasonableness of a sponsor's trend assumptions. OPM is concerned about cost-sharing changes proposed by plans, and we would have similar concerns with regard to supplemental benefits. OPM wants to maintain high member satisfaction and ensure top quality service by plans, and we would have similar interests.

Chapter 89 of title 5 U.S.C. gives OPM broad discretion to negotiate prices and levels of benefits. For example, 5 U.S.C. 8902(i) states that OPM may negotiate with carriers if it believes the rates charged do not "reasonably and equitably" reflect the cost of the benefits provided. In addition, rates may be determined "on a basis which, in the judgment of the Office, is consistent with the lowest schedule of basic rates generally charged for new group health benefit plans issued to large employers." OPM is permitted to ensure that any adjustment in rates from one year to the next is consistent with the general practice of carriers which issue group health benefit plans to large employers. We interpret this to mean that we would have the authority not only to determine whether the bids submitted accurately reflect the costs of the plan, but also to determine whether the bids are in keeping with premiums charged in other insurance contexts. If bids increase at a rate higher than the premiums in the general insurance market (with appropriate adjustments for comparable populations), we may

determine that further negotiations are needed. In addition, OPM has broad authority to negotiate the level of benefits, including the ability to prescribe "reasonable minimum standards for health benefits plans." (See 5 U.S.C. 8902(c).) We are considering similar regulations to those used by OPM in 48 CFR Chapter 16 and are soliciting comments on this subject. To the maximum extent feasible and consistent with the appropriate discharge of our responsibilities, we prefer to rely on competition rather than negotiation.

b. Bid and Benefit Package Review

We believe we have the authority to negotiate in four broad areas—(1) administrative costs; (2) aggregate costs; (3) benefit structure; and, (4) plan management, if dissatisfied with some or all aspects of bid submissions. We would evaluate administrative costs for reasonableness in comparison to other bidders and in comparison to a PDP sponsor's other lines of business. We would examine aggregate costs to determine whether the revenue requirements for qualified prescription drug coverage are reasonable and equitable. We would be interested in steps that the sponsor is taking to control costs, such as through various programs to encourage use of generic drugs. We would examine and discuss any proposed benefit changes. Finally, we would discuss indicators and any identified issues with regard to plan management, such as customer service.

In addition to the negotiation process, we would assure that bids and plan designs meet statutory and regulatory requirements. In general, we would examine bids to determine whether the bid meets the standard of providing qualified prescription drug coverage, as described in § 423.104(b) of this proposed rule and in subpart C of this preamble. We would examine the actuarial analysis accompanying the bid to ensure that it has been prepared in accordance with our actuarial guidelines and properly certified. We would examine bids to determine whether the revenue requirements for qualified prescription drug coverage are accurate and reasonable, and that the requirements relating to actuarial determinations are met. We note that section 1860D–11(e)(2)(c) of the Act requires that the portion of the bid attributable to basic prescription drug coverage must be supported by the actuarial bases and reasonably and equitably reflect revenue requirements for benefits provided under the plan, less the sum of the actuarial value of reinsurance payments. We would also

review the structure of premiums, deductibles, copayments, and coinsurance charged to beneficiaries and other features of the benefit plan design to ensure that it is not discriminatory. We would review cost sharing both above and below the out-of-pocket threshold with regard to its impact on groups of beneficiaries. We would also look to see that there is no differential impact on groups of beneficiaries by geographical location within the plan's region or service area attributable to different levels of cost sharing between preferred and non-preferred network providers.

As 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 eligible enrollee on the basis of health status, including medical condition (related to mental as well as physical illness), claims experience, receipt of health care, medical history, genetic information, evidence of insurability, and disability. In general, this means that we would review benefit plans for features that, when applied, have differential impacts on beneficiaries with particular medical conditions. Factors we would consider in determining whether a benefit structure is discriminatory include, but are not limited to—(1) the benefit design—including the initial coverage limit, the tiered cost-sharing, the use of categories and classes in a formulary, and the choice of drugs provided in each category. (For example, if the tiered cost-sharing for drugs used to treat HIV is much higher than the cost-sharing for other types of drugs, we would view this benefit structure to be discriminatory); (2) the use of any discriminatory limits such as 90-day limits or requirements for pre-authorization; and (3) supplemental benefits such as supplemental coverage of drugs that would encourage a healthier population to join the PDP. As provided in section 1860D–11(e)(2)(D)(ii) of the Act, plans using formulary designs based on categories and classes that are consistent with the guidelines established by the U.S.P. as discussed in subpart C, will be recognized as satisfying the non-discrimination design related to formulary structure as it pertains to categories and classes. However, adopting the USP model categories and classes would not prohibit us from reviewing other aspects, including the

use of any limits or tiers, as discussed above.

c. Approval of the Supplemental Premium

As provided under section 1860D–11(e)(2)(C)(ii) of the Act, we will determine that the portion of the bid attributable to supplemental benefits reasonably and equitably reflects the revenue requirements for that coverage under the plan. Unless the supplemental portion of the bid (which is paid by the enrollee in the form of the supplemental premium) is risk adjusted for the average level of risk among enrollees, plans with average risk scores above or below 1.0 would be over compensated or under compensated by enrollees for supplemental benefits. Therefore, on the basis of this authority, we are proposing to require additional information, consisting of estimates of the projected risk scores of the plan's enrollees in the subsequent year, to be submitted by each plan for purposes of negotiating the appropriate risk adjustment of the supplemental portion of the bid. We would review and negotiate that information, and would approve a uniform supplemental premium reflecting the average risk factor for the plan's expected enrollment.

d. Rebate Reallocation for MA–PD Plans

The negotiation process for MA–PD plans could include the resubmission of modified benefit structures (other than changes in that portion of their supplemental benefits related to drugs) once we know the outcome of the national average monthly bid calculation and its impact on beneficiary premiums. Part D drug benefits, including benefits offered through supplemental Part D coverage) could not be changed during this process because any changes would have an impact on government reinsurance payments and, therefore, on the portion of the bid related to basic drug benefits. The MMA requires that all MA bid and benefit package submissions be provided to us no later than the first Monday in June. In the prescription drug program enrollee premiums must be based on a percentage of the national average monthly bid amount that can only be calculated once all bids have been received, if not actually approved. (While the enrollment weights are determined from the previous year's reference month, the bid amounts are not.) Therefore, the prescription drug portion of benefit packages submitted by MA–PD plans would be based on estimates of monthly beneficiary

premiums. Some of these MA–PD plans would have allocated portions of their Part C rebates to buy-down of the Part D premium. Once the final national average monthly bid amount and the base beneficiary premium have been calculated, some of these rebate allocations in the bids could be either excessive or insufficient to achieve the desired premium level.

Excessive rebate allocation would result in a portion of the rebate that is not provided to the beneficiary as required by law, since a premium of less than zero is not permitted. Compliance with the statute will require a reallocation of the excessive portion of the rebate credit back to other allowed uses of the Part C rebate, that is, to supplemental benefits (including reduced cost sharing other than cost sharing for Part D drugs) or to credits to the Part B or supplemental premiums. On the other hand, insufficient rebate allocation may result in minimal premiums that may be seen as burdensome by plans, enrollees, and the financial institutions managing electronic funds transfer.

The statute does not address this situation, but section 1860D–11 of the Act does grant us broad authority to negotiate the terms and conditions of the proposed bids and benefit plans. Our proposed regulatory approach would be to allow the negotiation process for MA–PD plans to include the resubmission of modified benefit structures once the outcome of the premium finalization process is known. MA–PD plans would be able to redistribute their Part C rebates to correct for the difference between the projected and final national average monthly bid amounts and to achieve the previously proposed level of Part D premiums. Under no circumstances could plans submit modified bids.

For example, an MA–PD organization submitted its bid and benefit package based on the assumption that the levels of the national average monthly bid amount and its prescription drug standardized bid would result in a \$35.00 monthly beneficiary premium for basic coverage, and that it would use \$35.00 of its Part C rebate to completely buy down the Part D premium. If the national average monthly bid amount is determined to be higher than expected, the plan's bid would end up below the benchmark and its base beneficiary premium would be adjusted by subtracting the difference between the bid and national average monthly bid amount. Therefore, the plan's monthly beneficiary premium would be less than the projected premium, for instance, \$34.00, and the \$35.00 amount allocated

from the Part C rebate for Part D premium buy-down would be excessive. In that case, we would require the MA organization to amend its benefit package to reallocate the excessive \$1.00 of the Part C rebate credit to additional supplemental benefits (other than for Part D drugs) or to Part B or supplemental premium credits. These adjustments would be mandatory in order to ensure that the entire amount of the rebate was provided to the beneficiary in some form.

Under an alternative scenario, the national average monthly bid amount is determined to be lower than expected and the plan's bid ends up above the benchmark. In this case, the plan's base beneficiary premium would be adjusted by adding the difference between the bid and national average monthly bid amount. Therefore, the plan's monthly beneficiary premium would be higher than projected, for instance \$36.00, and the \$35.00 amount allocated from the Part C rebate for Part D premium buy-down would no longer be sufficient to eliminate the Part D premium as planned. In that case, we would allow the MA organization to amend its benefit package to reallocate an additional \$1.00 of the Part C rebate credit from additional supplemental benefits (other than for Part D drugs) or from Part B or supplemental premium credits to eliminate the Part D premium. These adjustments would be optional since the Part C rebate has already been provided to the enrollee. We would not permit an MA organization to simply eliminate a minimal premium instead of reallocating the rebate because doing so would mean that the cost of providing the prescription drug benefit had been overstated. However, the MA organization could elect to charge the new increased premium and to amend its benefit package submission accordingly.

e. Private Sector Price Negotiation and Formulary Design

The Act envisions that most price negotiation including discounts, rebates, or other direct or indirect subsidies or remunerations would take place between PDP sponsors or MA organizations (or their subcontractors) and pharmacies and pharmaceutical manufacturers. (Section 1860D–11(i) precludes CMS from interfering with negotiations between drug manufacturers and pharmacies, or PDP sponsors, or requiring a particular formulary or pricing structure.) In other words, price negotiation would be conducted by the private drug benefit managers and plans that are already familiar with negotiating prices of

prescription drugs on a local, regional or national basis. Moreover, we expect that providing information on discounted drug prices to beneficiaries will encourage further competition on lower prices. Because beneficiaries will choose a drug plan based on drug prices and formulary coverage, the plans have strong incentives to negotiate lower prices on drugs that beneficiaries use—just as private benefit managers currently do on behalf of the Federal government, state governments, and employer and retiree plans. We expect that in addition to price levels for drugs, these negotiations will also include such terms as prohibitions on substitutions of drugs if the net result would be higher costs for patients or the plans. The nature of the negotiations that we propose to conduct with bidders is discussed later with respect to full-risk and limited-risk bids, and in subpart Q of this preamble with respect to fallback plans.

We expect that the private negotiations between PDP sponsors and drug manufacturers would achieve comparable or better savings than direct negotiation between the government and manufacturers, as well as coverage options that better reflect beneficiary preferences. This expectation reflects the strong incentives to obtain low prices and pass on the savings to beneficiaries resulting from competition, relevant price and quality information, Medicare oversight, and beneficiary assistance in choosing a drug plan that meets their needs. This is similar to the conclusion of other analyses, for example, CBO's recent statement that "Most single-source drugs face competition from other drugs that are therapeutic alternatives. CBO believes that there is little, if any, potential savings from negotiations involving those single-source drugs. We expect that risk-bearing private plans will have strong incentives to negotiate price discounts for such drugs and that the Secretary would not be able to negotiate prices that further reduce federal spending to a significant degree." In accordance with the Medicaid best price exemption provided under section 1860D–2(d)(1)(c) of the Act and codified in § 423.104(h)(2) of our proposed rule, drug plans may even be able to negotiate better prices than those paid under Medicaid. It also reflects Medicare's recent experience with drug price regulation for currently covered drugs, in which regulated prices for many drugs have significantly exceeded market averages.

By not allowing us to require any particular formulary, the statute ensures that the Pharmacy and Therapeutics

committees of prescription drug plans and MA–PD plans have the flexibility to make changes in their classifications and lists of preferred drugs based on the most current evidence-based information (subject to the limitations of § 423.120(b)). We will evaluate plan formulary categories and classes in comparison to the model guidelines developed by U.S.P. In addition to evaluating any discriminatory features, as discussed above, we will evaluate the number of categories in formularies that do not meet the model guidelines and the choice of drugs available in those categories with respect to meeting the needs of the Medicare population. After the initial year of the program, we will also review the history of plan formulary appeals to identify issues with the plan's formulary. We will conduct additional research on evaluating formularies and drug benefit designs and we would welcome comments on evaluation. As noted previously, we may also review plan cost sharing (that is, tiers).

f. Bid Level Negotiation

The FEHBP standard in 5 U.S.C. 8902(i) requires us to ascertain that the bid "reasonably and equitably reflects the costs of benefits provided." In addition, we note that section 1860D–11(e)(2)(c) of the Act requires that the portion of the bid attributable to basic prescription drug coverage must "reasonably and equitably" reflect revenue requirements * * * for benefits provided under that plan, less the sum * * * of the actuarial value of reinsurance payments." Analogous to the manner in which FEHBP views its management responsibilities, we see this requirement as imposing the fiduciary responsibility to evaluate the appropriateness of the overall bid amount.

In general, we expect to evaluate the reasonableness of bids submitted by at-risk plans by means of the actuarial valuation analysis. This would require evaluating the plan's assumptions regarding the expected distribution of costs, including average utilization and cost by drug coverage tier, for example, in the case of standard coverage—(1) those with no claims; (2) those with claims up to deductible; (3) those with claims between the deductible and the initial coverage limit; (4) those with claims between the initial coverage limit and the catastrophic limit; and (5) those with claims in excess of the catastrophic limit. We could test these assumptions for reasonableness through actuarial analysis and comparison to industry standards and other comparable bids. Bid negotiation could take the form of

negotiating changes upward or downward in the utilization and cost per script assumptions underlying the bid's actuarial basis. We ask for comment on the most effective and least burdensome way to obtain pricing and utilization data for use in our actuarial review, as well as comments on the broader issues discussed in this section.

Arguably, appropriate assurance that plan bids reasonably and equitably reflect the revenue requirements associated with providing the Part D benefit requires knowing the final drug price levels the plans are paying that are implicit in their bids. Consequently, in addition to looking at final aggregate prices, if we found that a plan's data differed significantly from its peers without any indication as to the factors accounting for this result, we could also ask bidders to provide information about rebates and discounts they are receiving from manufacturers and others, in order to ensure that they are negotiating as vigorously as possible. Section 1860D-11(b)(1)(C) of the Act allows us to ask for necessary "information on the bid". In other words, we would be able to inquire as to the "net cost" of drugs since this is the key dollar value we would need to make accurate "apples to apples" comparisons on drug prices between PDPs. Under this approach, if the particular bids appear to be unusually high (or low), we could go back to the bidders and request that they explain their pricing structure, the nature of their arrangements with manufacturers, and we might ask further questions and take further action to perform due diligence to ensure that there is no conflict of interest leading to higher bids. For instance, we would look at certain indicators, such as unit costs or growth rates in the bid amounts to see if they are in keeping with private market experience to the extent feasible for a comparable population (for example, retirees). (In this case, we would be using the authority in 5 U.S.C. 8902(i) to negotiate bids that are "consistent with the group health benefit plans issued to large employers".) If the overall bids were unjustifiably high, we would have the authority to negotiate the bids down to a level that is more in keeping with bids that a private market would provide. While there is not a private drug-only insurance market, we could look at the rates used in overall coverage or determine which part of such coverage is made up by drug coverage, and make appropriate adjustments for Medicare utilization differentials. We could exercise our authority to deny a bid if

we do not believe that the bid and its underlying drug prices reflect market rates. Our strong expectation, however, is that we will be able to rely on the incentives provided by competitive bidding, and we would use our authority under this part only on the rare occasion we find that a plan's data differs significantly from its peers without any indication as to the factors accounting for this result.

Under the previous M+C program, we permitted M+C organizations to waive premiums or to offer mid-year benefit enhancements to their benefit packages. However, in order to maintain the integrity of the bidding process, we believe that it is no longer appropriate to allow either MA organizations or PDP sponsors to waive premiums or offer mid-year enhancements as they would be *de facto* adjustments to benefit packages for which bids were submitted earlier in the year. These adjustments would be *de facto* acknowledgement that the revenue requirements submitted by the plan were overstated. Allowing premium waivers or mid-year benefit enhancements would render the bid meaningless. Excessive amounts included in the bid will be subject to recovery by the government in the risk corridor calculations following the coverage year.

Consequently, we are proposing to interpret the statutory provisions on competitive price negotiation as prohibiting us from setting a regulated price of any particular drug or imposing by regulation an average discount in the aggregate on any group of drugs (such as single-source brand-name drugs, multiple-source brand name drugs, or generic drugs), but as allowing justification of aggregate price levels for groups of drugs. In addition, we could, under the specific circumstances previously discussed, negotiate regarding the level of the overall risk bid. This approach would allow us to exercise the authority similar to FEHBP as visualized in the MMA to ensure that per capita rates charged "reasonably and equitably" reflect the cost of the benefits provided, and that beneficiaries receive the full benefits of vigorous price negotiation by their drug plans.

g. Approval of Plans

After negotiations on the terms and conditions of the bid, we must approve or disapprove the bid. After negotiations, we would approve a plan only if—

- The plan is found to be in compliance with requirements specified in this regulation;
- The plan meets the actuarial valuation requirements; and

- The plan design does not discourage enrollment by certain eligible beneficiaries.

In § 423.272(c), we would approve limited risk plans only if fewer than two qualifying prescription drug plans offered by different entities, one of which must be offered by a stand-alone PDP sponsor, were submitted and approved in a region. We would approve only the minimum number of limited risk plans needed to meet these access requirements and would give priority to plans bearing the highest levels of risk; however, we may take into account the level of the bids submitted by these plans. Except as authorized under section 1860D-11(g) of the Act and in § 423.863 with regard to fallback plans, we would not, under any circumstances, approve a plan that elected to bear no risk or a minimal level of risk.

h. Special Rules for PFFS Plans

As provided in section 1860D-21(d) of the Act, and codified in § 423.272(d), PFFS plans that offer prescription drug coverage are exempt from review and negotiation (under sections 1860D-11(d) and (e)(2)(C)) of their prescription drug bids and premium amounts but are otherwise subject to all other requirements under this part, with the following exceptions. While we will not negotiate PFFS bids, those bids must meet the actuarial valuation requirements applicable to all risk bids. These plans are not required to negotiate discounted prices for prescription drugs. If they do negotiate, the proposed requirements under § 423.104(h) related to negotiated prices would apply. If the plan provides coverage for drugs purchased from all pharmacies, without charging additional cost sharing, and without regard to whether they are participating pharmacies, § 423.120(a) and § 423.132 of this proposed rule (requiring certain network access standards and the disclosure of the availability of lower cost bioequivalent generic drugs) would not apply to the plan. PFFS plans are also exempt from drug utilization management program and medication therapy management program requirements.

Finally, we note that section 1860D-21(d)(7) of the Act provides that costs incurred for off-formulary drugs will not be excluded in determining whether a beneficiary has reached the out-of-pocket threshold if a PFFS plan does not use a formulary. We believe that section 1860D-21(d)(7) is a tautology and simply states that PFFS plans without formularies, by definition, cannot have

non-formulary drugs to exclude from the out-of-pocket threshold calculation.

7. National Average Monthly Bid Amount

In § 423.279, we outline the calculation of the national average monthly bid amount. For each year, beginning in 2006, we would compute a national average bid based on approved bids in order to calculate the national base beneficiary premium. As a practical matter, we realize that we might need to calculate and announce the national average monthly bid amount before negotiations on all bids were completed in order to allow time for finalization of premiums and benefit packages. Therefore, we anticipate that we would identify a date by which the national average monthly bid amount would be published, and we would use the bids that had passed a certain level of approval as of that date as the basis for the calculation.

As provided in section 1860D–13(a)(4)(A) of the Act, in computing the national average monthly bid amount, we would exclude bids submitted for MA private fee-for-service (PFFS) plans, specialized MA plans for special needs individuals, PACE programs under section 1894 of the Act (pursuant to section 1860D–21(f) of Act) and reasonable cost reimbursement contracts under section 1876(h) of the Act (according to section 1860D–21(e) of the Act). The exclusion from the calculation of bids of PFFS, cost plans, specialized MA plans, and PACE suggests that they are different from, and not comparable to, the average bid in some way. We interpret this difference to be based solely on price levels because the legislation—

- Does not define any other basis for determining these bids;
- Continues to compare these bids to the national average bid amount to determine adjustments to enrollee premiums; and
- Provides for payments to such plans (including risk adjustment) in the same manner as to non-excluded plan types.

Therefore, these excluded plan types would still submit bids on the same basis as all other plans, that is, the 1.0 risk prescription drug plan beneficiary, even though these bids are not included in the national average bid amount at this time.

The national average bid amount would be equal to the weighted average of the standardized bid amounts for each PDP and for each MA–PD plan described in section 1851(a)(2)(A)(1) of the Act. The national average monthly bid amount would be a weighted average, with the weights being equal to

the proportion of Part D eligible individuals enrolled in each respective plan in the reference month (as defined in § 422.258(c)(1)). For calendar year (CY) 2006, we would determine the enrollment weights on the basis of assumptions that we would develop. One possible approach would be to use the following procedure to assign weights to individual bids for PDPs and MA–PD plans for CY 2006:

- Obtain total Medicare enrollment by region, and enrollment in each (local) MA plan that offers a drug benefit by region. These enrollments would be as of a specific date, for example, March 31, 2005.
- Assign each (local) MA–PD plan in each region a weight equal to its MA enrollment.
- Subtract the MA enrollment from the total Medicare enrollment for each region to arrive at the PDP-eligible enrollment.
- Divide the PDP-eligible enrollment for each region by the number of companies offering PDPs in each region to arrive at the weight for each company in each region.
- For each company in a region, divide the company weight by the number of plans offered by that company to arrive at the PDP weight.
- The regional average monthly bid amount would be calculated by weighting each plan's bid by its assigned weight.
- The national average monthly bid amount would be calculated by weighting each regional average monthly bid amount by the region's proportion of Part D eligible individuals (Medicare enrollment) and summing these products.

Using this methodology, after subtracting MA enrollments, each company offering PDP(s) in a region gets equal weight. An exception might occur based on capacity limits indicated by MA–PD plans. This assumes that beneficiaries would select a company, and then select a plan from that company. It also dilutes the effect of any potential artificially high bids designed solely to increase the national average monthly bid amount. If a company offers multiple plans in a region, each plan gets an equal allocated share of its company's assigned weight.

New MA–PDs would get a zero weight. This treatment is consistent with the weight assignment specified in the statute for subsequent years. Starting with the second year, all new plans would get zero weight because they have no prior year enrollment. We request comments on the “unequal” inclusion of plans in the calculation of the national average monthly bid. We

note that many MA–PDs would operate in small geographic areas with small potential enrollment, and so we believe that the impact of this approach for new local MA–PDs is likely limited. We recognize, however, that this approach is perhaps more problematic related to the treatment of the new regional MA–PD plans, as these plans in a given region are likely to have larger enrollment than local MA–PD plans. This particular approach implicitly assigns persons in new MA–PD plans (both local and regional) to the PDP weights, hence giving potentially too much weight to the PDPs.

Alternatively, assigning equal weights to PDPs and new MA–PD plans (even if limited to just the regional MA–PDs) could likely assign too much weight to the new regional MA–PD plans, which at least in 2006 are expected to have lower enrollment. Another possible alternative would be to base weights on regional MA–PD plan projections of enrollment, subject to our assessment of reasonableness of the estimates. In this approach we would use the proportion of projected enrollment for each plan as weights. However, particularly in the first year or so, projections may be quite inaccurate, leading to a distorted and unrepresentative benchmark. We welcome comments on these and other alternative approaches for how to weight bids in 2006.

The assigned weights are price inelastic, that is, the recommended weight assignment methodology implies that price is not a factor in plan selection. In the absence of experience on which to base the relationship between price and plan choice in this population, and, therefore, on how many people would be expected to join each plan, we believe that the fairest method for 2006 is simply to assume an equal weight for each plan.

In subsequent years, the weights for the weighted average would be calculated as a percentage with the numerator equal to the number of Part D eligible individuals enrolled in the plan in the reference month and the denominator equal to the total number of Part D eligible individuals enrolled in all plans (except for those plans whose bids are not included in the national average bid amount, as described above) in the reference month. It represents the proportion of the Part D eligible enrolled individuals in the plan. We would multiply the portion of each plan bid attributable to basic benefits by its proportion of total Part D enrolled individuals and sum each product to arrive at the national average monthly bid. In § 423.279(c), we would also establish an appropriate methodology

for adjusting the national average monthly bid amount to take into account any significant differences in prices for covered Part D drugs among PDP regions. We welcome comments on the existence of regional price variation in drug prices and on any factors that could lead to that variation. As part of carrying out the Congress' requirement that our geographic adjustment methodology be "appropriate," we believe the method would first require gathering data from PDPs and MA-PDs on regional drug prices. Therefore, we may not implement a geographic adjuster for the first few years of the program unless we have acquired sufficient information on pricing to accurately characterize that variation. If we were to determine that there is significant geographic variation in prices, we anticipate that we would announce the adjustment factors in advance of the bidding process for any year in which geographic adjustment would be applied to bids in the calculation. (This would be subject to notice and comment like any other change in payment methodology.) If we were to determine that there is only minimal price variation, we would not implement a geographic adjuster for the

national average monthly bid calculation. Additionally, we would implement any geographic adjuster in a budget neutral manner to avoid a change in aggregate payments from the total amount that would have been paid if we had not applied an adjustment.

8. Rules Regarding Premiums

In § 423.286, we propose that the monthly beneficiary premium would be the result of the calculation of a national base beneficiary premium subject to certain adjustments. Congressional intent was to arrive at an average monthly beneficiary premium in CY 2006 representing a certain percentage of the average total estimated benefit provided by the drug plans on a national basis (including benefits subject to Federal reinsurance subsidies). Taking into account that projected reinsurance subsidies are excluded from plan bids, the applicable percentage becomes approximately 32 percent, which is applied to the national average monthly bid amount.

To determine the uniform plan premium, in § 423.286(d), we would adjust the base beneficiary premium for certain plan characteristics including whether the plan's bid would be above or below the national average bid, and

whether the plan offers supplemental benefits. (Since the bid has to be approved and premiums established for the entire year, we are interpreting the phrase "if for a month" in section 1860D-13(a)(1)(B)(i) of the Act and 1860D-13(a)(1)(B) (ii) of the Act as referring to the beneficiary premium as a monthly amount.) The base premium is adjusted to reflect the full difference between the plan's standardized bid amount and the national average monthly bid amount (which may be adjusted for regional price differences). To the extent that the plan's standardized bid amount is below the national average monthly bid amount, the base premium is adjusted downward by the difference. To the extent that the plan's standardized bid amount is above the national average monthly bid amount, the base premium is adjusted upward by the difference. The base premium would also be adjusted by adding the premium amount approved after negotiations for risk adjustment of the supplemental benefits, if any (as discussed above). Table F-2 illustrates a calculation of the base beneficiary premium and the adjustment for the difference between the bid and the national average monthly bid amount.

TABLE F-2.—PREMIUM ILLUSTRATION

Benchmark	Plans in region	Bids	Beneficiary premium		
	Plans	Approved plan bid	Amount by which bid exceeds benchmark	Amount by which bid is below benchmark	Applicable percent of nat'l premium ± difference
National average monthly bid amount ¹					
111	Plan 1	125	14.00	0.00	\$50
	Plan 2	111	0.00	0.00	36
	Plan 3	101	0.00	(10.00)	26
Est. Reinsurance Percentage			21.25	(Assumed)	
Applicable Percent =			0.3238	(25.5 /(100 – 21.25))	
Base Beneficiary Premium =			36.00	(111 * .3238) ²	

¹ A. Assumes no geographic adjustment.

² B. Rounded to nearest dollar.

The sum of the base beneficiary premium, the adjustment for difference between the bid and the national average bid, and the supplemental benefit premium would be the monthly beneficiary premium. The monthly beneficiary premium (except for any supplemental premium) would be eliminated or reduced for low-income subsidy-eligible individuals, as described in section 1860D-14 of the Act and § 423.780. (This adjustment reflects the fact that the government would pay all or a portion of the

monthly beneficiary premium for subsidy-eligible individuals.)

In § 423.286(d)(3), the monthly beneficiary premium would be increased for enrollees subject to the late enrollment penalty. The penalty amount for a Part D eligible individual for a continuous period of eligibility (as described in § 423.46) would be the greater of an amount that we determine is actuarially sound for each uncovered month in the same continuous period of eligibility; or 1 percent of the base beneficiary premium for each uncovered month in that period. The beneficiary

premium amount is cumulative which means that each month the beneficiary is subject to a penalty, the penalty accumulates. Once the beneficiary enrolls in Part D, that accumulated penalty would be added to their premium amount each month. So for example, if the penalty amount is \$.36 per month in 2004, and is subject to 12 months of this penalty, the beneficiary would pay an additional \$.36 * 12 or \$4.32 per month for as long as they are enrolled in Part D. During the first several years of the program, we currently expect that we would specify

the penalty amount would be 1 percent of the base beneficiary premium per month. Once we have sufficient data on experience under the program with respect to individuals who enroll after their Initial Enrollment Periods, we will be able to determine the appropriate penalty amount, that is, either one percent or a greater amount to be adopted.

We note that achieving very high (indeed, virtually universal) access to prescription drug coverage for beneficiaries who participate in Part D was a key Congressional consideration in enacting MMA. We would encourage comments from insurers, actuaries, and others with experience, data, or expertise in this area. We are particularly interested in receiving comments on the most appropriate level for the late enrollment penalty, the likelihood of whether a \$.36 per month of delay penalty (that is, 1 percent for each month of delayed enrollment) constitutes an adequate safeguard against selection bias, and the importance of strongly encouraging widespread enrollment to maximize the affordability and stability of Part D premiums."

Except as provided with regard to any enrollment penalty, low-income assistance, or employer group waivers under section 1857(i) and section 1860D-22(b) of the Act and § 423.458(c) (as discussed in Subpart J of the preamble to our proposed rule), the monthly beneficiary premium for a prescription drug plan or MA-PD in a PDP region must be the same for all Part D eligible individuals enrolled in the plan. The monthly beneficiary premium charged under a fallback plan is discussed in § 423.867 of our proposed rules and in Subpart Q of this preamble.

9. Collection of Monthly Beneficiary Premiums

a. Means of Collection

In § 423.293(a), the beneficiary would have the same options on the method for premium payments as under Part C. Section 1860D-13(c)(1) of the Act applies the provisions of section 1854(d) of the Act (as amended by the MMA) to Part D premium collection. The beneficiary would have the option of having the amount withheld from his or her social security benefit check similar to the way Part B premiums are withheld. Beneficiary premium payments could also be paid directly to the PDP sponsor or MA organization through an electronic funds transfer mechanism (for example, an automatic charge of an account at a financial institution or a credit or debit card

account). We could specify other means of payment, including payment by an employer or under employer-based retiree health coverage (as defined in section 1860D-22(c)(1) of the Act) on behalf of an employee or former employee (or dependent). All premium payments withheld from social security checks would be credited to the appropriate Trust Fund (or Account) and would be paid by us to the PDP sponsor or MA organization involved. Premiums from beneficiaries enrolled in fallback plans would not be collected by the plan. Instead, these premiums would be withheld from social security checks (or from other benefits as permitted under section 1840 of the Act). Beneficiaries who do not receive social security checks or otherwise have premiums deducted from other benefits or annuities would pay us directly. Failure to make premium payments could result in disenrollment as provided under section 1854(d)(1) of the Act and § 423.44(d) of our proposed regulations.

b. Collection of Late Enrollment Penalties

Concerning collection of the late enrollment penalty calculated under § 423.286(d)(3), after the early years of the program we would estimate and specify the portion of the penalty that would be attributable to increased actuarial costs assumed by the PDP sponsor or MA organization (and not taken into account through risk adjustment provided under § 423.329(b)(1) or through reinsurance payments under § 423.329(c)) as a result of that late enrollment. When the premium is withheld from social security benefits, we would pay only the portion of the late enrollment penalty attributable to the increased actuarial costs to the PDP sponsor or MA organization. When the premium is paid directly to the plan, we would reduce payments otherwise made to the PDP sponsor or MA organization by an amount equal to the amount of the enrollment penalty not attributable to increased actuarial cost. (Fallback plans would not receive any enrollment penalties applicable to their enrollees because they are not at risk.)

At least in the initial years of the program we do not anticipate paying plans additional funds related to late enrollment individuals. In the initial years there will not be a significant number of people who can have delayed enrollment for a significant period of time. Moreover, in the initial years of the program the risk corridors are more generous and afford more protection. Consequently we do not think it is

necessary to provide a portion of the enrollment penalty to plans until experience indicates that actual risk has increased.

G. Payments to PDP Sponsors and MA Organizations Offering MA-PD Plans for All Medicare Beneficiaries for Qualified Prescription Drug Coverage

1. Overview (§ 423.301)

Subpart G of part 423 implements section 1860D-15 and the deductible and cost sharing provisions of 1860D-14(a) of the Act. This section sets forth rules for the calculation and payment of CMS direct and reinsurance subsidies for prescription drug plans and MA-PD plans; the application of risk corridors and risk-sharing adjustments to payments; and retroactive adjustments and reconciliations to actual enrollment and interim payments. References to part 422 of our regulations are to the new MA rules published elsewhere in this issue of the **Federal Register**.

2. Definitions

We propose definitions for a number of terms used in the computation of payments under this subpart, such as "allowable reinsurance costs", "actually paid" and "coverage year" in § 423.308 of our regulations, but discuss these separately in the appropriate sections of this preamble. We do this because these terms are complex and are best clarified in the context of the discussion of the pertinent provisions.

3. General Payment Provisions (§ 423.315)

The payment provisions required by section 1860D-15 of the Act include 4 different payment mechanisms. The first payment mechanism involves monthly payments that (along with reinsurance subsidies) subsidize on average 74.5 percent of the value of the basic prescription drug benefit, thereby maintaining beneficiary premiums for basic coverage on average at 25.5 percent. The direct subsidy is determined based on a national bidding process. Sponsors who wish to offer plans submit bids based on the projected costs of an average beneficiary. After our review and approval, these bids become the basis for the direct subsidy that is equal to the plan's standardized bid, risk-adjusted for health status as provided in § 423.329(b), minus the base beneficiary premium (as determined in § 423.286(c) and as adjusted for any difference between the standardized plan bid and the national average monthly bid amount (as described under § 423.286(d)(1))). The risk-adjustment

applied to the bid compensates the plan for individual enrollee differences in health status from the average beneficiary and thus reduces the impact from any adverse risk selection. Further adjustments to the direct subsidy payments would be made to account for actual enrollment and updated health status information.

The second and third payment mechanisms would substantially reduce the uncertainty and risk of participating in this new program. Since the Medicare prescription drug benefit is new, there is uncertainty surrounding the utilization, costs, and risk profiles (participation rates and characteristics) of potential enrollees. Federal reinsurance subsidies and risk corridor payment adjustments work along with the risk-adjustment included in the direct subsidy to substantially reduce the uncertainty and risk of participating in this new program. Through reinsurance subsidies, in which we act as the re-insurer, we would subsidize a large portion of any catastrophic expenses (defined as expenses over an individual's out-of-pocket limit) through a reinsurance subsidy. Through risk corridor arrangements, exposure to unexpected non-catastrophic expenses would be limited. These risk sharing arrangements are structured by the statute as symmetrical risk corridors, that is, agreements to share a portion of the losses or profits resulting from expenses above or below expected levels, respectively.

Finally, according to section 1860D–14 of the Act, PDP sponsors and MA organizations would receive payments to cover certain premium, cost-sharing, and extended coverage subsidies for low-income subsidy eligible individuals. With the exception of interim estimated payments of cost-sharing subsidies, these payments are discussed separately in subpart P of this preamble and in § 423.780 of our proposed regulations.

Certain payments would be exceptions to these general payment provisions. Under private fee-for-service (PFFS) plans, reinsurance would be calculated differently and risk sharing would not be available. Reinsurance subsidies and risk sharing would not be available for fallback plans, and are paid in accordance with contractual terms related to actual costs and management fees tied to performance measures.

4. Requirement for Disclosure of Information (§ 423.322)

a. Data Submission.

As provided under sections 1860D–15(c)(1)(C), 1860D–15(d)(2) and 1860D–

15(f) of the Act and in § 423.322 of our proposed regulations, we would condition program participation and payment upon the disclosure and provision of information needed to carry out the payment provisions. Such information would encompass the quantity, type, and costs of pharmaceutical prescriptions filled by enrollees that can be linked to individual enrollee data in our systems; that is, linked to the Medicare beneficiary identification number (HIC#). We would appreciate comments on the content, format and optimal frequency of data feeds. We believe that more frequent feeds than annually (weekly, monthly, quarterly) would allow us to identify and resolve data issues and assist the various payment processes.

We are evaluating our minimum data requirements with regard to prescription drug claims. Our goal would be to determine the least burdensome data submission requirements necessary to acquire the data needed for purposes of accurate payment and appropriate program oversight. Our view is that we will need at least the following data items for 100 percent of prescription drug claims for the processes discussed below:

- Beneficiary name (first, middle initial, last).
- Beneficiary HIC#.
- Beneficiary birth-date.
- Eleven-digit NDC code.
- Quantity dispensed.
- Prescription drug cost before co-payment (ingredient cost, dispensing fee, sales tax amount).
- Beneficiary co-payment amount, and

• Date prescription filled.

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, but do not reflect subsequent price concessions from manufacturers, such as rebates. We anticipate that we will need similar data on prescription drug claims for appropriate risk-adjustment, reconciliation of reinsurance subsidies, calculation of risk sharing payments or savings, and program auditing. Data will also be required for assessing and improving quality of care. We will welcome comments on the nature and format of data submission requirements for the following processes:

- Risk adjustment process would require 100 percent of drug claims in order to develop and calibrate the weights for the model for this new benefit. Consequently, PDP sponsors

and MA organizations offering MA-PD plans would be required to submit 100 percent of prescription drug claims for Part D enrollees for the coverage year. Risk adjustment would require the submission of prescription drug agent identifying information, such as NDC codes and quantity, in order to allow the standardized pricing of benefits in the model. Because we would use standardized pricing, cost data on each prescription is not a requirement for risk adjustment, although it is needed for other purposes.

- The reinsurance subsidy payment process would require 100 percent of claims for each enrollee for whom the plan claimed allowable reinsurance costs. (Although reconciliation of the reinsurance subsidy does not require NDC codes or quantities, it does require member, cost and date of service data.) All claims for enrollees with expenses in excess of the out-of-pocket limit would be necessary to verify that the costs were allowable because the totality and order in which the claims are incurred would define which claims would be eligible for reinsurance payments. While the start of reinsurance payments begins with claims after the out-of-pocket threshold has been reached, which is \$5,100 in total spending (2006) for defined standard coverage, it may be associated with a higher dollar total spending amount under alternative coverage. Whatever the level, we would need to receive all claims by date of service including the amount of beneficiary cost sharing in order to determine the occurrence of the out-of-pocket threshold. Any plan-incurred costs for claims for supplemental benefits cannot be included in determining whether the out-of-pocket threshold has been met.

- The risk sharing process would require 100 percent of claims for all enrollees for the calculation of total allowable risk corridor costs. The plan would need to segregate costs attributable to supplemental benefits from those attributable to basic benefits since supplemental benefit costs are not subject to the risk corridor provisions. Again, all claims would be necessary to verify that the costs were allowable because the order in which the claims were incurred would help determine whether the claims were solely for basic coverage. For instance, a claim processed between a beneficiary's deductible and initial coverage limit (in standard coverage) would count towards risk sharing, but another claim (processed identically but immediately after the initial coverage limit has been reached) would not. Unlike the reinsurance subsidy, which is limited to

individuals with expenses in excess of the out-of-pocket threshold, risk sharing involves costs (net of discounts, chargebacks and rebates, and administrative costs) for all enrollees for basic coverage, but only those costs that are actually paid by the sponsor or organization. Because all plans participate in risk sharing, potentially all claims for all Part D enrollees in all plans must be reviewed. Like the reinsurance reconciliation, risk sharing does not require NDC codes or quantities, but does require member, cost, and date of service data.

- The program audit process would require at least a statistically valid random sample of all Part D drug claims. We believe that several points of reference including HIC#, cost, date of service, and NDC code would be required for unique identification of individual claims in any random sample drawn from the population. If we receive 100 percent claims to support the payment processes, this sample could be drawn from our records. We believe it would be useful to obtain the prescribing physician's National Provider Identifier (NPI) number, as required by the administrative simplification provisions of HIPAA, in the elements of collected data for purposes of fraud control once it is available. Prior to May 2007 when the NPI is expected to be used, we would be interested in alternative means for identifying the physician prescriber.

(Nothing in this data collection discussion should be construed as limiting OIG authority to conduct any audits and evaluations necessary for carrying out our proposed regulations.)

b. Allowable Costs

Section 1860D-15(b)(2) and 1860D-15(e)(1)(B) of the Act and § 423.308 of our proposed regulations, specify that to determine "allowable costs" for purposes of both the reinsurance and risk corridor payments, only the net costs actually paid after discounts, chargebacks, and average percentage rebates, as well as administrative costs, are to be counted. We encourage comments on appropriate methodologies and data sources that can be used in making these adjustments. For example, we would like to receive comments on how price concessions (discounts, chargebacks, rebates, or any other periodic financial remuneration) would be most accurately and efficiently applied to prescription drug claims data to satisfy this requirement. We would also be interested in any information or data on the effect on costs such adjustments can be expected to yield. We are particularly interested

in how data would be appropriately allocated and applied to the reinsurance subsidy tied to individual expenses in excess of the out-of-pocket limit.

We understand that much of the rebate accounting is not applied in the context of point of sale claims data, but rather in periodic accounting adjustments, and that rebates are frequently reported along with administrative fees paid by the manufacturer. We are concerned that these accounting practices would be incompatible with the need to report all price concessions for purposes of determining allowable reinsurance and risk corridor costs and we, therefore, are proposing to require that they be segregated. Moreover, we are proposing to require that any administrative fees paid to Part D plans be based on the fair market value of services rendered, and that any fees determined to be above or below fair market value would be considered additional price concessions.

Due to the nature and timing of rebate accounting, we believe that this will require a form of step-down cost reporting in which rebates received at the aggregate level may be apportioned down to the level of plan enrollees incurring reinsurance expenses on a reasonable basis. Since Medicare beneficiaries would be expected to have higher per capita prescription drug utilization than other populations, we believe it would be appropriate to allocate rebates (and other similar price concessions) on the basis of percentage of dollars spent rather than of covered lives. Alternatively, one could create a ratio of total rebate amounts to total spending and reinsurance-related spending to total spending to derive the share of rebates to be allocated to reinsurance, and then adjust down the reinsurance amount. A similar ratio could be created for risk corridor spending. Another way that the current market expresses these relationships is in an average rebate per script value that could even be differentiated by brand versus generic rebates per script. In apportioning rebates and other financial remunerations to Medicare costs, we would look to ensure that plans appropriately take into account the distribution of claims between basic and supplemental benefits, and apportion price concessions in a proportionally accurate way.

In whatever manner price concessions will be apportioned, plans must require and keep accurate records on all price concessions and ensure that these are clearly accounted for and segregated from administrative fees. All cost reporting would be subject to inspection

and audit (including periodic audits) by us and the OIG. As stated below, to the extent either we or the OIG discover that a sponsor was overpaid for reinsurance or risk sharing (that is, the records do not support the payments made, or there is insufficient documentation to determine whether the payments are correct), we may recoup the overpayments. The reopening and overpayment provisions are discussed at the end of this part G.

c. Coverage Year

In § 423.308 we propose that the term "coverage year" would mean a calendar year in which covered Part D drugs are dispensed if the claim for such drugs (and payment on such claim) is made not later than 3 months after the end of the year. In other words, drug claims paid past the close of the 3-month period would not be considered part of that coverage year (or the next), and would not be used to calculate that year's payments or in reconciling risk adjustment payments for the year.

This limit would be imposed in order to provide timely closure for payment determination processes such as reinsurance, risk corridors and employer subsidies. While the period of 3 months would be significantly less than the fee-for-service Medicare medical claims standard of 18 months, we believe that a shorter period is warranted due to the highly automated and point of sale nature of prescription drug claim processing. We understand that the vast majority of prescriptions are not filled without the claim being simultaneously processed and therefore, there is a much shorter claims lag to be considered. We believe that the number and value of drug claims that would potentially be missed would be immaterial, consisting primarily of paper claims. The 3-month close-out window would not limit the liability of the plan or its claims processing contractor for reimbursing any lagging claims, but would simply establish a timely cut-off for finalizing payments. Any rebates for the coverage year not reflected in the fourth quarter data (sent to close out the year) must be credited against future payments. Although we are closing the year for claims purposes, the plan must account for all rebates that occur throughout the coverage year and send us all the data.

A shorter period would allow for payment processes that are dependent on the knowledge of total allowable costs for each coverage year to be concluded on approximately the same schedule as other reconciliations involving enrollment or risk adjustment data. On this schedule, calculations of

risk sharing could begin as soon as five to six months after the close of the payment year. If the claims submission standard were a longer period, final reconciliations would be significantly delayed. We are interested in receiving comments on this timetable, specifically whether we should adopt a shorter or longer period than 3 months, and including data with which to estimate the proportion and value of drug claims that could be excluded with a 3-month close-out window.

5. Determination of Payment (§ 423.329)

a. Direct Subsidies

As directed in section 1860D-15(a)(1) of the Act and codified in § 423.329(a), we would provide direct subsidies to PDP sponsors and MA organizations offering MA-PD plans. These subsidies would be in the form of advance monthly payments. Payments would be equal to the plan's standardized bid, risk adjusted for health status as provided in § 423.329(b), minus the base beneficiary premium (as determined in § 423.286(c) and adjusted for any difference between the standardized plan bid and the national average monthly bid amount (as described under § 423.286(d)(1))). The standardized bid would be the portion of the plan's bid attributable to basic coverage. This portion would be risk-adjusted by multiplying by the prescription drug risk score attributable to each enrollee. Between the government direct subsidy and the adjusted base beneficiary premium, the plan would receive its entire risk-adjusted standardized bid in advance each month. Payment for supplemental benefits would come from enrollees in the form of additional premium. By statute, the sponsor must bear all risk for such supplemental benefits.

We would note that a plan's total per capita payment could never exceed its bid, risk-adjusted for the beneficiary's health status. This would be the case even if the difference between the plan's bid and the national average monthly bid amount were greater than the beneficiary monthly premium, mathematically resulting in a "negative premium" amount. We do not believe that the statute envisions plan payments in excess of negotiated costs, since this would violate the revenue requirements provisions discussed in the Subpart F of this preamble.

b. Risk Adjustment

In section 1860D-15(c)(1) of the Act, we are directed to develop and publish a prescription drug risk adjustment methodology taking into account the

similar methodologies under § 422.308(c)(1) to adjust payments to MA organizations for benefits under Part C on the basis of costs incurred under original Medicare. In § 423.329(c) we propose to establish this risk adjustment methodology. We would develop and publish this risk adjustment methodology in the 45-day notice for the announcement of 2006 Medicare Advantage rates. Section 1860D-15(c)(1)(D) of the Act requires us to publish the risk adjustment for Part D at the same time we publish risk adjustment factors under section 1853(b)(1)(B)(i)(II) of the Act. Because these risk adjustment factors under Part C can only be published after 45-day advance notice under section 1853(b)(2) of the Act, we would use the same notice procedures we use under Part C for risk adjustment. We believe this would promote consistency and uniformity in the process, and, especially for MA-PD plans, allow entities to review notices published on the same day for purposes of commenting on or learning about risk adjustment. As usual, the 45-day notice would solicit public comment on any change in proposed payment methodologies. We are expecting that this new prescription drug risk adjustment methodology would initially be based on the relationship of prescription drug utilization within the entire Medicare population to medical diagnoses, and that it would be applied at the individual beneficiary level. Our longer-term plan would be to refine the risk adjustment model to account for predictable risk based on both medical and drug claim data.

Section 1860D-15(c)(1)(C) of the Act and § 423.329(b)(3) of this proposed rule authorize us to specify and require the submission of data from PDP sponsors regarding drug claims that can be linked at the individual level to part A and part B data in a form and manner similar to the Medicare Advantage process provided in § 422.310 and such other information as we determine necessary. Similarly, MA organizations that offer MA-PD plans must submit data regarding drug claims that can be linked at the individual level to other data that these organizations are required to submit to us. A primary requirement, therefore, would be claims linked to the Medicare beneficiary HIC#. Other proposed data submission elements are discussed in section 3(a) of this part of the preamble. We may also be interested in linking this data to the plan level and would then require the inclusion of the PDP or Medicare Advantage plan identifier (H#). We would use this data

to further refine our prescription drug risk adjustment factors and methodology in order to make payments that accurately reflect plan risk.

Any risk adjustment methodology we adopt should adequately account for low-income subsidy (LIS) individuals (and whether such individuals incur higher or lower-than average drug costs). Our risk adjustment methodology should provide neither an incentive nor a disincentive to enrolling LIS individuals, and we request comments on this concern and suggestions on how we might address this issue.

Our particular concern is that a risk adjustment methodology, coupled with the statutory limitation restricting low-income subsidy (LIS) payments for premiums to amounts at or below the average, could systematically underpay plans with many LIS enrollees (assuming LIS enrollees have higher costs than average enrollees). If the risk-adjustor fails to fully compensate for the higher costs associated with LIS recipients, an efficient plan that attracts a disproportionate share of LIS eligible individuals would experience higher costs to the extent the actual costs of the LIS beneficiaries are greater than the risk-adjustment compensation. Failing to discourage enrollment by LIS beneficiaries in 2006, the plan would experience higher than expected costs in that year and presumably be driven to reflect these higher costs (due to adverse selection, not efficiency) in its bid for 2007. In this hypothetical, plans would have a disincentive to attracting a disproportionate share of LIS beneficiaries. One possible solution would be to assure that the initial risk-adjustment system, which will be budget neutral across all Part D enrollees, does not undercompensate plans for enrolling LIS beneficiaries. In fact, to the extent that an initial risk-adjustor might at the margin tend to overcompensate for LIS beneficiaries, plans would have a strong incentive to disproportionately attract such beneficiaries. Plans could attract LIS beneficiaries both by designing features that would be attractive to such beneficiaries but also by bidding low. We would appreciate comments on this concern and suggestions on how we might address this potential problem.

c. Risk Adjustment Budget Neutrality

In accordance with section 1860D-15(c)(1)(A) of the Act and § 423.329(b)(1), our risk adjustment methodology would be implemented in a budget-neutral manner. A requirement for budget neutrality assumes that there is a known budget. We interpret the statute to require that the risk

adjustment methodology must not result in a change in aggregate amounts payable in section 1860D-15(a)(1) of the Act, that is, the risk adjustment methodology must be "budget neutral" to some aggregate of direct subsidy payments made before risk adjustment. (Since direct subsidy payments are made only to full-risk or limited risk plans, this budget by definition would not include payments to fallback plans.)

For comparison, in the current M+C (now Medicare Advantage) program the budget for risk-adjustment budget neutrality is defined to be the aggregate government payments made to plans under the 100 percent demographic payment system. Since the health-status-risk-adjustment methodology currently results in lower aggregate payments than the demographic methodology, M+C budget neutrality distributes among participating plans the difference between total payments under the 2 methodologies via a factor that allocated the difference in the same proportion as the allocation of risk-adjusted payments. However, there is no corresponding predetermined limit to aggregate payments in Title I, that is, to the aggregate government direct subsidy payments made before risk adjustment, so there is no amount to use as a basis for comparison in determining budget neutrality.

In the M+C program, the reason for the difference between the total payments under the demographic methodology and total payments under health status risk adjustment is that the average health status of enrollees in M+C is different than the average health status for the program as a whole (that is, M+C plus original Medicare). In Part D, there is no equivalent to original Medicare since beneficiary access subsidized coverage through enrollment in private plans. The Part D risk adjustment system would be based on these enrollees. Since there is no group of beneficiaries outside the system like there is under Part C, total payments with and without risk adjustment are always equal or budget neutral. Therefore, we believe that risk adjustment as applied to Part D benefits should be budget neutral to the risk of the individuals who actually enroll without any additional adjustment. We would appreciate comments on this approach.

d. Reinsurance Subsidies

i. Allowable Reinsurance Costs

As provided in section 1860D-15(e) of the Act and § 423.329(c), we would reduce the risk of participating in this new program by providing reinsurance

subsidies. Subsidies would be limited to 80 percent of allowable reinsurance costs for drug costs incurred after an enrollee has reached the annual out-of-pocket threshold. The annual out-of-pocket threshold would be \$3,600 in 2006. Under standard coverage this corresponds to total gross covered prescription drug costs of \$5,100, and would be increased annually as provided in section 1860D-2(b)(4)(B)(i)(II) of the Act and 1860D-2(b)(4)(B)(ii) (with regard to rounding).

In meeting the various actuarial tests required of alternative coverage, there could be instances where a sponsor wanting to provide basic alternative coverage would have to enhance plan benefits in order to meet the test of equal total actuarial value relative to defined standard coverage. This could occur with the use of a tiered co-pay benefit structure that could shift utilization to a cheaper set of drugs, thus allowing plans to lower cost sharing to achieve the same total dollar value as defined standard coverage. In these instances, since cost sharing is reduced relative to defined standard coverage, the out-of-pocket threshold would be associated with a higher total drug costs than the \$5,100 under standard coverage in 2006. For sponsors offering enhanced alternative coverage, the out-of-pocket threshold would also be associated with higher total drug spending. In this instance, however, it would be due to fact that the plan's supplemental benefits would be displacing part of the cost sharing that enrollees would otherwise have incurred.

Allowable reinsurance costs are a subset of gross covered prescription drug costs. Gross covered prescription drug costs are those costs incurred under the plan, excluding administrative costs, but including costs related to the dispensing of covered Part D drugs during the year and costs relating to the deductible. These costs are determined whether paid by the individual or under the plan, and regardless of whether the coverage under the plan exceeds basic prescription drug coverage. Allowable reinsurance costs, on the other hand, are the subset of these costs that are attributable solely to basic or standard benefits and that are actually paid by the sponsor or organization or by (or on behalf of) an enrollee under the plan. Actually paid—means that these costs must be net of any discounts, chargebacks, and average percentage rebates, and would exclude any amounts not actually incurred by the sponsor. The reinsurance payments are then calculated by determining the

portion of allowable reinsurance costs that are incurred after the enrollee has reached the out-of-pocket threshold (\$3,600 out of pocket in 2006). The reinsurance subsidy would provide 80 percent of such excess amount.

ii. Payment of Reinsurance Subsidy

Since allowable reinsurance costs can only be fully known after all costs have been incurred for the payment year, we would propose to make payments on an incurred basis to assist PDP sponsors and MA organizations with cash flow. Under § 423.329(c)(2)(i), we would provide for payments of reinsurance amounts based on plan actual reinsurance-eligible allowable costs with a one-month lag period. In other words, no payments would be made until enrollees reached the true out-of-pocket threshold. This would require timely submission of drug claim data. In this approach rebates would be recognized in the month after they were received and would be offset against the previous month's actual costs.

Alternatively, we could consider payments of reinsurance amounts on a monthly prospective basis based on the reinsurance assumptions submitted and negotiated with each plan's approved bid. We would take these assumptions into account in developing either a plan-specific or program-wide approach. We note that any program-wide approach involving some kind of average of the amounts included in the bids would have to adjust for the fact that plans providing enhanced alternative benefits would incur lower reinsurance costs. We are also aware that allowable reinsurance costs would be predominantly incurred in the latter parts of the coverage year and are considering the most appropriate methodology for distributing interim payments. One possible approach would require the submission of a schedule of the estimated timing of incurred allowable reinsurance costs along with the bid. For example, we might take schedules from each plan or we could propose an incremental schedule (X% of the total in January, Y% in February, etc.). We are aware that the prospective payment of estimated costs would create an incentive to overstate reinsurance, however, and are interested in ensuring that payments are not excessive. Since equal payments would be most compatible with our systems, in the first two years of the program (and for the first two years of new plans thereafter) we could also consider another approach paying $\frac{1}{12}$ th of the net present value of estimated allowable reinsurance costs in each month of the coverage year. The net

present value would be calculated on the basis of all estimated reinsurance payments due at the end of the year and discounted by the most recently available rate for one-year Treasury bills. We would welcome comments on these approaches and on the appropriate treatment of interest in such a system.

For subsequent years of the program, we could consider an approach of paying $\frac{1}{12}$ th of the two-year prior year's actual expenses. Such an approach would need to be trended forward by an appropriate index to account for expected growth in plan costs. In other words, in 2008 the interim payments would be based on actual reconciled reinsurance payments for 2006 trended forward by an estimated two-year growth factor. Regardless of which process we used for making reinsurance payments, as discussed below, if, at the end of the year, the data demonstrates the sponsor was overpaid through the interim payments—or if there is insufficient evidence to support the reinsurance payments claimed—we would recover the overpayments either through a lump sum recovery or by reducing future payments during the coverage year. Similarly, if the data demonstrates that the sponsor was underpaid, we would pay the sponsor.

iii. Adjustments to Reflect the True Out-of-Pocket Threshold

The statute provides that the reinsurance subsidy would be paid only for the plan's share of individual expenses in excess of an enrollee's true out-of-pocket (TrOOP) threshold. As indicated above, if the PDP sponsor offers enhanced alternative coverage or an MA–PD plan offers benefits beyond basic coverage as part of its supplemental benefits, the plan's spending for these benefits would not count toward the TrOOP threshold. Since benefits beyond basic coverage reduce cost sharing that would otherwise be incurred, they shift the effective prescription drug catastrophic limit beyond the associated total spending under the standard benefit (\$5,100 in 2006) and raise the effective reinsurance attachment point at the same time.

In addition, to the extent that plan cost sharing is paid or reimbursed by secondary insurance coverage or otherwise, that cost sharing does not count toward the out-of-pocket threshold. Beneficiaries are required to report the existence of secondary coverage or other types of coverage we identify and plans must identify these payments and ensure that true out-of-pocket spending is accounted for accurately in claims processing. This is

more fully discussed in subpart C and subpart J of this preamble.

iv. Adjustments for the Insurance Effect of Supplemental Coverage

Supplemental benefits increase the level of total drug spending after which reinsurance payments begin (reinsurance attachment point). Assuming 2 identical groups of enrollees with respect to utilization, one enrolled in enhanced alternative coverage and one in defined standard coverage, the total allowable reinsurance costs for the group with standard coverage would be greater than for the group with enhanced alternative coverage. Thus, one might hold that the differences in benefit packages are accounted for without the need for further adjustment. If one would examine average total spending for both groups, however, one would find that the average spending under enhanced alternative coverage would be greater than the average under defined standard coverage because of the impact of the insurance effect (or "moral hazard"), that is, the tendency of increased coverage resulting in increased utilization due to decreased financial stake in the costs associated with utilization). All other things being equal, this higher total spending would result in higher allowable reinsurance costs than would otherwise occur if the total spending under enhanced alternative coverage were comparable to that under standard coverage.

We are therefore proposing (in the definition of allowable reinsurance costs) to adjust allowable reinsurance costs to reflect the impact of this induced utilization. We would make this adjustment to comply with the requirement in section 1860D–15(b)(2) of the Act that in no case shall the allowable reinsurance costs exceed the costs "that would have been paid under the plan if the * * * coverage * * * were standard prescription drug coverage". We are looking for comments on whether this adjustment should be made and how best to adjust the experience of PDPs with enhanced alternative coverage or MA–PD plans offering supplemental coverage to account for the insurance effect.

v. Reinsurance Subsidies to Private Fee-For-Service Plans

As provided under section 1860D–21(d)(4) of the Act and proposed in § 423.329(c)(3), we would base reinsurance payments for PFFS plans on an alternative methodology. Rather than negotiating reinsurance assumptions submitted with the PFFS plan bid or otherwise adjusting for potential price

level differences between PFFS and other MA organization bids, we would estimate the amount of reinsurance payments that would be payable if the plan were an MA–PD plan described in section 1851(a)(2)(A)(i) of the Act. In doing so we would take into account the average reinsurance payments made under § 423.329(c)(2) for basic benefits for populations of similar risk under such MA–PD plans. Estimated payments would not be subject to any reconciliation process to compare the amounts paid to the actual allowable reinsurance expenses, and would not allow for payment recoveries in the event that actual allowable reinsurance costs exceed payments.

6. Low-Income Cost-Sharing Subsidy Interim Payments

As provided under section 1860D–14 of the Act and in § 423.780 of our proposed regulations, CMS will provide additional assistance for certain low-income beneficiaries in the form of premium, deductible and cost-sharing subsidies. Since actual expenses incurred by these low-income beneficiaries can only be fully known after all costs have been incurred for the payment year, we would propose to make estimated payments on an interim basis to assist PDP sponsors and MA organizations with cash flow. Under § 423.329(d)(2)(i), we would provide for interim payments of low-income deductible and cost-sharing amounts on a monthly prospective basis based on estimates of low-income cost sharing submitted and negotiated with each plan's approved bid. Like the possible option of reinsurance subsidy interim payments discussed above, a decision on whether these assumptions would be taken into account in developing a plan-specific or program-wide approach has yet to be determined.

We are aware that low-income cost sharing would not necessarily be incurred evenly throughout the coverage year and are considering the most appropriate methodology for distributing interim payments. Since equal payments would be most compatible with our systems, in the first two years of the program (and for the first two years of new plans thereafter) we are considering an approach paying $\frac{1}{12}$ th of the net present value of estimated low-income cost sharing in each month of the coverage year. The net present value would be calculated on the basis of all estimated costs due at the end of the year and discounted by the most recently available rate for one-year Treasury bills. An alternative approach would require the submission of a schedule of the estimated timing of

incurred low-income cost sharing along with the plan bid. For example, we might take schedules from each plan or we could propose an incremental schedule (X% of the total in January, Y% in February, etc.). We are aware that the prospective payment of estimated costs creates an incentive to overstate low-income cost sharing, and are interested in ensuring that our interim payments are not excessive. We would welcome comments on these approaches and on the appropriate treatment of interest in any methodology. For subsequent years of the program, we are considering an approach of paying $\frac{1}{12}$ th of the two-year prior year's actual expenses. Such an approach would need to be trended forward by an appropriate index to account for expected growth in plan costs. In other words, in 2008 the interim payments would be based on actual reconciled low-income cost sharing subsidy payments for 2006 trended forward by an estimated two-year growth factor. Again, any reconciliation at the end of the year would need to be based on the sponsor providing adequate information in order to determine the subsidy amounts for the year. If the sponsor could not provide such information, interim payments would be recovered. In addition, the low-income payments would be subject to the same inspection and audit provisions applying to the other payments made under section 1860D–15 of the Act.

7. Risk Sharing Arrangements

a. Risk Sharing Methodology and the Target Amount

As provided under section 1860D–15(e) of the Act and proposed in § 423.336, we would establish risk corridors. Risk-sharing payments would limit exposure to unexpected expenses not already included in the reinsurance subsidy or taken into account through risk adjustment. These would be structured as symmetrical risk corridors that are agreements to share a portion of the losses or profits resulting from expenses for basic benefits either above or below expected levels, respectively. However, plans would always be at full financial risk for all spending on supplemental drug coverage. In addition, in accordance with section 1860D–21(d)(5) of the Act and section 1860D–15(g) of the Act, the risk sharing provisions are not available to PFFS and fallback plans.

The expected level of expenses for basic benefits included in the standardized bid is known as the “target amount”. The target amount for any plan would be equal to the total amount of direct subsidy payments from us, and premium payments from enrollees to that plan for the year based upon the risk-adjusted standardized bid amount, less the administrative expenses and return on investment assumed in the standardized bid. Since the standardized bid is the portion of the accepted bid amount attributable to basic prescription drug coverage, the target amount can be thought of as “prepayments” of prescription drug expense for basic benefits. The standardized bid has also taken into account (and excludes) any utilization effects of offering supplemental coverage. The objective of risk sharing would be to compare total actual incurred prescription drug expenses to the prepayments, to compute the difference, and to reimburse or recover a portion of the difference.

In § 423.336(a)(2)(A), we would establish risk corridors, defined as specified risk percentages above and below the target amount. For instance, in § 423.336(a)(2)(ii), for 2006 and 2007, the first risk corridor is defined as 2.5 percent above the target amount and the second as 5 percent above the target amount. This means that, for 2006 and 2007, the first risk corridor is between 100 percent and 102.5 percent of the target amount and the second risk corridor is between 102.5 percent and 105 percent of the target amount. A third risk corridor is above 105 percent of the target amount.

The term, symmetrical risk corridors—means that the same size corridors exist below the target amount as above it. The actual upper or lower limits of each corridor equal the target amount plus or minus the product of the risk percentage times the target amount, as illustrated in Table G–1. Since these risk corridors would be symmetrical, plans with adjusted allowable costs below the 1st threshold lower limit would have to share the savings with the government.

b. Allowable Risk Corridor Costs

The costs applicable to the computation of risk sharing are known as allowable risk corridor costs. These costs are defined in section 1860D–15(e)(1)(B) of the Act and proposed in § 423.308 as the part of costs for covered

Part D drugs that are only attributable to basic benefits. Allowable risk corridor costs cannot include costs attributable to benefits outside the basic benefit. We would interpret this as both the actual differences in benefits structure and the insurance effect of supplemental coverage on basic coverage. In section 1860D–15(e)(1)(B) of the Act, reference is made to section 1860D–11(c)(2) of the Act that provides for a utilization adjustment using as its reference point standard prescription drug coverage. We are interpreting this to mean the statutorily defined standard prescription drug coverage described in Subpart C. Also, allowable risk corridor costs must actually be paid by the sponsor or organization under the plan and must be net of any chargebacks, discounts or average percentage rebates. The allowable risk corridor costs also do not include any administrative expenses of the sponsor or organization. (Administrative expenses would not include costs directly related to dispensing of Part D drugs during the year.) Note that unlike allowable reinsurance costs, allowable risk corridor costs do not include any amount paid by the enrollee. In § 423.336(a)(1), we propose that allowable risk corridor costs must be adjusted in accordance with section 1860D–15(e)(1)(A) of the Act, by subtracting expenses reimbursed through other separate payments. Thus, reinsurance payments made under § 423.329(c)(2) and the non-premium low-income subsidy payments made under § 423.782 [in Subpart P] of these proposed regulations to the sponsor of the plan for the year must be subtracted. The PDP sponsor or MA organization would already have received compensation for these costs, and thus they do not fall within the construct of risk corridors that are directed at limiting exposure to unexpected expenses.

If adjusted allowable risk corridor costs exceed the prepayments by a certain amount, we would reimburse a percentage of the difference to help plans with a portion of the unanticipated expenses associated with their drug coverage. On the other hand, if prepayments exceed adjusted allowable risk corridor costs, we would reduce future payments or otherwise recover a percentage of the difference to reduce the impact on the Trust Fund of excessive bids.

TABLE G-1. ILLUSTRATION OF RISK SHARING ARRANGEMENTS FOR HYPOTHETICAL PLAN

A. Assumptions in bid			Actual costs for basic benefit		
	PMPM	Totals		PMPM	Totals
Enrollees	10,000
(Subsidy-eligible)	0
Avg. Payment	114.00
Premium	30.60
Avg. Direct Subsidy	83.40
Admin	17.00
Est. Allowable Cost	97.00	970,000	100.00	1,000,000
Reinsurance Cost	0.00
Total Premiums	306,000
Total Direct Subsidy	834,000
Less Total Admin	(170,000)
Target Amount	970,000
B. Risk corridor limits		Risk Corridor limit %	C. Threshold	Risk sharing %	Allowable costs minus threshold
2nd upper limit050	1,018,500	80%
1st upper limit025	994,250	50%	5,750
Target Amount000	970,000	0%
1st lower limit	(.025)	945,750	(50%)
2nd lower limit	(.050)	921,500	(80%)
B. Risk corridor limits		Risk Corridor limit %	C. Threshold	Risk sharing %	Allowable costs minus threshold
2nd upper limit050	1,018,500	80%
1st upper limit025	994,250	50%	5,750
Target Amount000	970,000	0%
1st lower limit	(.025)	945,750	(50%)
2nd lower limit	(.050)	921,500	(80%)
B. Risk corridor limits		Risk Corridor limit %	C. Threshold	Risk sharing %	Allowable costs minus threshold
2nd upper limit050	1,018,500	80%
1st upper limit025	994,250	50%	5,750
Target Amount000	970,000	0%
1st lower limit	(.025)	945,750	(50%)
2nd lower limit	(.050)	921,500	(80%)

In Table G-1, a hypothetical plan with average payments of \$114 per member-per-month (PMPM), based on expected prescription drug costs of \$97 PMPM, actually incurs costs equal to \$100 PMPM. In this simplified example there are no reinsurance or low-income subsidies. The actual incurred costs are compared to the “prepayment” included in the risk-adjusted standardized bid (in this case the target amount of \$970,000) by looking at the risk corridors in which they fall. The risk corridors have been calculated based on the target amount plus or minus the risk percentages associated with each risk corridor limit. For instance the 1st upper limit is defined as the target amount (\$970,000) plus 2.5 percent of the target amount (\$24,250), so the 1st upper limit is calculated to be \$994,250. The actual allowable costs of \$1,000,000 fall between the 1st upper limit and the 2nd upper limit, so the costs eligible for risk sharing is the difference between the allowable costs (\$1,000,000) and the 1st threshold upper limit (\$994,250), or \$5,750. Since the amount of risk sharing in this corridor is set at 50 percent, the actual change in payment due to risk sharing is 50 percent of \$5,750, or an additional \$2,875.

As mentioned above, in order to arrive at a value for actual risk corridor costs that can be appropriately compared to the target amount, allowable risk corridor costs would be adjusted to remove expenses reimbursed through total reinsurance payments and non-premium low-income subsidy payments. The statute indicates that

allowable risk corridor costs should be reduced by reinsurance payments and by the subsidy payments for low-income individuals. The subsidy payments for low-income individuals under section 1860D-14 of the Act include subsidies for both premium and for cost sharing. We are proposing to interpret “the total subsidy payments made under section 1860D-14” under section 1860D15(e)(1)(A)(ii)(II) of the Act in the context of “costs incurred by the sponsor or organization” in the definition of allowable risk corridor costs. Since premiums are not a cost, we propose to limit our interpretation of “the total subsidy payments” to payments related to cost sharing.

In proposing this interpretation, we note that when adjusted allowable risk corridor costs are calculated by subtracting only non-premium subsidies, as we are proposing to do, the results are the same as for an identical plan without any subsidy-eligible individuals. However, if the adjusted allowable risk corridor costs are calculated by subtracting total low-income subsidies (that is, for premiums, cost sharing and coverage above the initial coverage limit), the risk sharing calculation results in lower recouped costs on the part of the plan and a different outcome from that in a plan without subsidy-eligible individuals. Since there should be no difference in these amounts, the calculation subtracting only non-premium subsidies must be the appropriate one. We believe that to do otherwise would result in a major disincentive for PDP and MA-PD

plans to enroll individuals eligible for the low-income subsidies, and we do not believe that this would be the logical outcome that was intended by the statute. We would welcome comments on our interpretation.

c. Changes in Risk Corridor Limits and Percentages (§ 423.336(a) and (§ 423.336(b))

The risk corridors and the percentage of risk to be shared would be set at certain levels for 2006 and 2007 with flexibility for us to increase the risk sharing percentage if bids, and therefore target amounts, are off during the early years of the program by a certain percentage set by the statute in section 1860D-15(e)(2)(B)(iii) of the Act. During 2006 and 2007, plans would be at full risk for adjusted allowable risk corridor costs within 2.5 percent above or below the target. Plans with adjusted allowable costs above 102.5 percent of the target would receive increased payments. If their costs were between 102.5 percent of the target (1st threshold upper limit) and at or below 105 percent of the target (2nd threshold upper limit), they would be at risk for 25 percent of the increased amount; that is, their additional payments would equal 75 percent of adjusted allowable costs for spending in this range. If their costs were above 105 percent of the target they would be at risk for 25 percent of the costs between the first and second threshold upper limits and 20 percent of the costs above that amount. That is, their additional payments would equal 75 percent of the difference between the first and second

threshold upper limits and 80 percent of the adjusted allowable costs over the second threshold upper limit. Conversely, if plan spending fell below the 97.5 percent of target, plans would share the savings with the government. They would have to refund 75 percent of the savings for any costs less than 97.5 percent of the target amount but at or above 95 percent of the target level, and 80 percent of any savings below 95 percent of the target.

In § 423.336(b)(2)(iii) the program will cover a higher percentage of the risk for costs between the 1st and 2nd upper threshold limits would apply in 2006 and 2007 if we were to determine that (1) 60 percent of prescription drug plans and MA-PD plans have adjusted allowable costs that are more than the first threshold upper limit for the year; and (2) these plans represent at least 60 percent of beneficiaries enrolled in such plans. In this case, additional payments to plans would increase from 75 percent to 90 percent of adjusted allowable costs between the first and second upper threshold limits. Conversely, there would be no change in savings shared with the government if costs fell below 97.5 percent of the target level.

For 2008–2011, the risk corridors and the percentage of risk to be shared would be modified so that PDP and MA-PD sponsors would assume an increased level of risk. Plans would be at full risk for drug spending within 5 percent above or below the target level. Plans would be at risk for 50 percent of spending exceeding 105 percent and at or below 110 percent of the target level. Additionally, they would be at risk for 20 percent of any spending exceeding 110 percent of the target level. Payments would be increased by 50 percent of adjusted allowable costs exceeding the first threshold upper limit and up to the second threshold upper limit and 80 percent for any additional costs exceeding the second threshold upper limit. Conversely, if plan spending fell below the target, plans would share the savings with the government. They would have to refund 50 percent of the savings if costs fell between 95 percent and 90 percent of the target level, and 80 percent of any amounts below 90 percent of the target.

For years after 2011, we would establish the risk threshold percentage as deemed necessary to create incentives for plans to enter the market. The only required parameters would be that the first threshold risk percentage could not be less than 5 percent and the second threshold risk percentage could not be less than 10 percent of the target amount.

d. Risk Sharing Payments or Recoveries

As proposed in § 423.336(c), we will make payments or recover savings after a coverage year after obtaining all of the information necessary to determine the amount of payment. In § 423.336(c)(1) we are proposing that within six months of the end of a coverage year, the PDP sponsor or MA organization offering a MA-PD plan would provide us with the information necessary to calculate the risk sharing as discussed in section 3(a) of this part of the preamble. This would include prior final reconciliation of reinsurance and low-income subsidies since allowable risk corridor costs must be reduced by the total reinsurance payments and non-premium low-income subsidies for the year. Once this information has been received, under § 423.336(c)(2) we would either make lump-sum payments or adjust monthly payments in the following payment year based on the relationship of the plan's adjusted allowable risk corridor costs to the predetermined risk corridor thresholds in the coverage year. We would not make payment if we did not receive the necessary information from the PDP sponsor or MA organization. In addition, as stated, below, we are considering certain corrective actions to recoup risk-sharing payments, in the event of lack of information.

8. Retroactive Adjustments and Reconciliation (§ 423.343)

In § 423.343(a) and § 423.343(b) we propose to make retroactive adjustments to the aggregate monthly payments to a PDP or MA-PD for any difference between the actual number and characteristics, including health status, of enrollees and the number and characteristics on which we had based the organization's advance monthly payments. Reconciliation of actual payments made would be done as needed. In order for total payments to be properly accounted for in all steps, the order of reconciliation processes would be first, enrollment; second, risk adjustment; third, low-income cost sharing; fourth, reinsurance; and finally, risk sharing.

Under § 423.343(c) and (d), we would provide for a final reconciliation process to compare the payments for reinsurance subsidies and low-income cost-sharing subsidies made during the coverage year to actual allowable reinsurance expenses and low-income cost sharing and to make additional payments or payment recoveries accordingly. The form and manner in which actual allowable reinsurance costs would be submitted for reconciliation has yet to be determined.

We are proposing that PDP sponsors and MA organizations offering a MA-PD plan would provide us with the information necessary to finalize reinsurance payments as discussed in section 3(a) of this part of the preamble within six months of the end of a coverage year. Once complete data were received for a coverage year, we would compare 80 percent of the allowable reinsurance costs attributable to that portion of gross covered prescription drug costs incurred in the coverage year after an individual has incurred costs that exceed the annual out-of-pocket threshold to the monthly reinsurance payments and compute the difference. We would then either make lump-sum payments or adjust monthly payments throughout the remainder of the payment year following the coverage year to pay out or recover this difference.

If an entity did not provide us with sufficient documentation for us to reconcile payments, we would reconcile by recovering payments for which the entity lacked documentation. For example, if CMS makes interim payments during the year for the low-income subsidy, but at the end of the year, the PDP sponsor or MA organization cannot provide documentation demonstrating the amounts of beneficiary cost-sharing, the reconciliation process would involve recouping the interim payments for such subsidy. The need to provide sufficient documentation to support final payment determinations applies even in the event of a change of ownership. Thus, new owners of a PDP sponsor or MA organization would be responsible for obtaining the documentation necessary to support payment, and the reconciliation process would be used to recover any payments for which the new owner lacked documentation. We believe this authority stems from the direction of the Congress that each PDP sponsor and MA-PD organization "provide the Secretary with such information as the Secretary determines is necessary to carry out this section," (section 1860D–15(f)(1)(A) of the Act) and that "payments under this section * * * are conditioned upon the furnishing to the Secretary in a form and manner specified by the Secretary, of such information as may be required to carry out this section," (section 1860D–15(d)(2)(A) of the Act).

We also request comment on the remedy that should be imposed in the event a PDP sponsor or MA organization offering an MA-PD plan fails to provide us with adequate information regarding risk-sharing arrangements. In the case of

risk corridor costs, the organization or sponsor may owe the government money if, for example, prepayments exceed adjusted allowable risk corridor costs. In this case, failure to provide information could result in a shortfall to the government, since the entity would not have the information necessary for the Secretary to establish the proper amount owed. Although we have not proposed regulations on this issue, some of the remedies we are considering for the final rule are: (1) Assume that the sponsor's or organization's adjusted allowable risk corridor costs are 50% of the target amount; (2) assume that the sponsor's or organization's adjusted allowable risk corridor costs are the same percentage of the target amount as the mean (or median) percentage achieved by all PDPs or MA-PDs whose costs are lower than the target amount; (3) assume that the sponsor's or organization's adjusted allowable risk corridor costs are the same percentage of the target amount as the mean (or median) percentage achieved by all PDPs or MA-PDs (whose costs are both higher and lower than the target amount). We use a 50% threshold for option (a) because we believe this threshold would constitute a lower limit; and it would be unlikely for any organization or sponsor to have costs lower than 50% of their total payments. We request comments on these options, as well as proposals of other options that would allow us to recoup risk-sharing payments in the event a sponsor fails to provide us the adequate information necessary to determine appropriate risk-sharing payments.

9. Reopening (423.346)

Finally, we believe that the provision in 1860D-15(f)(1) of the Act providing the Secretary with the right to inspect and audit any books and records of a PDP sponsor or MA organization regarding costs provided to the Secretary would not be meaningful, if upon finding mistakes pursuant to such audits, the Secretary were not able to reopen final determinations made on payment. In addition, we believe that sections 1870 and 1871 of the Act provide us with the authority to reopen final determinations of payment to PDP sponsors and MA organizations. Therefore, we propose in this rule to include reopening provisions patterned after those used in Medicare claims reopening, found in Part 405 of the regulations, subparts G and H. Including reopening provisions would allow CMS to ensure that the discovery of any overpayments or underpayments could be rectified. Under our proposed provisions, reopening could occur for

any reason within one year of the final determination of payment, within four years for good cause, or at any time when there is fraud or similar fault. CMS could initiate a reopening on its own, or a sponsor or organization could request reopening, but such requests would be at the discretion of CMS. The Supreme Court has determined that in the context of reopening cost reports, a fiscal intermediary's decision not to reopen a final determination is not subject to judicial review, *see Your Home Visiting Nurse Services, Inc. v. Shalala*, 525 U.S. 449, 456 (1999), and we believe the same reasoning would apply in the context of Part D.

Good cause would be interpreted in the same manner as in Part 405 (*see Medicare Carriers Manual section 12100*). Thus, good cause would exist, if (a) new and material evidence, not readily available at the time of the determination, is furnished; (b) There is an error on the face of the evidence on which such determination or decision is based; or, (c) There is a clerical error in determination. In order to meet the standard under (a) the evidence could not have been available at the time the determination was made. A clerical error constitutes such errors as computational mistakes or inaccurate coding. An error on the face of the evidence exists if it is clear based upon the evidence that was before CMS when it reached its initial determination that the initial determination is erroneous. Thus, for example, good cause would exist in cases where it is clear from the files that rebates or administrative costs were not appropriately accounted for, where computation errors had been made, where a sponsor or organization included non-Part D drugs in their calculations, where individuals not enrolled in the plan were included in calculating payment, and in similar situations. Reopening could occur at any time in cases of fraud or similar fault, such as in cases where the sponsor or organization knew or should have known that they were claiming erroneous Medicare payment amounts.

I. Organization Compliance With State Law and Preemption by Federal Law

1. Overview

In our proposed regulation at § 423.401 we would implement the requirements of section 1860D-12(a) of the Act that address licensing, the assumption of financial risk for unsubsidized coverage and solvency requirements for unlicensed sponsors or sponsors who are not licensed in all States in the region in which it wants to offer a PDP. The provisions of this

section specify that a sponsor of a PDP must be organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State that it offers a PDP. However, as required by section 1860D-12(a)(1) of the Act, we have provided in our proposed regulations at § 423.410 for a waiver of the State licensure requirement for the reasons and under the conditions set forth under section 1860D-12(c) of the Act. In addition, under the requirements of section 1860D-12(a) of the Act, to the extent an entity is at risk, it must assume financial risk on a prospective basis for covered benefits that are not covered by reinsurance. The PDP sponsor can obtain insurance or make other arrangements for the cost of coverage provided to enrollees to the extent that the sponsor is at risk for providing the coverage.

In § 423.420, we specify that sponsors that have been granted a waiver by us or those operating in States that do not have licensing requirements for PDPs must maintain reasonable financial solvency and capital adequacy. We intend to develop these reasonable standards through guidance, after consulting with the National Association of Insurance Commissioners (NAIC), as required by statute. The guidance would be issued by January 1, 2005. Although we believe these standards would be interpretive guidance, we are interested in receiving comments on the issue. In addition, as noted in § 423.410, we would establish an application and certification process for waiver applicants.

We expect that the development of solvency standards for purposes of PDP sponsors under Part D will be less complex than the situation presented to us by the development of solvency standards for provider-sponsored organizations (PSOs) under the Balanced Budget Act of 1997. (PDP sponsors in contrast to PSOs are fairly straightforward insurance risk models whereas the PSO situation involved having to consider such issues as the role that physical plant assets played in establishing solvency standards.) Although drug only plans are not a common product in the insurance market today, there are other single lines of business plans licensed by States (for example, dental plans, behavioral mental health plans) that can provide some possible models.

We also have experience from determining solvency standards for federally qualified health maintenance organizations under Title XIII of the Public Health Service Act and competitive medical plans under

Section 1876 of the Social Security Act. In addition, we are aware that the solvency standards have been applied to at least two drug-only plans (Medica and PacifiCare) and believe that these could also provide a model for the licensing of the entities. However, we believe that these two products are lines of business operated under a current insurance license, and therefore, our greatest concern would be how to go about developing standards for organizations that may have experience managing a drug benefit but have not had any experience as risk bearing entities and/or are not structured as risk-bearing entities. We would welcome comments regarding this issue.

Factors which may be considered in discussions with the NAIC include the ability of an organization to maintain assets greater than total unsubordinated liabilities and the ability of the organization to generate a surplus on a consistent basis as demonstrated by history or an acceptable financial plan.

2. Waiver To Expand Choice

a. Overview

In our regulations at § 423.410 we would implement the provisions of section 1860D–12(c) of the Act that address waiver of certain requirements to expand choice. Generally, section 1860D–12(c) of the Act specifies that in order to expand access to prescription drug plans, we may waive the State licensure requirement under circumstances similar to those permitted under Part C for provider-sponsored organizations, as described in section 1855(a) of the Act. However, we note that the States would be expressly preempted from regulating in all areas except licensure and solvency (see section 1860D–12(g) of the Act and § 423.440). Additional requirements referenced under section 1855(a) of the Act such as State consumer protection and quality standards, do not apply to and are not incorporated in these regulations.

b. Waiver When State Imposes Certain More Stringent Standards

Section 1860D–12(c) of the Act provides that a prospective PDP sponsor may request a waiver from State licensure requirements from us under the waiver provisions at section 1855(a)(2)(B), 1855(a)(2)(C) and 1855(a)(2)(D). Because the Congress directed us to use many of the same grounds for approving a waiver as used pursuant to § 1855(a)(2)(B), § 1855(a)(2)(C), and § 1855(a)(2)(D), We have adopted the regulatory provisions in proposed § 422.372. Thus, our

regulation at § 423.410(c)(1) would use the same standard used in § 422.372(b)(1) and allows a waiver when the State has failed to complete action on a licensing application within 90 days of receipt of a substantially complete application.

c. Distinct Waivers

Proposed § 423.410(c)(2) uses the same standards as used in § 422.372(b)(2) for determining when a State has denied an application based on discriminatory treatment. The regulation provides that the following activities may also constitute a basis for us to waive State licensure requirements: (1) The State denies an application based on requirements that are not generally applicable to PDP sponsors or other entities engaged in a similar business or (2) the State requires as a condition of licensure that the PDP sponsor offer any product or plan other than a prescription drug plan.

Section 423.410(c)(3) of our proposed regulations, addresses denial of an application based on application of different solvency requirements—when a State imposes solvency requirements that are more stringent than the solvency standards that would be established by us under § 423.420. In addition, a waiver may be granted if the State imposes procedures or standards relating to solvency that are different from the solvency requirements established by us. CMS will utilize a waiver application process similar to that used under its federally waivered PSO program in which the waiver applicant will be required to submit certain documents that would indicate that the State is imposing procedures or standards relating to solvency that are different from CMS standards. CMS would utilize this documentation in its waiver determination process.

In our regulations at § 423.410(c)(4), we would implement section 1860D–12(c)(2)(A)(ii) of the Act, which provides that we may grant a waiver when a State imposes requirements other than those required under Federal law.

Section 1860D–12(c)(2)(B) of the Act also establishes special rules for the approval of a waiver by us. We propose to implement these special rules at § 423.410(d) and (e) of these regulations. The special rules allow that we will grant a waiver when a State does not have any licensing process for PDP sponsors. Also, even if a State does have a licensing process for years beginning before January 1, 2008, a waiver will be granted if the PDP sponsor merely submits its completed application for licensure to the State. The PDP sponsor

seeking a waiver will submit a waiver application indicating its understanding of State law which CMS will confirm through contacts with the State regulator.

d. Relationship of Waiver to State Regulation

The statute requires, at section 1860D–12(c)(3) of the Act, that the waivers granted under the provisions of section 1855 of the Act must also meet the conditions of approval established at section 1855(a)(2)(E), 1855(a)(2)(F) and 1855(a)(2)(G) of the Act. Accordingly, we would implement the applicable waiver requirements from section 1855(a)(2)(E) and 1855(a)(2)(F) that relate to licensure or solvency in the regulations at § 423.410(f)(1) through § 423.410(f)(3).

Section 423.410(f)(1) of our proposed regulations establishes that except in States without a licensing process for PDP sponsors and except in the case of regional plan waivers described in § 423.410 (b), a waiver only applies to a specific State, is effective for 36 months and cannot be renewed. We propose to implement section 1855(a)(2)(F) of the Act at § 423.410(f)(2) where we specify our requirement concerning prompt action on applications. This requirement would establish that we would grant or deny a waiver application under this section within 60 days after we determine that a substantially complete waiver application has been filed. A substantially complete application would have to clearly demonstrate and document a PDP sponsor's eligibility for a waiver. In addition, section 1860D–12(c)(3) of the Act establishes that if a State does not have a licensing requirement for PDP sponsors, then the requirements of section 1855(a)(2)(E)(i) and section 1855(a)(2)(E)(ii) do not apply. We propose to implement these provisions at § 423.410(f)(3) where we would establish that if a State does not have a licensing process for PDP sponsors, we would approve a waiver for a PDP sponsor that meets our solvency standards and that this waiver would not be time limited.

With respect to section 1855(a)(2)(E)(i) of the Act, we believe that the most reasonable interpretation of this provision is that when a PDP sponsor is granted a waiver (because the State does not have a PDP sponsor licensing process), one waiver that we grant can be applied to all States in which there are no PDP sponsor licensing requirements. However, the waiver granted on the basis that a State does not have a licensing process cannot be applied in a State that does have a

PDP sponsor licensing process. In a State that may have denied licensure to the entity in question, one of the other bases for approving a waiver may be applicable. In addition, a waiver granted for other reasons such as failure to act on an application on a timely basis, or denial based on discriminatory treatment will apply only to the States in question and not other States.

We would implement the regional plan waiver rule provided at section 1860D-12(c)(1)(B) of the Act in the regulations at § 423.410(b) of our proposed rule. This allows us to use the proposed waiver authority at section 1858(d) of the Act—Temporary Waiver of State Licensure Requirement for the licensing of PDPs. This temporary waiver would be available in the event a prospective PDP sponsor proposes that its prescription drug plan would cover a multi-State region, but is not yet licensed in all of the States. (Under those circumstances, we can waive the State licensure requirement until the State has completed processing of the application.) In the interim, the PDP sponsor would be required to comply with the solvency standards established by us. In the event the State ultimately denies the application, we can extend the waiver through the contract year as we deem appropriate to provide for transition.

3. Preemption of State Laws and Prohibition of Premium Taxes

Section 1860D-12(g) of the Act incorporates section 1856(b)(3) of the Act which states: “the standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) for MA organizations under this part.” Accordingly, we specify in our proposed regulations that to the extent there are Federal standards, those standards supersede any State Law. For purposes of this section, with the exceptions of State licensing laws or State laws related to plan solvency, State laws do not apply to prescription drug plans and PDP sponsors.

We do not believe, however, that the language in 1856(b)(3) means that each and every State requirement applying to PDP sponsors would now become null and void. In areas where we have neither the expertise nor the authority to regulate, we do not believe that State laws would be superseded or preempted. For example, State environmental laws, laws governing private contracting relationships, tort law, labor law, civil rights laws, and similar areas of law would, we believe, continue in effect and PDP sponsors in

such States would continue to be subject to such State laws. Rather, our Federal standards would merely preempt the State laws in the areas where Congress intended us to regulate such as the rules governing pharmacy access, formulary requirements for prescription drug plans, and marketing standards governing the information disseminated to beneficiaries by PDP sponsors. We believe this interpretation of our preemption authority is in keeping with principles of Federalism, and Executive Order 13132 on Federalism, which requires us to construe preemption statutes narrowly.

By the same token, in areas where Congress specifically stated that State law would not be preempted—that is, State licensing laws and State laws related to plan solvency—we would construe the preemption exception narrowly, and only view the exception as applying to true licensing or solvency requirements. By this we mean that if a State conditioned licensing on a PDP sponsor meeting requirements in an area we also regulate outside of licensure or solvency, then such condition could not be viewed as a “licensing” law and would not be excepted from preemption. For example, if a State conditioned licensure on a PDP sponsor adhering to the State’s guidelines for prescription drug plan marketing materials, we would not view the marketing guidelines as a licensure requirement and we would still view the Federal marketing rules as preempting the State requirements.

Additionally, in accordance with the incorporation of section 1854(g) of the Act into section 1860D-12(g) of the Act, States are expressly prohibited from imposing a premium, or similar type of tax, on premiums paid by us to prescription drug plans or PDP sponsors, on premiums applicable to Medicare enrollees of the prescription drug plans under Part F, or on any other payments made by us to PDP sponsors under subpart G of the regulations,—including the direct subsidy, reinsurance payments and risk corridor payments.

J. Coordination Under Part D Plans With Other Prescription Drug Coverage

1. Overview and Terminology

We propose in subpart J of part 423 to implement sections 1860D-2(a)(4), 1860D-2(b)(4)(C), 1860D-2(b)(4)(D), 1860D-11(j), 1860D-21(c), 1860D-22(b), 1860D-23(a), 1860D-3(b), 1860D-23(c), 1860D-24(a), 1860D-24(b), and 1860D-24(c) of the Act that were added by section 101 of the MMA. We provide a brief summary of each of these

provisions. Following this overview we provide a more detailed discussion of how we propose implementing each of these statutory provisions in this subpart.

We propose to implement section 1860D-21(c) of the Act at § 423.458 of the proposed rule and explain that the requirements of Part D generally apply under Part C for prescription drug coverage offered by MA-PD plans although certain waivers are available. We propose to implement section 1860D-22(b) of the Act at our proposed § 423.458(c) that provides employer group waiver authority for prescription drug plans.

We outline options that we have identified related to the data-exchange that will be necessary between both State pharmaceutical assistance programs and other insurers and Part D plans in order to accurately apply incurred costs to appropriate Part D enrollee records. For purposes of this subpart, provisions in the statute that address coordination requirements generally apply in a similar manner to both State pharmaceutical assistance programs and other drug plans and to both prescription drug plans and MA-PD plans. The main difference between coordination requirements related to SPAPs and other drug plans is that we are prohibited from charging user fees to SPAPs. On the other hand, Part D plans may impose fees only related to the cost of coordination on both SPAPs and other drug plans.

We propose to implement section 1860D-11(j) of the Act at § 423.464(a) of the proposed rule and require sponsors of Part D plans to coordinate with State pharmaceutical assistance programs and other prescription drug plans. In this section we specify the other plans with which Part D plans must coordinate benefits in accordance with section 1860D-24(b) of the Act and define State Pharmaceutical Assistance Programs, in accordance with section 1860D-23(b) of the Act.

a. Part D Plans

Wherever we mention or reference “Part D plans” we mean any or all of “MA-PD plans, prescription drug plans (PDPs) and fallback prescription drug plans”. Likewise, the term “Part D plan sponsor” refers to MA organizations offering MA-PD plans, PDP sponsors, and eligible fallback entities offering fallback plans. If a statement or reference applies exclusively to a specific type of plan, we use that exact term to limit the reference.

b. Employer-sponsored Group Prescription Drug Plan

Section 1860D–22(b) applies to “employment-based retiree health coverage” that is defined under section 1860D–22(c)(1) of the Act. This term means coverage for individuals (or their spouses and dependents) under a group health plan based on their status as retired participants. We use the term “employer-sponsored group prescription drug plan” to mean a prescription drug plan under a contract between a PDP sponsor and employers, labor organizations, or the trustees of funds established by one or more employers or labor organizations to furnish prescription drug benefits under employment-based retiree health coverage.

c. State Pharmaceutical Assistance Program

A State Pharmaceutical Assistance Program is a program operated by or under contract with a State for purposes of this part if it: (1) Provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals; (2) provides assistance to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls; (3) meets the benefit coordination requirements specified in this part; and (4) does not change or affect the primary payor status of a Part D plan. Since an SPAP cannot discriminate under the Part D plans with respect to either eligibility or the amount of assistance provided, in accordance with section 1860D–23(b)(2) of the Act and in our proposed rule at § 423.464(e)(1)(ii), to the extent that a program does discriminate it cannot, by definition, be considered an SPAP. A non-conforming State program that did discriminate in either of these ways (eligibility or amount of assistance provided) would not meet the definition of a State Pharmaceutical Assistance Program.

We are interpreting the non-discrimination language to mean that SPAPs, if they offer premium assistance or supplemental assistance on Part D cost sharing, must offer equal assistance by all PDPs or MA–PD plans available in the State and may not steer beneficiaries to one plan or another through benefit design or otherwise. State programs cannot, for example, use the threat of withholding SPAP enrollees to negotiate coverage, premium or formulary changes with PDPs or MA–PD plans. Violations of the non-discrimination rule will jeopardize

the program’s special status with respect to true out-of-pocket costs. That is, a State program that discriminates does not qualify under the definition of an SPAP, and consequently, its contributions to cost sharing do not count toward the out-of-pocket limit.

Section 1860D–23(b) of the Act also provides that an SPAP is a State program that provides financial assistance for the purchase or provision of prescription drugs, and we interpret this to mean that it provides that assistance with State funds. Therefore, the definition of SPAP would exclude State Medicaid programs, section 1115 demonstration programs, and any program where program funding is from Federal grants, awards, contracts, entitlement programs, or other Federal sources of funding. (We would clarify that this does not exclude some Federal administrative funding or incidental Federal monies.)

For purposes of this part, we are proposing that a Pharmacy Plus demonstration waiver under section 1115 of the Act shall not be considered a State pharmaceutical assistance program. Pharmacy Plus waivers are granted to allow states to treat these individuals as Medicaid eligible for the purposes of receiving drugs and primary care services. Expenditures for these limited services receive federal matching payments in the same manner as do services for full benefit Medicaid beneficiaries. We do not believe that these waivers, having expenditures that are federally matched in this manner, should be considered SPAPs as the effect of this would be to allow federally matched payments to be used to meet an out of pocket expense to gain further payments from the Federal Medicare program.

2. Application of Part D Rules to MA–PD Plans on and After January 1, 2006 (§ 423.458)

In accordance with section 1860D–21(c)(1) of the Act, and as provided under proposed § 423.458(a), the provisions of Part D apply under Part C to prescription drug coverage provided by an MA–PD in lieu of other Part C provisions that would apply to such coverage, unless otherwise provided. As permitted under section 1860D–21(c)(2) of the Act, we will waive Part D provisions to the extent that we determine they duplicate, or conflict with, provisions under Part C, or as necessary in order to improve coordination of Part D benefits with the Part C program. For instance, under section 1860D–21(c)(3) of the Act, we will waive the pharmacy network access requirements as described at

§ 423.120(a)(3) of the proposed rule in the case of an MA–PD plan that provides access (other than through mail-order pharmacies) to qualified prescription drug coverage through pharmacies owned and operated by the MA organization if we determine that the organization’s pharmacy network is sufficient to provide comparable access for enrollees under the plan. As discussed in other parts of this preamble, Part D rules generally apply to section 1876 cost HMOs/CMPs and PACE organizations in the same or in a similar manner as the rules apply to MA–PD local plans. The waiver provision under section 1860D–21(c)(2) of the Act applicable to MA–PD plans similarly extends to section 1876 cost HMOs/CMPs and PACE organizations. We provide for this waiver authority for cost HMOs/CMPs and PACE organizations by adding a paragraph (d) to section 423.458 of our proposed rule.

In reviewing requested waivers we will follow a process similar to the process we initially established under the M+C program related to the employer group waiver authority provided in section 1857(i) of the Act and codified in regulation at § 422.106(c). Under § 422.106(c), MA organizations could submit written requests to our permission to waive requirements that hinder the design of or offering of MA plans to employers. We would make approved waivers available to all similarly situated MA organizations that meet the conditions of the waiver. Accordingly, we will use a similar approach to the one we established under § 422.106(c) in implementing our authority to waive those Part D provisions that can be shown to (1) duplicate or conflict with Part C requirements or (2) should be waived in order to improve coordination of the benefits provided under Parts C and D of Medicare. However, we will not, under our waiver authority, waive Part D rules that are specifically directed to MA–PDs or to the Part C program. We ask for your comments on both the process we propose for authorizing additional waivers under this section and for what additional waivers should, or should not, be permitted under this waiver authority.

3. Application to PACE Plans

Section 1860D–21(f) of the Act indicates that Part D provisions shall apply to PACE organizations in a manner that is similar to those of an MA–PD local plan and that a PACE organization may be deemed to be an MA–PD local plan. As discussed in detail in Subpart T, PACE organizations

would not be deemed as MA–PD plans but would be treated in a manner that is similar to MA–PD plans for purposes of payment. Proposed § 423.458(d) establishes regulatory authority for CMS to waive Part D provisions for PACE organizations and indicates that PACE organizations may request waivers from CMS. Because many of the Part D requirements duplicate, conflict with, or inhibit coordination of existing PACE requirements, we anticipate a significant number of waivers would necessary for PACE organizations. We are concerned about the potential burden this would place on PACE organizations and propose to include a provision that would allow for CMS to identify all Part D provisions requiring waivers and waive these provisions on behalf of PACE organizations. In other words, we are considering a special rule for PACE organizations that would automatically apply the waivers granted in the final rule (see discussion in subpart T of this preamble) without a plan-specific application process.

We would like to receive comments on this proposed approach and on any other related suggestions for minimizing burden on PACE plans.

4. Application to Employer Groups

a. Employer Group Waivers

Section 1860D–22(b) of the Act extends the waiver authority that is provided for MA organizations related to Part C by section 1857(i) of the Act and implemented at § 422.106(c) to prescription drug plans related to Part D. This waiver authority is intended to provide prescription drug plans an opportunity, similar to the opportunity afforded MA organizations under Part C, to furnish Part D benefits to participants or beneficiaries of employment-based retiree health coverage sponsored by employers and labor organizations in the most efficient and effective manner possible. Section 1860D–21(b) of the Act specifically authorizes prescription drug plans to establish separate premium amounts for Part D enrollees who are participants or beneficiaries of employment-based retiree health coverage sponsored by employers and labor organizations. It also contemplates separate Part D plans for participants and beneficiaries of such employment-based retiree health coverage. In administering this waiver, we propose to follow the template first established at § 422.106(c) that we created under Part C to implement the waiver authority under section 1857(i) of the Act.

While we discuss coordination of Part D coverage with employment-based

retiree health coverage at some length later in this part, we believe it is important to include a brief discussion here on the Part D waivers that we specifically would not permit related to employer group retiree coverage under the authority provided in section 1860D–22(b) of the Act. Although the statute permits “* * * in relation to employers, including authorizing the establishment of separate premium amounts for enrollees in a prescription drug plan * * *” we interpret “separate premium amounts” to mean the amount of premium the retiree or the enrollee pays. Under the MA program many employer groups subsidize the premiums that would otherwise be payable by their retirees through partial or full payment or subsidization of the MA plan premiums on their members’ behalf. We believe that a similar practice related to PDP Part D plan premiums would be permissible and find support in section 1860D–22(a)(6)(B) of the Act. Alternatively, we do not believe that the statutorily defined Part D premium could be different for employees or retirees than it is for individuals enrolled in the same PDP plan. Thus, the combined Part D premium contributed by the employee or retiree and the employer group would need to be identical to the premium charged to an individual enrolled in the same PDP plan. These principles apply to waiver requests by MA–PD plans under section 1857(i) of the Act.

Generally, we also would not permit waivers that directly increase Medicare spending. For example, a section 1860D–22(b) waiver would not be permitted that had the effect of changing the definition (in Subpart C of our proposed rules) for incurred costs (which are defined for purposes of calculating the true out-of-pocket threshold—TrOOP). An alternative example of a waiver we would not permit would be a waiver that would increase the premium subsidy. We also note that section 1860D–22(b) applies to “prescription drug plans,” not non-Part D plans that “wrap around” or supplement the benefits provided under the PDP. Consequently, section 1860D–22(b) of the Act would not apply to a request to waive rules under this Part that effect an employer-sponsored non-Part D plan that wraps around a Part D plan, including the TrOOP rules. The exclusion of costs paid by group health plans from TROOP is irrelevant when the group health plan is itself a part D plan (in other words, the exclusion applies when the group health plan pays costs not otherwise covered under the part D plan).

We invite comment on the process we propose for authorizing additional waivers that prescription drug plan sponsors can request under this section. We also ask for comment on the manner in which additional waivers should be permitted and what additional waivers, if any, we should not allow.

b. Employer Options

The enactment of Title I of the MMA has provided sponsors of retiree prescription drug plans with multiple options for providing drug coverage to their retirees. For the benefit of the employers and unions, we discuss these options. We believe the availability of these various options will make it easier for sponsors to continue to assist their retirees in having access to high-quality prescription drug coverage.

Generally, employers and unions who offer drug benefits to their retirees (and their dependents) who are eligible for Medicare Part D may do so as follows:

1. Provide prescription drug coverage through employment-based retiree health coverage. If those coverage is at least actuarially equivalent to the standard prescription drug coverage under Part D, the sponsor is eligible for a special Federal subsidy for each individual enrolled in the sponsor’s employment-based retiree health coverage who is eligible for Part D but elects not to enroll in Part D, directly reducing the cost of providing a high-quality drug benefit. It is important to note that employers can still make arrangements with Medicare Advantage organizations to offer a Medicare Advantage (MA) only plan without the Part D benefit, but then still take the retiree drug subsidy and through a separate private contract with the MA organization arrange for an employer-sponsored retiree drug benefit that is not subject to the application of the true out-of-pocket provision and retains the employer’s flexibility to design a benefit that is at least equivalent to the Part D benefit.

2. Provide prescription drug coverage that supplements, or “wraps-around,” the coverage offered under the PDP or MA–PD plans in which the retirees (and their dependents) enroll. For example, this option would permit beneficiaries who receive retiree coverage from employers who provide some financial assistance, but not enough to qualify for the retiree drug subsidy, to supplement the new drug benefit subsidy from Medicare with their existing employer assistance and thereby receive more generous coverage than they have now.

3. Subsidize the monthly beneficiary premium for whatever PDP or MA–PD plan in which the employer or union’s

retirees (and their dependents) elect to enroll.

4. Provide a prescription drug plan (PDP) or Medicare Advantage—prescription drug plan (MA–PD plan) either under contract with a PDP sponsor or Medicare Advantage (MA) organization or by directly sponsoring a PDP or an MA–PD plan. This plan may consist of enhanced alternative coverage (as defined under proposed § 423.104(g)), or drug coverage that is more generous than that offered under the standard prescription drug coverage under Part D (as defined under proposed § 423.104(e)). Medicare would subsidize the cost of this coverage through direct and reinsurance subsidies (as calculated under proposed § 423.329(a)(1) and (2)). At its option, the employer or union may elect to subsidize the monthly beneficiary premium (as calculated under proposed § 423.286). Many employers already have arrangements with Medicare Advantage plans and we expect that this will continue, as well as new arrangements being established.

The first option is the subject of subpart R of this preamble. The latter three options, all of which involve the employer or union's retirees (and their dependents) enrolling in Part D, are discussed in this subpart.

We note that if employers or unions elect to sponsor enhanced alternative coverage under Part D or to provide supplemental coverage that wraps around Part D, either election will have an impact on when its retirees (and their dependents) are eligible for the additional Medicare subsidies for catastrophic drug coverage. By delaying the provision of government-financed catastrophic coverage, these plans would lower the cost of Part D to the Federal government by lowering our reinsurance payments while preventing beneficiaries from facing any gaps in coverage. As discussed in Subpart C, individuals enrolled in a PDP or MA–PD plan are eligible for Medicare subsidies on top of their employer subsidies for catastrophic drug coverage after they incur out-of-pocket drug costs in the amount specified under proposed § 423.104(e)(5)(iii). Under the reinsurance provisions discussed in subpart G, Medicare would reimburse PDP sponsors and MA organizations offering MA–PD plans 80 percent of their gross costs for providing this catastrophic coverage (excluding administrative costs and net of discounts, rebates, and similar price concessions). Only drug costs paid by a Part D enrollee, or on behalf of a Part D enrollee by another person, would count toward the annual out-of-pocket

threshold, with the exception of amounts reimbursed by insurance or otherwise, a group health plan, or another third-party payment arrangement. We refer to those drug expenditures that count toward the out-of-pocket threshold as “true out-of-pocket (TrOOP) expenditures.”

Under these rules, employers and unions who provide retirees (and their dependents) enhanced alternative coverage or wrap-around coverage in effect push out the total drug spending that triggers the Medicare subsidy for catastrophic coverage, since participants in the plan will have lower cost-sharing, and thus have lower out-of-pocket costs. This approach limits the “crowd-out” of employer contributions by the new Medicare subsidy, resulting in more comprehensive coverage at a lower cost to the Federal government by lowering reinsurance payments.

When an employer or union elects to provide a PDP or MA–PD plan under contract with the PDP or MA–PD sponsor, the PDP sponsor, under proposed § 423.458(c), or the MA organization, under 42 CFR 422.106(c), may submit written requests to us for permission to waive requirements under Part D that hinder the design of or offering of PDP or MA–PD plans to employers. We believe these waivers will help efficient administration and integration of their enhanced Part D coverage with other retiree health benefits offered by the sponsor. For example, the PDP sponsor or MA organization could request permission to restrict enrollment in its PDP or MA–PD plan to the sponsor's retirees (and their dependents) and offer a benefit that resembles or enhances the sponsor's existing coverage. We encourage employers and unions to carefully review each option and determine which one is most beneficial to it and its retirees (and their dependents). The variety of options gives employers many ways to retain and enhance drug coverage for their retirees, and we seek comment on how we can use all of these subsidized options to maximize enhancements in retiree coverage.

c. Implications for Beneficiaries

For beneficiaries, the significance of the above discussion, as well as of the earlier discussion (in subpart C) of incurred costs that count toward the true out-of-pocket threshold, is that these rules would lead to new options for drug coverage. All Medicare Part D coverage would at a minimum provide basic coverage, funded with a generous Federal subsidy that did not exist before. In addition, there would be a

number of ways in which some beneficiaries can get access to more comprehensive benefits, such as filling in any coinsurance requirements in coverage in whole or in part. Such access will be dependent on individual eligibility for other subsidies or coverage, and individual willingness to continue to pay for enhancements in their coverage, such as:

- If they are eligible for a more comprehensive retiree health benefits policy sponsored by their former employer, their retiree plan sponsor may qualify for a subsidy payment.
- If they have limited income, they may be eligible for Part D low-income subsidies of premium and cost sharing through a Part D plan.
- They may be eligible for financial assistance through a State Pharmaceutical Assistance Program that can pay for an enrollee's cost sharing and still have these payments count toward the out-of-pocket limit.
- They may qualify for charitable assistance from bona fide non-profit charities that can also pay for an enrollee's cost sharing and still have these payments count toward the out-of-pocket limit.
- They may have access to a PDP or MA–PD (through either individual enrollment or employer group enrollment) that offers an enhanced alternative prescription drug plan for an additional premium. In this case, either the plan sponsor and/or the beneficiary must bear some of the drug costs that would otherwise have been subsidized by Part D reinsurance subsidies. While they would consequently not receive the additional subsidy until they reached a higher level of drug expenditures, the substantial savings in drug costs as a result of the highly subsidized, standard drug benefit would permit such coverage to be financed while still saving money for the beneficiary and the plan sponsor.

5. Medicare Secondary Payer Procedures

Section 1860D–2(a)(4) of the Act extends the Medicare secondary payer (MSP) procedures applicable to MA organizations under section 1852(a)(4) of the Act and 42 CFR 422.108 to PDP sponsors. Section 1852(a)(4) of the Act provides that an MA organization may charge or authorize a provider to seek reimbursement for services from a beneficiary or third parties to the extent that Medicare is made a secondary payer under section 1862(b)(2) of the Act. Accordingly, under § 423.462 of this proposed rule, PDP sponsors would be required to follow the same rules as MA organizations regarding:

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

Because Medicare would not pay for covered Part D drugs to the extent that there is a third party that is to be the primary payer under the provisions of section 1862(b)(2) of the Act and 42 CFR part 411, PDP sponsors must, for each prescription drug plan: (1) identify payers that are primary to Medicare under section 1862(b)(2) of the Act and 42 CFR part 411, (2) determine the amounts payable by those payers, and (3) coordinate their benefits to plan enrollees with the benefits of the primary payers.

The PDP sponsor may charge other individuals or entities for covered Part D drugs for which Medicare is not the primary payer. If an enrollee receives from a PDP sponsor covered Part D drugs that are also covered under State or Federal workers' compensation, no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the PDP sponsor may charge the insurance carrier, the employer, any other entity that is liable for payment for the covered Part D drugs under section 1862(b) of the Act and 42 CFR part 411, or the prescription drug plan enrollee, to the extent that he or she has been paid by the carrier, employer, or entity for covered Part D drugs.

When Medicare, and thus a Part D plan, is secondary to other payers, beneficiary costs incurred for covered Part D drugs would not be considered "covered" costs under the Part D plan. Consequently, these costs would be excluded from a beneficiary's incurred costs, as described in section II.C.2.a of this preamble and would not count as incurred costs against the annual deductible or the out-of-pocket threshold.

When Medicare is a secondary payer to employer coverage in the case of certain working Medicare beneficiaries, a PDP sponsor may charge a group health plan (GHP) or large group health plan (LGHP) for covered Part D drugs it furnishes to a Medicare enrollee who is also covered under the GHP/LGHP, and may charge the Medicare enrollee to the extent that he or she has been paid by the GHP/LGHP.

Because Medicare Part D coverage is a Federal program operated under Federal rules, State laws do not—and should not—apply, with the exception

of State laws regarding licensing or related to plan solvency or as otherwise provided by statute or regulation. Given the requirement in section 1860D-2(a)(4) of the Act that we extend MSP procedures applicable to MA organizations to PDP sponsors, PDP sponsors would also be permitted, under section 1852(a)(4) of the Act, to fully recover from liable third parties according to section 1862(b)(2) of the Act. In accordance with section 1860D-12(g) of the Act that extends the State preemption provisions under section 1856(b)(3) to Part D, under § 423.462 of our proposed rule that mirrors § 422.108(f), States would be prohibited from exercising authority over prescription drug plans in any area governed by Medicare Part D (including our regulations under chapter 423) other than State licensing laws and State laws relating to plan solvency. This is consistent with specific preemption authority now provided by section 1856(b)(3) of the Act with respect to MA organizations.

6. Coordination Of Benefits With Other Providers Of Prescription Drug Coverage

Section 1860D-23(a) of the Act authorizes us to establish procedures and requirements to promote the effective coordination of benefits between a Part D plan and a State Pharmaceutical Assistance Program with respect to payment of premiums and coverage, and payment for supplemental prescription drug benefits. We are to establish procedures and requirements before July 1, 2005, to ensure effective coordination. In developing these procedures and requirements, we are to consult with State pharmaceutical assistance programs, prescription drug plan sponsors, MA organizations, States, pharmaceutical benefit managers, employers, data processing experts, pharmacists, pharmaceutical manufacturers, and other experts. In addition, as specified at section 1860D-24(a) of the Act and implemented in this section of the regulations, we will apply the coordination requirements for State pharmaceutical assistance programs to other prescription drug plans including Medicaid (including a plan operating under a waiver under section 1115 of the Act), group health plans, the Federal employees health benefits plan, military coverage (including TRICARE), and other coverage that we specify. Under section 1860D-23(c)(1) of the Act, coordination between State pharmaceutical assistance programs and Part D plans does not change or affect the primary payor status of a Part D plan with respect to a State pharmaceutical

assistance program. Nor does it affect the primary or secondary payment position of the Part D plan related to the payments made by other plans providing prescription drug coverage. Under the requirements of section 1860D-11(j) of the Act, Part D plan sponsors will not be permitted to impose fees on SPAPs or other plans providing prescription drug coverage that are unrelated to the costs of that coordination.

The elements to be coordinated would include enrollment file sharing, claims processing, payment of premiums for both basic and supplemental drug benefits, third-party reimbursement of out-of-pocket costs, application of protection against high out-of-pocket expenditures (defined in section 1860D-2(b)(4) of the Act), and other administrative processes and requirements that we specify. Enrollment file sharing might include information such as beneficiary name, date of birth, health insurance claim number, sex, name and address of benefit administrator, insured's identification number, electronic transaction routing information (RxBin, RxPCN, RxGRP), group number, patient relationship, and coverage effective dates. Claims processing information might include collecting information similar in nature to that currently contained in a Medicare provider Remittance Advice statement. Information must be sufficient to successfully link with enrollment files and in order to allow Part D plans to make a correct determination of true out-of-pocket (TrOOP) expenditures on the part of beneficiaries.

On rare occasions Part D plans would also be required to coordinate benefits with other Part D plans. In the event that a beneficiary disenrolled from one plan mid-year and enrolled in another, the two plans would be required to exchange information sufficient to allow the beneficiaries' claims to be processed as if there had been no break in enrollment. Specifically, the second plan would need to obtain the enrollee's claim data and adjust its claims processing system accumulators to reflect that a certain level of expenditures and out-of-pocket costs had already been incurred in order that the correct sequence of claims processing could be maintained. This is not to say that the second plan could claim the first plan's costs as their own allowable costs, but that their systems would process future claims as if the earlier costs had been incurred by the second plan. We solicit comments on any other issues that may be involved in

coordination of benefits between Part D plans.

We may impose user fees for the transmittal of information necessary for benefit coordination related to third party reimbursement (other than by a SPAP) of Part D enrollees' costs for covered Part D drugs. Please see our later discussion on options we are considering related to coordination of benefits under the Part D program and also the critical nature of securing accurate and timely information for purposes of the TrOOP calculation. As we mention in that discussion, the statute permits us to impose user fees on the employer (or other third party) plan, but not on SPAPs under any method of operation, for the transmittal of benefit coordination information under Part D. Section 1860D-24(a)(3) of the Act specifically provides authority for imposing user fees under Part D similar to the authority under section 1842(h)(3)(B) of the Act for collection of user fees (otherwise known as "claim-based cross-over fees") under fee-for-service coordination with Medicare supplemental policies. However, we are also provided authority to retain a portion of these users fees to offset costs we incur for determining whether enrollee out-of-pocket costs are being reimbursed by third parties and for alerting Part D plans when, in fact, they are being reimbursed.

As we also later discuss in this preamble, any user fees, if collected, would not be assessed until the benefit is implemented in 2006. Before that time, we will fund the development and implementation of coordination of benefit requirements. We will also fund the development and implementation of a system to assist in the coordination of benefits—if and when it is determined that our development of the system is the appropriate option. We request comment on the method we should employ in imposing user fees and especially concerning whether it would be advisable to impose user fees on a monthly or quarterly basis based on the volume of data exchanged, and whether we should require electronic payment of user fees.

In section 1860D-24(c)(1) of the Act, a Part D plan sponsor may continue to use cost management tools (including differential payments) when administering benefits. This could include cost management tools related to managing supplemental benefits financed by a State pharmaceutical assistance program or another plan providing prescription drug coverage offered through a Part D plan. However, we believe that the intent of the statute at section 1860D-24(c)(1) of the Act is

clear in allowing Part D plans to continue to use cost management tools (such as tiered or differential cost sharing) even if an SPAP or other drug plan provides wrap-around or supplemental coverage for individuals enrolled in the Part D plan. We solicit comment on how we can ensure that wrap-around coverage offered by SPAPs and other insurers does not undermine or eliminate the cost management tools established by Part D plans. We also request comment on the most effective way to administer this provision without creating undue administrative burden on either Part D plans or the SPAPs and other insurers that might choose to provide wrap-around coverage for eligible individuals.

a. Coordination With SPAPs

The statute envisions a closer coordination of benefits between SPAPs and Medicare drug plans. For example, as provided in § 1860D-23(c) and in § 423.464(e)(3), a Part D enrollment card may also be used to access benefits under an SPAP, and the SPAP's emblem may be used on the card. Additionally, payments for beneficiary cost sharing made by an SPAP may be counted toward the incurred costs that count in the calculation of the true out-of-pocket (TrOOP) threshold in providing protection against catastrophic costs as provided in § 1860D-2(b)(4)(C)(ii) and in § 423.464(e)(2) of this proposed rule. SPAPs have filled a significant gap in prescription drug coverage for many Medicare beneficiaries in the absence of a Medicare drug benefit. Now that so many States are involved and so many beneficiaries have relationships with these programs, it will be important to ensure that coordination between Medicare Part D and SPAPs occurs as efficiently and effectively as possible. However, section 1860D-23(c)(5) of the Act provides that nothing in the statute should be construed to require that a State Pharmaceutical Assistance Program coordinate or provide financial assistance with respect to any Part D plan.

For purposes of this part, we are proposing that a Pharmacy Plus demonstration waiver program under section 1115 of the Act not be considered an SPAP. We grant Pharmacy Plus waivers that allow States to treat individuals participating in these waiver programs as Medicaid eligible only for the purpose of receiving prescription drug and primary care services. We do not believe that Pharmacy Plus waiver programs should be considered SPAPs. The statute makes a clear distinction between SPAPs, defined in section 1860D-23(b) of the

Act, and the Medicaid program (which includes State plans operating under Title XIX of the Act as well as State plans operating under a waiver under section 1115 of the Act) described in section 1860D-24(b)(1) of the Act. In so far as the Pharmacy Plus waiver programs operate under 1115 waivers, they are considered part of the Medicaid program and thus are not considered SPAPs. This distinction is important for purposes of the application of TrOOP. Section 1860D-2(b)(4)(C)(ii) of the Act is clear in allowing only a person, CMS, or an SPAP to make payments that will count toward TrOOP for an individual Part D enrollee. In so far as beneficiary cost sharing is reimbursed under Title XIX of the Act, including a waiver operating under section 1115 of the Act, or through any other mechanism including public assistance, it cannot be counted toward TrOOP. However, since the MMA allows states to use state-only SPAP funds to assist beneficiaries with out-of-pocket expenditures, States would be better off using their current contributions to wrap around the Federal Medicare Part D benefit than in continuing their Pharmacy Plus programs.

Medicare Part D plans may coordinate with SPAPs in a number of ways including accepting premiums for basic Part D or enhanced alternative coverage; accepting a lump sum per capita payment from the State for enrollee coverage through Part D plans; and coordinating on a claim-specific basis when Part D plan pays first and the SPAP is the secondary payor. All data exchanges between SPAPs and Part D plans are to be consistent with applicable privacy laws, in order to ensure the confidentiality of individually identifiable beneficiary information. In accordance with section 1860D-23(c)(2) of the Act, and in order to help coordination between State pharmacy assistance programs and Part D plans, a single card may be used to access benefits under both Part D and State pharmacy assistance programs. These cards may contain an emblem or symbol indicating that a connection between the two programs exists. We do not know how SPAPs will actually choose to coordinate with Medicare drug plans, and we welcome comment in this regard—particularly from States. We would like to better understand what SPAPs plan to do in 2006 relative to Part D interaction (such as in payment of premiums or claim-specific wrap-around), and how Medicare can assist State preferences in this regard. Our goal is to make the coordination of benefits process as functional for the

beneficiary, pharmacy, and States as possible.

We assume that some SPAPS will pay Part D plans' premiums on behalf of enrollees. For SPAPs that choose to wrap-around coverage rather than paying premiums, we propose to include SPAP information in a coordination of benefits system described below. In this way, pharmacies will know that a claim should be sent to the SPAP following adjudication by the Part D plan.

We request comment on this proposed approach, including the feasibility of the approach for SPAPs and the ease of administration for pharmacies. We also request comment on whether or not SPAPs that choose to coordinate benefits on a wrap-around basis should be required to provide feedback on how much of the remainder of the claim they have actually paid. Since SPAP payments count as true out-of-pocket spending toward catastrophic coverage, the Part D plans could simply assume that any amounts not paid by the Part D plan and sent to an SPAP for reimbursement would count toward calculating TrOOP. We are concerned that we may need information from SPAPs to determine more precisely the SPAP contribution or payment. But we are also mindful of systems implications for States and would appreciate comments in this regard, particularly from SPAPs.

b. Coordination With Other Prescription Drug Coverage

Other plans providing prescription drug coverage that Part D plans would need to coordinate with are any of the following (1) Medicaid programs (including a State plan operated under a waiver under section 1115 of the Act); (2) Group health plans, as defined in § 411.101; (3) FEHBP; (4) Military Coverage (including TRICARE) under chapter 55 of title 10 of the United States Code; and (5) other prescription drug coverage as we specify. We discuss coordination issues in detail in sections (d) and (e), below.

There is a relatively limited applicability of coordination of benefits between Part D plans and State Medicaid programs under the statute. The drugs that must be excluded from Medicare coverage are, with limited exception, drugs that may also be excluded from Medicaid coverage under section 1927(d)(2) of the Act. We anticipate that there may be situations involving State Medicaid programs that choose to continue coverage of a drug that is excluded from Medicare Part D coverage. For example, States may wish to continue coverage for barbiturates,

benzodiazepines, or prescription vitamins. In these situations, a Part D plan providing primary coverage would need to coordinate this coverage with a State on behalf of a dually eligible beneficiary. We request public comment on other situations that may involve benefit coordination between States and Part D plans (other than situations where the State is acting as an employer). In general, we invite comment on the other administrative processes and requirements that we might identify in order to help coordination between Part D of Medicare and other prescription drug plans.

c. Coordination of Benefits

Sections 1860D-23(a)(1) and 1860D-24(a)(1) of the Act require that, by July 1, 2005, we establish requirements for coordination of benefits between Part D plans and SPAPs and other insurers including Medicaid programs, group health plans, the Federal Employees Health Benefits Plan (FEHBP), military coverage (including TRICARE), and other coverage we may specify at a later date. As discussed previously, the elements that are to be coordinated must include: Enrollment file sharing; claims processing and payment; application of the protection against high out-of-pocket expenditures (by tracking TrOOP and the annual out-of-pocket threshold); and, other processes we specify.

We envision a system of information sharing between Medicare, Part D plans, SPAPs, group health plans, insurers, and other third-party arrangements. Our goal is that the design and implementation of a Part D coordination of benefits system enable pharmacies to obtain information about secondary insurers as well as the correct billing order. Ideally, we would anticipate that a pharmacy would query the system and be provided with information it can use to bill all the insurers involved in the correct order, as well as ascertaining and applying the correct TrOOP calculation in order to assess the correct beneficiary co-payment at the point of service. Since prescription drug benefits are administered at the point of sale, coordinating insurance coverage at the point of sale is a technical communications challenge. In the case of administering a drug benefit, the goal is that the beneficiary pays the correct coinsurance or co-payment at the point of sale and that the pharmacy is subsequently reimbursed the correct amount from the other source or sources. Unlike coordination of benefits under Medicare when data is exchanged in only a single direction (from Medicare to the employer or other

insurer), coordination of benefits for beneficiaries enrolled in Part D plans must include a reliable feedback loop of paid claims data from the employer, union or other insurer back to the Part D plan for purposes of tracking TrOOP. Additionally, given the real-time claims environment for pharmacy benefits, the feedback would ideally be in real-time so that beneficiary liability (if any) can be known at the point of sale, the correct insurer pays the correct share of the total drug cost, and the TrOOP calculation can be updated as quickly and accurately as possible. This suggests the need for an organized system to share, update, and push data back and forth between pharmacy benefit managers and pharmacies. This will be further discussed in the section on tracking true out-of-pocket (TrOOP) costs, below.

As mentioned above, under section 1860D-23(c)(1) of the Act, coordination between State pharmaceutical assistance programs and Part D plans does not change or affect the primary payor status of a Part D plan with respect to a State pharmaceutical assistance program. Nor does it affect the primary or secondary payment position of the Part D plan related to the payments made by other plans providing prescription drug coverage. Part B of Medicare has historically included limited coverage of certain outpatient prescription drugs. Part A of Medicare covers prescription drugs more extensively, but only when an individual is an inpatient in a Medicare-certified facility receiving Medicare-covered inpatient care. In additional circumstances, for instance when a person has elected Medicare hospice coverage, prescription drugs are also covered under original Medicare.

The new statutory definition of a covered Part D drug excludes drugs covered and paid for under Part A or Part B of Medicare for a given individual. Section 1860D-2(e)(2)(B) of the Act provides that a drug that would otherwise be a covered Part D drug will not be so considered if payment for the drug as so prescribed and dispensed or administered is available under Parts A or B for that individual. This language indicates that the Congress was aware that some drugs could qualify for payment under Part A or B in some circumstances, and Part D in other circumstances, depending on setting of dispensing or administration. This means, for example, that if a form of administration of a drug is covered under Part B in a region when injected incident to a physician office visit, that drug administered in that manner in that setting cannot meet the definition

of a covered Part D drug. However, that same drug can be covered under Part D when picked up at a retail pharmacy to be self-administered by the patient. For another example, in certain instances a drug could be covered under Part B at certain times and under Part D at other times. Many patients, for instance, take their medicines at specific times throughout the day. If these patients receive a service in a hospital outpatient department and remain in the hospital for several hours of post surgery observation, he/she may receive one or more doses from the hospital pharmacy. This medication would be considered part of their Part B service and covered under the hospital OPD payment.

We note that individuals can elect Part D of Medicare if they are entitled to Part A or enrolled in Part B. This means that individuals with only Part A or only Part B will still have access to Part D. Although most Medicare beneficiaries have both Parts A and B, there are nearly 2 million Medicare beneficiaries who have only Part A, while there are approximately 500,000 Medicare beneficiaries who have only Part B. We interpret the definition of covered Part D drug to exclude coverage under Part D for drugs otherwise covered and available under Parts A or B for individuals who choose not to enroll in either program. We interpret the words "payment is available" to mean that payment would be available to any individual who could sign up for A or B, regardless of whether they are actually enrolled. All individuals who are entitled to premium-free Part A are eligible to enroll in Part B. This includes individuals who are entitled to Part A based on age, disability, and ESRD. All individuals who are entitled to Part B only are age 65 and, in almost all instances, not eligible for premium-free Part A. However, they are eligible to buy into Part A for a premium. Thus, for all Part D individuals, Part A drugs and Part B drugs are "available" if they choose to pay the appropriate premiums. Consequently, Part D would not be required to pay for drugs covered under Parts A and B on the basis of a Part D eligible individual's status with regard to Parts A and B. In addition, we believe that the phrase "for that individual" in § 1860D-2(e)(2)(B) of the Act is intended to capture the fact that under local medical review policies, a drug that might be covered under Part B for an individual in one area of the country may not be covered under Part B in another area of the country. Thus, what is covered "under Part B for that individual" may be different in different geographic regions. The result of these

interpretations would be that any drug covered under A or B could not be covered under D, whether it was covered for that individual or not.

We would wish to ensure that Part D coverage coordination works seamlessly for beneficiaries with Parts A and B of Medicare, and that beneficiaries do not lose Medicare coverage otherwise available to them due to unforeseen difficulties encountered in the coordination process. This is a critical consideration for effective and efficient coordination between the original Medicare program and the new coverage provided under Part D. Specific options concerning coordination of benefit procedures that we are considering are outlined below.

Pharmacy-dispensed drugs covered by Part B (for instance, DME drugs, immunosuppressive drugs, and oral anti-cancer drugs) are not reimbursed unless the pharmacy has a Medicare supplier number; thus, a beneficiary could lose Part B coverage by filling a prescription at the wrong pharmacy. (We recognized this problem in the interim final rule on the discount card program and stated that, for drugs potentially covered by Part B, "non-Medicare participating pharmacies should refer the beneficiary to a participating pharmacy." See 68 FR 69840, 69852). To reduce this risk, we are proposing to—

1. Encourage Part D plans to enroll pharmacies with Medicare supplier numbers in their networks;

2. Encourage Part D plans to inform beneficiaries whether their network pharmacies have a Medicare supplier number, and explain why this is important when filling prescriptions for drugs potentially covered by Part B; and

3. Develop educational materials reminding pharmacies without Medicare supplier numbers that they must refund any payments collected from beneficiaries enrolled in Part B for Part B drugs unless they first notify the beneficiary (through an advanced beneficiary notice (ABN)) that Medicare likely will deny the claim.

Statutory "refund requirements" apply to claims for "medical equipment and supplies" that Medicare denies because the supplier lacked a supplier number, unless—

1. The beneficiary signed an ABN notifying him or her that Medicare would deny payment, and agreed to be personally responsible for payment; or

2. The supplier did not know and could not reasonably have known that Medicare would deny payment.

For this purpose, coverage of medical equipment and supplies includes durable medical equipment (DME),

certain drugs and other supplies necessary for use of an infusion pump, oral immunosuppressive drugs and anti-cancer drugs, and "such other items as the Secretary may determine." (See the Medicare Claims Processing Manual, Chapter 30, sections 150.1.3 and 150.1.5.) Suppliers are presumed to know that Medicare will not pay for medical equipment and supplies furnished by a supplier that lacks a supplier number. (See section § 150.5.4 of Chapter 30 of the Medicare Claims Processing Manual.) We are considering whether a drug denied Part B coverage for this reason should become a covered Part D drug, and the claim should thus be processed under Part D, and would like to receive comments on the relative likelihood of this occurrence and on alternative means of addressing such circumstances.

We are also considering whether a drug denied Part B coverage for any other reason should become a covered Part D drug. For instance, we believe that a drug denied Part B coverage and payment for therapeutic inappropriateness, drug-disease contraindication, incorrect drug dosage, duration of drug treatment or for similar reasons related to medical necessity should not be considered a covered Part D drug. Rather, we believe that such a denial or non-coverage decision under Part B, while appealable under Part B, would not cause the drug to become a covered Part D drug. We welcome comment in this area.

For drugs potentially covered by Part B that are dispensed by a pharmacy that is a Medicare supplier, we are considering the development of automatic cross-over procedures. That is, we are considering requiring that: (1) The pharmacy submit the claim to the appropriate Part B carrier; and (2) the carrier, if it denies the claim, submit the claim automatically to the PDP (or its claims processing agent) through which the beneficiary has Part D coverage. This assumes that the beneficiary receives Part D through a PDP. For beneficiaries enrolled in MA-PD plans, coordination of benefits will generally occur internally within the MA organization. (Similar cross-over procedures are used today in connection with dual-eligibles—individuals entitled to both Medicare and Medicaid and related to coordination between Medicare and Medicare supplemental insurers.)

We also believe that similar cross-over procedures for any physician-administered drugs that may be covered under Part B or Part D will need to be developed. This would involve: (1) The physician submitting the claim to the appropriate Medicare carrier; and (2) the

carrier automatically submitting the claim to the Part D plan (or its claims processing agent) if it denies payment under Part B. We particularly welcome comment on the feasibility of these proposed Part D and Part B coordination of benefits proposals and welcome suggestions on other methods or procedures that might be more efficient or better suited to coordination of prescription drug benefits.

Another type of coordination of benefits occurs when Medicare pays secondary to another insurance (MSP). Medicare currently pays secondary when payment has been made or can reasonably be expected to be made by another party such as workers compensation, automobile insurance, a liability insurance policy, or another health insurance policy (for example, when a beneficiary's spouse has primary insurance through their employment). Beneficiaries provide information, when available, regarding third party coverage as part of the initial enrollment questionnaire. Medicare also attempts to identify additional situations in which Medicare should pay secondary, and when we believe this is the case we follow up with employer plans for information. We do not anticipate significant changes to this mechanism, except that Medicare will now, in relatively limited circumstances, pay secondary for a Part D beneficiary who has other insurance. We do not know how many beneficiaries with employer-sponsored insurance that is the primary payor to Medicare will enroll in Part D. We do know that approximately two-thirds of individuals with primary employer-sponsored insurance do voluntarily pay for Part B coverage. We request public comment on the likelihood that beneficiaries with primary employer-sponsored insurance will elect Part D. We believe that the number of instances where automobile, workers' compensation or liability insurance will be paying primary on behalf of Part D enrollees will be relatively small. So, generally, we believe that most instances of coordination of benefits of under Part D will occur when Medicare is primary and another insurer is secondary.

d. Collection of Data on Third Party Coverage

Section 1860D-2(b)(4)(D)(i) of the Act authorizes us to establish procedures for determining whether a beneficiary's Part D out-of-pocket costs are actually reimbursed by a group health plan, insurance or otherwise, or another third-party arrangement. These procedures provide for—

- Determining whether costs for a Part D enrollee are being reimbursed through insurance or otherwise, a group health plan, or other third-party arrangement; and Alerting Part D plans in which beneficiaries are enrolled about reimbursement of prescription drug costs they receive through insurance or otherwise, a group health plan, or other third party arrangement.

• Section 1860D-2(b)(4)(D)(ii) of the Act permits Part D plans to request information on third party insurance from beneficiaries. We would expect Part D plans to update Medicare records based on the information provided by beneficiaries to reflect changes in coverage, including the primary or secondary status of such coverage relative to Medicare. As discussed in the subpart B preamble, beneficiaries who materially misrepresent (as defined in standards and processes we propose to establish in § 423.108(b)(4)(iv) of the proposed rule) information on third parties may be disenrolled from any Part D plan for a period specified by CMS and may also be subject to late enrollment penalties upon enrollment in another plan.

In the current Medicare fee-for-service claims processing environment, coordination of benefits when Medicare is the primary payor and another insurer is secondary (for example, employer-based retiree insurance, Medicaid, or Medigap) is performed as a convenience to the beneficiary and employer plan (coordination of benefits is required by statute for claims involving Medigap plans) and is voluntary on the part of the employer plans. The coordination of so-called "cross-over" claims is a one-way communication of claims information from Medicare to the secondary plan. This "cross-over" does not occur in real time. Instead, Medicare communicates with employer plans on a batch basis, and claims information may not reach the secondary insurer until weeks after the covered service is rendered. Coordination of benefits is, nonetheless, a valuable service to employers and Medicaid since these payors get an electronic claim that has already been subjected to claims edits and on which Medicare has already paid its portion. As a matter of fact, the service is so cost effective that employers willingly pay Medicare for the "cross-over" service. We have agreements with numerous employers purchasing "cross-over" data. In 2004 Medicare expects approximately 550 million Part A and Part B claims to "cross-over" to a secondary insurers including Medigap, Medicaid, employers, other insurers, and third

party administrators providing wrap-around coverage.

Section 1860D-2(b)(4)(D)(i) of the Act authorizes us to establish procedures for determining if costs for Part D enrollees are reimbursed by other payors, and for alerting Part D plans about such arrangements. This provision could be read to mean that we only have to determine the presence of alternative coverage and merely has to alert Part D plans of such. However, it could also be read to mean that we have to determine if specific claim costs have been reimbursed by alternative coverage. In contrast, section 1860D-24(a) of the Act directs us to establish requirements for Part D plans to coordinate benefits with other payors in the same manner as we are directed to coordinate Part D benefits with SPAPs. This provision could mean that the responsibility for coordination of benefits lies with the Part D plans. However, section 1860D-24(c)(2) of the Act provides that the requirements of section 1860D-24 shall not affect the application of procedures established under section 1860D-2(b)(4)(D) of the Act. This arguably preserves the flexibility CMS has under the later section to impose requirements on alternative coverage arrangements. In addition, section 1871 of the Act generally authorizes us to prescribe such regulations as may be necessary to carry out administration of the insurance programs under title XVIII of the Act that now includes Part D.

We assume that employer and union plans may respond to the new Medicare prescription drug benefit in a number of ways. We expect that many of the employers and unions that currently provide supplemental drug coverage to their retirees will opt to pay premiums to Part D plan sponsors. In today's Medicare Advantage market, the most prevalent model is one that employers and unions pay premiums to MA organizations. We expect this model to continue to have wide appeal under Part D. In the case of the PDP market, while many employers and unions may choose to pay premiums to PDPs for Part D for their retirees, others may choose to coordinate benefits with PDPs. In general, employers and unions that continue to offer assistance to Medicare-eligible retirees will either (1) provide qualified coverage of prescription drugs in such a way that retiree-beneficiaries do not need to enroll in Part D of Medicare, in which case the employer may qualify for a Federal subsidy under section 1860D-22(a) of the Act; or (2) provide assistance that requires retiree-beneficiaries to enroll in Part D (either by paying Part D basic or supplemental

premiums); or (3) provide supplemental (“wrap-around”) benefits through alternative secondary coverage. The last option has implications for coordination of benefits between Part D plans and employer/union-sponsored retiree drug coverage, and in particular, on the accurate processing of claims with respect to the out-of-pocket threshold.

e. Tracking True Out-of-Pocket (TrOOP) Costs

As we discuss in the preamble to subpart C of this rule, section 1860D-2(b)(4)(C) of the Act provides that beneficiary costs for covered Part D drugs are only considered incurred when those costs are incurred by a Part D enrollee for covered part D drugs covered under (or treated as covered under) a Part D plan that are not paid for under the Part D plan due to the 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 proposed § 423.104(e)(5)(iii), including any price differential for which the Part D enrollee is responsible under proposed § 423.120(a)(6) and § 423.124(b)(2). Further, section 1860D-2(b)(4)(C)(ii) of the Act provides that costs shall be treated as incurred by a Part D eligible individual only when they are paid by another person (such as a family member, on behalf of the individual) and the individual (or other person) is not reimbursed by insurance or otherwise, a group health plan, or other third-party arrangements, with the exception of amounts reimbursed by a SPAP or under the low-income subsidy provided for under proposed § 423.782. We refer to beneficiary expenditures for covered Part D drugs meeting these requirements as “true out-of-pocket costs”, or TrOOP. We are considering a number of options for facilitating the exchange of data needed to track TrOOP, and will discuss alternatives around both mandatory versus voluntary reporting of claim and out-of-pocket costs, and centralized versus distributed responsibility for tracking the information in the extended discussion, below.

The case in which the employer or union arranges wrap-around coverage through a third party administrator or insurer other than through a Part D plan in which the retiree-beneficiary is enrolled is the potentially complex and challenging to administer, especially given the true out-of-pocket costs (TrOOP) requirements. The degree of difficulty in making coordination of benefits work with respect to wrap-around coverage is related to the ability of plans to efficiently coordinate

insurance coverage at the point of sale. We cannot estimate the number of employer/labor plans that might choose to wrap-around prescription drug coverage other than through a Part D plan. We welcome comment that would help us estimate the scope and impact of such coverage, as well as the impact on the operational capabilities of plans (and their subcontractors).

Medicare Part D plans will need to be particularly involved with employer/union plans that wrap-around Part D coverage due to the implications such wrap-around coverage has for administering TrOOP maximums. Payments made on behalf of a beneficiary by a third party (such as by employer/labor-sponsored supplemental prescription drug coverage) are not considered incurred costs and, therefore, do not count in the TrOOP calculation. Thus, employer/labor-sponsored wrap-around coverage effectively pushes out the total spending “attachment point” or starting point at which protection from high out-of-pocket beneficiary expenditures begins.

As discussed in subpart G of this preamble, although Part D plans will receive reinsurance payments from us for a portion of the costs they incur for prescription drug coverage provided to beneficiaries after the true out-of-pocket threshold has been met, Part D plans will also bear “risk” for a portion of the costs they incur above the threshold. The critical nature of the TrOOP calculation makes coordination of benefits under the Part D program of vital interest to all parties. Both CMS and Part D plans must know how much an employer/union-based plan or other plan pays on a prescription drug claim following adjudication of that claim by the Part D plan. Likewise, beneficiaries have a vested interest in the TrOOP calculation due to the financial relief they receive after meeting the annual out-of-pocket threshold.

Responsibility for tracking TrOOP costs is somewhat unclear. On the one hand, the government is given authority to establish procedures for tracking TrOOP costs. For instance, as we discuss later in this preamble section and as we propose to codify in regulation at § 423.464(c), section 1860D-24(a)(3) of the Act authorizes us to impose user fees for disseminating information necessary for benefit coordination. On the other hand, responsibility for obtaining and applying the necessary information to prescription drug claims is assigned to the Part D plan sponsors. It is of great importance to establish clear responsibilities for TrOOP tracking and calculation processes in regulation in

order to ensure that qualified beneficiaries receive appropriate coverage once they have met the out-of-pocket cost limit.

There is sufficient ambiguity in the statutory language to support a proposal to mandate that group health plans, insurers, and otherwise, and other third-party arrangements provide claims data for Part D enrollees to us for purposes of administering TrOOP. Exercising such authority would not be in violation of HIPAA confidentiality requirements. However, exercising such authority would impose administrative burden on group health plans, insurers, and otherwise, and other third-party arrangements that provide coverage or reimbursement of health care expenses to Medicare Part D beneficiaries. Moreover, mandatory reporting of enrollment file and claims data will not be sufficient, in and of itself, to capture all forms of enrollee cost-sharing reimbursement.

For instance, if the third party reporting of claims payments and reimbursements are strictly voluntary, serious challenges to implementing a system for tracking TrOOP will continue to exist. A voluntary system would be incomplete and all payors that rely on voluntarily reported data would need to have back-up procedures for accounting for initially unreported data. A voluntary system would also leave CMS and Part D plans open to criticism that the data is incomplete and that benefits paid out based on TrOOP calculations are inaccurate. However, group health plans, insurers and otherwise, and other third-party arrangements might prefer a voluntary system.

By way of comparison, the current (voluntary) Medicare Secondary Payer (MSP) program achieves \$4.5 billion in savings. This means that there is some compliance with the provisions even though there is no mandatory insurer-reporting requirement. However, under the MSP provisions there are enforcement provisions. There are tax penalties for non-compliance with the MSP rules. In addition, there is a mandated reporting of some information through the IRS/SSA/CMS data match project that obtains tax and spousal information from the IRS and SSA. Our contractor then sends the employer a questionnaire concerning the identified Medicare beneficiary or spouse of a beneficiary to determine if there is coverage that is primary to Medicare. Failure to complete the questionnaire can result in the imposition of a Civil Monetary Penalty. However, even with these enforcement provisions, it is estimated that Medicare is still losing millions of dollars where employer

plans should be primary. Payments made by plans primary to Medicare under the Medicare Secondary Payer provisions 1862(b) would not count against the TrOOP.

In the cross-over area discussed previously in this section of the preamble, we are more successful, but there are still numerous payers who do not have cross-over agreements with us. So although there is substantial participation related to cross-over claims, there is also significant room for improvement. In the context of the current discussion, the issue is primarily that the sending of paid claims data to us for its use in the TrOOP calculation will be an added administrative cost on third-party payers, which (without explicit reporting requirements in the statute or an even an enforcement mechanism) may lead to lower compliance.

We are considering the following options for operationalizing the data exchange related to the Part D coordination of benefits system and TrOOP accounting:

Option 1: The PDPs and MA-PD plans would be solely responsible for tracking TrOOP costs. This option places the entire responsibility for tracking TrOOP costs with the PDPs and MA-PD plans. As part of their overall benefit management responsibility they would be responsible for establishing the systems infrastructure and ensuring that all data points are reporting timely and accurate data about beneficiaries' Part D costs. Each PDP and MA-PD plan must establish arrangements with all payers for enrollment file sharing and claims payment information exchanges. This coordination applies equally to plans that are primary or secondary payer to Medicare. Under this scenario, any payer who had a beneficiary on behalf of whom they expected to make either a primary or secondary payment to Medicare Part D would need to be able to (1) identify the Part D plan in which the beneficiary was enrolled, (2) establish the telecommunications links; (3) transmit enrollment information to the specific PDP or MA-PD plan in which their covered individual is enrolled, and (4) transmit claims payment data to the PDP or MA-PD each time a claim was paid which may need to be included in the TrOOP calculation. Data collected by a PDP or MA-PD plan would be annotated to the Medicare Beneficiary Database and be available to pharmacies for the purposes of proper billing.

Option 2: We would procure a TrOOP facilitation contractor to establish a single point of contact between payers, primary or secondary. Under this

scenario, we would procure a TrOOP facilitation contractor based on a strategy of voluntary compliance, similar to the existing MSP coordination of benefits model. We would procure a contractor to receive enrollment and claims payment information from all plans primary and secondary to Medicare. This would establish a single point of contact between the Medicare program and employers, State Pharmacy Assistance Programs, as well as primary and secondary payers for enrollment and claims payment information.

Under this single point of contact option, a payer primary or secondary to a Part D plan would be required to send an enrollment file to the TrOOP facilitation contractor (a contractor procured by us). The TrOOP facilitation contractor would match the payer enrollment information to Medicare enrollment records and update the Medicare Beneficiary Database with the information. The other payer enrollment file information would also be used the TrOOP facilitation contractor to match claims payment data which would also be submitted to the TrOOP facilitation contractor. Once a claim was matched against the enrollment data, the TrOOP facilitation contractor would aggregate the claim records files by Part D plan and transmit the information. The PDP or MA-PD plan would be responsible for using the data in applying the TrOOP and applying other TrOOP requirements such as the application of a formulary.

PDPs and MA-PD plans would also request information about other coverage during the enrollment process and could add change or delete information input into the system by the TrOOP facilitation contractor. We can use existing fee-for-service coordination of benefits processes to implement many of the processes needed to implement these provisions. Information concerning primary and secondary plans would be shared with and PDPs and MA-PD plans, as well as annotated in the Medicare common working file/Medicare Beneficiary Database to enhance pharmacy billing and beneficiary customer service.

Under either option, we would enter into voluntary data sharing agreements with employers/unions and other plans to participate in a shared system. The same mechanism would accept information provided directly by Part D plans, SPAPs, group health plans, FEHBP, military plans, and other insurance or payors as we may specify.

We are committed to ensuring that claims are processed appropriately under Part D. Therefore, to foster proper billing and coordination of benefits we

are also considering the establishment of the Medicare beneficiary eligibility and other coverage query system using the HIPAA 270/271 eligibility query. Information collected under this section for the purpose of TrOOP application would be available to be queried by pharmacies to facilitate proper billing. We are concerned that with the significant expansion of health care options available to beneficiaries that providing information to pharmacies about Medicare and other coverage is essential to facilitate proper claims processing. We are requesting comments concerning the development of this system.

In either event, the system(s) would need to be operational by January 1, 2006. Note that user fees might be imposed on third-party payers (but not on SPAPs) for the transmittal of information under either model. Were responsibility to reside solely with Part D plans to develop and operate a coordination of benefits system or systems (without a defined role for us in such development and operation), the statute would still permit imposition and collection of user fees. Please see our preamble discussion on user fees earlier in this preamble related to proposed § 423.464(c).

We could propose (with or without mandatory reporting by insurers) placing requirements on Part D plans and enrollees that would facilitate private market arrangements to report the data. We are considering mandating that beneficiaries enrolling in Part D plans provide third-party payment information and consent for release of data held by third parties as part of their enrollment application and which could be validated through a HIPAA-compliant beneficiary "release" or authorization. For instance, if we were to clearly require that all Part D plans coordinate benefits and that all Part D enrollees provide consent for release of third-party data on their Part D enrollment forms, the Part D plans would have the authority to implement inter-plan reporting mechanisms in order to coordinate benefits. However, back-up procedures would still be necessary to capture expense reimbursements made outside prescription drug claim processing systems as, for instance, by HRA administrators. Thus, although the statute is unclear as to which entity should have primary responsibility for tracking TrOOP costs (CMS or the Part D plans), to facilitate the accurate calculation of TrOOP we could do this either through reliance on data collection provisions in section 1860D-15(c)(1)(C) of the Act, or in reliance on

our authority to collect information related to contracting in section 1860D–12(b)(3)(D) of the Act that incorporates into Part D section 1857(e) of the Act, allowing the contract to require the contracting organization to provide to us the information as we decide necessary and appropriate. However, section 911(c)(2) of the MMA strictly forbids matches of data between Medicare contractors and us to identify MSP situations. The fact that the MMA is silent with regard to matches or data exchanges for the purposes of Part D TrOOP cost administration could be taken in different ways. One way to read the statute would be that the omission was intentional and the Congress specifically intended for the type of exception not to be applicable for TrOOP. However, an equally good case could be made that TrOOP administration procedures were to be defined by us and therefore the spirit of the provision contained in 911(c)(2) should be considered as it applies to TrOOP.

We ask for comment on these options and are seeking input on the best means to ensure an efficient and effective coordination of benefits related to the Part D Medicare program. We are also interested in discussion of other temporary or phased-in approaches that may be necessary or advisable given the short timeframe between publication of the final rule and program implementation. Under any of the scenarios presented it is clear that the ultimate responsibility for calculating TrOOP belongs to the Part D plan. The only issues are what role in facilitating TrOOP tracking CMS should have, if at all.

It is important to note that the sequencing of primary and secondary insurance claims will be a critical issue for tracking TrOOP costs. If, for example, a secondary plan does not provide feedback to the system in real time, it is possible that the TrOOP cost information the Part D plan has access to may not be entirely up to date at any given time. Also, if a paper claim is submitted after the fact to the Part D plan or supplemental insurer (due to an appeal reversal, for instance), the TrOOP calculation would not be up to date in real time at the point of service. Another complicating factor in the sequencing of claims is cancelled prescriptions. Generally, a claim is adjudicated when a prescription is filled. If the prescription is not picked up, and is eventually cancelled, the claim needs to be cancelled. If, in the meantime, other claims have been adjudicated, the sequencing is thrown off by the cancelled prescription,

potentially disrupting the calculation of the initial deductible and TrOOP, and making coordinating benefits and tracking TrOOP costs more difficult.

Ideally, we would prefer that the system actually coordinate the adjudication of claims and provide real-time claims processing across multiple insurers, but we do not believe that such a complex and unique system could be operational by January 1, 2006. And, as previously mentioned, we do not have statutory authority to enforce a mandatory reporting requirement that employers, group health plans, other insurance or third-party arrangements participate in such a system. We believe, however, that the type of voluntary system we envision would provide information sufficient to permit the coordination of benefits that the statute requires and that beneficiaries and pharmacies desire. In any case, the goal would be to minimize the prevalence of paper claims submitted post point of service. In addition, we request public comment on methods for Part D plans to receive information from beneficiaries or others regarding payment made by entities that do not participate in this coordination of benefits system, since there is no requirement that third-party payers participate in this voluntary system.

We anticipate that the majority of employers, group health plans and other third-party payment arrangements would participate in a voluntary system since they would receive a clean claim from the pharmacy that has already been adjudicated by the Part D plan. In return for the clean claim, we would request that third-party payers provide information back to the coordination of benefits system regarding how much they paid on the claim for purposes of calculating the TrOOP under Part D. We anticipate that there will be times that the information in the system is not consistent with what the beneficiary informs the pharmacy is the most current state of insurance. We request comment and relevant information (if any exists from current market practices) on how these situations should be resolved under Part D at the point of sale.

K. Proposed Application Procedures and Contracts With PDP Sponsors

(If you choose to comment on issues in this section, please include the caption “Subpart K—Proposed Application Procedures and Contracts with PDP Sponsors” at the beginning of your comments.)

1. Overview

Subpart K of proposed part 423, would implement provisions established by sections 1860D–12(b)(1), 1860D–12(b)(3)(A), 1860D–12(b)(3)(B), 1860D–12(b)(3)(C), 1860D–12(b)(3)(D) and 1860D–12(b)(3)(F) of the Act that relate to contract requirements for PDP sponsors. The proposed provisions in this rule would address conditions necessary to contract with Medicare as a PDP sponsor, as well as contract requirements and termination procedures that would apply to Medicare-contracting PDP sponsors.

2. Background

Section 1860D–12(b)(1) of the Act provides that an entity seeking to participate in the Medicare program as a PDP sponsor must enter into a contract with us for that offering. The contract may cover more than one prescription drug plan in a region or across multiple regions and would require the PDP sponsor to adhere to all applicable requirements and standards included in Part D of Title XVIII of the Act and our provisions at proposed part 423, as well as the terms and conditions for payments described in regulation and the statute. While the provisions discussed in proposed subpart K would, in general, also apply to “fallback plans”, eligibility limitations and contract requirements for applicants that have offered or are offering “fallback plans” are discussed in proposed subpart Q of this preamble.

Section 1860D–12(b)(3) of the Act states that certain MA contracting provisions in the Act should be applied to contracts with PDP sponsors in the same manner that they apply to contracts with MA organizations. Therefore, it is our intent to apply, where applicable, the contracting provisions used for MA organizations to contracts with PDP sponsors. The contracting provisions in this proposed rule are, for the most part, the current MA contract requirements with some changes made to accommodate the differences between MA and PDP sponsors and to implement specific changes mandated in the Act. However, we realize that the programmatic differences between this proposed rule and the existing MA contracting provisions will require changes. We are studying this issue, requesting comments and planning to implement the appropriate changes in the final rule.

We discuss the following five requirements in this subpart:

- Protection against fraud and abuse (proposed § 423.504(d));

- Contract provisions (proposed § 423.505);
- Effective date and term of contract (proposed § 423.506);
- Procedures for non-renewal (proposed § 423.507) and termination (proposed § 423.508 through § 423.510); and
- Minimum enrollment (proposed § 423.512).

The sixth requirement (intermediate sanctions) identified in section 1860D-12(b)(3) of the Act is discussed in more detail in proposed subpart O of this preamble.

In addition, section 1860D-12(b)(3)(D) of the Act incorporates section 1857(e) of the Act, which provides the Secretary the authority to include in the contract “such other terms and conditions not inconsistent with this part * * * as the Secretary may find necessary and appropriate.” Since the contracting aspects of the proposed MA and PDP programs are quite similar, as are the procedures and requirements, we need to support their contracts. We propose to apply the provisions of part 422 to PDP sponsor contractors and applicant organizations, with few exceptions, in proposed subpart K. In some cases it was necessary to make changes to accommodate differences between MA and PDP sponsors, for example, application timeframes, payment, provider contract requirements, and certifications. We have noted these changes where they occur throughout the preamble.

We are interested in receiving comments on the contracting provisions of this rule. We are interested in receiving comments on provisions that should not be applied, and whether for PDPs there are other contracting considerations that are not addressed in these MA contract provisions. Specific issues on which we seek comment include: the type of business transactions which should be reported to CMS, the proposed required administrative and management arrangements, how these provisions should be applied to large companies with multiple business units, and the record maintenance requirements.

Maintenance of a single application and evaluation procedure, and a single set of contract requirements for both the MA and PDP programs would bring simplicity, consistency, and reduced administrative burden for those entities that are managing both programs. The requirements at proposed § 423.501 through § 423.516 would be similar to the requirements in § 422.500 through § 422.524. A summary of our proposed provisions are discussed below.

3. Definitions

In proposed § 423.501, we would define contract-related terms that would be limited to use in this proposed subpart. These definitions would be almost the same as those in § 422.500 for application to the MA program except in cases where the MA definition is inapplicable—such as in definitions that reference hospitals or hospital services. Of particular note are the proposed terms “first tier” and “downstream” entity because a PDP sponsor may often accomplish its responsibilities under its Medicare contract by contracting with these entities. For purposes of this proposed subpart the following definitions would apply:

Business transaction would mean any of the following kinds of transactions:

- (a) Sale, exchange, or lease of property.
- (b) Loan of money or extension of credit.
- (c) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—
 - (1) Salaries paid to employees for services performed in the normal course of their employment; or
 - (2) Health services furnished to the PDP sponsor’s enrollees by pharmacies and other providers, and by PDP sponsor staff, medical groups, or independent practice associations, or by any combination of those entities.

Significant business transaction would mean any business transaction or series of transactions of the kind specified above in the definition of “business transaction” that, during any fiscal year of the PDP sponsor, have a total value that exceeds \$25,000 or 5 percent of the PDP sponsor’s total operating expenses, whichever is less.

Downstream entity would mean a party that enters into a written arrangement below the level of the PDP sponsor’s contract with the “first tier” entity. These written arrangements would continue down to the level of the ultimate provider of both health and administrative services. Usually in the context of the drug benefit the ultimate provider would be the pharmacist but it might also include other entities, such as an organization providing medication therapy management.

First tier entity would mean any party that enters into a written arrangement with a PDP sponsor or contract applicant to provide administrative services or health services for a Medicare eligible individual under Part D.

Party in interest would mean the following:

(a) Any director, officer, partner, or employee responsible for management or administration of a PDP sponsor.

(b) Any person who is directly or indirectly the beneficial owner of more than 5 percent of the organization’s equity; or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization.

(c) In the case of a PDP sponsor organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law.

(d) Any entity in which a person described in paragraphs (a), (b), or (c) of this definition—

(1) Is an officer, director, or partner; or

(2) Has the kind of interest described in paragraphs (a), (b), or (c) of this definition.

(e) Any person that directly or indirectly controls, is controlled by, or is under common control with the PDP sponsor.

(f) Any spouse, child, or parent of an individual described in paragraphs (a), (b), or (c) of this definition.

Related entity would mean any entity that is related to the PDP sponsor by common ownership or control and—

(a) Performs some of the PDP sponsor’s management functions under contract or delegation;

(b) Furnishes services to Medicare enrollees under an oral or written agreement; or

(c) Leases real property or sells materials to the PDP sponsor at a cost of more than \$2,500 during a contract period.

4. Proposed Application Requirements

Under proposed § 423.502, in order to obtain a determination on whether it meets the requirements to become a PDP sponsor, an entity, or an individual authorized to act for the entity (the applicant), would be required to complete and submit a certified application in the form and manner required by us. In addition to the application, the entity or individual authorized to act for the entity would be required to submit documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards as described in proposed subpart I of this proposed part; or submit a Federal waiver as described in proposed subpart I of this proposed part. The authorized individual would be required to describe thoroughly how the entity would meet the proposed

requirements described in this proposed part.

We would be responsible for determining whether an entity is qualified to be a PDP sponsor and if that entity meets the proposed requirements of part 423. Also, in this proposed section, we would specify that an applicant that submits material that he or she believes would be protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act, or because of exceptions provided in 45 CFR part 5 (the Department's regulations providing exceptions to disclosure), would have to label the material "privileged" and include an explanation of the applicability of an exception described in 45 CFR part 5.

Current fallback plans, entities that bid to be fallback plans, and, in some circumstances, entities that served as fallback plans the prior year would not be eligible to apply as a PDP sponsor. (See proposed subparts F and Q of this preamble for details on proposed "fallback plans".)

5. Proposed Evaluation and Determination Procedures For Applications To Be A Sponsor

Proposed § 423.503 would establish procedures for us to evaluate and determine an entity's application for a contract as a PDP sponsor. These provisions mostly mirror the provisions applicable to MA specified at 42 CFR 422.502. This evaluation and determination of the application would be done on the basis of information contained in the application itself and any additional information that we would obtain through on-site visits, publicly available information, and any other appropriate procedures.

If the application is incomplete, we would notify the contract applicant, and we propose to allow 10 days from the date of the notice for the contract applicant to furnish the missing information. After evaluating all relevant information, we would determine if the contract applicant's application meets the applicable requirements of proposed § 423.504. We note that the MA provision in § 422.502(a)(2) currently provides a 30-day window for the MA program to furnish missing information. We believe a 10-day period is necessary for the Part D program because of the June bidding deadline specified at § 423.265(b). An organization would need to apply as close to the first of the year as possible in order to have its contract approved before submitting bids. Once a contract is approved, an organization is not required to reapply each year. See

§ 423.506(c) for renewal of contract information.

If a PDP sponsor, MA organization, or Medicare cost plan fails to comply with the terms of a previous year's contract with us under Title XVIII of the Act, or fails to complete a corrective action plan during the term of the contract, we may deny an application from a contract applicant based on the contract applicant's failure to comply with that prior contract with us even if the contract applicant meets all of the current proposed requirements.

We would notify each applicant that applies for a contract as a PDP sponsor under this part, of its determination on the application and the basis for the determination. The determination may be one of the following:

- *Approval of application.* If we approve the application, we would give written notice to the contract applicant, indicating that it meets the requirements for a contract as a PDP sponsor.

- *Intent to deny.* If we find that the contract applicant does not appear to meet the requirements for a PDP sponsor contract, we would give the contract applicant "notice of intent to deny" the application for a PDP contract and a summary of the basis for this preliminary finding. Within 10 days from the date of the notice, the contract applicant would have to respond in writing to the issues or other matters that would be the basis for our preliminary finding and would have to revise its application to remedy any defects we identify. We note that the MA provision in § 422.502(e)(2) currently provides a 60-day window for the MA program to remedy any defects we identify. We believe a 10-day period is necessary for the Part D program because of the June bidding deadline specified at § 423.265(b). An organization needs to apply as close to the first of the year as possible in order to have its contract approved prior to submitting a bid.

If we deny an application, written notice would be given to the contract applicant that would indicate the following:

- That the contract applicant does not meet the contract requirements under Part D of Title XVIII of the Act.
- The reasons why the contract applicant does not meet the contract requirements.
- The contract applicant's right to request reconsideration in accordance with the proposed procedures specified in proposed § 423.645.

This proposed section would also establish oversight of a PDP sponsor's continued compliance with the proposed requirements for a PDP

sponsor. If a PDP sponsor fails to meet those proposed requirements, we would terminate the contract in accordance with proposed § 423.509 of this proposed rule.

6. General Provisions

Proposed § 423.504 would specify the general provisions that would apply to PDP sponsor contracts. Again, for the most part, we would adopt the provisions that already apply to MA organizations through the regulations at 42 CFR 422.501. We have recently proposed changes to the compliance program requirements for MA organizations at 42 CFR 422.501(b)(3)(vi)(G) to include provisions that would require MA organizations to report misconduct it believes may violate various criminal, civil or administrative authorities. These self-reporting requirements are identified below in the discussion of the elements of a PDP compliance program. We have based the compliance program requirements for PDP sponsors on these new and recently proposed MA requirements. We believe that mandatory reporting of potential fraud by government contractors is critical, especially in light of the corporate fraud scandals that occurred over the past several years. It is also in keeping with the Sarbanes-Oxley Act of 2002, under which the Securities and Exchange Commission adopted new regulations designed to make corporate compliance and disclosure requirements stronger and more effective. In short, we believe that the self-reporting requirements included in this rule are keeping with the change in the legal, regulatory, and business climates since the compliance program requirements were first implemented. Subject to the provisions at proposed § 423.265(a)(1), in subpart F—Submission of bid, we are proposing that in order to enroll beneficiaries in any prescription drug plan it offers and be paid on behalf of Medicare beneficiaries enrolled in those plans, a PDP sponsor would have to enter into a contract with us. The contract could cover more than one prescription drug plan.

In accordance with those regulations, we also propose that any entity seeking to contract as a PDP sponsor would be required to meet the following conditions:

- Complete an application as described in proposed § 423.502.
- Be organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan, or have secured a Federal waiver, as

described in proposed subpart I of this preamble.

- Meet the proposed minimum enrollment requirements of proposed § 423.512(a) unless waived under proposed § 423.512(b).
- Have administrative and management arrangements satisfactory to us that could be demonstrated by at least the following:
 - + A policy making body that would exercise oversight and control over the PDP sponsor's policies and personnel that would ensure that management actions would be in the best interest of the organization and its enrollees.
 - + Personnel and systems that would be sufficient for the PDP sponsor to organize, implement, control, and evaluate financial and marketing activities, the furnishing of prescription drug services, the quality assurance, medication therapy management, and drug-utilization management programs, and the administrative and management aspects of the organization.
 - + At a minimum, an executive manager whose appointment and removal would be under the control of the policy making body.
 - + A fidelity bond or bonds, procured and maintained by the PDP sponsor, in an amount fixed by its policymaking body, but not less than \$100,000 per individual, that would cover each officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the PDP sponsor.
 - + Insurance policies or other arrangements, secured and maintained by the PDP sponsor and approved by us, that would insure the PDP sponsor against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.
 - + A compliance plan that would consist of the following:
 - Written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State standards.
 - The designation of a compliance officer and compliance committee accountable to senior management.
 - Effective training and education between the compliance officer and organization employees.
 - Effective lines of communication between the compliance officer and the organization's employees.
 - Enforcement of standards through well-publicized disciplinary guidelines.
 - Procedures for internal monitoring and auditing.
 - Procedures for ensuring prompt response to detected offenses and

development of corrective action initiatives relating to the organization's contract as a PDP sponsor.

- If the PDP sponsor discovers from any source evidence of misconduct related to payment or delivery of prescription drug items or services under the contract, it must conduct a timely, reasonable inquiry into that misconduct;
 - If, after reasonable inquiry, the PDP sponsor has determined that the misconduct may violate criminal, civil or administrative law, the sponsor must report the existence of the misconduct to the appropriate Government authority within a reasonable period, but not more than 60 days after the determination that a violation may have occurred. If the potential violation relates to federal criminal law, the civil False Claims Act, federal Anti-Kickback provisions, the civil monetary penalties authorities (primarily under sections 1128A and 1857 (as incorporated through section 1860D-12) of the Act), or related statutes enforced by the HHS Office of Inspector General, the report must be made to that Office.

- The PDP sponsor must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees, etc.) in response to the potential violation referenced above.

The PDP sponsor's contract must not have been non-renewed under proposed § 422.507 within the past 2 years, unless—

+ During the 6-month period beginning on the date the organization notified us of the intention to non-renew the most recent previous contract, there was a change in the statute or regulations that had the effect of increasing PDP sponsor payments in the payment area or areas at issue; or

+ We have otherwise determined that circumstances warrant special consideration.

Section 1860D-4(b)(1)(A) of the Act assures pharmacy access by requiring a PDP sponsor to permit the participation of any pharmacy that meets the terms and conditions under the plan. Based on this requirement, we are considering adding the following language to the contract provisions: The PDP sponsor would agree to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy. We are interested in public comment on the inclusion of such a provision.

Section 1857(c)(5) of the Act, which is incorporated by section 1860D-12(b)(3)(B) of the Act, authorizes us to

exercise the authority granted to the Secretary under Part D of Title XVIII without regard to provisions of the statute or regulations that we determine to be inconsistent with the furtherance of the purpose of Title XVIII of the Act. Based on this authority, we propose to provide, in proposed § 423.504(c) (Contracting authority), that we may enter into contracts under this proposed subpart without regard to Federal and Departmental acquisition regulations set forth in title 48 of the CFR. We note that some of the Federal Acquisition Regulation (FAR) provisions may apply to "fallback plans". (See proposed subparts F and Q for any contracting provisions unique to fallback plans.)

In proposed § 423.504(d) (Protection against fraud and beneficiary protections), we set forth the proposed requirements that we would have in place to protect against fraud and abuse in our PDP sponsor contracts. As directed by the statute, these are the same requirements as those in sections 1857(d)(1) and (d)(2) of the Act. The proposed requirements are as follows:

- We would annually audit the financial records (including, but not limited to, data relating to Medicare utilization, costs, reinsurance cost, low-income subsidy payments, and risk corridor cost) of at least one-third of the PDP sponsors, including fallback plans, offering prescription drug plans. We welcome comments on whether fallback plans, because of the payment arrangements, require a different audit approach, possibly more frequent. The Comptroller General would monitor these auditing activities.

• Each contract under this proposed section would be required to provide that we, or any person or organization designated by us, would have the right to—

+ Inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the PDP sponsor's contract;

+ Inspect or otherwise evaluate the facilities of the organization when there is reasonable evidence of some need for such inspection; and

+ Audit and inspect any books, contracts, and records of the PDP sponsor that pertain to the ability of the organization or its first tier or downstream providers to bear the risk of potential financial losses; or services performed or determinations of amounts payable under the contract.

Section 1860D-12(b) of the Act allows contracts with PDP sponsors to cover more than one prescription drug plan. At proposed § 423.504(e) (Severability of contracts), we are proposing that the contract would provide, upon our

request, that the contract could be amended to exclude any State-licensed entity, or a PDP plan specified by us; and a separate contract for any excluded plan or entity would be deemed to be in place when such a request is made.

7. Contract Provisions

Section 1860D–12(b)(3)(D) of the Act requires that provisions of section 1857(e) of the Act relating to additional contract terms of MA contracts would apply in the same manner to PDP sponsors. Section 1857(e) of the Act allows that the contract would contain other terms and conditions not inconsistent with Part D of the Act, including requiring the organization to provide us with the information that we may find necessary and appropriate. The additional contract provisions for the MA program are adopted for use in this proposed rule with modifications as necessary to accommodate differences between the MA program and the prescription drug program. Elsewhere in this preamble, we have also identified additional contract terms that would apply uniformly to both MA organizations offering MA–PDs and PDP sponsors (see, for example, subpart D discussing e-prescribing). In proposed § 423.505 (Contract provisions), we would require the contract between the PDP sponsor and us to contain the provisions specified in proposed § 423.505(b). The following is a summary of the proposed additional contract provisions that reflect any changes from the MA contract provisions:

- Specific Provisions.

In proposed § 423.505(b), we would list the specific provisions that would be contained in the contract between the PDP sponsor and us. Changes were made from the MA provisions to accommodate the different bidding and payment system for PDP sponsors. The PDP sponsor would be required to agree to comply with the following proposed provisions:

- + All the applicable proposed requirements and proposed conditions set forth in this proposed part and in general proposed instructions.
- + To accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments, as provided in proposed subpart B of this proposed part.

- + To comply with the proposed prohibition in proposed § 423.34(a) on discrimination in beneficiary enrollment.

- + To provide the basic benefits as proposed under proposed § 423.108 and, to the extent applicable,

supplemental benefits proposed under proposed § 423.112.

- + To disclose information to beneficiaries in the manner and the form prescribed by us under proposed § 423.128.
- + To operate quality assurance, cost and utilization management, medication therapy management, and fraud, abuse and waste programs as proposed under proposed subpart D of this proposed part.

- + To comply with all proposed requirements in proposed subpart M of this proposed part governing coverage determinations, grievances, and appeals.

- + To comply with the proposed reporting requirements in proposed § 423.514 and the proposed requirements in proposed § 423.329(b)(3) of proposed subpart G for submitting drug claims and related information to us for its use in risk adjustment calculations;

- + Each contract under this proposed part would provide that—

- The PDP sponsor offering a prescription drug plan would be required to provide us with the information as we determine is necessary to carry out proposed payment provisions in proposed subpart G of this proposed part; and
- We would have the right, as applied under section 1860D–12(b)(3)(C) of the Act and in accordance with section 1857(d)(2)(B) of the Act, to inspect and audit any books, contracts, and records of a PDP sponsor or MA organization that pertain to the information regarding costs provided to us under proposed § 423.504(d)(2)(iii) of this proposed section.

- + To be paid under the contract in accordance with the proposed payment rules in proposed subpart G of this proposed part.

- + To submit its bid, including all required information on premiums, benefits, and cost-sharing, by the proposed due date, as provided in proposed subpart F of this proposed part.

- + That its contract could possibly not be renewed or could be terminated in accordance with this proposed subpart and proposed subpart N of this proposed part.

- + To comply with the proposed confidentiality and proposed enrollee record accuracy requirements described in proposed § 423.136.

- + To comply with State Law and preemption by Federal Law requirements described in proposed subpart I of this proposed part.

- + To comply with the proposed coordination requirements with plans and programs that provide prescription

drug coverage as described in proposed subpart J of this proposed part.

- + To provide benefits by means of point of service systems to adjudicate drug claims, except where necessary to provide access in underserved areas, I/T/U pharmacies (as defined in proposed § 423.100), and long-term care pharmacies.

- Communication with CMS.

In proposed § 423.505(c), we would require the PDP sponsor to have the capacity to communicate with us electronically in the manner we specify.

- Maintenance of records.

In proposed § 423.505(d), we are proposing to detail the proposed requirements for record maintenance and retention, which would be unchanged from the MA regulations. We would require PDP sponsors to maintain books, records, documents, and other evidence of accounting procedures and practices for a period of 6 years so as not to prematurely foreclose our ability to pursue fraudulent or other abusive activities. The other evidence of accounting procedures and practices would have to be sufficient to do the following:

- + Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computation of the bid of PDP sponsors).

- + Enable us to inspect or otherwise evaluate the quality, appropriateness and timeliness of services performed under the contract, and the facilities of the organization.

- + Enable us to audit and inspect any books and records of the PDP sponsor that pertain to the ability of the organization to bear the risk of potential financial losses, or to services performed or determinations of amounts payable under the contract.

- + Properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the PDP sponsor's bid and necessary for the calculation of gross covered prescription drug costs, allowable reinsurance costs and allowable risk corridor costs (as defined in proposed § 423.308).

- + Establish the basis for the components, assumptions and analysis used by the PDP in determining the actuarial valuation of standard, basic alternative, or enhanced alternative coverage offered in accordance with our guidelines described in proposed § 423.265(b)(3).

We would also require the PDP sponsor to include at least records of the following:

- + Ownership and operation of the PDP sponsor's financial, medical, and other record keeping systems.
- + Financial statements for the current contract period and 6 prior periods.
- + Federal income tax or informational returns for the current contract period and six prior periods.
- + Asset acquisition, lease, sale, or other action.
- + Agreements, contracts, and subcontracts.
- + Franchise, marketing, and management agreements.
- + Matters pertaining to costs of operations.
- + Amounts of income received by source and payment.
- + Cash flow statements.
- + Any financial reports filed with other Federal programs or State authorities.
- + All prescription drug claims for the current contract period and 6 prior periods.
- + All price concessions for the current contract period and 6 prior periods accounted for separately from other administrative fees. This includes concessions offered by manufacturers to PDP sponsors.
- Access to Facilities and Records.
- In proposed § 423.505(e), the PDP sponsor would be required to agree to the same access to facilities and records as under the MA program. The PDP sponsor would be required to agree to the following:
 - + HHS, the Comptroller General, or their designee could evaluate, through inspection or other means—
 - The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;
 - The facilities of the PDP sponsor; and
 - The enrollment and disenrollment records for the current contract period and six prior periods.
 - + HHS, the Comptroller General, or their designees could audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of the PDP sponsor, related entity(s), contractor(s), subcontractor(s), or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the contract.
 - + The PDP sponsor would have to agree to make available, for the purposes specified in this section, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that we could require.

- + HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 6 years from the end of the final contract period or completion of audit, whichever is later unless—
 - We determine there is a special need to retain a particular record or group of records for a longer period and notify the PDP sponsor at least 30 days before the normal disposition date;
 - There is a termination, dispute, or allegation of fraud or similar fault by the PDP sponsor, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, or fraud or similar fault; or
 - We determine that there is a reasonable possibility of fraud, in which case we may inspect, evaluate, and audit the PDP sponsor at any time.
- Disclosure of Information.
- Under proposed § 423.505(f), the PDP sponsor would be required to agree to submit to us certified financial information that would have to include the information, as we could require, that would demonstrate that the organization has a fiscally sound operation. The certified financial information would include the information, as we could require, pertaining to the disclosure of ownership and control of the PDP sponsor. Also, the certification would include all information that would be necessary for us to administer and evaluate the program and to simultaneously establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining prescription drug coverage. This information would include, but would not be limited to—
 - + The benefits that would be covered under a prescription drug plan;
 - + The PDP monthly basic beneficiary premium and PDP monthly supplemental beneficiary premium, if any, for the plan;
 - + The service area of each plan;
 - + Plan quality and performance indicators for the benefits under the plan including—
 - Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years;
 - Information on Medicare enrollee satisfaction;
 - The recent records regarding compliance of the plan with requirements of this part, as determined by us; and
 - Other information determined by us to be necessary to assist beneficiaries in making an informed choice regarding PDP plans;

- + Information about beneficiary appeals and their disposition;
- + Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization; and
- + Any other information deemed necessary to CMS for the administration or evaluation of the Medicare program.

The PDP sponsor would also be required to disclose all informational requirements to its enrollees, under proposed § 423.128(b) and, upon an enrollee's request, the financial disclosure information required under proposed § 423.128(c)(4). (See proposed subpart C of this proposed part.)

- Proposed Beneficiary Financial Protections.

Under proposed § 423.505(g), the PDP sponsor would be required to adopt and maintain arrangements satisfactory to us to protect its enrollees from incurring liability (that is, as a result of an organization's insolvency or other financial difficulties) for payment of any fees that would be the legal obligation of the PDP sponsor. The beneficiary financial protection provisions would remain unchanged from the MA program. To meet this proposed requirement, the PDP sponsor would have to ensure that all contractual or other written arrangements prohibit the organization's contracting agents from holding any beneficiary enrollee liable for payment of any such fees; and the PDP sponsor would have to indemnify the beneficiary enrollee for payment of any fees that would be the legal obligation of the PDP sponsor for covered prescription drugs furnished by non-contracting pharmacists, or that would not have otherwise entered into an agreement with the PDP sponsor, to provide services to the organization's beneficiary enrollees.

To meet these proposed requirements of this proposed section, other than the proposed provider contract requirements discussed above, the PDP sponsor would use contractual arrangements; insurance acceptable to us; financial reserves acceptable to us; or any other arrangement acceptable to us.

- Proposed Requirements of Other Laws and Regulations.

One of the requirements we have incorporated from the existing MA rules is the requirement that plans comply with all Federal, State and local laws and regulations (see proposed § 422.505(h)). We have updated the list to include HIPAA Administrative and Simplification rules. Proposed

§ 423.505(h) would require the PDP sponsor to comply with—

- + Title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR part 84.

- + The Age Discrimination Act of 1975 as implemented by regulations at 45 CFR part 91.

- + The Rehabilitation Act of 1973.

- + The Americans with Disabilities Act.

- + HIPAA Administrative Simplification rules at 45 CFR Parts 160, 162, and 164

- + Other laws applicable to recipients of Federal funds.

- + All other applicable laws and rules.

PDP sponsors receiving Federal payments under PDP sponsor contracts, and related entities, contractors, and subcontractors paid by a PDP sponsor to fulfill its obligations under its contract with us, would be subject to certain laws that are applicable to individuals and entities receiving Federal funds. PDP sponsors would be required to inform all related entities, contractors and subcontractors that payments they receive would be, in whole or in part, from Federal funds. These proposed provisions would remain unchanged from the MA program.

- Proposed Requirements for PDP Sponsor Relationship with Related Entities, Contractors, and Subcontractors.

In proposed § 423.505(i), notwithstanding any relationship(s) that the PDP sponsor may have with related entities, contractors, or subcontractors, the PDP sponsor would maintain ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with us. The PDP sponsor would have to agree to require all related entities, contractors, or subcontractors that provide Part D items or services (including administrative services) to agree that—

- + The Department of Health and Human Services (HHS), the Comptroller General, or their designees would have the right to inspect, evaluate, and audit any pertinent contracts, books, documents, papers, and records of the related entity(s), contractor(s), or subcontractor(s) involving transactions related to our contract with the PDP sponsor; and

- + HHS', the Comptroller General's, or their designee's right to inspect, evaluate, and audit any pertinent information for any particular contract period should exist through 6 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

This proposed section would also require all contracts or written arrangements between PDP sponsors and providers, related entities, contractors, subcontractors, "first tier", and "downstream" entities that provide Part D items or services (including administrative services) to contain the specified proposed provisions. These proposed provisions would remain unchanged from the MA program.

- Proposed Additional Contract Terms.

In proposed § 423.505(j), the PDP sponsor would agree to include, in the contract, other terms and conditions as we may find necessary and appropriate in order to implement proposed requirements in this proposed part.

- Severability of Contracts.

In proposed § 423.505(k), the PDP sponsor would have to agree to include in the contract a severability provision that would establish that, upon our request, the contract would be amended to exclude any State-licensed entity, or PDP sponsor specified by us; and a separate contract for any excluded plan or entity would be deemed to be in place when the request is made.

- Certification of Data that Determines Payment.

In proposed § 423.505(l), we would require, as a condition of receiving a monthly payment under proposed subpart G of this proposed part, the PDP sponsor to agree that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, would request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data could include specified enrollment information, claims data, bid submission data, and other data that we specify. We recommend that PDP sponsors collect such certifications from their downstream partners to support their best knowledge, information and belief in signing their own certifications. In addition, we propose a certification for when PDP sponsors submit updated drug pricing data to CMS for beneficiary enrollment purposes.

The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, would be required to certify (based on best knowledge, information, and belief) that each enrollee for whom the organization would request payment is validly enrolled in a program offered by the organization and the information relied

upon by us in determining payment) is accurate, complete, and truthful.

The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, would be required to certify (based on best knowledge, information, and belief) that the claims data it would submit under proposed § 423.329(b)(3) are accurate, complete, and truthful. If the claims data are generated by a related entity, contractor, or subcontractor of a PDP sponsor, the entity, contractor, or subcontractor would be required to similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data. The PDP sponsor or related entity, contractor, or subcontractor would acknowledge that the claims data would be used for the purpose of obtaining Federal reimbursement.

The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, would be required to certify (based on best knowledge, information, and belief) that the information in its bid submission and assumptions related to projected reinsurance and low income cost sharing subsidies is accurate, complete, truthful, and fully conforms to the requirements specified in proposed § 423.265. The CEO, CFO, 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, is accurate, complete, truthful, and fully conforms to the requirements in § 423.336(c) and § 423.343(c).

The CEO, CFO, 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 price comparison is accurate, complete, and truthful.

8. Effective Date and Term of Contract

Section 1860D-12(b)(3)(B) of the Act provides that we include the contract period and effectiveness requirements that are included in section 1857(c) of the Act. Proposed § 423.506 would provide that contracts be effective on the date specified in the contract, and that the contracts would be for a term of 12 months. The contract period for a fallback plan is specified in

§ 423.871(b). In addition, contracts could be renewed from year to year, but only in the event that we inform the PDP sponsor that a renewal is authorized and only if the PDP sponsor does not provide us with a notice of intention not to renew. We do not require an application process for contract renewals. Because of the need for us to establish a national average monthly bid amount from approved bids in order to calculate the base beneficiary premiums, we propose to not allow a PDP contract to be effective at any time other than the first of the year. These proposed provisions would be similar to the MA provisions in § 422.505.

9. Non-Renewal of Contract

Section 1860D-12(b)(3)(F) of the Act requires that the provisions of section 1857(h) of the Act relating to procedures for termination (or non-renewal) of MA contracts would apply to PDP sponsors with respect to determinations and appeals. A non-renewal would be different from a termination in that either the PDP or us chooses to end the contract by following the proposed provisions described below.

In proposed § 423.507, we are proposing that a PDP sponsor could elect not to renew its contract with us as of the end of the term of the contract for any reason, provided it would notify us in writing by the first Monday of June in the year in which the contract would end. The PDP sponsor would also have to notify each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective. This notice would have to include a written description of alternatives available for obtaining Medicare prescription drug services within the PDP region, including MA-PDs, and other PDPs, and would have to receive our approval. The general public would also have to be notified at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the PDP sponsor's service area.

If a PDP sponsor chooses to non-renew a contract as described in proposed § 423.507(a)(3), we would not enter into a contract with the organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS.

For purposes of this section, we could elect not to authorize renewal of a contract for any of the reasons listed in proposed § 423.509(a), which would also permit us to terminate the contract, or if the PDP sponsor commits any of

the acts in proposed § 423.752 that supports the imposition of intermediate sanctions or civil money penalties under proposed § 423.750 of proposed Subpart O.

We would provide notice of our decision whether to authorize renewal of the contract to the PDP sponsor by May 1 of the contract year. If we decide not to authorize a renewal of the contract, we would provide notice to the PDP sponsor's Medicare enrollees by mail at least 90 days before the end of the current calendar year. We would also notify the general public at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the PDP sponsor's service area. We would give the PDP sponsor written notice of its right to appeal the decision not to renew in accordance with proposed § 423.642(b).

10. Modification or Termination of Contract by Mutual Consent

In proposed § 423.508, we are proposing that a contract could be modified or terminated at any time by written mutual consent. If the contract is terminated by mutual consent, the PDP sponsor would have to provide notice to its Medicare enrollees and the general public as provided in proposed § 423.507. If the contract is modified by mutual consent, the PDP sponsor would be required to notify its Medicare enrollees of any changes that we determine are appropriate for notification within timeframes specified by us. This proposed section would remain unchanged from the MA program.

11. Termination of Contract by CMS

In proposed § 423.509, we may terminate a contract with the PDP sponsor for any of the following reasons:

- The PDP sponsor fails substantially to carry out the terms of its contract with us (proposed § 423.509(a)(1)).
- The PDP sponsor carries out its contract with us in a manner that would be inconsistent with the effective and efficient implementation of this proposed part (proposed § 423.509(a)(2)).

• We determine that the PDP sponsor no longer meets the proposed requirements of this proposed part for being a contracting organization (proposed § 423.509(a)(3)).

• There is credible evidence that the PDP sponsor committed or participated in false, fraudulent, or abusive activities affecting the Medicare program, including submission of false or

fraudulent data (proposed § 423.509(a)(4)).

- The PDP sponsor experiences financial difficulties so severe that its ability to provide necessary prescription drug coverage is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that a risk to health exists (proposed § 423.509(a)(5)).

• The PDP sponsor substantially fails to comply with the requirements in proposed subpart M of this proposed part relating to grievances and appeals (proposed § 423.509(a)(6)).

• The PDP sponsor fails to provide us with valid risk adjustment, reinsurance and risk corridor related data as required under proposed § 423.329 (proposed § 423.509(a)(7)).

• The PDP sponsor substantially fails to comply with the proposed service access requirements in proposed § 423.120 (proposed § 423.509(a)(8)).

• The PDP sponsor substantially fails to comply with the proposed marketing requirements in proposed § 423.128 (proposed § 423.509(a)(9)).

• The PDP sponsor substantially fails to comply with the coordination with plans and programs that provide prescription drug coverage as described in proposed subpart J of this proposed part (proposed § 423.509(a)(10)).

• The PDP sponsor substantially fails to comply with the proposed cost and utilization management, proposed quality improvement, proposed medication therapy management, and fraud, abuse and waste program requirements as described in proposed subpart D of this proposed part (proposed § 423.509(a)(11)).

If we decide to terminate a contract for reasons other than the grounds described above in proposed § 423.509(a)(4) or (a)(5), we would notify the PDP sponsor in writing 90 days before the intended date of the termination. The PDP sponsor would then notify its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination. The PDP sponsor would also notify the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the PDP sponsor's service area.

We propose adding § 423.509(a)(4) as a reason for immediate termination without corrective action. If we have credible evidence that a PDP sponsor committed or participated in false, fraudulent, or abusive activities affecting the Medicare program, we may

determine that providing the sponsor with additional time to submit a corrective action plan would only expose beneficiaries to a plan we have already determined engaged in fraudulent or abusive behavior.

Therefore, we propose to terminate the contract as soon as possible in order to protect the beneficiaries enrolled with the affected sponsor as well as the Medicare trust fund.

For terminations based on violations described in proposed § 423.509(a)(4) or § 423.509(a)(5), we would notify the PDP sponsor in writing that its contract has been terminated effective the date of the termination decision by us. If termination is effective in the middle of a month, we would have the right to recover the prorated share of the prospective monthly payments made to the PDP sponsor covering the period of the month following the contract termination.

We would also notify the PDP sponsor's Medicare enrollees in writing of our decision to terminate the PDP sponsor's contract. This notice would occur no later than 30 days after we notify the plan of our decision to terminate the contract. We would also simultaneously inform the Medicare enrollees of alternative options for obtaining prescription drug coverage, including alternative PDP and MA-PDs in a similar geographic area. We would notify the general public of the termination no later than 30 days after notifying the plan of our decision to terminate the contract. This notice would be published in one or more newspapers of general circulation in each community or county located in the PDP sponsor's service area.

Before terminating a contract for reasons other than the grounds specified in proposed § 423.509(a)(4) or § 423.509(a)(5), we would provide the PDP sponsor with reasonable opportunity to develop and receive our approval of a corrective action plan to correct the deficiencies that are the basis of the proposed termination. If a contract is terminated based on § 423.509(a)(4) or § 423.509(a)(5), the PDP sponsor would not be given the opportunity to submit a corrective action plan. If we decide to terminate a contract, we would send written notice to the PDP sponsor informing it of its termination appeal rights in accordance with proposed § 423.642 of this proposed part.

12. Termination of Contract by the PDP Sponsor

In proposed § 423.510, we are proposing that the PDP sponsor may terminate its contract if we fail to

substantially carry out the terms of the contract. The PDP sponsor would be required to give advance notice as follows:

- To us, at least 90 days before the intended date of termination. This notice would have to specify the reasons why the PDP sponsor is requesting contract termination.
- To its Medicare enrollees, at least 60 days before the termination effective date. This notice would have to include a written description of alternatives available for obtaining Medicare drug services within the services area, including alternative PDPs, MA-PDs, and original Medicare and would have to receive our approval.
- To the general public at least 60 days before the termination effective date by publishing a notice approved by us in one or more newspapers of general circulation in each community or county located in the PDP sponsor's geographic area.

The effective date of the termination would be determined by us and is at least 90 days after the date we receive the PDP sponsor's notice of intent to terminate. Our liability for payment to the PDP sponsor would end as of the first day of the month after the last month for which the contract is in effect. We would not enter into an agreement with an organization that has terminated its contract within the preceding 2 years unless there are circumstances that warrant special consideration, as determined by us. This proposed section would remain unchanged from the MA program.

13. Proposed Minimum Enrollment Requirements

Section 1860D-12(b)(3)(A) of the Act applies the minimum enrollment requirements of section 1857(b)(1) and section 1857(b)(3) of the Act to Part D of the Act. However, the statute also gives the Secretary the authority to increase the minimum number of enrollees as the Secretary deems appropriate. In proposed § 423.512, we are proposing to retain the minimum enrollment requirements used for the MA program and that appear in section 1857(b)(1) of the Act. Our rationale for retaining the MA minimum enrollment level is to avoid conflicts that could occur if we adopted a higher minimum for Part D, which could imply that MA plans that could not meet the higher Part D standard would be unable to offer a drug benefit as required by law. In reality, we expect that stand-alone PDPs would have enrollments that far exceed these minimum levels. We are interested in receiving comments on whether these numbers should be

increased for PDP sponsors. We are also interested in receiving comments on whether the 1,500 standard, which was directed at local MA organizations, has applicability in the context of PDPs. Thus, our regulations would provide that, in general, the Secretary would not enter into a contract with a prospective PDP sponsor, unless the organization has at least 5,000 individuals who are enrolled for the purpose of receiving prescription drug benefits from the organization. Another option would be for the prospective PDP sponsor to have a minimum enrollment number of 1,500 individuals if the organization primarily serves individuals residing outside of urbanized areas. Urban area is defined in § 412.62(f) as essentially including MSAs and NECMAs as defined by OMB. The PDP sponsor would be required to maintain a minimum enrollment as discussed in this proposed section, however, as directed by section 1860D-12(b)(3)(A)(ii) of the Act, the proposed minimum enrollment requirements would be waived for any PDP sponsor in its first contract year in a region.

14. Proposed Reporting Requirements

In proposed § 423.514, we would require each PDP sponsor to have an effective procedure to develop, compile, evaluate, and report to us, to its enrollees, and to the general public, at the times and in the manner that we require statistics indicating the following:

- The cost of its operations;
- The patterns of utilization of its services;
- The availability, accessibility, acceptability of its services;
- Information demonstrating that the PDP sponsor has a fiscally sound operation; and
- Other information that we may require;

This proposed section would also contain proposed provisions for each PDP sponsor to report significant business transactions to us annually, within 120 days of the end of its fiscal year (unless for good cause shown, we authorize an extension of time). The information provided to us, would have to contain a description of significant business transactions as defined in proposed § 423.501 between the PDP sponsor and a party in interest. For those transactions, the PDP sponsor would be required to show that the costs of the transactions do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or if they do exceed, a justification that the higher costs are consistent with prudent

management and fiscal soundness requirements.

For purposes of this proposed section, the PDP sponsor would be required to produce a combined financial statement for itself and a party of interest if 35 percent or more of the costs of operation of the PDP sponsor go to a party in interest or 35 percent or more of the revenue of a party in interest is from the PDP sponsor. We would require the combined financial statements to include the following information:

- The display, in separate columns, of the financial information for the PDP sponsor and each of the parties in interest.
- The elimination of inter-entity transactions in the consolidated column.
- The examination of statements by an independent auditor in accordance with generally accepted accounting principles and include appropriate opinions and notes.

Upon written request from a PDP sponsor showing good cause, we could waive the proposed requirement that the organization's combined financial statement include the financial information discussed above for a particular entity.

In this proposed section, for any employees' health benefits plan that includes a PDP sponsor in its offerings, the PDP sponsor would be required to furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (for the particular PDP sponsor) under the Employee Retirement Income Security Act of 1974 (ERISA). The PDP sponsor would also be required to furnish the information to the employer or the employer's designee, or to the plan administrator, as the term "administrator" is defined in ERISA. This proposed section would also require each PDP sponsor organization to notify us of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities and each PDP sponsor would be required to make the information reported to us under this proposed section available to its enrollees upon reasonable request. These provisions would remain unchanged from the MA regulations.

15. Proposed Prohibition of Midyear Implementation of Significant New Regulatory Requirements

In proposed § 423.516, we propose that we may not implement, other than at the beginning of a calendar year, provisions under this proposed section that would impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan.

L. Effect of Change of Ownership or Leasing of Facilities During the Term of Contract

(If you choose to comment on issues in this section, please include the caption "Subpart L—Effect of Change of Ownership or Leasing of Facilities During the Term of Contract" at the beginning of your comments.)

1. Overview

Proposed Subpart L of proposed part 423 would describe the impact that a PDP sponsor organization's "change of ownership" (CHOW) or leasing of facilities during the term of its contract would have on the status of the organization's contractual relationship with us, as well as required procedures to be followed by a contracting PDP sponsor to effect a CHOW.

2. Provisions

In developing the proposed provisions for this proposed subpart as it relates to PDP sponsor organizations, we reviewed the experience that MA contractors and we have had under the provisions of subpart L of Part 422. A single set of CHOW requirements for both MA and PDP contractors would simplify management, assure consistency, and reduce administrative burden for those entities that are managing both programs. To that end, as a starting point we are proposing that the requirements in proposed §§ 423.551, 423.552, and 423.553, of this proposed rule, for the PDP sponsor, would be essentially the same as the requirements found in §§ 422.550, 422.552 and 422.553 for the MA program. Those proposed requirements and procedures are summarized in section 3, below.

Since the impact of a change of ownership on a PDP sponsor's contract with us would be similar to its effect on an MA organization's contract, we believe that the two sets of requirements should be similar. However, we are considering the modification of existing change of ownership provisions in both rules in order to reduce the administrative burden of these requirements and to increase the effectiveness of these provisions. We request comments regarding how these provisions could be modified to accomplish these objectives. In particular, we seek comments regarding: the situations which constitute a change of ownership, how these provisions should be applied to large companies with multiple business units, the notification requirements related to a change of ownership, the novation agreement provisions, and the provision

related to the leasing of a PDP's facilities.

3. Proposed General Provisions

In proposed § 423.551(a), we would present the three situations that constitute CHOW in the context of proposed subpart L. We would state that—

- The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law, constitutes a CHOW;
- Transfer of substantially all the assets of the sponsor to another party constitutes a change of ownership; and
- The merger of the PDP sponsor's corporation into another corporation, or the consolidation of the PDP sponsor's organization with one or more other corporations, resulting in a new corporate body, constitutes a CHOW.

We note that § 422.551(a)(2) if carried over from the MA rule would provide that a change of ownership occurs whenever there is a "[t]ransfer of title and property to another party * * *". This provision would seem to apply to any transfer no matter how small and, read literally, would include a partial transfer of the employer's assets such as a spin off or the sale of a single facility or operating division of the employer. Combined with the absolute assignment rule of (d), this has the potential to lead to absurd results. Therefore, in our proposed rule, we would change § 423.551(a)(2) to include only asset sales that are essentially transfers of the entire business enterprise. We request comments on situations where a sponsor transfers to another party substantial assets, but less than substantially all of its assets. In such comments, please describe the different scenarios that might develop under such circumstances, especially the extent to which benefits covered by the agreement might reasonably be expected to be provided by the old or new owner and the best approach for either transferring, issuing, or reissuing sponsor agreements."

The proposed exception to the three provisions discussed above would be that a transfer of corporate stock or the merger of another corporation into the PDP sponsor's organization, with the PDP sponsor organization surviving, would not usually constitute a CHOW.

Proposed § 423.551(c) of this proposed section, would require a PDP sponsor that has a Medicare contract in effect under proposed § 423.502 of proposed Subpart K and is considering or negotiating a CHOW, to notify us at least 60 days before the anticipated effective date of the change. The PDP

sponsor would also be required to provide updated financial information and a discussion of the financial and solvency impact of the CHOW on the surviving organization.

In this proposed section we would also state that if the PDP sponsor fails to give us the required notice in a timely manner, it would continue to be liable for payments that we make to it on behalf of Medicare enrollees after the date of the CHOW.

Proposed § 423.551(d) would define a novation agreement, the legal vehicle that we would use to recognize the new owner of a PDP sponsor organization's corporation, as the successor in interest to the Medicare contract. For this proposed rule, a novation agreement would be an agreement among the current owner of the PDP sponsor, the prospective new owner, and us. This agreement would have to be signed by all three parties and, to be effective, contain the proposed provisions at proposed § 423.552. The agreement would also have to allow us to recognize the new owner as the successor in interest to the current owner's Medicare contract. The new owner has to be sure to get adequate data to substantiate claims for reimbursement from the previous owner, because the new owner would be responsible at the time of the reconciliation process.

Proposed § 423.551(e) would detail the consequences of a CHOW that occurs without a novation agreement. Under this proposed section, if there is not a novation agreement, the existing Medicare contract would become invalid and, if the new owner wanted to participate in the Medicare program as a PDP sponsor, it would have to apply for, and enter into a contract in accordance with proposed subpart K of this proposed part.

4. Proposed Novation Agreement Requirements

Proposed § 423.552(a) would provide the three conditions that should be met for our approval of a novation agreement. Consistent with our approach in the MA program, we are proposing that the first condition would be for the PDP sponsor to give us notice, at least 60 days before the effective date of the CHOW. That notice would also include updated financial information and a discussion of the financial and solvency impact of the CHOW on the surviving organization. If notice were not timely, the contractor would continue to be liable for payments that we make to it on behalf of Medicare enrollees after the date of "CHOW" as described in proposed § 423.551(c)(2). The second proposed condition would

be that the PDP sponsor would submit three signed copies of the novation agreement that contains the proposed provisions specified in proposed § 423.552(b) to us at least 30 days before the proposed CHOW date, and one copy of other relevant documents required by us. The final condition would be our determination after reviewing a novation agreement concerning the following:

- The proposed new owner is in fact a successor in interest to the contract.
- Recognition of the new owner as a successor in interest of the Medicare program.
- The successor organization meets the requirements to qualify as a PDP sponsor under proposed subpart K.

Proposed § 423.552(b) would identify the four required provisions of a properly constituted novation agreement. In this proposed section, we would require the agreement to state that the new owner would assume all obligations under the Medicare contract and the previous owner would be required to waive its right to reimbursement for covered services furnished during the rest of the current contract period. The previous owner would also be required to guarantee performance of the contract by the new owner during the contract period, or post a performance bond that is satisfactory to us. The last condition would require the previous owner to agree to make its books, records, and other necessary information available to the new owner and to us to permit an accurate determination of costs for the final settlement of the contract period. We would have to be able to recognize the new owner as the successor in interest to the current owner's Medicare contract and the novation agreement would be effective, once signed by all three relevant parties.

5. Effect of Leasing of a PDP Sponsor's Facilities

Proposed § 423.553 would address provisions related to when a PDP sponsor leases its facilities to another party and its PDP sponsor contract with us. Specifically, we are proposing that if a PDP sponsor leases all or part of its facilities to another entity, the other entity would not acquire PDP sponsor status under section 1860D-12(b) of the Act. If a PDP sponsor leases all of its facilities to another entity, its Medicare contract would terminate. If the other entity wants to participate in the Medicare program as a PDP sponsor, it would be required to apply for and enter into a contract in accordance with proposed § 423.502. If the PDP sponsor leases part of its facilities to another

entity, its contract with us would remain in effect while we survey the PDP sponsor to determine whether it continues to be in compliance with the applicable proposed requirements and qualifying conditions specified in proposed Subpart K of this part.

M. Grievances, Coverage, Reconsiderations, and Appeals

(If you choose to comment on issues in this section, please include the caption "Subpart M—Grievances, Coverage Determinations, Reconsiderations, and Appeals" at the beginning of your comments.)

1. Introduction

Proposed subpart M of part 423 would implement sections 1860D-4(f), 1860D-4(g), and 1860D-4(h) of the Act, which set forth the procedures PDP sponsors must follow with regard to grievances, coverage determinations, and appeals.

Under section 1860D-4(f) of the Act, a PDP sponsor must provide meaningful procedures for hearing and resolving grievances between the sponsor (including any entity or individual through which the sponsor provides covered benefits) and enrollees.

Section 1860D-4(g) of the MMA addresses the procedures for coverage determinations and redeterminations of PDP sponsors. In general, the MMA requires that a PDP sponsor's procedures meet the same requirements as those that apply to MA organizations (under paragraphs (1) through (3) of section 1852(g)) of the Act for organization determinations and redeterminations. This includes the same timeframes for making these determinations and redeterminations, including the requirements for expedited procedures when the standard timeframes could seriously jeopardize an enrollee's life, health, or ability to regain maximum function. In addition, section 1860D-4(g)(2) of the Act specifies that if a PDP sponsor has tiered cost sharing for formulary drugs, it must establish an exceptions process. Under the exceptions process, consistent with guidelines established by the Secretary, a nonpreferred drug could be covered under the terms applicable for preferred drugs 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 addresses appeals of a PDP sponsor's coverage determinations and redeterminations. Here, the MMA requires that the PDP sponsors follow

appeals requirements that are similar to those applicable to MA organizations under paragraphs (4) and (5) of section 1852(g) of the Act (regarding independent review entity (IRE) review and ALJ hearings, respectively). As a result, in our regulations at § 423.612(b), we propose to require a 60-day timeframe for requesting an appeal, which has been a long-standing requirement throughout the entire Medicare managed care appeals process. To the extent the proposed requirements differ from the MA rules, we discuss these differences below. In addition, section 1860D-4(h)(2) of the Act specifies that appeals, involving coverage of a covered part D drug that is not on a PDP's formulary, are permissible 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 on the individual, or both. The proposed regulations needed to implement the above provisions are discussed below.

2. General Provisions (§ 423.560 Through § 423.562)

Subpart M begins with proposed § 423.560, which sets forth several definitions for terms used in the subpart. These definitions are generally self-explanatory and mirror those used in subpart M of part 422 for MA, but have been modified to reflect applicability to Part D drug benefits.

Section 423.562, General Provisions, provides an overview of the responsibilities of PDP sponsors and the rights of PDP enrollees with respect to grievances, coverage determinations, and appeals. The responsibilities of PDP sponsors under § 423.562(a) include establishing and maintaining procedures for grievances, coverage determinations, exceptions to tiered cost-sharing formulary structures, requests for formulary exceptions, and appeals. This section would also specify that enrollees receive written information about the grievance and appeal procedures available to them through the PDP sponsor, and about the QIO complaint process available to enrollees. Like under the MA program, the proposed regulations indicate that if a PDP sponsor delegates any of its responsibilities under subpart M to another entity or individual through which the sponsor provides covered drug benefits, the PDP sponsor is ultimately responsible for ensuring that the applicable grievance, coverage determination, and appeal requirements are met.

Section 423.562(b) of our proposed rule explains the basic rights of PDP enrollees in relation to PDP sponsors under subpart M and references the regulations that explain the rights. These include, for example, the right to a timely coverage determination and appeal rights pursuant to that coverage determination.

Section 423.562(c) of our proposed rule specifies that an enrollee has no appeal right when there is no payment liability, or when benefits have been provided by a non-network provider (that is, a non-network pharmacy), except in those situations in which, under subpart C, the PDP is obligated to cover such drugs. Finally, § 423.562(d) explains that, unless otherwise noted, the general Medicare appeals rule under part 422, subpart M, is applicable for appeals to an Administrative Law Judge (ALJ) or the Medicare Appeals Council (MAC).

3. Grievance Procedures (§ 423.564)

As defined in § 423.560 of our proposed rule, a grievance means any complaint or dispute, other than one that constitutes a coverage determination, expressing dissatisfaction with any aspect of a PDP sponsor's operations, activities, or behavior, regardless of whether remedial action is requested. An enrollee might file a grievance, for example, if he or she has a complaint about the timeliness of filling a prescription, or the accuracy of the prescription. As required by section 1860D-4(f) of the MMA, the grievance procedures in this subpart generally mirror those found in part 422, Subpart M, for MA. Thus, our regulations would require that each PDP sponsor have procedures to ensure that grievances are heard and resolved in a timely manner, but they would not include prescriptive details on the procedures. The only exceptions to this approach, under § 423.564(d), involve certain limited situations where a PDP sponsor must respond to a grievance within 24 hours, such as a grievance over a PDP sponsor's decision to invoke an extension relating to a coverage determination or redetermination, or a PDP sponsor's refusal to grant an enrollee's request for an expedited coverage determination or redetermination where the enrollee has not yet purchased or received the drug that is in dispute.

Section 423.564(c) of our proposed rule explains the distinction between the grievance procedures of the PDP sponsor and the quality improvement organization (QIO) complaint process. This section further establishes that

when an enrollee submits a quality of care complaint to a QIO, the PDP sponsor must cooperate with the QIO in resolving the complaint.

Section 423.564(e) of our proposed rule concludes the grievance procedures by proposing minimum record keeping requirements for a PDP sponsor, which include recording the receipt date of a grievance, its final disposition, and the date the enrollee is notified of the disposition.

4. Coverage Determinations (§ 423.566 Through § 423.576)

These proposed provisions implement the MMA requirement that PDP sponsors establish procedures for making coverage determinations and redeterminations regarding covered drug benefits that are essentially the same as those in effect for MA organizations under part 422, subpart M for MA. Therefore, for the drug benefits under Part D, we have continued standard and expedited requirements for coverage determinations and redeterminations.

Section 423.566(a) of our proposed rule specifies that each PDP sponsor must have a procedure for making timely coverage determinations regarding the drug benefits an enrollee is entitled to receive and the amount, if any, that an enrollee is required to pay for a benefit. The PDP sponsor is required to establish both a standard procedure for making coverage determinations and an expedited procedure for situations in which applying the standard procedure could seriously jeopardize the enrollee's life, health, or ability to regain maximum function.

As proposed in § 423.566(b), actions that would constitute coverage determinations include: a PDP sponsor's failure to provide or pay for a covered Part D drug (including failure to pay because the drug is not on the plan's formulary, because the drug is determined not to be medically necessary, because the drug is furnished by an out-of-network pharmacy, or because the sponsor determines that the drug otherwise would be excluded under section 1862(a) of the Act); failure to provide a coverage determination in a timely manner that would adversely affect the health of the enrollee; decisions on the amount of cost sharing; or decisions on whether the preferred drug is appropriate for an enrollee. Section 423.566(c) lists those individuals who can request a standard coverage determination as the enrollee (including his or her authorized representative) and the prescribing physician on behalf of the enrollee. We

note that we have not included the legal representative of a deceased enrollee's estate (as is specified in § 422.566(c)(1)(iii)) since that individual would be considered an authorized representative. Those individuals who can request an expedited determination or an expedited redetermination are similarly an enrollee (including his or her authorized representative), or the prescribing physician on behalf of the enrollee. In these situations we propose that a prescribing physician need not be an appointed representative of the enrollee in order to assist in obtaining either a standard or an expedited coverage determination. We welcome comments on any additional individuals or entities that should be able to request a coverage determination.

The standard timeframes and notice requirements for coverage determinations are proposed in § 423.568. These requirements include a determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after receipt of the request if the request is for prescription drug benefits. An extension of the timeframe by up to 14 calendar days is allowable if the enrollee requests the extension, or if the PDP sponsor can justify how a delay is in the interest of the enrollee. For example, the receipt of additional medical evidence may change the outcome of the decision. An enrollee must be notified of the reasons for the delay, and informed of the right to file an expedited grievance if the enrollee disagrees with the sponsor's decision to invoke an extension. If the request is for payment, the determination must be made no later than 30 calendar days after receipt of the request. Consistent with § 1860D-4(g)(1) of the MMA, the timeframe and notice requirements for requests involving payment are the same as those that apply for clean claims under the Medicare Advantage program. This section also establishes the requirement for written notice for PDP sponsor denials and the form and content of the denial notice, including that the notice must explain the reason for the denial and the availability of appeal rights.

Sections 423.570 and 423.572 propose the requirements regarding expedited coverage determinations, including how an enrollee or an enrollee's prescribing physician can make an oral or written request (§ 423.570(b)), and how the PDP sponsor must process requests (§ 423.570(c)). We clarify in § 423.570(a) that requests for payment of prescription drugs already furnished for an enrollee cannot be expedited.

Section 423.570(b)(2) specifies that a prescribing physician may provide

written or oral support for a request for expedition, and under § 423.570(c)(3)(ii), we clarify that when requests for expedition are made or supported by an enrollee's prescribing physician, the PDP sponsor must grant the request if the physician indicates that applying the standard timeframe could seriously jeopardize the enrollee's life or health, or the ability to regain maximum function. Section 423.570(d) proposes actions following a denial of a request and explains that when a sponsor denies a request for an expedited determination that the request automatically be transferred to and processed under the standard determination procedures, which require the determination within 14 calendar days. For accepted requests for expedited determination, § 423.572 proposes that the PDP sponsor must make its expedited determination and notify the enrollee and the prescribing physician, as appropriate, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request. Section 423.572(b) proposes the requirements for extensions, and includes the enrollee's right to file an expedited grievance if the enrollee disagrees with the PDP sponsor's decision to invoke an extension. Proposed § 423.572(c) explains that if the PDP sponsor first notifies an enrollee of an adverse expedited determination orally, then it must mail written confirmation to the enrollee within 3 calendar days. Finally, § 423.572(d) explains the requirements for the content of the expedited determination notice, and § 423.572(e) explains that a failure to provide a timely notice would constitute an adverse coverage determination, which may be appealed. Similar to the expedited requirements for MA under Part C, these sections would require that drug coverage determinations be made as expeditiously as the enrollee's health condition requires. Note that given the requirement that timing of determinations (and redeterminations) be based on an enrollee's health condition, the PDP sponsor has a responsibility to ensure that an enrollee's health situation and needs are fully considered in reviewing any requests (for example, if an enrollee has a chronic condition that has necessitated ongoing use of the drug in question). Again, however, if the enrollee already received the drug and the determination involves who should pay for the drug (or how much), there is generally no need for an expedited

determination since the enrollee's health needs have been met.

5. Formulary Exceptions Procedures (§ 423.578)

a. Exceptions to a Plan's Tiered Cost-Sharing Structure

As noted above, section 1860D-4(g)(2) of the Act specifies that an enrollee may request an exception to a plan's tiered cost-sharing structure. Under such an exception, a "nonpreferred drug *could* (emphasis added) be covered under the terms applicable for a preferred drug" under certain conditions. At a minimum, the prescribing physician would have to determine that the preferred drug either would not be as effective for the individual or would have adverse effects for the individual, or both. The statute then requires that each PDP sponsor establish exceptions procedures consistent with guidelines issued by the Secretary for making determinations on such requests. Unfavorable determinations constitute coverage denials that would be subject to all the appeals rights discussed in subpart M of part 423.

How this section of the statute is implemented will have significant consequences for PDP sponsors and Medicare beneficiaries. Although the only specific criterion established by law for assessing exceptions requests is the prescribing physician's determination explained above, we believe that the statute's direction that exceptions be made in accordance with "guidelines established by the Secretary" indicates that PDP sponsors be able to establish additional criteria, subject to the Secretary's guidance. This flexibility raises two key, intertwined questions. First, to what extent should the Secretary limit a plan's discretion in establishing exceptions criteria? And second, how detailed must the criteria be? The absence of detailed criteria, although perhaps desirable for a PDP sponsor, may not afford Part D enrollees the type of drug access intended under the law. However, making tiering exceptions too easy to obtain could eliminate a sponsor's ability to obtain volume pricing discounts, and thus, offer optimal value to beneficiaries.

Based on existing models in the state and private sectors and on Federal managed care models, we believe that PDPs' formularies are likely to include tiered cost sharing; such tiering allows PDP sponsors to obtain better prices on preferred drugs, resulting in savings for both enrollees and the PDPs. Tiering will presumably be particularly critical for stand-alone PDPs (that is, non MA-PD plans), which will not have direct

relationships with doctors and thus will have no clear method of cost/utilization control other than through their pricing structure.

However, it is very difficult to predict exactly how PDP sponsors will design their tiering structures. For example, although the statute refers to "preferred" and "nonpreferred" drugs, actual tiering structures are likely to include three or more classes of drugs (such as "generic," "preferred brand," "non-preferred brand," etc.). We believe that this uncertainty strongly suggests that the proposed regulations not include overly prescriptive requirements with respect to a PDP's exceptions criteria. Instead, we would provide general guidance on the scope of issues that must be addressed under a PDP's exceptions criteria on the procedural elements of that process, but still allow for flexibility and innovation in this regard as we gain experience with the new program.

Thus, we would propose under § 423.578 that a PDP sponsor must establish an exceptions process that addresses each of the following sets of circumstances: (1) The enrollee is using a drug and the applicable tiered cost-sharing structure changes during the year; (2) the enrollee is using a drug and the applicable tiered cost-sharing structure changes at the beginning of a new plan year; and (3) there is no pre-existing use of the drug by the enrollee. For purposes of this subpart, "using a drug" means the enrollee is receiving the drug in the course of treatment, including time off if it is part of the treatment. A PDP's exceptions criteria would not necessarily need to be different under each scenario.

While we thought it necessary to require PDP sponsors to include certain criteria in the exceptions process, we also recognize the need to avoid a situation where a PDP sponsor's cost-sharing rules are effectively driven by the exceptions criteria, rather than the other way around. Thus, in § 423.578(a)(2) we have proposed a limited number of elements that must be included in any sponsor's exception criteria: (1) A description of the process used by the PDP to evaluate the physician's certification; (2) consideration of the cost of the requested drug compared to that of the preferred drug; (3) consideration of whether the formulary includes a drug that is the therapeutic equivalent of the requested drug; and (4) consideration of the number of drugs on the plan's formulary that are in the same class and category as the requested drug.

We also considered including a number of other exceptions criteria such

as—(1) requiring PDP sponsors to establish a blanket rule permitting continued access to a drug at a given price when there is a mid-year change in the tiering structure; (2) requiring an enrollee who is using a drug that is subsequently removed from the sponsor's formulary or is no longer designated as the "preferred drug" to try a preferred drug(s), and experience adverse effects, before being permitted to resume using the original drug; (3) requiring a sponsor to establish exceptions criteria that are specific to particular classes of covered Part D drugs, such as cholesterol-lowering drugs; and (4) requiring sponsors to give enrollees an opportunity to request exceptions to a plan's tiered cost-sharing structure other than on a case-by-case basis. Additionally, we contemplated the possibility of establishing criteria for the review process used to evaluate plan formularies and tiering structures, and developing exceptions criteria that are specific to particular classes of covered Part D drugs. Based on public comment and any additional information that is available at the time on the formulary structure, we may add further detail to these criteria or include additional criteria in the final rule.

Consistent with existing MA rules, we are proposing that an enrollee, the enrollee's authorized representative or the prescribing physician may request an exception. The statutory requirement that the prescribing physician determine that the preferred drug either would not be as effective for the individual generally, or would have adverse effects for the individual, would constitute a minimum threshold for approving an exception request. Thus, we are proposing that a PDP sponsor may require a written certification to that effect from the prescribing physician, as well as certain limitations on the content requirements sponsors could impose for these certifications. However, we would permit PDP sponsors flexibility in how this standard is applied. For example, a PDP sponsor could require that a physician certify that the preferred drug would be less effective than the nonpreferred drug, or the PDP sponsor could choose to apply a more stringent standard (such as requiring that the prescribing physician's certification also include the enrollee's patient history or require the enrollee first try the preferred drug, absent medical contraindications).

A PDP's exceptions procedures would also be required to describe how a determination on an exception request would affect the enrollee's cost sharing obligations under the PDP's tiering

structure. For example, would a request for a nonpreferred drug result in payment at the preferred brand drug level, or at the generic drug level, if available?

b. Exceptions and Appeals Rules for Non-Formulary Determinations

Section 1860D-4(h)(2) of the Act establishes a limitation on requests for exceptions when a particular drug is not on a plan's formulary at all. The statute specifies that an enrollee may appeal a determination not to provide coverage of a non-formulary drug "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." Notably, this limitation is set forth under the "appeals" provisions of the statute, as opposed to under the preceding coverage determination and redetermination provisions that are discussed above for exceptions to tiered cost-sharing rules. Thus, we believe the intent of this provision is to limit appeals to cases where the prescribing physician has made the determination described by the law.

Unlike for the tiering exceptions, the statute does not specifically require that PDP sponsors develop an exceptions process to review requests for exceptions for non-formulary drugs. However, we do not believe that the statute intends to preclude an enrollee from obtaining a coverage determination from a PDP sponsor absent a determination by the prescribing physician, or to require that the physician's determination alone should result in a favorable coverage determination by the PDP. Thus, we propose to require that PDP sponsors also establish exceptions criteria for addressing these situations. Requiring sponsors to use an exceptions process to review requests for coverage of non-formulary drugs will create a more efficient and transparent process and will ensure that enrollees know what standards are to be applied. Additionally, requiring a similar exceptions process for conducting these types of reviews will help ensure that a PDP sponsor's formulary is based on scientific evidence rather than tailored to fit exceptions and appeals rules for formulary drugs.

Under this exceptions process, which we propose at § 423.578(b), a PDP must allow enrollees to request (1) Coverage of covered Part D drugs that are not on a sponsor's formulary; (2) continued coverage of a drug the sponsor has

removed from its formulary; (3) an exception to a sponsor's policy regarding coverage for a step therapy; and (4) an exception to a sponsor's dosing limitation. A PDP's criteria would need to include a description of the criteria it will use to evaluate the prescribing physician's determination, clarify how the plan evaluates the relative safety and efficacy of the requested drug, and describe the cost-sharing scheme that will be applied if coverage is provided. Again, an enrollee, the authorized representative, or prescribing physician could request an exception, and the PDP sponsor may require a written certification from the prescribing physician that the non-covered drug is medically necessary to treat the enrollee's disease or medical condition. An enrollee would have a right to a redetermination by the PDP of any unfavorable coverage determination.

Like for tiering exceptions, we are proposing that enrollees be required to request reconsideration by an independent review entity (IRE), as opposed to having these cases automatically forwarded to the IRE. We welcome comments on both these issues.

c. Treatment of Determinations Regarding Exceptions Requests

From a procedural standpoint, we propose at § 423.578(c)(1) that determinations on exception requests constitute plan coverage determinations under § 423.566 and should be completed in the same timeframes. Enrollees would then have an opportunity to request a plan redetermination. Unfavorable redetermination decisions could then be appealed to the independent review entity. The IRE's review would focus on whether the PDP had properly applied its formulary exceptions criteria for the individual in question. If it determined that the PDP sponsor correctly applied its exceptions criteria, the sponsor's determination would be upheld. Thus, the IRE would not have any discretion with respect to the validity of the plan's exceptions criteria or formulary. (CMS would be responsible for evaluating and approving a PDP's exceptions criteria and formulary as part of the annual plan approval process.) In many instances, however, evaluating whether the criteria for a formulary exception had been satisfied would necessarily involve an element of medical judgment (*e.g.*, would a patient suffer significant adverse effects by using the plan-preferred drug?). In those situations, the IRE's medical staff would be responsible for reviewing the sponsoring plan's

determination as to whether the formulary exceptions criteria had been applied properly. Note that part D enrollees could subsequently access higher levels of the appeals process like for any other unfavorable coverage determination, consistent with the statutory reference to section 1852(g)(4) and (5) of the MA provisions.

Although not required by statute, we thought it important to put in place certain safeguards regarding the issuing and effect of a coverage determination made as part of the exceptions process. We believe that these safeguards will help to ensure that the exceptions process is both fair and efficient for enrollees. First, to ensure that enrollees who file exceptions requests for drugs that are being removed from a sponsor's formulary are not disadvantaged by a sponsor's failure to issue a timely decision, we establish in § 423.578(c)(1) and § 423.578(c)(2) that if a sponsor fails to issue a timely decision, the sponsor must continue to provide coverage until a decision is made on the request. Section 423.578(c)(2)(i) allows enrollees to receive up to a one-month supply of the requested drug, but a sponsor could adjust the supply to account for a shorter time frame.

Once a sponsor approves an exceptions request, we believe an enrollee should not have to continue filing exceptions requests for future refills of the drug. Therefore, we provide in § 423.578(C)(3) that once a sponsor approves a drug pursuant to the exceptions process, an enrollee is entitled to continue receiving refills of the drug for as long as the physician continues prescribing the drug and for as long as the drug continues to be considered safe and effective for treatment of the enrollee's disease or medical condition.

The final safeguard implemented under § 423.578 prohibits PDP sponsors from assigning drugs approved under either exceptions process to a special formulary tier, co-payment, or other cost-sharing requirement. In other words, sponsors must employ reasonable criteria (*for example*, the cost of the requested drug compared to the cost of other similar drugs on the plan's formulary) in determining the co-payments or other cost-sharing requirements of drugs approved for coverage under the exceptions process.

We recognize that these provisions represent a critical component of the new prescription drug benefit, and we particularly welcome suggestions from commenters on these proposals. Our goal is to foster the establishment of exceptions processes that employ criteria designed to maximize available

drug benefits for all Medicare beneficiaries, while ensuring that plan sponsors have the flexibility they need to negotiate the best process on behalf of enrollees.

6. Appeals

a. Redeterminations (§ 423.580 Through § 423.590)

Sections 423.580 through § 423.590 explain the right to a redetermination and the requirements that apply to PDP sponsors for both standard and expedited redeterminations. If a decision regarding a coverage determination is unfavorable (in whole or in part) to the enrollee, the enrollee may file an oral or written request with the PDP or MA-PD plan for a redetermination on the decision. Note that, unlike the existing MA regulations, the proposed regulations would not identify Social Security Administration (SSA) field offices as a possible location for filing redetermination requests. Using any filing location other than the plan itself can significantly affect the speed with which the appeal is resolved. Moreover, given that section 931 of the MMA mandates the transfer of responsibility for Medicare appeals from SSA to DHHS by no later than October 1, 2005, we believe that an explicit regulatory reference to SSA field offices would not be appropriate.

For an expedited redetermination, an enrollee or the prescribing physician (acting on behalf of an enrollee) may submit an oral or written request for redetermination. However, requests for payment of drugs already received cannot be expedited. The proposed requirements for making standard redetermination determinations of covered benefits in § 423.590(a) specify that the PDP sponsor must issue its determination as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date of receipt of the request. Under § 423.590(b), for standard redeterminations involving requests for payment, the PDP sponsor must issue its redetermination no later than 60 calendar days from the date of receipt of the request. In the case of expedited redeterminations, § 423.590(d) specifies that a PDP sponsor must complete its redetermination and give the enrollee and the prescribing physician 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. For both the standard and expedited redetermination for covered benefits, the PDP sponsor may extend the timeframe for making its determination

by up to 14 calendar days if the enrollee requests the extension, or if the sponsor justifies a need for additional information and how the delay is in the interest of the enrollee. An extension would not be provided for redeterminations involving requests for payment.

If the PDP sponsor's redetermination results in an affirmation, in whole or in part, of its original adverse coverage determination, the sponsor must give written notification to the enrollee and advise the enrollee of the right to file an appeal with the IRE that contracts with CMS.

b. Independent Review Entity (IRE) Reconsideration (§ 423.600 Through § 423.604)

The MMA gives the Secretary the flexibility to establish an appeals process similar to that used for the MA appeals process. Thus, the proposed IRE reconsideration process set forth at § 423.600 through § 423.604 is much like that applicable to MA organizations under Part C. Note that when the PDP sponsor's redetermination affirms, in whole or in part, its adverse coverage determination, any issue remaining in dispute may be appealed by the enrollee to the IRE that contracts with CMS. However, unlike under the MA program, PDP sponsor redeterminations involving tiering issues or coverage of a non-formulary drug would not be automatically forwarded to the IRE. Instead, an enrollee would need to request an IRE review. This proposed requirement modifies the MA procedure that affords automatic referral to the IRE whenever the MA organization's original denial is upheld by the organization's redetermination. We believe that this change is appropriate given the statutory limitation that an appeal request be made only if the prescribing physician determines that all covered Part D drugs on the formulary would not be as effective or would have adverse effects. Moreover, many of the drug appeals may involve relatively small monetary amounts, raising doubts about the efficacy of forwarding all such cases to an IRE.

Thus, § 423.600 proposes that an enrollee who is dissatisfied with the PDP sponsor's redetermination may file a written request for reconsideration by the IRE. We also propose that when an enrollee files for an appeal, the IRE is required to solicit the views of the prescribing physician. Also, in order for an enrollee to request a reconsideration of a PDP sponsor's determination not to provide for a covered drug that is not on the PDP formulary, the prescribing physician 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 nonformulary drug, would have adverse effects for the individual, or both.

Section 423.602 proposes the requirements for the IRE reconsideration determination notice, including the requirement that if the determination is adverse (that is, does not completely reverse the PDP sponsor's adverse coverage determination), the enrollee must be informed of the right to request an ALJ hearing and the procedures that must be followed to obtain the hearing.

Section 423.604 of our proposed rule explains that a reconsideration by the IRE is final and binding on the enrollee and the PDP sponsor, unless the enrollee requests an ALJ hearing.

c. Administrative Law Judge (ALJ) Hearings, Medicare Appeals Council (MAC) Appeals, and Judicial Review (§ 423.610 Through § 423.630)

As stated above, Section 1860D–4(h)(1) of the Act merely requires the Secretary to establish a reconsideration and appeals process that is "similar" (as determined by the Secretary) to the process used for MA organizations under the authority of 1852(g)(4) and (5) of the Act. Although we believe the Congress gave us a good deal of discretion in designing these procedural rules under Part D, we have determined as a policy matter to adopt most of the ALJ, MAC, and judicial review procedures currently used in the MA program.

Section 1852(g)(5) of the Act provides the right to a hearing and to judicial review for an enrollee dissatisfied by reason of the enrollee's failure to receive a covered Part D drug to which he or she believes he or she is entitled, and at no greater charge than he or she believes he or she is required to pay. Section 1852(g)(5) of the Act also specifies the amount in controversy needed to pursue a hearing and judicial review and authorizes representatives to act on behalf of individuals that seek appeals. In general, we would be implementing section 1869 changes that apply to Part D through cross-reference to the appropriate Part 405 regulations.

If the IRE's reconsideration determination is not fully favorable, the enrollee may request a hearing before an ALJ if the amount remaining in controversy meets the threshold requirement established annually by the Secretary. The threshold requirement will be published annually in the **Federal Register**. Although a PDP sponsor generally is not a party to the IRE appeal and may not request a

hearing before an ALJ, the sponsor is considered a party to the ALJ hearing for the limited purpose of participation in the hearing. If the ALJ hearing does not result in a fully favorable determination, the enrollee may request MAC review of the ALJ decision.

Following the administrative review process, the enrollee is entitled to judicial review of the final determination if the amount remaining in controversy meets the threshold requirement established annually by the Secretary and published in the **Federal Register**.

7. Effectuation of Reconsideration Determinations (§ 423.636 Through § 423.638)

Sections 423.636 and 423.638 propose the requirements for effectuation of coverage determinations reversed by the PDP sponsor, redeterminations reversed by the independent review entity, or reversals by an ALJ or higher level of appeal. For example, § 423.636(a)(1) requires that for redeterminations of requests for benefits, if the PDP sponsor reverses its determination, it must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days after the date it receives the request for redetermination. When the PDP sponsor is reversed by the independent review entity, § 423.636(b)(1) requires that it must authorize the benefit under dispute within 72 hours from the date it receives notice reversing the redetermination, or provide the benefit as expeditiously as the enrollee's health requires, but no later than 14 calendar days from the date of the reversal notice. For redeterminations of requests for payment, § 423.636(a)(2) requires that if the PDP sponsor reverses its coverage determination, it must pay for the benefit no later than 60 calendar days after the date it receives the request for reconsideration. Under § 423.636(b)(2) if a sponsor's redetermination is reversed by the independent review entity, it must pay for the benefit no later than 30 calendar days from the date it receives notice reversing the redetermination.

Section 423.638 proposes that for expedited redeterminations reversed by the PDP sponsor or the independent review entity, the PDP sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires but no later than 72 hours after the date it receives the request for redetermination, or in the case of reversal by the independent review entity, from the date it receives the reversal notice.

Finally, for reversals by an ALJ or higher level of appeal, under § 423.636(c) and § 423.638(c) the PDP sponsor must pay for, authorize, or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days from the date it receives notice reversing its determination.

8. Federal Preemption of Grievances and Appeals

We believe that the grievance procedures for the Part D Drug Program under Title I should be the same as those that apply to the MA program under Title II.

Section 232(a) of the MMA amended 1856(b)(3) of the Act so that it now reads: "The standards under this part shall supersede any State law or regulation (other than State licensing laws or State law relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part." Section 1860D-12(g) of the Act then incorporates this preemption rule for PDP sponsors and prescription drug plans. As we discussed earlier in Part I of this preamble, we believe that these preemption provisions would not cause all State laws to be superseded—particularly in areas where we have no authority to regulate. In the context of our grievance and appeals rules, because our regulations provide for doing so, we would continue to defer to state law on the issue of authorized representatives of enrollees in the appeals process. We do not believe that the Congress intended for the Secretary to regulate matters for which the Secretary is not authorized to promulgate standards (for example, spousal rights, powers of attorney, or legal guardianship). Often, authorized representative matters are non-Federal issues. However, because we do have the authority to regulate in the field of grievances, we are concerned that state grievance requirements will now be preempted, and we may need to reexamine our Federal grievance requirements. We request comments on this preemption issue and the specific state grievance requirements that should be incorporated into Federal regulatory requirements at § 423.564.

We also note that tort law, and often contract law, are generally developed based on case law precedents established by courts, rather than by legislators through statutes or by state officials through regulations. In addition, we do not believe we would have the authority under Part D to set specific tort remedies or to govern resolution of private contracting

disputes between PDPs and MA-PDs and their subcontractors. We believe that the Congress did not intend for our regulations to supersede each and every State requirement applying to MA-PDs and PDPs—even those for which the Secretary lacks expertise and authority to regulate. Thus, we do not believe, for example, that wrongful death or similar law suits based upon tort law would be superseded by the appeals process established in these regulations. Similarly, State contract law would continue to govern private contract disputes between PDPs or MA-PDs and their subcontractors.

Under principles of Federalism, and Executive Order 13132 on Federalism, which generally require us to construe preemption narrowly, we believe that an enrollee should still have state remedies available in cases in which the legal issue before the court is independent of an issue related to the organization's status as a stand alone PDP or an MA-PD plan.

9. Employer Sponsored Prescription Drug Programs and Appeals

The waiver provisions of section 1857(i) of the Act were incorporated into Part D through section 1860D-22(b) of the Act. When an employer, whether by contracting with MA-PDs or PDPs or otherwise, provides prescription drug benefits in addition to those covered under Part C and Part D of Title XVIII of the Social Security Act to their retirees, such employer may have established a group health plan governed by both Title I of the Employee Retirement Income Security Act of 1974, as amended (ERISA), and State law (to the extent such State law is not preempted by ERISA). In addition, when MA-PDs, PDPs, and programs described in 42 U.S.C. 1395w-132 offer benefits covered under Part D, they also would fall under the requirements of Part 423 of our proposed regulations, with respect to Part D benefits.

In drafting our Part C, MA rules, we consulted the Department of Labor (DOL), employer groups, and the health plan industry in trying to eliminate unnecessary Federal regulation of claims and appeals issues that impact matters within the jurisdiction of both DOL and DHHS. Based on our experience under Part C, we have reason to believe that some Medicare eligible individuals may receive integrated prescription drug benefits, *i.e.*, Part D benefits through an MA-PD, PDP, or program described in 42 U.S.C. 1395w-132 and supplemental benefits through an ERISA-covered plan. For example, an employer-sponsored plan may pay the

cost-sharing amount for a prescription drug that is offered by an MA-PD or PDP. Clearly, if the enrollee had a dispute about Part D coverage, he or she could file an appeal with the PDP sponsor. If the enrollee's dispute involved only the amount of cost sharing paid by the employer-sponsored plan, he or she would file an appeal in accordance with the procedures of the ERISA covered plan. In some cases, however, the dispute might involve independent coverage decisions under both Part D and the ERISA plan; possibly necessitating parallel appeal procedures on the same case. In this regard, we are soliciting comments on whether, and to what extent, the application of parallel procedures in this context might be a problem for plans, employers, and/or eligible individuals. We also are soliciting suggestions for addressing problems, if any, resulting from the application of parallel procedures.

N. Medicare Contract Determinations and Appeals

(If you choose to comment on issues in this section, please include the caption "Subpart N—Medicare Contract Determinations and Appeals" at the beginning of your comments.)

1. Overview

Section 1860D-12(b)(3)(F) of the Act directs that the "procedures for termination" in section 1857(h) of the Act be incorporated into contract requirements for PDP sponsors. To enhance the flow of this proposed rule, we have separated the provisions of section 1857(h) of the Act into two portions and addressed the two portions in different subparts of this part.

2. Proposed Provisions of the Subpart

As discussed above, § 423.509 of subpart K of this part implements the provisions of sections 1857(h)(1)(A) and 1857(h)(2) of the Act that address reasons for our termination of contracts, opportunity for PDP sponsors to develop a corrective action plan before termination, and procedures for immediate termination if we identify an imminent and serious health risk to enrollees.

Sections 423.641(b) through 423.669 specifies the procedures outlined in section 1857(h)(1)(B) of the Act. These sections specify that we would provide the organization with reasonable notice and opportunity for hearings (including the right to appeal an initial decision) before termination of its contract. Additionally, the requirements at § 423.641(a) specifies the procedures for making and reviewing our

determination that an entity is not qualified to enter into a contract as a PDP sponsor under this part. Finally, § 423.641(c) identifies procedures for reviewing our decision as specified at § 423.507(b) not to renew a contract with a PDP sponsor.

Section 1860D-12(b)(3) of the Act states that we must apply certain specified provisions of section 1857 of the Act including the procedures for termination in section 1857(h) of the Act in the same manner as they apply to contracts under section 1857(a) of the Act. Therefore, we are proposing that a single set of procedures relating to contract determinations and appeals apply to both MA and PDP sponsor contractors. The requirements at § 423.641 through § 423.669 would mirror the requirements at § 422.641 through § 422.698 for the MA program.

A summary of the specific process and content of the proposed appeals and determination system for PDP sponsors found in this subpart are below.

Sections 423.641 through 423.669 of our regulations detail the specific process and content of the appeals and determinations system, as it relate to PDP sponsors. The topics covered in these sections fall into the following five categories:

(1) *Contract determinations.* Sections 423.641 through 423.643 would describe the types of contract determinations, the notice requirements, and the effect of contract determinations on the PDP sponsor contract.

(2) *Reconsideration.* Sections 423.644 through 423.649 would describe when a PDP sponsor organization may request a reconsideration of our contract determination, the procedures for requesting a reconsideration, the internal operation of the reconsideration, the notice requirements for relating the reconsideration determination to all parties, and the impact of this determination on the PDP sponsor's contract.

(3) *Hearing.* Sections 423.650 through 423.667 would discuss in detail the process surrounding a hearing, including when a hearing may be requested by a PDP sponsor and how to make the request, the internal operation of the hearing (for example, designation of participants in the hearing, witnesses and evidence that can be presented, and record of the hearing), and the notice and effect of the hearing decision on the PDP sponsor's contract. If the contractor has submitted a request for a hearing timely, the effective date of the contract determination may have been postponed pending the reconsideration determination. Finally, this section discusses the right for review of the

hearing decision by the Administrator and the effect of that review decision.

(4) *Reopening.* Section 423.668 would present the opportunity for reopening of the contract or reconsidered determination of a hearing officer or the Administrator.

O. Intermediate Sanctions

(If you choose to comment on issues in this section, please include the caption "Subpart O'Intermediate Sanctions" at the beginning of your comments.)

1. Overview

Suppart O would implement most of the provisions of section 1860D-12(b)(3)(E) of the Act. This section of the statute provides that the contract requirements at section 1857(g) of the Act that govern "intermediate sanctions" for Medicare Advantage (MA) organizations, with a few exceptions, will apply to contracts for PDP sponsors. Therefore, with two exceptions, the requirements in § 423.750 through § 423.760 would mirror the requirements at § 422.750 through § 422.760. The two changes we are proposing to make to comply with the MA provisions are found below in the section called, "Basis for Imposing Sanctions."

Freezing marketing or enrollments has generally been our first and most frequently used sanction authority. The MMA requires at least two qualified plans, that is a PDP per region. If we were to freeze the enrollment or marketing of a PDP sponsor, that is one of only two plans in a region, beneficiaries would no longer have the level of choice the MMA intended. If we are contemplating sanctioning a plan that is one of only two PDP sponsors in a region, we may have to consider using other remedies including civil monetary penalties to maintain an adequate level of choice for beneficiaries. However, we do not want to discriminate in our treatment of PDPs when imposing sanctions. Our goal would be to have consistent policies and procedures across all regions in regard to sanctions. Therefore, we request comment on whether closing enrollment should be used in any situation or should we generally rely on civil monetary penalties as a sanction for PDPs.

2. Kinds of Sanctions (§ 423.750)

Section 423.750 of our regulations would describe four types of sanctions that we may impose on PDP sponsors, if warranted under § 423.752. These sanctions are identical to those we have imposed on M+C contractors. The range of potential sanctions, and the fact that one or more of them may be imposed at

any one time, would permit us to tailor our action to a specific situation.

Three of these sanctions would disrupt the operation of the PDP sponsor in relation to Medicare beneficiaries (that is, suspension of new enrollment (§ 423.750(a)(2), suspension of our payments to the PDP sponsor for enrolled beneficiaries (§ 423.750(a)(3), and suspension of all marketing activities (§ 423.750(a)(4)). We may keep the sanction in force until we are satisfied that the organization has corrected and will not repeat, the deficiency on which the sanction was based.

The fourth sanction that we could impose on an organization is civil monetary penalties ranging from \$10,000 to \$100,000, depending on the violation. Both the Office of the Inspector General (OIG) (§ 423.756(f)(2)) and CMS (§ 423.756(f)(3)) may impose civil monetary penalties.

3. Basis for Imposing Sanctions (§ 423.752)

Sections 423.752(a) and 423.752(b) of our regulations would list the seven violations for which sanctions may be imposed on a PDP sponsor organization. These violations are the same as those that warrant the imposition of sanctions for MA contractors, with the exception of two deletions we are proposing below. Specifically, sanctions would be imposed if the PDP sponsor engages in any of the following:

(1) Fails to provide required medically necessary services with adverse effect on the enrollee.

(2) Imposes premiums on beneficiaries that are in excess of those permitted in subpart F of part 423 of these proposed regulations.

(3) Expels or will not re-enroll a beneficiary in violation of this part.

(4) Engages in the practice of health screening or "cherry picking."

(5) Misrepresents or falsifies information furnished to CMS, any other entity or individual under the Part D drug benefit program.

(6) Employs or contracts with an individual or entity excluded from participation in the Medicare program as specified under section 1128 or 1128A of the Act (or with an entity that employs or contracts with the individual or entity) for the provision of certain services.

Additionally, as an alternative to the sanctions listed above, we would be able to decline to authorize renewal of the organization's contract (or may elect to terminate the contract entirely in accordance with § 423.509). In addition, § 423.509(a) would provide that a PDP sponsor organization be sanctioned if it

fails to carry out the terms of its contract as specified under this section.

Section 1860D-12(b)(3)(E) of the Act would specifically exclude two of the bases for sanctions at section 1857(g)(1) of the Act for MA contractors from application to PDP sponsor organizations as specified in part 423. Specifically, we would not impose sanctions on a PDP sponsor in the event it fails to enforce the limit on balance billing under a private-fee-for-service plan as required at § 422.216(a)(4), or fails to prohibit interference with practitioners' advice to enrollees, as required at § 422.206, since we do not believe these provisions are applicable in the context of the Part D drug benefit.

4. Procedures for Imposing Sanctions (§ 423.756)

Section 423.756 of our proposed regulations would specify our procedures for conducting the sanction process for PDP sponsor organizations. This process would mirror that used for the MA program. A brief summary of the process is as follows—

- We must send a timely notification of sanction to the PDP sponsor, outlining the nature and basis of the proposed sanction, and copy OIG.
- We must provide the PDP sponsor with an 15 or 30 day extension, to respond. If requested, an uninvolved CMS official will conduct an informal reconsideration of the determination with a written decision.
- Non-monetary sanctions would be effective 15 days from the organization's receipt of a final notice of sanction and remain in effect until we determine that the violation is corrected. CMS or the OIG, depending on the basis for the sanction, may impose civil monetary penalties.

5. Maximum Amount of Civil Money Penalties Imposed by CMS (§ 423.758)

Section 423.758 of our proposed regulations would provide that we be given discretion, as we have been in the M+C program, to determine the amount of monetary penalty to impose on a PDP sponsor within the limits specified at § 423.758. Three situations where monetary penalty limits are listed are as follows—

(1) If the deficiency in which the determination was based has adversely affected the health of an enrollee (or has substantial probability of doing so), the penalty may be \$25,000 per determination.

(2) We may apply a monetary penalty for each week that a deficiency remains uncorrected after the organization receives our notice of sanction or notice

of reconsideration determination, up to \$10,000 per week.

(3) If we determine that a PDP sponsor has terminated its contract without following the process required in subpart K at § 423.510, the penalty imposed may be either \$250 per Medicare beneficiary enrolled in the organization at the time the PDP sponsor terminated its contract, or \$100,000, whichever is greater.

6. Other Applicable Provisions (§ 423.760)

Section 423.760 of our proposed regulation provides that the provisions of section 1128A of the Act (except subsections (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a civil money penalty or procedure under section 1128A of the Act.

P. Premiums and Cost-Sharing Subsidies for Low-Income Individuals

Section 1860D-14 of the Act establishes a program to provide subsidies for assistance with premium and cost-sharing amounts for Part D eligible individuals with lower income and resources. The proposed regulations in this subpart and in regulations published by the Social Security Administration (SSA) adding a subpart D to a new part 418 of title 20 of the Code of Federal Regulations implement section 1860D-14 of the Act.

The statute divides subsidy eligible individuals into two different groups based on income and resources: (1) Full subsidy eligible individuals; and (2) other low-income subsidy eligible individuals. The different groups are entitled to different amounts of subsidy assistance. In this proposed regulation, we are defining the eligibility criteria and the amounts of subsidy assistance provided.

1. Eligibility for the Low-Income Subsidy (§ 423.773)

In order to qualify for a full subsidy, an individual must live in one of the fifty States or the District of Columbia and have countable income below 135 percent of the Federal poverty level for the individual's family size. For purposes of this section, "federal poverty line" (FPL) has the meaning given that term in section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2)), including any revision required by that section.

In addition, an individual must have resources that do not exceed three times the resource limit under section 1613 for applicants for Supplemental Security Income (SSI) under title XVI, which in 2006 is \$6,000 if single, or

\$9,000 if married. Thereafter, this resource limit will be increased annually by the percentage increase in the Consumer Price Index (all items, U.S. city average) as of September for the year before, rounded to the nearest multiple of \$10.

Individuals not eligible for the full subsidy may be eligible for the partial subsidy if they live in one of the fifty States or the District of Columbia and have income below 150 percent of the FPL for their family size, and have resources in 2006 that do not exceed \$10,000 if single, or \$20,000 if married. Beginning in 2007 and for each subsequent year, the resource limit will be increased annually by the percentage increase in the Consumer Price Index (all items, U.S. city average) as of September for the year before, rounded to the nearest multiple of \$10.

Low-income Part D eligible individuals who reside in the territories are not eligible to receive premium and cost-sharing subsidies under this subpart. Subpart S of this proposed rule addresses the provision of covered Part D drugs to low-income individuals residing in the territories.

In making income and resource determinations for the low-income subsidy for Part D, the statute refers to certain sections of the SSI program rules. For example, the MMA refers to income being determined in the same manner as for Qualified Medicare Beneficiaries (QMBs) under the Medicaid program, without use of the more liberal methodologies that States are permitted to use. The QMB provisions reference the SSI rules (specifically, section 1612 of the Act, which are the rules of the SSI program for determining income). Our proposed definition of income is consistent with the MMA in that it references SSI rules.

The MMA provides that we will compare the individual's income to the appropriate FPL applicable to "the family of the size involved." As there is no reference in the MMA statute to using previous definitions of family size, we propose to define family size to include the applicant, his or her spouse who lives in the same residence, and the number of individuals related to the applicant who live in the same residence and who depend on the applicant or the applicant's spouse for at least one-half of their financial support.

We considered limiting family size to 1 or 2 individuals to more closely resemble the SSI rules where family size is not actually defined but where benefits are paid on the basis of an eligible individual or eligible couple. This is the definition we propose to use

in determining eligibility for Transitional Assistance under the drug card. The decision to limit family size under the drug card was based on the short duration of that program (18 months), the limited benefit (\$600 a year), and the fact that we would have to rely entirely on a computer and systems-based process for determining Transitional Assistance eligibility and verifying income and other information from applicants. However, we do not believe it was the intent of the Congress to similarly limit the definition for purposes of determining eligibility for subsidies under the Part D program. Unlike the provisions authorizing the Medicare-approved drug discount card program, there are no provisions with respect to the low-income subsidy program that give the Secretary specific authority to define family size. Instead, we are interpreting the term "family of the size involved." We believe that this term implies a definition that is greater than an individual or couple and that includes other dependent relatives residing in the applicant's household. In addition, in order for the term "family size" to have meaning in the context of subsidy determinations, the notion of dependency needs to take into account the impact of a dependent on the relative need of the applicant or the applicant's spouse in attaining the subsidy. Accordingly, we have specified that dependents included in the calculation of family size are only those relatives residing in the residence who are financially dependent on the applicant or the applicant's spouse for one-half of their support.

In determining the income to be compared to the FPL for the size of the family involved, we would include income of the Medicare beneficiary and spouse, if any. Thus, if a married individual applies, both the income of the applicant and his or her spouse who lives in the same residence, regardless of whether the spouse is also an applicant, is counted and measured against the appropriate standard for the low-income subsidy. In our view, this best comports with the statutory reference to determining income in the manner described in section 1905(p)(1)(B) of the Act (for QMBs). In making a standard QMB income determination, States will consider the income of one spouse as available to the other spouse. Moreover, since both spouses will be considered in the family size determination, it would be counterintuitive to count a spouse's presence while not including that spouse's income. Other members who meet the one-half support test will be

counted in the family size calculation, but income of these dependents will be ignored in the eligibility determination. The one-half support test ensures that a family member with sizable income is not erroneously counted as a dependent while that person's income is ignored.

The MMA (at section 1860D-14(a)(3)(D)) provides that resources will be determined according to section 1613 of the Act. The resource standard depends upon whether the applicant is a single individual or a member of a married couple and whether the resources will be measured against the basic or alternative resources standards. See section 1860D-14(a)(3)(D) and (E) and H.R. Conference Report No. 108-391 at 470. However, that section does not define resources, it defines what are not resources. The MMA also provides for the development of a simplified application in which applicants attest to their level of resources and submit only minimal documentation. The implication of this provision is that the Congress envisioned a simple process. In order to keep the process simple and minimize administrative cost, we intend to only consider liquid resources (that is, those that could be converted to cash within twenty days) and real estate that is not an applicant's primary residence as resources that are available to the applicant to pay for the Part D premiums, deductibles and copayments. Thus, we will not consider other non-liquid resources (for example, a second car) to be available to the applicant for this purpose.

We do not believe this policy will have a significant impact on program costs. We believe any such program costs associated with not counting non-liquid resources other than countable real estate would be offset by the administrative savings resulting from a more simplified program. As we indicate further in this section, we are working with SSA on a quality assurance strategy that will strike an appropriate balance between administrative costs and program goals and objectives.

Section 1860D-14(a)(3)(B)(v)(I) of the Act requires that full-benefit dual eligibles (as defined under section 1935(c)(6) of the Act) and individual receiving benefits under the SSI program be treated as full subsidy eligible individuals with respect to premium assistance, elimination of the deductible, continuation of coverage above the initial coverage limit, and elimination of cost-sharing above the annual out-of-pocket threshold. However, copayment subsidies for these individuals will vary depending on whether the individual is in an

institution or has income below or above 100 percent of the FPL. Full benefit dual eligible individuals with income above 100 percent of the FPL will have copayments not to exceed \$2 for a generic or a preferred multiple source drug or \$5 for an other drug.

Under Medicaid, the term "dual eligibles" generally refers to low-income Medicare beneficiaries who qualify for some level of medical assistance. Those entitled to full benefits under Medicaid generally have most of their health care expenses, including prescription drugs, paid for by a combination of Medicare and Medicaid. However, Federal law also specifies several groups of dual eligibles who, while not entitled to full Medicaid benefits, are entitled to more limited medical assistance, specifically payment of Medicare Part A or Part B premiums and/or cost sharing, such as payment of Medicare deductibles and coinsurance. These groups are certain QMBs, specified low-income Medicare beneficiaries (SLMBs), qualified disabled and working individuals (QDWIs), and certain qualifying individuals (QIs).

For purposes of the low-income subsidy under Part D, we propose to define the term "full benefit dual eligible individual" as an individual who for any month has coverage under a PDP or MA-PD and is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. Comprehensive benefits referred to in this section do not include those benefits received under section 1115 Pharmacy Plus demonstrations. For individuals who become medically needy by spending down excess medical expenses, the individual is not eligible as medically needy until he or she satisfies their spenddown obligation. This requirement is reflected in the proposed regulations at § 423.772.

Section 1860D-14(a)(3)(B)(v)(II) of the Act authorizes the Secretary to treat QMBs, SLMBs, and QIs who are not full benefit dual eligible individuals as full subsidy eligible individuals. This authority does not apply to QDWIs. As indicated in the proposed regulations at § 423.773(c), the Secretary proposes to elect to exercise this authority and treat these individuals as being eligible for full subsidy assistance. This decision is based on the fact that nearly all QMBs, SLMBs, and QIs, by definition, will likely meet the requirements to be considered a full subsidy individual. Generally, QMB, SLMB, and QI individuals have income below 135

percent of the FPL and resources that do not exceed twice the SSI limit. The exception will be in the few States that have more liberalized income and asset rules for these groups under section 1902(r)(2) of the Act. We do not believe that treating these groups as subsidy eligible will have a large cost impact. Further, we believe that it will ease the administrative burden of having to educate these individuals on the need to apply for the subsidy.

Section 1860D-14(a)(1) distinguishes between noninstitutionalized full benefit dual eligible individuals with incomes at or below 100 percent of the FPL and other non-institutionalized individuals covered as full subsidy eligibles. This distinction is made solely for purposes of the reduction in cost-sharing below the out-of-pocket threshold. Therefore, full benefit dual eligibles (and, as proposed above, at the Secretary's election QMBs, SLMBs, and QIs) receive a full premium subsidy, have no annual deductible, and have coverage above the initial coverage limit. However, with respect to cost-sharing below the out-of-pocket threshold, these individuals have a two-tiered system depending upon whether their incomes are at or below 100 percent of the FPL or above 100 percent of the FPL. For those noninstitutionalized full benefit dual eligible individuals below 100 percent of the FPL, a copayment is imposed that does not exceed the lesser of \$1 for a generic or a preferred multiple source drug or \$3 for any other drug, or the amount charged to other individuals with income below 135 percent of the FPL who meet the resource standard based on three times the SSI standard. For individuals in this group above 100 percent of the FPL, a copayment not exceeding \$2 for a generic or a preferred multiple source drug is imposed, or \$5 for an other drug.

Finally, the statute gives the Secretary the option to permit a State to make subsidy eligibility determinations by using the methodology it uses under section 1905(p) of the Act if the Secretary determines that this would not result in any significant difference in the number of individuals who are made eligible for the subsidy. This would permit a State to use the same resource methodologies that it uses to determine Medicaid eligibility for QMBs, SLMBs, and QIs if the Secretary determines that the use of those methodologies would not result in any significant differences in the number of individuals who are made eligible for a subsidy. This includes the less restrictive methodologies the State uses under section 1902(r)(2) of the Act to

determine eligibility for QMBs, SLMBs, and QIs. At this time, the Secretary proposes not to exercise this option.

This means that when making eligibility determinations for other low-income subsidy eligibles, all States will use the same resource methodologies across the country. The rationale for not electing this authority is twofold. First, uniformity in the application process is a desired goal and having alternative resource methodologies that would vary among States would detract from that goal. Second, based on the administrative burden and complexity that would be involved in administering this alternative process, we see very little benefit in terms of the number of individuals who would be determined subsidy eligible.

2. Eligibility Determinations, Redeterminations and Applications (§ 423.774)

In accordance with section 1860D-14(a)(3)(B)(i) of the Act, an application for subsidy assistance may be filed with either a State's Medicaid program office or SSA. Inquiries made by individuals to PDPs or MA-PDs concerning application or eligibility for the low-income subsidy should be referred to State agencies or SSA. Eligibility determinations would then be made by the State for applications filed with the State Medicaid agency or by the Commissioner of Social Security for those filed with SSA. The Congress believes that more beneficiaries would enroll in the new Part D benefit if given the option to apply at the Social Security office as well as State Medicaid offices. While our goal is to provide a single application and determination process for the low-income subsidy, we recognize that the statute provides that redeterminations and appeals of eligibility determinations are to be made in the same manner as for medical assistance for those individuals who are determined eligible by the State Medicaid agency. Similarly, the Commissioner will decide how to conduct redeterminations and appeals for those subsidy determinations made by Social Security. We invite comments on State Medicaid agency procedures how to best implement the redetermination and appeal process that we believe would best be accomplished if the two separate processes produce the same outcome.

We note that eligibility determinations for low-income subsidies would be effective beginning with the first day of the month in which the individual applies for a subsidy, but no earlier than January 1, 2006, provided the applicant meets the

requirements for eligibility when he or she applies and has enrolled with a prescription drug coverage provider or MA plan with prescription drug coverage. Initial eligibility determinations would remain in effect for a period not to exceed 1 year.

Because States and Social Security offices would be performing subsidy determinations, States and SSA would need to share data with CMS. We will then use the data to notify the PDP sponsor or MA organization of the individual's eligibility. We will also use the data to provide information on income so that PDP sponsors and MA organizations may determine the amount of Part D premiums and copayments that may be charged to an individual eligible for the low-income subsidy as discussed later in this preamble.

Section 1860D-14(a)(3)(E)(ii) of the Act directs the Secretary and the Commissioner of SSA to develop a model simplified application form for the determination and verification of Part D eligible individual's assets or resources for the other low-income subsidy provision. We believe it is important to develop a simplified application for income as well as resources and to develop an application that will address both the full and the other low-income subsidy provisions. Therefore, we are working with SSA to develop a model application form to be used to determine eligibility for all subsidies. The application will reflect the definitions of income and resources discussed earlier in this subpart.

With regard to the method and degree to which income and resources will be verified, our general policy is to not spend more on verification than the expected return in terms of benefit savings. Therefore, we intend to use the most efficient and cost-effective process that will balance the need for program integrity with the goal of reducing paperwork burden and cost.

We envision a process based on an operations research strategy whereby States and SSA will build on existing verification processes used for other programs. We plan on maximizing the use of automated data matches for verification of income and certain liquid resources (which minimize both paperwork burden and cost), and relying on specific targeting or profiling criteria derived from a database that would identify a subset of applications for purposes of in-depth verification. This in-depth verification process will enable SSA and States to focus on elements attested to by the applicant that do not lend themselves to verification by electronic means (that is,

countable real estate). By developing a targeted approach, we believe we can strike an appropriate balance between administrative costs and program goals and objectives. We request comments on this approach.

In developing a simplified application, we also considered a number of other issues in order to streamline the application process. For example, the proposed rules permit a personal representative to assist in the application process. We are proposing to define personal representative as an individual who is authorized to act on behalf of the applicant, an individual acting responsibly on behalf of an applicant who is incapacitated or incompetent, or an individual of the applicant's choice who is requested by the applicant to act as his or her representative in the application process.

In addition, we would permit the use of a proxy signature process to allow applications to be taken over the phone or by an Internet process. Under a proxy signature process, an individual attests to the accuracy of the information provided under penalty of perjury prior to submitting the information for processing. Our proposed requirements specify that the individual applying for the low-income subsidy, or a personal representative on his or her behalf complete the application for the low-income subsidy, and certify as to the accuracy of the information provided.

Section 1860D–14(a)(3)(E)(iii)(II) of the Act provides that statements from financial institutions shall accompany applications in support of the information provided therein. As previously discussed, we believe States and SSA will be able to verify information through data matches. As a result, we would reduce an applicant's burden in producing financial statements by not requiring paper copies except when specifically requested. For example, SSA and States may verify some resources for the low-income

subsidy through data matches with 1099 files from the IRS, which show the annual amount of interest earned on interest bearing accounts. If the data from the 1099 files indicates the applicant's interest is below a threshold amount relating to the resource limit and the applicant has no countable real estate, the State or SSA could decide that no further information is needed from the applicant relating to certain types of resources. When the threshold is exceeded, additional information may be requested of the individual to support the application. Use of this process would ease the burden on individuals preparing to file an application and will reduce the administrative burden on States and SSA in handling paper verification. Accordingly, § 423.774(d) requires the submission of statements from financial institutions only if requested by the State or SSA.

3. Premium Subsidy (§ 423.780) and Cost-Sharing Subsidy (§ 423.782)

In accordance with section 1860D–14 of the Act, the proposed regulations specify the Part D premium subsidy and the Part D cost-sharing subsidy amounts available to subsidy eligible individuals, with the specific subsidy amounts varying depending upon the individual's income and resources/assets level. Table P–2 below shows the premium and cost-sharing subsidy amounts for the different groups of eligible individuals.

a. Full Subsidy Eligible Individuals

In accordance with section 1860D–14(a)(1)(A) of the Act, full subsidy eligible individuals are entitled to a full premium subsidy equal to 100 percent of the "premium subsidy amount," not to exceed the basic premium for coverage under the prescription drug plan selected by the beneficiary.

Under section 1860D–14(b)(2) of the Act, the premium subsidy amount is equal to the greater of the low-income

benchmark premium or the lowest monthly beneficiary premium for a prescription drug plan that offers basic prescription drug coverage in the region. The premium subsidy determined would apply regardless of whether the individual enrolls in a PDP or MA-PD. However, in the event the low-income benchmark premium is less than the lowest monthly beneficiary premium for basic prescription drug coverage offered by a PDP sponsor in a PDP region, in accordance with section 1860D–14(b)(3) of the Act, the premium subsidy will be equal to the monthly beneficiary premium for basic prescription drug coverage offered by a PDP sponsor in the PDP region.

Under section 1860D–14(b)(2) of the Act, the low-income benchmark premium amount for a PDP region equals either the weighted average of the monthly beneficiary premiums for all basic prescription drug plans (if all prescription drug plans in the PDP region are offered by the same PDP sponsor), or the weighted average of monthly beneficiary premiums for basic prescription drug coverage and the monthly beneficiary premiums attributable to basic prescription drug coverage for alternative prescription drug coverage for both PDP and MA-PD plans. Because section 1860D–14(b)(2)(A)(ii) of the Act references section 1851(a)(2)(a)(i) of the Act, the premiums of cost plans under section 1876 of the Act, PACE plans, specialized MA plans for special needs individuals and private fee-for-service plans are excluded for purposes of determining the weighted average in the region. This is because section 1851(a)(2)(a)(i) of the Act refers only to MA coordinated care plans. We interpret the calculation of the "weighted average" as described in the regulations at § 423.279(b) of this proposed rule.

Table P–1 below is an illustration of the premium subsidy determination.

TABLE P–1.—DETERMINATION OF THE PREMIUM SUBSIDY

Plan options in region		Low-income premium subsidy (full)		
Plans	Monthly beneficiary premium ¹	Percentage of part D enrollees in each plan ² (percent)	Premium times percentage (weighted average)	Maximum premium subsidy for eligible individual enrolling in plan
PDP 1 Offered by Sponsor A	40.00	15	6.00	36.00
MA-PD Plan 1	38.00	5	1.90	36.00
PDP 2 Offered by Sponsor B	36.00	40	14.40	36.00
MA-PD Plan 2	20.00	15	3.00	20.00
MA-PD Plan 3	0.00	25	0.00	0.00

TABLE P-1.—DETERMINATION OF THE PREMIUM SUBSIDY—Continued

Plan options in region		Low-income premium subsidy (full)		
Plans	Monthly beneficiary premium ¹	Percentage of part D enrollees in each plan ² (percent)	Premium times percentage (weighted average)	Maximum premium subsidy for eligible individual enrolling in plan
Weighted Average Basic Premium in Region =	25.30

The greater of the Low Income Premium Benchmark Amount (25.30) or the lowest PDP premium in the region (36.00) equals 36.00, so the maximum premium subsidy is the lower of 36.00 or the actual plan premium for basic coverage.

¹ Assumes no supplemental premium or late enrollment penalties.

² Assumes enrollment weights from the prior year's reference month (not first year of program).

Table P-1 illustrates the determination of the premium subsidy amount in a hypothetical region in which there are 2 PDPs, each offered by different sponsors, and 3 MA-PD plans. Because there are PDPs offered by more than one sponsor, the maximum premium subsidy amount is the greater of 2 amounts: the low-income premium benchmark amount or the lowest PDP premium in the region. The former is calculated by summing the products of the plan (basic) premium and the plan percentage of Part D enrollment in the region, and equals \$25.30. The lowest PDP premium in the region, however, is \$36.00. Therefore, in this exhibit, the full premium subsidy amount for the region is determined to be \$36.00. Consequently, a Part D eligible individual meeting the requirements for a full premium subsidy would have a choice of 3 zero-premium plans in which to enroll (PDP 2, MA-PD 2, and MA-PD 3), because the maximum premium subsidy amount equals or exceeds the premiums for these plans. However, if this individual chose to enroll in PDP 1 or MA-PD 1 for some reason, he or she would be obligated to pay the difference between the plan premium and the premium subsidy amount (\$4 or \$2, respectively) each month.

We anticipate that fallback plan premiums would be treated the same as those for risk-bid plans in the calculation of the low-income benchmark premium amount.

In accordance with section 1860D-14(b)(2) of the Act, the low-income benchmark premium amounts are determined without the addition of any amounts attributable to late enrollment penalties.

Individuals eligible for the full premium subsidy who are subject to late enrollment penalties under proposed § 423.46 would also be entitled to a subsidy equal to 80 percent of any late enrollment penalty for the first 60 months in which the penalties are imposed, and 100 percent of any penalties in any subsequent month, in

accordance with section 1860D-14(a)(1)(A)(ii) of the Act and proposed § 423.780(c).

Section 423.782 of the proposed rule incorporates the provisions of section 1860D-14(a)(1)(B), 1860D-14(a)(1)(C), 1860D-14(a)(1)(D), and 1860D-14(a)(1)(E) of the Act relating to the elimination of the deductible, continuation of coverage above the initial coverage limit (that is, no coverage gap), and reductions in cost-sharing. Specifically, full subsidy eligible individuals have no deductible. In addition, these individuals have continuation of coverage from the initial coverage limit (under paragraph (3) of section 1860D-2(b) of the Act and § 423.104(e)(3)) through the out-of-pocket threshold (under paragraph (5) of the same section). In other words, there is no coverage gap, or "donut hole," for these individuals.

In accordance with section 1860D-14(a)(1)(D)(i) of the Act, institutionalized full-benefit dual eligible individuals have no cost-sharing below the out-of-pocket threshold. We are proposing to define "institutionalized individual" for this subpart as a full-benefit dual eligible individual who is an institutionalized individual as defined in section 1902(q)(1)(B) of the Act.

Under section 1860D-14(a)(1)(D)(ii) of the Act, full-benefit dual eligibles in 2006 with incomes that do not exceed 100 percent of the poverty line for their family size will pay no more than \$1 for generic drugs or preferred multiple source drug (as defined in section 1927(k)(7)(A)(i) of the Act). In addition, they would pay \$3 for any other drug, or, if less, the amount charged to other individuals with income below 135 percent of poverty who meet the three times the SSI resource standard test, for costs below the out-of-pocket threshold. These \$1 and \$3 copayment amounts are increased beginning in 2007 by the percentage increase in the CPI (all items, U.S. city average), rounded to the nearest multiple of 5 cents. The cost-sharing subsidies would count toward

the application of the out-of-pocket threshold.

After the out-of-pocket threshold is reached, cost-sharing would be eliminated for all full subsidy individuals and full benefit dual eligible individuals. In accordance with section 1860D-14(a)(1)(D)(iii) of the Act, all other full subsidy eligible individuals and full benefit dual eligibles with income above 100 percent of the FPL in 2006 will pay copayment amounts of \$2 for a generic drug or preferred multiple source (as defined in section 1927(k)(7)(A)(i) of the Act) and \$5 for any other drug, for costs up to the out-of-pocket threshold. In accordance with section 1860D-2(b)(4) and 1860D-2(b)(6) of the Act, these copayments are indexed based on an annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of 5 cents (see § 423.104(e)(5) of this proposed rule). Also, all other full subsidy eligible individuals and full benefit dual eligible individuals have continuation of coverage from the initial coverage limit (under paragraph (3) of section 1860D-2(b) of the Act and § 423.104(e)(3)) through the out-of-pocket threshold (as specified under paragraph (4) of the section), with limited cost-sharing.

After the catastrophic threshold is reached, cost-sharing would be eliminated for all full benefit dual eligible individuals.

b. Other Low-Income Subsidy Eligible Individuals

In accordance with section 1860D-14(a)(2)(A) of the Act, for other low-income subsidy eligible individuals who do not qualify for the full subsidy or as full benefit dual eligible individuals, their premium subsidy would be on a sliding linear scale basis. The sliding scale premium subsidy would range from 100 percent of the beneficiary base subsidy (as discussed earlier, equal to the greater of the low-income benchmark premium or the lowest monthly beneficiary premium for

a prescription drug plan that offers basic prescription drug coverage in the PDP region), for individuals at or below 135 percent of the FPL for their family size, to no subsidy for individuals at 150 percent of the FPL for their family size. In contrast to full subsidy eligible individuals or full benefit dual eligible individuals, other subsidy eligible individuals subject to the late enrollment penalties under § 423.46 would be responsible for 100 percent of the penalties. We welcome comments concerning the manner in which the sliding scale premium subsidy is calculated for individuals with income from 135 percent up to 150 percent of the FPL. For ease of administration, we could set a scale in a stepped fashion, for example, a set decrease in the subsidy amount for every 5 percent increase in income level.

Other subsidy eligible individuals would have their annual deductible reduced from \$250 to \$50. This \$50 is indexed in accordance with section 1860D–2(b)(6) of the Act beginning in 2007 based on the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of \$1.

Other subsidy eligible individuals would have continuation of coverage from the initial coverage limit (under paragraph (3) of section 1860D–2(b) of the Act) through the out-of-pocket threshold (under paragraph (4) of that section), meaning no coverage gap or “donut hole.” For coverage through the out-of-pocket threshold, these individuals would pay 15 percent coinsurance, substituting for the higher beneficiary coinsurance described in section 1860D–2(b)(2) of the Act (see § 423.104(e)(2) of this proposed rule). The cost-sharing subsidies would count toward the application of the out-of-pocket threshold. After the out-of-pocket threshold is reached, these individuals’ cost-sharing would be limited to the copayment or coinsurance amount specified under section 1860D–2(b)(4)(A)(i)(I) of the Act (see § 423.104(e)(5) of these proposed rules), which, in 2006, means co-payment amounts of \$2 for a generic drug or preferred multiple source (as defined in section 1927(k)(7)(A)(i) of the Act) and \$5 for any other drug. In accordance with section 1860D–2(b)(4) and 1860D–2(b)(6) of the Act, the \$2 and \$5 copayments would be indexed based on

an annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of 5 cents.

A question has been raised concerning whether an MA–PD plan could choose to reduce or eliminate copayments for dual eligible individuals. We believe that specialized MA plans (under section 231 of the MMA, as defined in proposed regulations at 42 CFR 422.2) offering benefits only to dual eligible individuals could choose to reduce or eliminate copayments for their members as a supplemental benefit. Otherwise, the Part D copayments stipulated by the MMA for low-income individuals cannot be reduced or eliminated. This is because any reduction of the copayments must apply to all plan members under the uniformity of benefits provisions, set forth in § 423.265(c). Accordingly, MA–PD plans other than special MA–PD plans for dual eligibles may not offer their members who are dual eligible lower copayments or co-insurance than those paid by its other plan members.

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Table P-2
Premium and Cost-Sharing Subsidy Amounts for Various
Subsidy Eligible Groups, in 2006

FPL & Assets*	Percentage of Premium Subsidy	Deductible	Copayment up to out-of-pocket limit	Copayment above out-of-pocket limit
Full benefit dual eligibles	100%	\$0	1. Institutionalized individuals-\$0. 2. <=100% FPL-The lesser of \$1-generic/preferred multiple source or \$3-other drugs or, the amount charged to other individuals with income below 135% FPL with assets <=\$6,000/<=\$9,000. 3. All other full benefit dual eligibles-- \$2-generic/preferred multiple source- \$5-other drugs.	
<=100% FPL <=\$6,000 <=\$9,000	100%	\$0	\$0 institutionalized individuals. For all others, the lesser of \$1-generic/preferred multiple source or \$3-other drugs or, the amount charged to other individuals with income below 135% FPL with assets <=\$6,000/<=\$9,000.	None
>100% <135% FPL <=\$6,000 <=\$9,000	100%	\$0	\$2-generic/preferred multiple source- \$5-other drugs.	None
<135% FPL >\$6,000- <=\$10,000 >\$9,000- <=\$20,000	100%	\$50	15 percent coinsurance	No more than \$2 for a generic or preferred multiple source drug or \$5 for other drugs
>=135%- <150% <=\$10,000 <=\$20,000	Sliding Scale Premium Subsidy (100%-0%)	\$50	15 percent coinsurance	No more than \$2 for a generic or preferred multiple source drug or \$5 for other drugs
<p>* 2006 assets figures are shown for individuals first, and then couples.</p> <p>** The premium subsidy is equal to the percentage shown in the above table of the greater of the low-income benchmark premium amount or the lowest basic PDP premium in the region. It also cannot exceed the basic premium for drug coverage under the prescription drug plan selected.</p>				

BILLING CODE 4120-01-C**4. Administration of Subsidy Program
(\$ 423.800)**

We would be establishing a process to notify the PDP sponsor or MA organization that an individual is both eligible for the subsidy and the amount of the subsidy. Because CMS has not yet developed such a process, comments are welcome concerning notification to the PDP sponsor or MA organization that an individual is eligible for a subsidy and the amount of the subsidy. Similarly, we request comments on the proposed requirement that the PDP sponsor or MA organization notify CMS that premiums or cost-sharing have been reduced and the amount of the reduction. We are also considering the process for reimbursing the sponsor or organization for the amount of the premium or cost-sharing reductions. Any individually identifiable information must be kept confidential. Finally, we are requesting comments on how to best reimburse subsidy eligible individuals with respect to out-of-pocket costs relating to excess premiums and cost-sharing incurred before the date the individual was notified of subsidy eligibility but after the effective date the individual became subsidy eligible.

Similarly, we are requesting comments on how to deal with premiums and cost sharing paid by charities or other programs, for example, the Ryan White program or State Pharmacy Assistance programs, on behalf of an individual during a period when he or she is determined to be subsidy eligible. We are specifically requesting comments on whether Medicare should treat these programs for purposes of premium or cost sharing reimbursement as we would other employer-sponsored insurance programs in which Medicare is a primary payer for purposes of coordination of benefits. In addition, we are requesting comments on whether beneficiaries should be responsible for reimbursing any cost sharing or premiums paid on their behalf by another program or charity.

In accordance with section 1860D-14(c)(2) of the Act, reimbursement to PDPs or MA-PDs may be computed on a capitated basis, taking into account the actuarial value of the subsidies and with appropriate adjustments to reflect differences in the risks actually involved. (Refer to Subpart G of this proposed rule for a discussion of interim payments and final reconciliation payments.)

Subsidy amounts under section 1860D-14 of the Act are counted toward

the counting of the out-of-pocket threshold at section 1860D-2(b)(4)(C)(ii) of the Act. Prescription drug plans and MA-PDs would be responsible for tracking the application of the low-income subsidy amounts as described in § 423.100 of these proposed rules.

Q. Guaranteeing Access to a Choice of Coverage (Qualifying Plans and Fallback Plans)

(If you choose to comment on issues in this section, please include the caption “Subpart Q” Guaranteeing Access to A Choice of Coverage Qualifying Plans and Fallback Plans” at the beginning of your comments.)

1. Overview (§ 423.851)

Subpart Q would implement the provisions of sections 1860D-3, 1860D-11(g), 1860D-12(b)(2), 1860D-13(c)(3) and 1860D-15(g) of the Act. In this section, we address a beneficiary’s right to have access to a choice of at least two plans; the requirements and limitations on the bid submission; review and approval of fallback prescription drug plans; contract requirements specific to fallback plans; and the determination of enrollee premium and our payments for those plans.

2. Terminology (§ 423.855)***a. Eligible Fallback Entity***

As provided under section 1860D-11(g)(2) of the Act, an “eligible fallback entity” for a particular contract period is defined as an entity that meets all the requirements to be a PDP sponsor (except that it does not have to be capable of withstanding potential financial losses as a licensed risk-bearing entity) and does not submit a bid under the risk bidding process for any PDP region for the first year of that contract period. An entity would be treated as submitting a bid under the competitive bidding process, and thus not be an eligible fallback entity, if the entity was acting as a subcontractor for an integral part of the drug benefit management activities of a PDP sponsor that is submitting a bid for a prescription drug plan. An entity would not, however, be treated as submitting a bid if it is a subcontractor of an MA organization, unless that organization is acting as a PDP sponsor with respect to a prescription drug plan, rather than offering an MA-PD plan. We anticipate that some eligible fallback entities may contract with other entities for the performance of some required pharmacy benefit management functions.

As the result of this restriction in bidding, eligible fallback entities would have decided not to submit either a full-

risk or limited risk bid in any region (either as a direct contractor, or as a subcontractor for a PDP sponsor) in order to be eligible to submit a fallback prescription drug bid in any region. Section 1860D-11(g)(2)(B) of the Act applies this restriction to the first year of a contract period. We interpret this to mean that an entity that submitted a risk bid in any region in the first year of a three-year contract cycle would not be permitted to be a fallback plan in the second and third year of the same contract cycle for any region. Taken together with the limitations in § 423.265(a)(2) on qualifying as a risk-bearing PDP, these requirements will force organizations to choose either the fallback process or the at-risk process. If an organization wins the fallback bidding, it is effectively barred under § 423.265(a)(2) from bidding as a risk plan in that region for 4 years—for the 3-year contract term, it is barred everywhere, and in the 4th year, it is barred from bidding as a risk plan in that region. We believe that the intent of this restriction was to maximize participation in the competitive bidding program and to limit the attractiveness of participating as a fallback plan for those plans that could participate on an at-risk basis. One of our objectives is to design our bidding process so that fallback plans are not required at all, that is, to support full-risk plans and to provide for limited-risk plans in a particular region if full-risk plans are not available. To the extent that any fallback plans may be required, we are required to submit an annual report to the Congress on the application of the fallback plan provisions and on further recommendations for limiting the need for such plans and maximizing participation by limited risk plans.

We could consider an alternative interpretation of what it means to “offer a fallback plan” in a region for purposes of section 1860D-12(b)(2)(C) of the Act. The alternatives would be—

1. Having a contract with us to be a fallback provider; or
2. Actually offering prescription drug benefits to enrollees when and if the fallback service area is “activated.”

With the second interpretation, a fallback entity may not necessarily be barred from the at-risk bidding for 4 years. If the fallback contract was not activated and no plan was offered during year 3, the entity could be eligible to bid at risk for year 4. Interpretation 2 seems reasonable and consistent with the conference negotiations, since the policy goal would be to prevent plans from converting their enrollment under a fallback contract to enrollment under an

at-risk plan. If a fallback contract were not activated, there would be no enrollment and no risk of conversion. This interpretation would be appropriate in the case of an Indefinite Delivery type of contract in which bidders are approved as potential contractors and orders may or may not later be placed against the contracts. However, there are a variety of contracting vehicles available, and we are not prepared to limit the type of contract used at this time. We are requesting comments on this interpretation of “offer a fallback plan,” and on the advantages and disadvantages of this type of contracting for eligible fallback entities.

b. Fallback Prescription Drug Plan

As provided under section 1860D–11(g)(4) of the Act, a fallback prescription drug plan is defined as a prescription drug plan offered by an eligible fallback entity that—

- Provides only actuarially equivalent standard prescription drug coverage (without supplemental benefits) as defined in § 423.100;
- Provides access to negotiated prices, including discounts from manufacturers;
- Meets the requirements for PDP sponsors except as otherwise indicated; and
- Meets other requirements as specified by us.

We would require that fallback plans offer actuarially equivalent standard coverage as defined in § 423.100 in order to ensure the incorporation of industry standard cost and utilization containment methods, such as tiered coinsurance structures. We would welcome comments on other requirements, or exceptions from requirements, that should be considered relative to fallback plans.

c. Qualifying Plan

Under § 423.855 of our proposed rule, a qualifying plan is defined as either a full-risk or limited risk prescription drug plan (PDP) or an MA–PD plan that provides basic coverage, or an MA–PD plan that provides supplemental coverage for no additional charge to the beneficiary. Specifically, if the MA–PD plan coverage includes supplemental prescription drug coverage, then in order to meet the definition of a “qualified plan” the MA–PD must be able to apply a premium rebate under Part C of Medicare as a credit against the supplemental coverage premium, leaving no cost to the beneficiary for the supplemental coverage. MA–PD plans must also be open for enrollment and not operating under a capacity waiver in

order to be counted as a qualifying plan in an area.

3. Assuring Access to a Choice of Coverage (§ 423.859)

a. Access Standards

As provided under section 1860D–3(a) of the Act and codified in our proposed regulations at § 423.859(a), we are required to ensure that each Part D eligible individual has available a choice of enrollment in at least two qualifying plans offered by different entities in the geographic area in which he or she resides. Therefore, beneficiaries in an area must have a choice of two plans that provide basic coverage (or an MA–PD plan that provides supplemental coverage for no additional charge to the beneficiary). However, to meet the access test, different sponsors must offer the two qualifying plans, and at least one of the plans must be a PDP.

b. Fallback Service Area

As provided in section 1860D–11(g)(3) of the Act, before the start of a contract year, we would determine if Part D eligible individuals in a PDP region have available a choice of enrollment in a minimum of two qualified plans offered by different entities, at least one of which is a prescription drug plan. In the event that we determine that beneficiaries within a PDP region or some portion of the PDP region do not have a choice of two qualified plans, we would establish a “fallback service area.” Thus, a fallback service area is any area within a PDP region in which we have determined that Part D eligible individuals do not have available a choice of enrollment in two qualified plans, at least one of which is a prescription drug plan. Three examples of the application of a fallback service area follow:

Example 1—We would establish a fallback service area in an area where an MA regional PPO plan is offered but no PDP is offered in the region. Since beneficiaries in the region would only have the choice of a MA–PD and not a stand-alone PDP, we would define the area as a fallback service area.

Example 2—A fallback service area would also be designated if only one PDP is offered in a region, but in some or all parts of the region neither a regional (PPO) MA–PD plan nor a local MA–PD plan are available to beneficiaries. Since beneficiaries would not have a choice of two qualifying plans, we would define the areas within the region that only have access to the PDP, and not an MA–PD plan, as fallback service areas. As a result, it

would be possible for only certain areas (counties) within a region to be designated as fallback service areas.

Example 3—A fallback service area would also be designated in any area in which only one entity offered all qualifying plans, even if that sponsor offered two PDPs, or one PDP and one MA–PD plan with basic coverage, covering the entire region.

In order to meet the requirement that two qualifying plans be available to beneficiaries in each service area, we could, as provided under section 1860D–11(f) of the Act and § 423.272(c) of these regulations, approve limited risk plans. If two qualifying plans were not approved in any particular service area even after our consideration of limited risk plan applications from entities applying to become PDP sponsors, beneficiaries in that service area would be provided with the opportunity to enroll in a fallback plan.

c. Waivers for Territories

Section 423.859(c) of our proposed regulations would make Medicare beneficiaries residing in the U.S. territories—which include American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands—eligible to enroll in Part D. As provided under section 1860D–42(a) of the Act, we would have the authority to waive any Part D requirements, including the requirement that access to two qualifying plans be assured in each service area, as necessary to assure access to qualified prescription drug coverage for Part D eligible individuals residing in the U.S. territories. For instance, if no fallback plans responded to our RFP for offering Part D coverage in a territory, but one PDP plan did, we might consider such a waiver as being in the interest of those beneficiaries. In addition, entities wishing to become prescription drug plans in the territories may request waivers or modifications of Part D requirements that facilitate their operation in those areas. We will publish in operational guidance a list of acceptable waivers and modifications of Part D requirements for entities that wish to operate prescription drug plans in the territories.

We will consider waiving the following requirements in order to assure sufficient access to qualified prescription drug coverage for Part D eligible individuals residing in the U.S. territories—

The proposed requirement set forth in section 1860D–3(a)(1) of the Act and § 423.859(a) of our proposed regulations that we ensure access to at least 2 qualifying plans offering standard

prescription drug coverage in each service area.

The proposed pharmacy access standard under section 1860D–4(b)(1) of the Act and § 423.120 of our proposed regulations, and the service area requirement set forth in § 423.112.

The proposed requirement set forth in section 1860D–4(k) of the Act and § 423.132 of our proposed regulations that PDP sponsors offering a prescription drug plan ensure that pharmacies inform Part D enrollees of any differential between the price of the covered drug to the enrollee and the price of the lowest priced generic drug that is therapeutically equivalent and bioequivalent and available at that pharmacy. This waiver mirrors language in the subpart C preamble regarding § 423.132 (public disclosure of pharmaceutical prices for equivalent drugs). There, we indicate that we will consider waiving this requirement for pharmacies under certain circumstances—including if the pharmacy is located in one of the U.S. territories. We propose replicating the waiver that is provided in the drug card regulation regarding public disclosure of prices for equivalent drugs. The rationale for this waiver in the drug card regulation was that few discount drug cards currently have contractual relationships with retail pharmacies in the territories; waiver of the requirement was meant to reduce the administrative complexity of endorsed card sponsors' contracts with participating retail pharmacies in the territories and, thus, encourage entities to apply to offer a discount card in the territories.

We request comments on the appropriateness of these proposed waivers of Part D requirements. In addition, we request comments regarding any additional waivers of Part D requirements we may wish to consider in order to assure access to qualified prescription drug coverage for Part D eligible individuals residing in the U.S. territories.

4. Submission and Approval of Bids (§ 423.863)

As provided in section 1860D–11(g)(1)(A) of the Act, we would establish a separate bidding process for fallback plans from the process addressed in § 423.265 of our regulations. We anticipate that we would "pre-qualify" bidders from eligible fallback entities in the first half of 2005 for the offering of fallback prescription drug plans in one or more regions in 2006. While formal awards would be made, the services of a fallback plan would only be used if at least two full-risk or limited-risk plans

(one of which could be an MA–PD plan) were unavailable. It is quite possible—and it is our policy objective—that we would never use the services of a fallback contractor because there would be at least two risk-bearing plans offered in every region of the country. We would re-solicit bids every three years thereafter in accordance with the three-year contracting cycle provided under 1860D–11(g)(7)(B) of the Act, or annually thereafter as needed to replace contractors between contracting cycles. However, a fallback prescription drug plan may be offered for any year within the contract period only if that area is a fallback service area for that year. We will provide additional guidance on the form and manner in which such fallback bids would be submitted. In general, we would enter into contracts with fallback plans using federal acquisition rules on a timetable ensuring that such contracts were in place at the same time as prescription drug plans would otherwise be offered. In the event that fallback contracts are required, we expect to award (only) two fallback contracts, through a competitive process factoring in price (discounts) and administrative costs.

As discussed in earlier sections of this preamble, section 1860D–11(i) of the Act specifies that we may not interfere with negotiations between drug manufacturers and pharmacies and PDP sponsors, and may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs. However, the revenue requirements standard in 5 U.S.C. 8902(i), discussed in subpart F of this preamble, requires us to ascertain that the bid "reasonably and accurately reflects the revenue requirements for benefits provided under that plan." Therefore, while we will not set the price of any particular drug, or require an average discount in the aggregate on any group of drugs (such as single-source brand-name drugs, multiple-source brand name drugs, or generic drugs), we will evaluate whether the bid is reasonably justified. As specified in 5 U.S.C. 8902(i), we will take steps to ensure that benefits are "consistent with the group health benefit plans issued to large employers," to ensure that the bid amounts submitted are comparable to those available on the private market. For example, if the price reference points appear to be particularly high (or low), we may request an explanation of the bidders' pricing structure, and the nature of their arrangements with manufacturers. We would also ensure that there is no conflict of interest leading to higher bids. In addition to

evaluating the reasonableness of the bid amounts submitted by fallback plans, we also propose to negotiate price-related performance targets with fallback plans, consistent with current market practices in which plan sponsors negotiate price-related reference points with PBMs. Additionally, we would also consider potential contractors based on what they bid for administrative functions like claims processing.

Unlike plans that contract on a risk basis, fallback entities are paid on the basis of cost, and thus these entities will have less of an incentive to negotiate low drug prices. Consequently, because the statute directs us to pay management fees that are tied to performance measures, and directs that there must be a measure for costs, we are contemplating tying the performance payments of fallback entities to the average discounts they are able to negotiate, including discounts from manufacturers. To the extent possible, we would like the concept of discount to reflect a broad measure of lower per member spending, this may be accomplished by greater reliance on generics or use of step therapy. Thus, for example, if a performance incentive was based on whether the plan was able to maintain an average discount of 20 percent below the Average Wholesale Price (AWP) of a drug (referred to as "AWP minus (-) 20 percent"), and if the plan averaged less of a discount, it might lose some of its performance incentive payments. If the plan was able to maintain an average discount greater than AWP–20 percent, it could qualify for additional incentive payments. Other potential targets might include average cost per prescription, average anticipated (or guaranteed) rebate per prescription, average dispensing fee per (type of) prescription, or average administrative fee per prescription.

We understand that this type of incentive contracting is found in the pharmacy benefit management market today, and believe that pursuing this type of approach will incentivize fallback plans to secure the best possible prices for beneficiaries and the Medicare program. However, we are aware that using a floating target such as AWP as a reference point may be counterproductive to our goal of minimizing costs, since the AWP can easily be raised to keep prices stable. Therefore, we are interested in identifying other potential reference points that would be less subject to manipulation, such as a relationship to average sales price, or to the prior year's negotiated and delivered prices. We considered whether this approach could

be viewed as a violation of the noninterference provisions of section 1860D–11(i) of the Act. We believe that section 1860D–11(g)(5)(B)(i) of the Act makes clear that the Congress contemplated taking prices into account in calculating incentive payments for fallback entities. Moreover, even though the performance measures will be defined in advance, the determination of incentive payments will be made at the end of the contract period, and thus does not represent interference in the bidding process. Therefore, we are proposing to place performance clauses in the contracts with fallback entities that would tie performance payments to the fallback plan's ability to negotiate certain levels of discounts on drug prices that will be passed on to beneficiaries and us as costs. We would also like to receive comments on alternative reference points or alternative methodologies that could promote competitive pricing.

Except as provided below, in section 6, all of the provisions of § 423.272 of our regulations regarding the review and approval of prescription drug plans apply to the approval or disapproval of fallback prescription drug plans. As indicated in § 423.265(d)(4), and discussed in subpart F of this preamble, all risk bids would be submitted as either full-risk or limited risk. After we evaluate all full-risk and limited risk bids, we will determine whether the region is, in whole or in part, a fallback service area and enter into (or activate) fallback plan contracts. In accordance with section 1860D–11(g)(1)(B)(ii) and section 1860D–11(g)(1)(B)(v) of the Act, only one fallback prescription drug plan would be approved to serve all fallback service areas in any one region, and we would not enter into a contract with just one fallback entity to offer all of the fallback plans throughout the United States.

As with risk bids, we believe we have the authority to negotiate with respect to fallback plans in four broad areas: administrative costs, aggregate costs, benefit structure, and plan management. We would evaluate administrative costs for reasonableness in comparison to other bidders. We would examine aggregate costs to determine whether the revenue requirements for actuarially equivalent standard prescription drug coverage as defined in § 423.100 are reasonable and equitable. We would be interested in steps that the plan is taking to control costs, such as through measures to encourage use of generic drugs, therapeutic interchange to preferred brand-name drugs, and formulary compliance. We would be interested in reviewing the formulary to

ensure that it is appropriate for a region in which beneficiaries do not have alternative plans from which to choose. We would examine and discuss any proposed benefit structures or changes to benefits, particularly with regard to any potentially discriminatory features. Finally, we would discuss indicators and any identified issues with regard to plan management, such as customer service.

5. Rules Regarding Premiums (§ 423.867)

Except as provided with regard to any enrollment penalty or low-income assistance, or employer group waivers under sections 1857(i) and 1860D–22(b) of the Act (§ 423.462(a) in subpart J), the monthly beneficiary premium charged under a fallback prescription drug plan offered in all fallback service areas in a PDP region must be uniform. It must equal 25.5 percent of an amount equal to our estimate of the average monthly per capita actuarial cost, including administrative expenses, under the fallback prescription drug plan of providing coverage in the region. In calculating administrative expenses, we would use a factor based on similar expenses of prescription drug plans that are not fallback prescription drug plans. We would like to receive comments suggesting the kinds of costs fallback plans might have that PDPs would not (for example, the cost of gearing up systems quickly, less ability to negotiate pharmacy network discounts) and what costs they would not have (for example, marketing).

Fallback plans would not receive a portion of any applicable late enrollment penalties since they do not bear risk for increased expenses attributable to individuals to whom the penalty applies. Monthly beneficiary premiums for enrollees in fallback prescription drug plans would be deducted from Social Security benefits (as provided in § 422.262(f)(1)) or in any other manner provided under section 1840 of the Act.

6. Contract Terms and Conditions (§ 423.871)

In general, the terms and conditions of contracts with eligible fallback entities offering fallback prescription drug plans would be the same as the terms and conditions of contracts for prescription drug plans, with the following exceptions:

- The contract term for a fallback prescription drug plan would be for a period of 3 years (except as may be renewed after a subsequent bidding process). However, a fallback prescription drug plan may be offered

for any year within the contract period only if that area is a fallback service area for that year.

- An eligible fallback entity with a contract under this part may not engage in any marketing or branding of a fallback prescription drug plan. This refers to marketing activities promoting the plan and its sponsor to Part D eligible beneficiaries as addressed in § 423.50 of this proposed rule, and not to required dissemination of information on approved plan characteristics to enrollees as required in § 423.128 of our proposed rule. Beneficiary education and outreach to employers potentially interested in providing supplemental coverage will remain solely our responsibility.

- We would establish performance measures for fallback prescription drug plans as discussed elsewhere in this subpart.

- Payment terms would include payment for actual costs (taking into account price concessions) of covered Part D drugs provided to Part D eligible individuals enrolled in the plan, and management fees tied to the performance measures that we establish.

- Each contract for a fallback prescription drug plan would require an eligible fallback entity offering a fallback prescription drug plan to provide us with the information that we determine is necessary to carry out the fallback plan payment provisions, and calculate accurate payments, including, but not limited to, all documentation relating to including 100 percent of drug claims, costs, rebates and discounts, and disclosure of all direct and indirect remuneration as offsets to the claim costs.

- We could amend the contract at any time, as needed, to reflect the exact regions or counties to be included in the fallback service area(s).

Other contract terms will be specified during the bid solicitation process. Competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5))) will be used in fallback plan contracting.

As discussed above, as part of the payment process for fallback plans authorized by section 1860D–11(g)(5) of the Act, we would assess the performance of plans with regard to specific performance measures and tie this performance to an incentive payment. These measures would include at least measures for cost containment, quality programs, customer service, and benefit administration (including claims adjudication). "Cost containment" refers to processes in place to ensure that costs

to the Medicare Prescription Drug Account and to enrollees are minimized through mechanisms such as generic substitution and price discounts. The term "quality programs" refers to drug utilization review processes in place to avoid adverse drug reactions and drug over utilization and to reduce medical errors. The term "customer service" refers to processes in place to ensure that the entity provides timely and accurate filling of prescriptions and delivery of pharmacy and beneficiary support services. We would be interested in surveying enrollees of fallback plans to assess customer satisfaction with plan services. The terms "benefit administration and claims adjudication" refer to processes in place to ensure that the entity provides efficient and effective benefit administration and claims adjudication, such as accurately programming and updating its benefit administration information systems, and providing timely and accurate claims adjudication.

7. Payment to Fallback Plans (§ 423.875)

The amount payable under approved fallback prescription drug contracts would be the amount determined under the specific contract negotiated for each such plan. In general, all such contracts would provide for payment for the allowable and allocable costs (taking into account negotiated price concessions) of covered Part D drugs provided to Part D eligible individuals enrolled in the plan and payment of management fees that are tied to the performance measures we established for the management, administration, and delivery of the benefits under the contract.

In contrast to PDP sponsors offering prescription drug plans and MA organizations offering MA-PD plans, eligible fallback entities are not required to bear any of the risk associated with the provision of the prescription drug benefit. They may, however, bear administrative cost risk related to the achievement of specified performance measures. In other words, they would receive reimbursement for the full contracted cost attributable to delivering the drug benefit, including management fees and administrative costs, but may not receive the full measure of available incentive payments tied to performance measures unless specified targets have been met.

We are considering alternatives for the fallback plan payment process. Under one proposal, we would establish an account against which the claims costs and management fees would be debited. This means that the entity offering the fallback plan would debit

the prescription drug claim costs and their negotiated administrative fees against this account in a manner to which we agree and would then be subject to certain cost reporting and settlement requirements, as, for instance, with regard to rebate allocation. An alternative approach would be to establish an estimated monthly payment per enrollee as a prospective payment for the fallback plan. Initially, that amount could change monthly to reflect differences between the costs of enrollees in a fallback plan versus payments to the plan under the prospective system. The objectives of this approach would be to provide the correct amount of money to the fallback plan to reflect their actual costs. We request comment on payment methodologies, particularly in regard to prospective or retrospective rebate allocation.

R. Payments to Sponsors of Retiree Prescription Drug Plans

1. Overview

Subpart R would implement section 1860D-22 of the Act, which provides for making subsidy payments to sponsors of qualified retiree prescription drug plans. Section 1201 of the MMA amends the Internal Revenue Code of 1986 to provide that these subsidy payments will be exempt from Federal tax. Further guidance on the Federal tax treatment of the subsidy will be under the auspices of the U.S. Department of the Treasury.

a. Options for Sponsors of Retiree Prescription Drug Programs

The enactment of Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) on December 8, 2003, has provided sponsors of retiree prescription drug plans with multiple options for providing drug coverage to their retirees. We believe the availability of these various options will encourage employers and unions to continue to assist their retirees in having access to prescription drug coverage.

Generally, employers and unions who offer drug benefits to their retirees (and their spouses and dependents) who are also eligible for Medicare Part D could—

(1) Provide prescription drug coverage through employment-based retiree health coverage. If employment-based retiree health coverage were at least actuarially equivalent to the standard prescription drug coverage under Medicare Part D, the sponsor would be eligible for a special Federal subsidy for each individual enrolled in the sponsor's plan who is also eligible for

Medicare Part D, but who nevertheless elects not to enroll in Medicare Part D;

(2) Contract with a PDP sponsor or Medicare Advantage (MA) organization to enroll Medicare beneficiaries covered under the retiree plan into a prescription drug plan (PDP) or Medicare Advantage-prescription drug (MA-PD) plan. Alternatively, the sponsor itself could apply to be a PDP sponsor or MA organization and offer a PDP or MA-PD plan to its retirees. That plan could consist of "enhanced alternative coverage" (as defined under § 423.4 of our proposed rule), that is, drug coverage that is more generous than that offered under the standard prescription drug coverage under Medicare Part D (as defined under § 423.4 of our proposed rule). Medicare would subsidize the cost of such coverage through direct and reinsurance subsidies. At its option, the sponsor could elect to subsidize the monthly beneficiary premium (as calculated under § 423.286 of the Drug Benefit);

(3) Provide prescription drug coverage that supplements, or "wraps-around," the coverage offered under the PDP or MA-PD plans in which their retirees (and retirees' spouse and dependents) enroll.

The first option is the subject of this subpart of our proposed rule. The latter options, all of which involve employers' or unions' retirees (and their spouses and dependents) enrolling in Part D, are discussed in detail in the preamble to subpart J. We note that employers also have the option of subsidizing the monthly beneficiary premium for the PDP or MA-PD plan in which the employer or union's retirees (and their spouses and dependents) elect to enroll.

If employers or unions elect to sponsor either an enhanced alternative plan covered under Medicare Part D or supplemental coverage that "wraps around" Medicare Part D, either election will have an impact as to when their retirees (and retirees' dependents) will be eligible for catastrophic drug coverage, with important consequences for participants, sponsors, the plans, and the Medicare program. By delaying the provision of government-financed catastrophic coverage, these plans would lower the cost of Part D to the Federal government by lowering our reinsurance payments while preventing beneficiaries from facing any gaps in coverage. As discussed in subpart C of this preamble, individuals enrolled in a PDP or MA-PD plan would be eligible for catastrophic drug coverage after they have incurred out-of-pocket drug costs in the amount specified under § 423.104(e)(iii)(A) of our proposed rule. Under the reinsurance provisions,

Medicare would reimburse PDP sponsors and MA organizations offering MA-PD plans 80 percent of their gross costs for providing catastrophic coverage (excluding administrative costs and net of discounts, rebates, and similar price concessions). Only drug costs paid by a Part D enrollee, or on behalf of a Part D enrollee by another person, would count toward the annual out-of-pocket threshold. Amounts reimbursed by insurance or otherwise, by a group health plan, or by another third-party payment arrangement would not count toward the threshold. We refer to those drug expenditures that count toward the out-of-pocket threshold as "true out-of-pocket expenditures" (TrOOP).

Under these rules, sponsors who provide retirees (and retirees' spouses and dependents) enhanced alternative coverage would, in effect, delay the total drug spending that would trigger catastrophic coverage, because plan participants would have lower cost sharing, and thus, have lower out-of-pocket costs. Similarly, employers or unions who would sponsor supplemental coverage that would "wrap-around" Medicare Part D coverage would raise the total drug spending that would trigger government-financed catastrophic coverage, since drug costs paid for by those plans would reduce beneficiary costs and would not count toward the true out-of-pocket annual limit.

When an employer or union elects to contract with a PDP sponsor or MA-PD organization, the PDP sponsor, under § 423.458(c) of our proposed rule, or the MA organization, under § 422.106(c), may submit written requests to us for permission to waive requirements under Part D that hinder the design or offering of PDP or MA-PD plans to employers. We believe these waivers would facilitate efficient administration and integration of their enhanced Part D coverage with other retiree health benefits offered by the sponsor, as another subsidized option for employers to offer enhanced coverage instead of using Medicare's alternative retiree drug subsidy. For example, the PDP sponsor or MA organization could request permission to restrict enrollment in its PDP or MA-PD plan to the sponsor's retirees (and their spouses and dependents) and offer a benefit that resembles or enhances the sponsor's existing coverage. Similarly, should the plan sponsor wish to enroll its retirees (and their spouses and dependents) in its own plan, with enrollment limited to those individuals, the sponsor could apply to be a PDP sponsor or MA

organization offering a MA-PD plan and request such waivers as necessary.

We encourage plan sponsors to carefully review each option and determine which one is most beneficial to the sponsor and its retirees. We believe that the variety of options will encourage sponsors to retain drug coverage for their retirees (and their spouses and dependents), and we seek comment on how we can use all of these subsidized options to maximize enhancements in retiree coverage.

b. The Retiree Drug Subsidy Provision

During the past 15 years, the availability and generosity of employment-related retiree health coverage has been eroding due to rising health care costs, increasing numbers of retirees (who may be more costly to cover than younger active workers), and the impact of changes in accounting rules. For example, in 1988 approximately 66 percent of the nation's private sector firms with 200 or more workers that offered health benefits to active workers also offered retiree health benefits to any of their retirees, including both the pre-65 and the ages 65 and older populations, but by 2003 only 38 percent of these firms were offering retiree health coverage. Most employers that offer retiree health benefits also provide retiree prescription drug coverage. A more detailed discussion of the trends in retiree coverage, as well as the limitations in the data available on these trends is provided in the impact analysis section of this proposed rule.

By providing heavily subsidized insurance coverage of prescription drug expenditures incurred by, or on behalf of, Medicare beneficiaries, the MMA would significantly reduce the cost of existing retiree beneficiary drug coverage. For retiree-beneficiaries who enroll in Part D, Medicare would become the primary insurer. MMA would then lower the sponsor's cost of drug coverage by having the sponsor's plan become a secondary payer of retiree drug coverage. However, plan sponsors may benefit from the greater flexibility and fewer prescriptive requirements of the alternative retiree drug subsidy.

The retiree drug subsidy is designed to accommodate plan sponsors seeking greater flexibility and less regulation. In addition, while the expenses associated with providing retiree drug coverage continue to be deductible expenses for Federal tax purposes, the payments associated with the retiree drug subsidy are not counted as taxable income for employers. As discussed in the Regulatory Impact Analysis of this

preamble, the after-tax nature of the retiree drug subsidy payments effectively increases the value of these payments for employers that are subject to the corporate income tax. For example, the tax-free \$611 average retiree drug subsidy amount would be equivalent to about \$940 of taxable income for employers with a marginal tax rate of 35 percent. As discussed further in the impact analysis, we believe that the tax treatment of the retiree drug subsidy payments will provide an additional incentive for employers to participate in the retiree drug subsidy program.

The intent of the MMA retiree prescription drug subsidy provisions is to slow the decline in employer-sponsored retiree insurance. By providing a special subsidy payment to sponsors of qualifying plans, the MMA provides employers with extra incentives and flexibility to maintain prescription drug coverage for their retirees. Our intention is to make these subsidy payments as reasonably available to plan sponsors as possible. We wish to take into account as much as possible the needs and concerns of plan sponsors, consistent with necessary assurances that Federal payments are accurate and in accordance with statutory requirements, that the interests of retiree-beneficiaries are protected, and that employers do not receive "windfalls" consisting of subsidy payments that are not passed on to beneficiaries.

We plan to conduct outreach to plan sponsors, retirees and retiree associations, and other interested parties on all aspects of the MMA. We encourage their input on the feasibility and advisability of the approaches we have identified, as well as any other issues presented by the new statute, or additional options beyond those we have identified. We look forward to employer, union, and other public comments on all aspects of this proposed regulation. We particularly seek comments on the sections noted in the preamble.

2. Definitions (§ 423.882)

The Act contains a number of definitions that are critical to understanding how the retiree drug subsidy functions. To make it easier to understand how these definitions work together to establish the subsidy amount, we first provide an overview of the structure of the subsidy program and then provide a description of the key concepts. As noted above, a significant portion of the Medicare population receives prescription drug coverage through employer and/or union

sponsored retiree health benefits. The Act provides for Medicare payment to plan sponsors who choose to provide prescription drug coverage that is at least as generous as the standard prescription drug benefit under Medicare Part D. The Congress intended for the subsidy to encourage as many sponsors as possible to retain this coverage for their retirees (and their spouses and dependents). The subsidy payment made to a sponsor of a qualified retiree prescription drug plan would be based on actual drug spending by individuals enrolled in the plan and not premium payments. The subsidy is 28 percent of certain costs that are incurred for certain prescription drugs for individuals covered under the qualified retiree prescription drug plan who are eligible for the Medicare Part D drug benefit but who are not enrolled in Medicare Part D. The statute defines a number of terms in order to distinguish between costs that are to be considered in determining the subsidy payment amount, and costs that may not be considered in determining the subsidy payment amount.

Only group health plans that provide health coverage to Part D eligible individuals based on their status as retiree participants (or spouses or dependents of retiree participants) may qualify as a retiree prescription drug plan. The term "group health plan" is defined later below. Additionally, to be considered a qualified retiree prescription drug plan, the sponsor's group health plan must be at least actuarially equivalent to the standard drug coverage under Medicare Part D (in accordance with section 1860D–22(a)(2)(A) of the Act and as discussed below in section 3(b) of this subpart). As required under section 1860D–22(a)(2)(A) of the Act, the sponsor must submit an actuarial attestation that its plan is at least actuarially equivalent to the standard Medicare Part D prescription drug benefit for the plan to be a "qualified retiree prescription drug plan." In addition to meeting tests of actuarial equivalence, the plan must be a group health plan that provides prescription drug benefits to Medicare Part D eligible individuals, as defined in § 423.882, based on their status either as retirees or as spouses and dependents of those retirees.

The next step is to identify the "qualifying covered retirees" (that is, those Medicare beneficiaries eligible to enroll in Medicare Part D who are enrolled in the retiree plan, but who are not enrolled in the Medicare Part D benefit) and determine the "gross covered retiree plan-related prescription drug costs" (gross costs) under the plan

for these individuals for the year. Gross costs refer to the costs directly associated with the dispensing of a prescription drug. (In the prescription drug industry, gross costs are frequently referred to as the "ingredient costs" (the cost of the drug itself) and the "dispensing fee" (the pharmacy charge for dispensing the drug to a patient)). The statute, however, specifically excludes the retiree health plan's administrative costs from gross costs. Having established that gross costs are the base upon which the subsidy payment is to be determined, the statute then specifies that the payment may be made only for those costs that fall between the "cost threshold" and the "cost limit". For 2006, the cost threshold is \$250 and the cost limit is \$5,000. In other words, the first \$250 in prescription drug costs for an individual during a year and any prescription drug costs for that year that exceed \$5,000 is disregarded. The dollar values for the cost threshold and cost limit are adjusted annually.

The statute then specifies that the amount of gross costs that fall between the cost threshold and cost limit must be reduced by any discounts, chargebacks, rebates, and other price concessions. These net costs actually paid by the sponsor or by or on behalf of the retiree are referred to as the "allowable retiree costs." The intent of this provision is to ensure that Medicare subsidy payments take into account the pricing adjustments and discounts that actually occur in the market today. Some pricing adjustments, such as manufacturer rebates, typically occur well after payment is made to the pharmacy. Since the ingredient costs and dispensing fees found in the claims data do not include the lower "prices" achieved as a result of manufacturer rebates and other price concessions, further adjustment is needed to account for these other pricing related factors when determining the costs under the plan that will be "allowable" for purposes of the Medicare subsidy payment amount.

To summarize, the statute provides that the retiree drug subsidy payment amount equals 28 percent of the allowable costs attributable to the portion of the gross costs that fall between the cost threshold and cost limit. The definitions below further articulate the meaning of the key terms involved in determining the subsidy payment amount. The definitions are organized to first describe the Medicare Part D eligible individuals, then terminology related to retiree plans, and finally, terminology related to the

subsidy payment amount and the basis upon which the payment is determined.

Part D Eligible Individual

Section 423.4 of our proposed rule defines a Part D eligible individual as an individual who is entitled to or enrolled in benefits under Medicare Part A or who is enrolled under Medicare Part B.

Qualifying Covered Retiree

Section 1860D–22(a)(4) of the Act defines a qualifying covered retiree as a Part D eligible individual who is not enrolled in a Part D prescription drug plan (PDP) or Medicare Advantage–Prescription Drug (MA–PD) plan but who is covered under a qualified retiree prescription drug plan. We note that the qualifying covered retiree is not necessarily the retired employee who is the participant under the plan; it also includes coverage of a Part D eligible individual who is covered under the plan as a spouse or dependent of a participant. (Under ERISA, an employee or former employee who is covered under an employment-related plan is referred to as the "participant.") Dependents of the participant are referred to as "beneficiaries," but to avoid confusion with "Medicare beneficiaries," we will refer to the beneficiaries under the health plan as "spouses and dependents.")

Employment-Based Retiree Health Coverage

Section 1860D–22 (c)(1) of the Act defines employment-based retiree health coverage. Employment-based retiree health coverage means coverage of health care costs under a group health plan based on an individual's status as a retired participant in the plan or as the spouse or dependent of a retired participant. The term includes coverage provided by voluntary insurance coverage or pursuant to statutory or contractual obligation.

Group Health Plan

The term "group health plan" has the same meaning as defined in section 607(1) of ERISA, 29 U.S.C. 1167(1). Section 1860D–22(c)(3) of the Act specifies that the definition of a group health plan includes plans maintained for their employees by the Federal government (including the Federal Employee Health Benefits Program (FEHBP) and the TRICARE program); plans maintained by State or local government; and church plans exempt from Federal taxes under section 501 of the Internal Revenue Code of 1986 (despite the fact that those types of group health plans are not generally subject to ERISA requirements).

Qualified Retiree Prescription Drug Plan

A qualified retiree prescription drug plan means employment-based retiree health coverage that meets the requirements set forth in § 423.884(a) through § 423.884(d) for a Part D eligible individual who is a participant or the spouse or dependent of a participant under the coverage.

Sponsor

Sponsor means plan sponsor as defined in section 3(16)(B) of ERISA, 29 U.S.C. 1002(16)(B). This term means an employer, an employee organization (generally a trade union) or a combination of employers and employee organizations. Section 1860D-22(c)(2) of the Act, however, modifies this definition in the case of a plan maintained jointly by one employer and an employee organization and for which the employer is the primary source of financing, in which case the term "sponsor" means the employer.

Covered Part D Drug

Covered Part D drug has the meaning given in § 423.4 of our proposed rule and as discussed in subpart C of this preamble.

Retiree Drug Subsidy Amount

The retiree drug subsidy amount is defined as 28 percent of the allowable retiree costs for each qualifying covered retiree. Section 1860D-22(a)(3) of the Act describes the subsidy payment to be made to the sponsor of a qualified retiree prescription drug plan with respect to each qualifying covered retiree who is covered under the plan.

Gross Covered Retiree Plan-Related Prescription Drug Costs

Section 1860D-22(a)(3)(C)(ii) of the Act defines gross covered retiree plan-related prescription drug costs to mean specified costs incurred for a qualifying covered retiree enrolled in a qualified retiree prescription drug plan "during a coverage year." (For ease of reference, we use the term "gross retiree costs" interchangeably with the defined term.) We explain below in the preamble discussion related to § 423.888, that we have tentatively determined that the subsidy should be based on calendar year data. For purposes of this definition, we simply use the term "year;" in the final regulation, we will clarify whether it is a plan year or a calendar year.

In accordance with section 1860D-22(a)(3)(C)(ii) of the Act, we define the term, gross covered retiree plan-related prescription drug costs, (gross retiree costs) to mean the costs incurred under a qualified retiree prescription drug

plan for a qualifying covered retiree that are directly related to the dispensing of covered Part D drugs during the year (other than administrative costs), whether they are paid under the plan or by the retiree. Costs for covered Part D drugs incurred under the plan that are paid for by the retiree include all retiree cost sharing under the plan (for example, deductibles or copayments). Costs for non-covered Part D drugs are not considered gross retiree costs, even if paid for under the plan.

As discussed above, dispensing fees are included in gross retiree costs, but administrative costs are excluded. Therefore, we expect to monitor dispensing fees carefully through our audit activities in order to ensure that other administrative costs are not improperly included in the dispensing fees.

Allowable Retiree Costs

In accordance with section 1860D-22(a)(3)(C)(i) of the Act, allowable retiree costs means gross covered retiree plan-related prescription drug costs between the cost threshold and cost limit that are actually paid by either the qualified retiree prescription drug plan or the qualifying covered retiree (or on the retiree's behalf), net of any manufacturer or pharmacy discounts, chargebacks, rebates, and similar price concessions. For the purposes of determining the subsidy payment, allowable retiree costs include cost sharing paid "on behalf of" the qualifying covered retiree by any person or entity. This would include amounts paid by family members and charitable organizations to assist the retiree in his or her cost-sharing obligations. Amounts paid by other group health plans and insurers, such as under a spouse's plan that provides secondary coverage towards the cost sharing, would also be considered allowable retiree costs.

We note that the rules for calculating allowable costs under the subsidy provisions of section 1860D-22 of the Act must not be confused with the rules that pertain to the amount of cost sharing that must be paid by beneficiaries who enroll in Medicare Part D. Under section 1860D-2 of the Act (§ 423.466(b) of our proposed rule), beneficiary cost sharing under the PDP or MA-PD plan only counts toward reaching the annual "out of pocket threshold" that triggers catastrophic coverage if it is paid by the beneficiary or by another person such as a family member. In general, beneficiary cost sharing for which the beneficiary is reimbursed through insurance, a group health plan, or other third-party payment arrangement will not count

toward the annual out-of-pocket threshold. The employer/union subsidy provisions contain no similar limitation. Thus, beneficiary cost sharing is an allowable cost regardless of who pays the cost sharing.

Because allowable retiree costs exclude gross retiree costs below the cost threshold, a plan sponsor will be entitled to a subsidy payment for a qualifying covered retiree only if that individual's gross retiree costs, or total drug spending under the plan for a year, exceed the cost threshold for that year.

As noted above, allowable retiree costs are drug costs that are *actually paid* by either the qualified retiree prescription drug plan or the qualifying covered retiree (or on the retiree's behalf), and therefore net of any drug discounts, chargebacks, rebates, and any other similar price concessions passed through to the plan or retiree. (For purposes of this discussion, we will refer to all of the immediately preceding terms as "rebates"; that is, discounts, chargebacks, rebates, and similar price concessions). We understand that much of the rebate accounting is not applied in the context of point of sale claims data, but rather in periodic accounting adjustments, and that rebates are frequently reported along with administrative fees paid by the manufacturer. We are aware and concerned that, in some cases, plan sponsors may accept lower administrative costs or receive services at or below fair market value in lieu of some or all of the rebates. We are concerned that this practice may result in improper shifting of costs in order to inappropriately maximize subsidy amounts. We intend to monitor these arrangements closely to ensure that allowable retiree costs are not improperly inflated. We are also concerned that these accounting and business practices would be incompatible with the requirement to disclose all price concessions for purposes of determining allowable retiree costs and we, therefore, are proposing to require that the true cost of rebates be segregated in all records. We require that all rebates passed through to the plan sponsor and retiree in any form be subtracted when calculating allowable retiree costs.

Due to the nature and timing of rebate accounting, we believe that this will require a form of step-down cost reporting in which rebates received at the aggregate level may be apportioned down to the level of plan enrollees incurring allowable retiree costs on a reasonable basis. Since Medicare beneficiaries would be expected to have higher per capita prescription drug

utilization than other populations, we believe it would generally be appropriate to allocate rebates (and other similar price concessions) on the basis of percentage of dollars spent rather than of covered lives. The method of apportioning and applying rebates will be influenced by the payment methodology that is implemented for the retiree drug subsidy (see discussion in section 5 of this subpart). For example, in a one-time annual retroactive payment system, where payment of the subsidy is made after the close of the year, it should not be too difficult to factor in the rebates credited to the sponsor (or plan) for the period in question since the subsidy payment may occur after the rebates have been credited. Conversely, under a monthly payment system, factoring in the rebates would require a process to reflect the rebates as they are realized, because they are not likely to be determined and known until after some subsidy payments occur.

We believe either approach would require a form of cost reporting in which rebates received at the aggregate plan level would be apportioned to plan enrollees. One approach would be to reduce the subsidy payments by a certain percentage calculated to equal the assumed size of the rebates expected to occur. After 2006, the amount of reduction could be based upon the rebates received in prior years. Once the actual rebates were credited for the year in which the subsidy payments were made, the payments could be reconciled. Alternatively, rebates could be accounted for and paid in the month in which they are received. We also briefly discuss how rebates could be applied to different payment methodologies in section 5(b) of this subpart.

In any case, plans must require and keep accurate records on all price concessions and ensure that these are distinctly accounted for separately from administrative fees. We are considering how to best account for all of the price concessions and rebates. We welcome comments on the nature and scope of price concessions in this industry, and on the various forms these arrangements may take, as well as on the pass-through issue. We also welcome comments on how rebates and other forms of remuneration can be most accurately applied to the cost data to efficiently satisfy the requirement that all rebates must be netted out of allowable retiree costs, while minimizing the burden on sponsors. All cost reporting would be subject to inspection and audit (including periodic audits) by CMS and the OIG. As discussed later, to the

extent either CMS or the OIG discover that a sponsor was overpaid for the retiree drug subsidy (that is, the records do not support the payments made, or there is insufficient documentation to determine whether the payments are correct), we may recoup the overpayments or take other appropriate action. The reopening and overpayment provisions are discussed in section 6 of this subpart R.

Dispensing Fees

For purposes of consistency, we plan to use the same definition that will be applied to PDP and MA-PD plans. See the discussion of dispensing fees in subpart C of the preamble to our proposed rule, which discusses possible definitions.

3. Requirements to Apply for the Retiree Subsidy (§ 423.884)

a. General Requirements

This section outlines the general requirements related to applying for the subsidy payment described in this proposed rule. First, in order to be considered a qualified retiree prescription drug plan, a plan must meet the definition of employment-based retiree health coverage as defined in § 423.882 of our proposed rule, and must also comply with the requirements proposed in § 423.884 and discussed in this section of the preamble. Additionally, a plan sponsor that wishes to be paid the Medicare subsidy must apply annually for the subsidy. In paragraph b, below, we describe the actuarial attestation that must be submitted with the subsidy application; in paragraph c, we describe the application process, including the information that must be submitted to establish that the sponsor qualifies for a subsidy; and in paragraph d, we describe the disclosure notices that plan sponsors are required to provide to beneficiaries. Finally, the sponsor must meet the requirements of proposed § 423.888(d) with regard to maintenance and access to records for purposes of audit, as discussed in section 5 of this subpart, below.

We intend to conduct outreach to plan sponsors, including State and local governments, who would be prospective applicants for these subsidy payments in order to encourage communication, better understand the needs of the employer community, and provide information on the retiree drug subsidy program, as well as to solicit suggestions on how we can best implement this program. We invite comments on the most effective methods of conducting

outreach, as well as prospective venues for conducting that outreach.

b. Attestation of Actuarial Value Amount

1. Attestation Requirements

In § 423.884(a) of our proposed rule we would require that the sponsor submit an attestation to us that the actuarial value of the prescription drug coverage under its retiree plan or plans is at least equal to the actuarial value of standard Medicare Part D prescription drug coverage. (A more complete discussion of actuarial equivalency follows, below.) In § 423.884(a)(1) of our proposed rule, we would require that the attestation be submitted annually after year 2006, but no later than 90 days prior to the earlier of the start of the calendar year or plan year. (Our tentative decision is to use a calendar year.) For purposes of the initial application for the subsidy for 2006, the attestation must be submitted by September 30, 2005. Additionally, we would require that an updated attestation be submitted when mid-year changes to the drug coverage materially affect the drug coverage's actuarial value. (A material change means any change that potentially causes a plan to no longer meet the actuarial equivalence test.) These submissions would not be required when non-material changes are made to the coverage (for example, when there are changes in the period of open enrollment). We would require that the attestation be submitted 90 days prior to the effective date of any material changes. If the impending changes result in the plan either no longer being a qualified retiree prescription drug plan or no longer providing creditable coverage because its benefits are no longer actuarially equivalent to Medicare Part D coverage for purposes of either actuarial test, we would require that beneficiaries be notified of this change 90 days prior to the change taking effect and informed regarding opportunities to enroll in Medicare Part D. (See subsequent discussion regarding disclosure notices.)

We believe that requiring attestation on an annual basis and 90 days prior to material changes in coverage, with a 90 day notice to beneficiaries when necessary, should provide sufficient assurance to beneficiaries and CMS that the plan meets requirements concerning actuarial equivalency and affords beneficiaries time to enroll in Medicare Part D without incurring a late enrollment penalty as provided for in § 423.56 of our proposed rule. We would also require that the attestation, which must be signed by an authorized

representative of the plan sponsor (or a plan administrator designated by the sponsor), include a certification, signed under penalty of perjury, that indicates that the information contained in the attestation is true and accurate to the best of the attester's knowledge and which acknowledges that the information is being provided to obtain Federal funds. We welcome comments on whether these proposals provide sufficient protection for beneficiaries and whether these proposals would be operationally feasible without creating an undue burden for sponsors.

2. Establishing Actuarial Equivalency

Section 1860D–11(c) of the Act provides the Secretary with the authority to determine the standards and methods for determining actuarial equivalence. In developing standards for actuarial equivalence, our intent is to consider how to maximize coverage for retirees while limiting costs for the government, and the retiree drug subsidy is one important option for achieving this objective. The MMA provisions creating Part D provide multiple options for plan sponsors, ranging from participating in the retiree drug subsidy to various mechanisms for enrolling retirees in Part D prescription drug plans while offering enhanced benefits. Our goal is not only to protect, but also to enhance coverage offered to retirees. As discussed elsewhere, prior to enactment of the MMA, employers have been systematically restricting drug coverage for future retirees. Taken together, these legal and behavioral factors introduce substantial uncertainty about how plan sponsors will assess their options and react to the new Part D benefit.

Congress has clearly and repeatedly articulated four key policy objectives for the Medicare retiree drug subsidy program. The first goal involves maximizing the number of retirees retaining employer-based drug coverage through the retiree drug subsidy program created by Section 1860D–22 of the Act. The second goal entails not creating windfalls, whereby retirees might receive a smaller subsidy from sponsors of their retiree drug plans than Medicare would pay on their behalf. The third goal is to minimize the administrative burdens on beneficiaries, employers and unions. The final goal is to minimize costs to the government of providing retiree drug subsidies (and not exceed the budget estimates). While the first, third and fourth goals received extensive discussion during the creation of MMA, the second goal has emerged largely in response to the possibility

that the MMA might have created an unintended windfall.

We believe the Secretary has authority to achieve these goals based on the requirements that plans qualifying for the retiree drug subsidy must offer at least actuarially equivalent benefits to those offered by standard Part D prescription drug plans (PDPs). Our proposed regulation reflects our attempt to accomplish the four objectives of maximizing the number of retirees benefiting from the retiree drug subsidy, avoiding windfalls, minimizing administrative burden and not exceeding budget estimates. In doing so, we are considering a range of potential options, each of which may have an impact on achieving the key objectives. We seek comments on how best to accomplish these goals, recognizing both that there may be tradeoffs, and that our implementation must be consistent with the statutory authority provided the Secretary.

The definition of actuarial equivalence in this context may have an impact on our policy objectives. One possible definition would stipulate that plans must meet the same test as for "creditable coverage." The test for creditable coverage requires that, on average, the total or "gross" value of the benefit package offered by the employer at least equal that of the standard Part D benefit offered by PDPs, without regard to the financing of this benefit package. As we discuss in subpart B of this preamble, the main concern in establishing creditable coverage is in determining the level of health benefit coverage the beneficiary has had, and not on how it was financed, since no payments are involved. However, when applying this gross value (of plan payout) test in the context of the retiree drug subsidy, we must be concerned with whether our subsidy payments to sponsors will exceed the costs that sponsors actually incur in sponsoring the coverage. This one test, or "single prong" approach, to defining actuarial equivalence could not by itself preclude the existence of windfall payments. This is because, without considering financing, an employer theoretically could impose the full cost of the benefit package on the employee through employee premiums, and still be eligible for a subsidy payment if the package the employee was buying met the actuarial equivalence test. Or, the employer could contribute a smaller amount toward the financing of the package than it would receive in a subsidy payment. We seek comments on whether additional steps associated with this approach could ever preclude windfalls. In particular, some observers

have argued that the forces in a competitive labor market, collectively bargained contracts, and constraints on changing state, local and other public sector retiree health plans obviate the likelihood of windfalls. We have serious reservations about the adequacy of such forces in precluding the existence of any windfalls without significant additional monitoring by Medicare or others to assure that benefit subsidy payments are passed on to augment benefits received by retirees. Such approaches may create excessive administrative burdens on retirees, employers, and unions, and thus alternative approaches to precluding windfalls are likely to be preferable.

Another possible policy option would be to use the "one prong" approach to determining actuarial equivalency, but to also limit the amount of the retiree drug subsidy so that it could not exceed the amount paid by plan sponsors on behalf their retirees. This would assure the elimination of windfalls. However, while this approach would be simple both to describe and operationalize, we have questions about the adequacy of the legal basis underpinning such a policy.

A third approach, which could be implemented in a variety of ways, would establish a "two-prong" test of actuarial equivalence: A "gross" test would assure the total value of benefits, and a "net" test would reflect only the value of benefits not financed by beneficiaries. This third approach is structured specifically to preclude windfalls. The first prong of the actuarial equivalency would again be a test based strictly on plan design. This test would evaluate whether the expected amount of paid claims (or "plan payout") under the retiree prescription drug coverage is at least equal to the expected amount of paid claims under the standard Medicare Part D benefit. The second prong of the actuarial equivalency test would be a "net value" test in which the gross value of the plan design would be reduced to account for the level of benefits financed solely by the beneficiary. For instance, the net value of the coverage could be calculated by subtracting the retiree premium from the expected amount of paid claims under the retiree drug program. In order to qualify for the subsidy, a sponsor's plan would have to meet both prongs of the actuarial equivalence standard.

The "net" prong of the two-prong test of actuarial equivalence could have several variants. While each variant of the two-prong test would preclude windfalls, each would present a different balance among potentially

competing objectives. At a minimum, we believe that the net value of the creditable coverage should as a policy matter at least equal the average per capita amount that Medicare would expect to pay as the retiree drug subsidy. (We estimate this value at \$611 in 2006.) While there may be policy advantages to this approach, we have questions about the adequacy of the legal basis underpinning such a policy. We specifically invite comment on the question of whether the statutory language could reasonably be interpreted to support this approach. Alternatively, a higher threshold could be required. For instance, we could require that this value be more closely related to the net value of the standard Medicare Part D benefit (which is the expected amount of paid claims under Medicare Part D less the monthly beneficiary Medicare Part D premium under § 423.286 of our proposed rule). However, as the threshold was raised, it would be more difficult for retiree plans to qualify, that is, to (1) not provide windfalls and (2) offer coverage that is at least as generous in overall actuarial value as the Medicare subsidy.

Another alternative benchmark value for the net test could be the after-tax value of the expected average per capita retiree drug subsidy. (There is special tax treatment available for the retiree drug subsidy. Plan sponsors get to deduct all the associated expenses but the value of the subsidy payments is not recognized as income for tax purposes.) Unfortunately, determining the appropriate amounts to use for this benchmark would pose significant problems because of the heterogeneity of the plan sponsors. For example, we estimate that at least 60 percent of retirees that are age 65 and older receive retiree health benefits from entities that are exempt from taxation (including both public and nonprofit entities, based on data from the 2001 Medical Expenditure Panel Survey); for those plan sponsors subject to taxation, their rates of taxation vary markedly. In addition, as mentioned above, we have questions about the adequacy of the legal basis underpinning this approach.

As noted above, adopting a two-prong test with the higher value for the net test could arguably provide greater protection to beneficiaries, but might drive plan sponsors out of participating in the retiree drug subsidy and toward using the Part D-based options for supporting and enhancing drug coverage. Conversely, adopting a lower value for the net test might qualify more plan sponsors to participate in the retiree drug subsidy, but it might also discourage some employers and unions

from increasing their contributions to reach the higher threshold level, and thereby increasing generosity of coverage. Public comment would help limit uncertainty by clarifying the likely responses of plan sponsors to these different approaches. In addition, we solicit comments not only on the desirability of the different options, but also (as noted above) on the legal bases for possible options.

In any case, the actuarial equivalence test(s) established by CMS must be applied to each sponsor's retiree prescription drug plan in order to determine if it is a qualified retiree prescription drug plan for purposes of qualifying for a subsidy. In considering the point of reference for a "plan," we recognize that there is tremendous diversity and complexity in prescription drug coverage options among employers and unions for retirees. There may be either different employer/union contribution levels or benefit designs within a single plan for various segments of retirees (referred to as "tiered cost sharing"). A qualified retiree prescription drug plan is defined with reference to the definition of a "group health plan" which section 1860D–22(c)(3) of the Act specifies is to be the definition of that term in section 607(1) of ERISA. That definition states that the term "means an employee welfare benefit plan providing medical care * * * to participants or beneficiaries directly through insurance, reimbursement, or otherwise * * *." Section 3(1) of ERISA in turn defines an employee welfare benefit plan as "any plan, fund, or program [which is] established or maintained by an employer or by an employee organization, or by both, to the extent that the plan, fund, or program was established or is maintained for the purpose of providing for its participants or their beneficiaries, through the purchase of insurance, or otherwise, * * * medical, surgical, or hospital care or benefits * * *."

Section 1860D–22(a)(2)(A) of the Act clearly indicates that a plan must meet the actuarial equivalence test in order to qualify for a subsidy. We propose to apply the ERISA definition in a way that is appropriate in the context of section 1860D–22 of the Act, and recognizes the diversity in retiree drug coverage among employers and unions. Our proposal is modeled on the approach adopted by the Department of Treasury at 26 CFR § 54.4980(B)(2), in the context of a different definition of "group health plan." In the Questions and Answers that relate to that section, Q–6 and A–6 take the position that all health benefits provided by a sponsor are

presumed to be under a single plan unless it is clear from the plan instruments and instrumental operation that the plans are separate plan arrangements. We believe this proposed approach is familiar to plan sponsors, is appropriately flexible, and protects retiree-beneficiaries. We welcome comments on how best to apply the statutory definition of a "plan" within this context, especially to sponsors that offer a multiple choice of retiree plans with various levels of sponsor contributions.

We believe we have discretion as to whether to require that the sponsor demonstrate that the value of the retiree coverage under the group health plan is actuarially equivalent to standard prescription drug coverage under Part D for each individual based on: (1) the benefit package received by the individual, or (2) on average across all participants and beneficiaries receiving coverage under the sponsor's group health plan. We propose to require sponsors to apply the actuarial equivalence test to each group health plan as a whole, with the standard met if *on average* the actuarial value of retiree drug coverage under the plan is at least equal to the value of standard prescription drug coverage under Part D. We believe that this approach would be less burdensome for sponsors.

As previously noted in subpart F of this preamble, we will provide additional information in the future on the processes for determining actuarial valuation, including that of retiree prescription drug coverage. We are currently considering the following guidelines—

- We anticipate that we would specify, as either recommended or required in further guidance, data sources, methodologies, assumptions, and other techniques in accordance with generally accepted actuarial principles. We would require that the actuarial attestation be provided to us and we would verify that the attestation was signed by a qualified actuary. In addition, we may select a random sample of attestations for which we would require additional information to provide a quality control review. Also, we expect that a detailed review of the actuarial attestation would be included in the auditing process.

- Section 1860D–11(c)(3)(B) of the Act specifies that PDP sponsors or MA organizations offering MA–PD plans may use qualified independent actuaries in developing bids. We believe it is appropriate to adopt this model with respect to this proposed rule, allowing retiree plan sponsors to use outside actuaries in their processes. We would

specify that a qualified actuary is an individual who is a member of the American Academy of Actuaries, because members of the Academy must meet not only educational and experience requirements, but also a code of professional conduct and standards of practice. These standards create a common ground for actuarial analysis. Furthermore, a member of the Academy is subject to its disciplinary action for violations of the code and standards. This same requirement is specified in the SCHIP legislation at section 2103(c)(4)(A) of the Act.

c. Sponsor Application for Subsidy Payment and Required Information

A plan sponsor who wishes to be paid the retiree drug subsidy must apply annually for the subsidy. We will provide the technical details (including important systems issues) to sponsors and other interested parties in the very near future in order to facilitate our developing appropriate guidance, which will, in turn, encourage sponsor participation and minimize the burden to sponsors to the maximum extent possible. We intend to actively seek comments from sponsors and to release guidance to sponsors in 2005. In order for plan sponsors to receive a subsidy payment for 2006, we would require that all plan sponsors apply for the subsidy payment no later than September 30, 2005. For future years, as described above in the discussion of attestation, we would require that plan sponsors apply for the subsidy no later than September 30 of the previous year. Table R-1, containing the key dates involved in the sponsor application process, is included at the end of this section.

We request comment on this approach, including how such a deadline might interfere with a sponsor's open season, and whether or not sponsors will already know, as early as 90 days prior to the start of the year, which plan option a beneficiary has enrolled in. For sponsors that institute retiree prescription drug coverage after September 30, 2005, we would require that these sponsors apply at least 150 days prior to the start of the new plan for the first plan year.

We would require that sponsors (or an administrator of the plan designated by the sponsor) provide all of the following information as part of the application for special subsidy payment—

- Employer Tax ID Number (if applicable);
- Sponsor name;
- Sponsor address;
- Contact name, job title and email address;

- Actuarial attestation and supporting documentation for each qualified retiree prescription drug plan for which the sponsor will be seeking subsidy payments;

- Identifying information for each of the separate plans.

Additionally, the following information must also be submitted for each plan—

- Full names of each qualifying covered retiree (as defined previously) enrolled in the sponsor's prescription drug plan (including spouses and dependents if Medicare-eligible), and the following information—

- Health Insurance Claim (HIC) number (when available);
- Date of birth;
- Sex;
- Social Security number; and
- Relationship to the retired employee.

(Nothing in this data collection discussion should be construed as limiting OIG authority to conduct any audits and evaluations necessary for carrying out our proposed regulations.)

Since we will be dealing with individually identifiable health information, we provide elsewhere in this preamble a separate discussion of privacy issues related to the submission of this information. We note that, in most cases, the plan sponsor would not have access to claims information or similarly protected health information regarding retirees. Therefore, throughout this preamble where we refer to information provided by the plan sponsor, we may in fact mean by the plan administrator, insurer, or group health plan on behalf of the plan sponsor. In addition, we are aware that sponsors may not have information on Medicare Part D eligible individuals who receive benefits under the employer-sponsored plan as spouses or dependents of a plan participant. We are also aware that many employers do not currently collect information about dependents, but plan administrators may maintain that information about dependents. Moreover, we are also aware that all plans do not consistently collect Medicare Health Insurance Claim (HIC) and Social Security numbers. Therefore, in order to be able to make and/or audit subsidy payments, we need a process to be able to identify the Medicare beneficiaries on whose behalf the subsidy payments would be made. We welcome comments on the proposed information list.

We encourage sponsors who plan to request a subsidy payment from Medicare to begin to evaluate the availability of this information and to plan for the creation of a file with this

type of information contained in it. Technical systems specifications for the file would be included in guidance to sponsors from CMS. We actively seek input from employers, plan sponsors, plan administrators, and other interested parties to facilitate our developing the most appropriate, efficient, and effective guidance.

We have worked with many employers and other insurers in the context of Medicare Secondary payer requirements, and we believe that this will help facilitate the identification process. We welcome the opportunity to work with employers and insurance companies in this regard. Additionally, we launched a "Voluntary Data Sharing" initiative in 2000 that allows CMS and employers to electronically exchange employee group health coverage information and Medicare entitlement information on a current basis. This process can, for example, identify whether a retiree or spouse is a Medicare beneficiary and the date of entitlement to Medicare. More information about the CMS Employer Voluntary Data Sharing initiative can be found at: http://www.cms.hhs.gov/medicare/cob/employers/emp_vdsa.asp.

Finally, an authorized representative of the requesting sponsor must sign the completed application. The application will specify the terms and conditions of eligibility to receive a subsidy payment. The application would require the sponsor to comply with all Federal laws and regulations, as well as the terms and conditions of eligibility for a subsidy payment, including auditing of claims for subsidy payment and combating fraud and abuse, any further certification that CMS may require. The sponsor would be required to acknowledge that the information is being provided to obtain Federal funds. The signed application would constitute an agreement between the sponsor and CMS and would be referred to as the "sponsor agreement." The sponsor would be required to include in all subcontracts with third party administrators and other subcontractors performing functions in connection with the sponsor retiree drug benefit an acknowledgement that the subcontractor knows and understands that all information provided in connection with the contract will be used for purposes of obtaining Federal reimbursement.

Once the full application for subsidy payment is submitted, we would match the names and identification numbers of retirees submitted by the sponsor with the Medicare Data Base (MDB) to determine which individuals are both eligible for Medicare Part D (that is,

individuals who are entitled to benefits under Medicare Part A or who are enrolled under Medicare Part B) but who are not enrolled in Medicare Part D. We would then provide to the sponsor (or to a plan administrator designated by a sponsor) the names and other necessary identifying information, if any, of the sponsor's qualifying covered retirees.

We recognize that there would be a need to update information from

sponsors on a routine basis in order to incorporate newly eligible retiree-beneficiaries and to prevent overpayments and underpayments as qualifying covered retirees make switches between Medicare Part D and the retiree drug plan. We are considering options for this enrollment update process. One possibility is to use a complete enumeration file submitted as part of the annual application process, with subsequent, periodic

updating. We would appreciate public comments on this issue.

We are also considering and seek comment on whether to require a surety bond type of instrument or preferred creditor status "as part of the enrollment process—in order to address situations related to businesses that may terminate or experience bankruptcy prior to completion of a final reconciliation.

TABLE R-1.—PROPOSED KEY DATES

Publication of final rule	Early 2005
Application for Subsidy Due Date for All Sponsors, regardless of whether they operate on a calendar or plan.	No later than September 30, year 2005.
Attestation of Actuarial Equivalence Due Date for all Sponsors	No later than September 30, 2005.
Retiree drug subsidy Program Begins	January 1, 2006.
Application for Subsidy Due Date for plans operating on a plan year basis.	September 30, 2006 (for 2007) and each September 30 thereafter for subsequent years.
Application for Subsidy and Attestation of Actuarial Value Due Date for plans operating on a calendar year basis.	September 30, 2006 (for 2007) and each September 30 thereafter for subsequent years.
Application for Sponsors that institute coverage after September 30, 2005.	150 days prior to the start of the new plan.
Notice to CMS of mid-year plan changes that materially affect actuarial valuation.	90 days prior to the plan change.
Notice to enrollees of plan changes that result in the plan no longer being a qualified retiree prescription drug plan.	90 days prior to the plan change.

d. Creditable Coverage and Notification

Section 1860D-22(a)(2)(c) of the Act specifies that in order for a sponsor's plan to meet the definition of a qualified retiree prescription drug plan, the sponsor must provide for disclosure of whether coverage is "creditable coverage" in accordance with the proposed requirements set forth under proposed § 423.56 of our proposed rule. The actuarial equivalence standard for creditable coverage is the same as one of the tests proposed for the actuarial equivalence standard for qualified retiree prescription drug plans in order to qualify for a retiree drug subsidy. The actuarial equivalence standard for creditable coverage is the "gross value" test (that is, whether the expected amount of paid claims (or "plan payout") under the retiree prescription drug coverage is at least equal to the expected amount of paid claims under the standard Medicare Part D benefit), which is the so-called first prong of the actuarial equivalence test for purposes of qualifying for the retiree drug subsidy.

As explained in subpart B of the preamble of our proposed rule, if a Medicare Part D eligible individual fails to enroll in Medicare Part D upon first becoming eligible for Medicare Part D, the individual would be subject to the late enrollment penalty if the individual elects to enroll in Medicare Part D at a

later date. However, the late enrollment penalty would be waived if the beneficiary had creditable prescription drug coverage during the time he or she was not enrolled in Part D.

Proposed § 423.56 of our proposed rule would require certain entities providing drug coverage, including group health plans, to disclose to Part D eligible individuals and CMS whether that coverage is considered "creditable coverage" as described in proposed § 423.56(a) of our proposed rule, or whether the value of the coverage to the individual is at least actuarially equivalent to standard prescription drug coverage under Medicare Part D. Consequently, plan sponsors under this proposed rule would be subject to the requirements in proposed § 423.56 of our proposed rule governing disclosure of creditable coverage.

As discussed in subpart B of our proposed rule and discussed below, we intend to describe the proposed process for providing this disclosure notice, including guidance on its content, placement, and timing of notice. The content of the disclosure notice and its timely receipt would be important components in the decision making process for beneficiaries, because the creditable status of the retiree's drug coverage would have a direct impact on the assessment of late enrollment penalties associated with Medicare Part D premiums. Notifying the retiree of any

subsequent changes in their creditable coverage status is equally important. Because retirees would have a limited time in which to make decisions about their Medicare Part D coverage without facing a penalty, it would be important that the notification of creditable status be provided in a timely and conspicuous manner. However, we are also concerned about the potential administrative burden imposed by this proposed requirement and therefore, we are soliciting comments on the format, placement, and timing of this notice.

We have considered several approaches to implementing this requirement. One possible approach would be to provide the sponsors with standard language that could be incorporated into the required disclosure materials the sponsors routinely disseminate to their enrollees in their retiree drug plans. (We could provide standard language to be inserted into these materials.) We are soliciting comments regarding the types of materials that could provide an appropriate vehicle for this purpose, as well as ways to ensure that the notice is conspicuous and readily identified by recipients, particularly in those instances where the coverage is not creditable.

Another possible approach would be to require each sponsor to issue a separate notice to each Part D eligible enrollee in their retiree drug plan. This

type of notice would be the most conspicuous and would subsequently increase the likelihood that beneficiaries are made aware of the creditable coverage status of their prescription drug coverage. Because retirees are subject to financial penalties for the failure to maintain creditable coverage when they enroll in Medicare Part D after the initial enrollment period, a separate notice may better inform beneficiaries and ensure that they take appropriate action to avoid the penalties. The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 101-193, requires entities that offer health insurance coverage to inform their members, in writing, of the type and duration of "creditable coverage." Implementing regulations at 62 FR 16901 (April 8, 1997) provided a "Certification of Creditable Coverage" that must be produced and disseminated to individuals when their coverage ends. We considered requiring that information about the creditable status of prescription drug coverage be included in this certification. However, since the certification required under HIPAA is not provided until after the coverage has ended, it would arrive too late to assist beneficiaries in deciding whether to enroll in Part D. However, the HIPAA certification may serve as a useful model, and we invite your comments about the administrative burden associated with producing and disseminating a similar notice of creditable status to beneficiaries.

The timing and frequency of these notices would also be a key consideration. The initial notice of creditable status would have to be coordinated with the first "Annual Coordinated Enrollment Period for Part D," which begins November 15, 2005, to ensure that retirees have this information when making their decisions regarding Part D coverage. Retirees would also need to know about any change in the creditable status of existing coverage before this change becomes effective so that they have sufficient time to decide whether to obtain Part D coverage. If a retiree's creditable drug coverage ends or is changed to the extent that it is no longer creditable, the retiree has a "Special Enrollment Period" during which he or she can enroll in Part D without financial penalty. Thus, we believe that this notice should be provided, at a minimum of these two important times, and also upon request by the beneficiary.

We view this process as an important one, and invite comments on how best to ensure that retirees receive timely

and adequate notice of the creditable status of their prescription drug coverage without imposing a significant administrative burden on sponsors that provide the coverage. We also note that section 1860D-22(a)(2)(C) of the Act requires sponsors to disclose the creditable status of this coverage to us, and we invite your comments on the possible methods of providing this disclosure.

4. Retiree Drug Subsidy Amounts (\$ 423.886)

As explained previously, § 423.886 governs the subsidy amount a sponsor of a qualifying retiree prescription drug plan receives for each qualifying covered retiree that is enrolled with the sponsor in a year. The sponsor is eligible to receive a subsidy payment for each qualifying covered retiree whose gross covered retiree plan-related prescription drug costs exceed the cost threshold. The amount of the subsidy would be 28 percent of the allowable retiree costs attributable to the gross retiree costs that are above the threshold and do not exceed the cost limit. For plan years ending in 2006, the cost threshold is \$250 and the cost limit is \$5000.

The cost threshold and cost limit for a plan year that ends after 2006 would be adjusted in the same manner that the annual Part D deductible and the annual Part D out-of-pocket threshold are adjusted annually under § 423.104(e)(1)(ii) and § 423.104(e)(4)(iii)(B) of our proposed rule, respectively. Accordingly, beginning in 2007, we will adjust the cost limit and cost threshold based on the annual percentage increase or decrease in average per capita expenditures for covered Part D drugs in the United States for Part D eligible individuals for the 12 month period ending in July of the previous year, with the cost threshold rounded to the nearest multiple of \$5 and the cost limit rounded to the nearest multiple of \$50.

CMS claims that are generated by an overpayment of the subsidy to a sponsor, including collection of interest, administrative costs, and late payment penalties would be governed by regulations at 45 CFR Part 30, subpart B.

5. Payment Methods, Including Provision of Necessary Information (\$ 423.888)

a. Plan Year Versus Coverage (Calendar) Year

Under section 1860D-22(a)(3)(B) of the Act, the cost threshold and cost limits that determine the amount of the subsidy are calculated for "plan years

that end in" 2006 and subsequent calendar years. However, section 1860D-22(a)(3)(A) of the Act refers to the subsidy amount for a qualifying covered retiree for a "coverage year," that is defined as calendar year. Thus, we believe that, in the context of section 1860D-22 of the Act, the reference to retirees enrolled in a qualified plan "during a coverage year" can be read to mean that the retiree must be enrolled during either a calendar year or plan year that ends in the specified calendar year. As explained below, we would prefer a strict calendar year basis and believe our proposed requirements would permit sponsors with non-calendar plan years to comply with reasonable modifications. We are interested in receiving comments on whether we should maintain our initial policy based on the calendar year or whether we should consider a plan year as the basis for the subsidy.

While a calendar year approach is more straightforward from the perspective of Federal administration of the subsidy program, use of "plan year" may better conform to the accounting systems of the plans and the sponsors. However, we note that the Federal subsidy is related to drug spending, not plan coverage. If we do elect to use a "plan year" as the basis for payment, we would use the definition of a "plan year" in section 3(39) of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1002(39), which includes, for a plan, the calendar, policy, or fiscal year on which the records of a plan are kept. If we do elect to use a "plan year," the statute makes clear that the cost threshold and the cost limit will apply based on the calendar year in which the "plan year" ends. For example, in the case of a July 1, 2006–June 30, 2007, "plan year," the cost threshold and the cost limit applicable in general in 2007 would also apply for this "plan year." Because the actuarial attestation would be due no later than April 1, 2006 (90 days in advance of the plan year), it is quite possible that the cost threshold and cost limits for 2007 would not yet have been calculated at that time.

Another issue that is unique to the use of a "plan year" as a basis for the subsidy payment that arises in the first year of the program is how to handle plan years that begin in 2005. For example, if a plan year ends on June 30, 2006, only six months of that plan year accrued after January 1, 2006. The following are at least three options for addressing this problem:

(1) The first option is to start counting gross costs for prescriptions filled after January 1, 2006. That is, even though

the plan year in this example began on July 1, 2005, gross costs of qualifying covered retirees would only take into account prescriptions filled beginning with January 1, 2006. These gross costs would have to exceed \$250 before their associated allowable costs would be subsidy eligible. Since subsidy payments are not authorized prior to the start of the Part D program, this option represents the strictest reading of the statute, in that gross costs and, therefore, allowable costs, are calculated without regard to the portion of the plan year that falls before January 1, 2006. It would, however, disadvantage plans that choose to use plan year instead of calendar year, since total subsidy payments for calendar 2006 would be lower than they would have been if calendar year had been used since the cost threshold must be met a second time in calendar 2006.

(2) The second option is to determine a subsidy amount as if the sponsor were authorized to receive subsidy payments for the entire "plan year" and then to prorate this amount based on the number of "plan year" months that fall in 2006. First, gross costs would be determined for the entire "plan year". Allowable costs and the subsidy amount would be derived based on the proportion of the gross costs that exceed the cost threshold but are less than the cost limit. Finally, the subsidy amount for the plan year would be prorated by the number of months of the plan year that fall in 2006. In our example of a July 1–June 30 plan year, six months would fall in 2006 so the annual subsidy amount would be cut in half. This option, while still consistent with the statute, would provide a larger payment than the first option.

(3) The third option would determine subsidy amounts on monthly basis as if the sponsor were authorized to receive subsidy payments for the entire "plan year", but would then pay only the amounts for the "plan year" months that fall in 2006. The process for determining the subsidy is similar to that described in option two, but rather than calculating an annual subsidy amount, one would determine the subsidy payments applicable to costs incurred for each month of the plan year. The sponsor would then receive the subsidy payments for the months in the plan year that fell in 2006 (that is, January 1 through June 30, 2006). This option would require that the sponsor determine the month in which costs are incurred. Therefore, it adds some complexity to the calculation of the subsidy. However, since subsidy eligible expenditures are weighted more toward the latter part of the plan year, this

option would produce a stream of subsidy dollars that would parallel the actual flow of the sponsor's plan expenditures.

We would like to receive your comments on these options or other possible approaches, as well as on the threshold issue of whether we should rely only on calendar years, as explained below. We again note that relying on calendar years avoids the complications discussed above.

b. Payment Methodology

Section 1860D-22(a)(5) of the Act specifies that payments to plan sponsors are to be made "in a manner similar to" the payment rules in section 1860D-15(d) of the Act, which apply to payments made to PDP sponsors and MA organizations under Part D. We believe that section 1860D-15(d) of the Act gives us broad discretion to determine a payment method. We wish to develop a payment methodology that is beneficial to the sponsors, and is cost efficient. Some of the factors to consider in developing a system that will pay subsidies are whether it is technologically feasible and what it would cost. Another issue is that pharmaceutical rebates, which must be excluded from allowable retiree costs, are generally not factored into the payments at the point of sale but instead not until much later in the process. We also recognize that highly automated insurance carriers or pharmacy benefit managers (PBMs) are used by almost all the sponsors for collection of the claims data that will be key elements of the data required for the payment of the subsidy.

Our proposed policy is predicated on the assumption that plan sponsors utilize the services of sophisticated point-of-sale claims payment agents such as PBMs. We further understand that PBMs (or comparable administrative entities) routinely adjudicate prescription drug claims on a real-time basis and have very limited claims (sometimes referred to as incurred, but not received) or payment lags. As a result, actual monthly expenditures are routinely known shortly after the close of a month. We outline below our proposed approach to calculating and paying the alternative subsidy to qualified retiree prescription drug plans in 2006 (using an actuarial attestation based on a plan year, but with the alternative subsidy computed on a calendar year basis):

- For each month starting with January 2006, the plan sponsor would certify by the 15th of the following month (that is, February, 2006 for January, 2006) the total amount by

which actual retiree-beneficiary gross drug spending exceeded the cost threshold yet remained below the cost limit. Medicare would pay 28 percent of the certified amount to the sponsor by the 30th of that month. Not later than 45 days after the end of the calendar year, the plan sponsor would submit a final reconciliation (but for outstanding rebates) to us for payment by or, if applicable, to us. (We recognize that plan sponsors may not receive some rebates until after the close of the their plan year.)

- In the month in which they are received (or recognized), the appropriate share of any discounts, rebates, or other price concessions, along with any adjustments to the actual expenditures for prior months, are reflected. Any amounts owed the government would offset the subsidy payment for that month, to the extent that the amount owed to the government would exceed any applicable monthly payment, the plan sponsor would pay this amount to us.

- Plan sponsors (or more likely, plan administrators, insurers or group health plans on their behalf) would maintain detailed records of claims payment and other matters. The specifics of the data retention, data submission, audit and financial requirements would be determined in future instructions.

We note that, due to our need for monthly coverage and spending data, this system could work equally well for plans whether their plan year is coterminous with or is different than the calendar year. Because the special subsidy is based on allowable gross drug spending, without regard to the relationship of this spending to plan coverage or reimbursement, we believe the amount of drug spending for each eligible retiree-beneficiary can be easily be extracted from the insurance coverage provided in a "plan year". We believe months, as opposed to a daily, weekly, or annual basis, constitute the appropriate unit for computing the special subsidy. We note that more detailed, disaggregated data would be needed for purposes of audits and annual reconciliations.

Actual monthly payments could be adjusted by the actual amounts received in that month for discounts, chargebacks and rebates appropriately attributed to allowable gross costs (as defined for purposes of claiming the special subsidy). Under this approach, payments would be based on actual drug spending and discount, chargeback or rebate payments. While arguably more data intensive, we believe this to be the most straightforward option, minimizing reliance on projections and

actuarial representations. It also would facilitate expeditiously paying sponsors full subsidy amounts to which they would be entitled. Any underpayment or overpayment would generally be dealt with through an adjustment to subsequent periodic payments. This option would provide a payment stream, which comes closest to subsidizing actual plan expenditures as they occur.

The following items would be three possible alternative options to our proposed methodology discussed above and the broad outline of the process for receiving subsidy payments. Under all three alternative options, sponsors would have to meet the specified filing deadlines in order to receive subsidy payments:

(1) The first alternative option would be to make a single payment after the close of the year. Under this option, by the start of the fourth month after the close of the plan or calendar year, sponsors whose attestation of actuarial equivalence had been approved for that year would submit to us the number of months of coverage for each qualifying covered retiree and their gross and allowable costs. (Partial years of coverage would result from individuals becoming qualifying covered retirees during the course of the year and also from decedents who die during the course of the year. In the case of new qualifying covered retirees, only their expenses from the month of their status change forward can be included in their gross and allowable costs, which would have to exceed the cost threshold in order for a payment to be made.) Gross and allowable costs would be derived directly from claims payments and retiree cost sharing for prescriptions dispensed during the plan year offset by appropriate rebate cost reporting (as discussed in section 2 of this subpart with respect to allowable retiree costs). The portion of gross costs that exceeded the cost threshold but were less than the cost limit would be derived. Discounts, chargebacks, and rebates, which already would have been factored for the year, would be removed from these gross costs to calculate allowable costs and the subsidy amount. We would review this submission and make a payment for the year by the end of the following month. This alternative option would be the simplest to administer and would obviate the need for interaction between CMS and sponsors other than during the review process. From the perspective of sponsors, however, this option may be less desirable since payment would not be received until after the close of the year.

(2) The second alternative option would be to make interim payments throughout the year with a settlement after the end of plan or calendar year. Under this alternative option, sponsors desiring to receive subsidy payments would develop an estimate of per capita subsidy payments based on the plan's claims history and the rebates or discounts received in the prior period. Sponsors would submit the estimate, as well as the basis for the estimate, at the same time that they submit their attestation of actuarial equivalence (which we have proposed in section 3(b) of the preamble to be three months prior to the start of the plan year). If the sponsor files on a timely basis and we agree that the sponsor offers a qualified retiree prescription drug plan, we would review the estimate and the documentation and determine an interim monthly per capita amount. Plans would be paid a percentage (70 percent for 2006 and 2007, 90 percent for subsequent years) of this interim payment level on a periodic basis for each qualifying covered retiree based on the sponsor's enrollment information which would be matched against Medicare records to verify qualifying status. We would pay less than 100 percent of this amount to minimize the possibility of having to recoup large amounts of money at the time of settlement. We are proposing to pay 70 percent in 2006 and 2007 given the significant uncertainty that will exist in estimating subsidy payments. We request comments on whether estimating techniques as to qualifying covered retirees and as to levels of drug spending during the year are reliable enough to justify a higher percentage. By the start of the fourth month after the close of the plan or calendar year, the sponsor would submit documentation on gross claim costs and rebates, as described in option 1, above. We would review the documentation and settle for the year by making an additional payment if more payment were due to the sponsor or by reducing subsequent interim payments to reflect any overpayment. This alternative option is more administratively complex than the first alternative option because it entails developing an interim payment amount and making those payments. It would, however, provide subsidy funding to sponsors during the plan or calendar year.

(3) The third alternative option would be to make lagged payments based mainly on actual experience on a periodic basis throughout the year with a settlement after the end of the year limited to reconciling estimated versus

actual discounts, chargebacks, and rebates. By the 15th of the month following the close of the payment period, sponsors whose attestation of actuarial equivalence had been approved would submit information to us on gross and allowable costs for the previous payment period for each qualifying covered retiree whose gross costs, coverage (that is, calendar) year to date, exceeded the cost threshold, but were not in excess of the cost limit. The information submission would be based on actual claims experience. Actual monthly payments could then be adjusted on a percentage basis for estimated discounts, chargebacks, and rebates (the sponsor would submit a justification, which we would approve, for the percentage used). By the 15th of the following month, we would review the submission and make payment. By the start of the fourth month after the close of the plan or calendar year, the sponsor would submit documentation on actual discounts, chargebacks, and rebates received for the plan compared to those estimated. Any under payment or overpayment would be dealt with through an adjustment to subsequent periodic payments.

We would like your comments on the operational aspects of the proposed policy, as well as the broad alternative options, and on their desirability from the perspective of plan sponsors.

In addition to the question of payment methodology, there is the issue of the periodicity of the subsidy payments. While this is not an issue with regard to an annual retroactive payment, the question of periodicity does arise with regard to the ongoing payment alternatives. We would like your comments on the use of bi-annual, quarterly or monthly payment periods under these approaches. We also considered a variable payment option in which the frequency of payment would vary in accordance with the size of the sponsor's plan. For example, a sponsor with 10,000 or more qualifying covered retirees would receive monthly payments while sponsors with less than 10,000 qualifying covered retirees would receive quarterly payments. We are concerned that this alternative may be inequitable in terms of cash flow and overly administratively complex to implement. Again we are asking for your comments, particularly with regard to the balance between timeliness versus administrative burden posed by monthly or quarterly payments versus annual payments. We are also asking for your comments on whether to use more than one of the payment alternatives described above based upon the size of

the sponsor's plan. For example, in order to minimize administrative burden on small businesses, sponsors with less than 100 qualifying retirees could receive an annual retroactive payment. We solicit comments, in particular on the issue of whether less frequent payments might be preferable for small employers because it would minimize their reporting burden.

Our understanding is that PBMs and other entities currently involved in the administration of claims are highly automated and capable of efficiently and effectively providing the necessary information at low (incremental) cost in a timely manner. We are particularly interested in your comments about the capabilities of the service providers and their views, as well as the views of the plan sponsors and others, on the most appropriate arrangement, as well as your comments on the feasibility of the proposed approach and proposed alternative options.

c. Data Collection

Regardless of what payment methodology is ultimately chosen for the subsidy, we would need certain data from the sponsors of the plans (or the plan administrators, insurers or group health plans designated by the sponsors) in order to accurately calculate the amount of the subsidy to which the sponsor is entitled. This data would include updating of the information that was provided during the application process such as the names of the qualifying covered retirees enrolled in the plan, including the spouses and the dependents, the Health Insurance Claim (HIC) numbers (when available), social security numbers, dates of birth, sex, and relationship to the retired employees. We would also require an affirmation that the Medicare benefits of each qualifying covered retiree are not secondary to the sponsor's retiree health coverage (if the Medicare benefits are secondary to the sponsor group health plan, that would indicate that the participant is not in retiree status and, thus, is not a qualifying covered retiree except in certain situations in which the retiree qualifies for Medicare based on ERSD status), and dates of enrollment in the sponsor's retiree plan.

The plan sponsor (or the designated administrator, insurer, or group health plan) would be required to submit cost data for each qualifying covered retiree. The timing of the submission and the relevant time period of the cost data is contingent on the payment methodology that is adopted in the final rule for the subsidy. A separate issue, however, is the level of detail of the cost data. There

are two options, and a combination of the two, to be considered:

(1) First, we could require that the sponsor (or the plan administrator, insurer, or group health plan designated by the sponsor) submit the aggregate total of all allowable drug costs of all of the qualifying covered retirees in the plan for the time period in question. This would be the cost incurred between the cost threshold and cost limit with an appropriate adjustment for rebates. This aggregate cost would not be broken down to each qualifying covered retiree. The sponsor (or administrator, insurer, or group health plan) would have to maintain the claims data to support its submission for audit purposes. While this option would probably be easier for the sponsors and would be the most protective of the individual's privacy, it may be the most problematic in terms of assuring the accuracy of the subsidy payment.

(2) A second option would be for the sponsor (or the plan administrator, insurer, or group health plan) to submit the aggregate allowable costs for each qualifying covered retiree for the time period in question. This would be more complex for the sponsor and would raise some privacy questions but would provide more assurance with regard to the accuracy of the subsidy payment.

(3) A third option would be to combine various elements of the first two options. For example, the sponsor (or the administrator, insurer, or group health plan) would be required to submit information with the specificity outlined in the second option for each of the first two years of the subsidy's availability. In the third and fourth years, however, the sponsor (or the administrator, insurer, or group health plan) would submit its claims data in accordance with the first option.

(4) A fourth potential option that we considered and subsequently ruled out would have been for the sponsor (or the plan administrator, insurer, or group health plan) to submit the actual claims data for each qualifying covered retiree. This option, however, would have been the most complex in terms of administering the subsidy program and the most problematic in terms of privacy. In addition, the benefits of this option would not have outweighed the higher costs associated with submitting actual claims data for each qualifying covered retiree.

As discussed in the next section, we would require the creation and retention of detailed, individual records reflecting both claims and financial data. In assessing the merits of the two options, it is important to understand our plans for vigorous implementation of our

audit authority. We believe that a vigorous audit program is consistent with permitting the reporting of more aggregated data. For example, plan sponsors could report the aggregate total of gross allowable drug costs for all qualifying covered retiree-beneficiaries incurred in a month, adjusted to reflect discounts, chargebacks and rebates (we discuss the issue of adjustments based upon rebates and other price concessions in section 2 of this subpart in connection with the discussion of allowable retiree costs). In the end-of-year report, CMS could require more detailed information on eligibility, drug spending, and discounts, rebates and chargebacks. Finally, we might require the retention of detailed enrollee records for audit or other analytical purposes. We believe that by requiring different levels of detail for data and records, depending on the purpose for which they are to be used, provides sponsors and plan administrators, insurers, or group health plans with a minimum amount of burden and a maximum amount of flexibility and time in which to produce the required records. We welcome your comments on these options or your proposals for other options. Regardless of what option is chosen, we would require that the data include the period of time when the cost was incurred, the period of Medicare eligibility for each qualifying covered retiree, and the period of enrollment in the sponsor's retiree plan for each qualifying covered retiree. This is because, as mandated by section 1860D-22 of the Act, only costs incurred while the Medicare beneficiary is enrolled in the sponsor's drug plan and not in Part D can be considered allowable retiree costs.

This proposed rule also specifies, as required by section 1860D-15(d) of the Act, that all information obtained pursuant to this subpart may be used by the officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this subpart R of part 423.

d. Audits

At § 423.888(d), we propose that the sponsor of the plan (or the plan administrator, insurer, or group health plan designated by the sponsor) would be required to maintain and provide access to sufficient records for our audits or audits of the OIG to assure the accuracy of the attestation regarding actuarial value and the accuracy of subsidy payments made under this subpart. This proposed rule specifies that the working documents and reports of the actuaries conducting the analyses

that serve as the basis for the attestation, and all documentation of the costs incurred and utilization for the amount of the subsidy payment, including the underlying claims data, would be made available for audit inspection. All records would be maintained for at least 6 years after the end of the plan year in which the costs were incurred. We believe that 6 years is a sufficient length of time to preserve our right to conduct follow-up audits and would not be too burdensome on the sponsors. Six years is also the length of time certain other Medicare records are required to be retained. In the event of an ongoing investigation, litigation or negotiation, we or the OIG may extend the 6-year retention period. We invite your comments on the appropriateness of this level of documentation, and any unique operational issues it may raise. We may conduct audits in a manner similar to the audits of financial records of PDP sponsors and MA organizations, as outlined in § 423.504(d)(2) of our proposed rule.

6. Appeals (§ 423.890)

Although the statute does not contain provisions for administrative appeals of the retiree drug subsidy amount, and although we do not believe there is a constitutional property interest in the retiree drug subsidy (*See American Manufacturers Mutual Insurance Co. v. Sullivan*, 526 U.S. 40 (1999) (individual did not have a property right in the receipt of payment of a bill for medical services before an agency determined that the services were reasonable and necessary); *Giese v. Barnhart*, 55 Fed. Appx. 799, 2002 WL 31856 (9th Cir. 2002) (there is no “termination” of benefits warranting due process when the individual never qualified for benefits in the first place), we believe that it is prudent policy to allow an opportunity for review of certain agency decisions issued in relation to this subpart. Examples of these decisions are as follows—

- A retiree prescription drug plan is determined not to be actuarially equivalent.
- An enrollee in a retiree prescription drug plan is determined not to be a qualifying covered retiree.
- A determination of the subsidy amount to be paid to a sponsor.

We propose using a three step process for review of subsidy determinations.

(1) In the first step, the sponsor could request an informal written reconsideration by us of the subsidy determination. Initial subsidy determinations would be final and binding unless the sponsor requested reconsideration in a timely manner or

we reopened the determination in accordance with the procedures discussed below. The request for reconsideration would have to be filed within 15 days of the date of the notice of the adverse determination. We believe a short time frame is necessary in order to ensure that subsidy amounts can be finalized in as expeditious a manner as possible. We note that the 15-day time frame is used in MA contract termination appeals (see § 422.650) and we believe employers are similar to MA organizations in their level of sophistication. We expect that sponsors possess adequate resources to meet the time line and pursue the appeals in the proper manner. The written reconsideration would be entirely on the papers. Sponsors would be able to submit a position paper and any additional evidence they wished us to consider. We would make its informal reconsideration determination on these papers and inform the sponsor of its decision. We could inform the sponsor of its determination orally (over the telephone) or in writing (by electronic mail or by post); however, on a sponsor’s request, we would put our decision in writing. We expect that when we make a reconsideration determination wholly favorable to the sponsor, a written decision will not be requested. Our reconsideration determination would be final and binding, unless the sponsor further appealed the determination or if we reopened the reconsideration determination in accordance with the reopening provisions discussed below.

(2) The second step of the appeals process would be an informal hearing before our hearing officer (who was not a party to the initial decision). Requests for a hearing would need to be made within 15 days of the date the sponsor received our reconsideration decision. If there is a dispute as to the date of receipt, unless there was evidence to the contrary, we would assume that the sponsor received the decision at least 5 days from the date on the written reconsideration decision. Because we expect that we would deliver only favorable decisions orally, we do not expect receipt of an orally communicated decision would be an issue in determining whether a party has met the deadline for requesting a hearing of an adverse determination. The hearing officer’s decision would be final and binding, unless further appealed to our Administrator. We have also proposed that the hearing officer appointed by the Administrator would be limited to a review of the record that was before us in making its initial or

review determination and no new evidence could be presented at the hearing stage. The hearing officer’s scope of authority would be limited to determining whether we applied our own policies in accordance with the facts that were before us. Our hearing officer would have to render the decision in an as expeditious manner as possible.

(3) The third step of the appeals process would be a review by our Administrator. A sponsor could request an Administrator review or the Administrator, on his or her own motion, could take review, but in either case this review would have to be requested (or taken) within 15 days of the hearing officer’s decision. Again, we would expect that sponsors received the hearing officer’s decision within 5 days of the date on this decision.

We believe a three-step appeals process allowing an opportunity for informal written review, followed by an oral hearing would conserve both agency and sponsor resources and ensure that a more formal hearing process is not invoked unless necessary. However, we also have considered other options, including having at the second level of appeal a telephone hearing with a CMS hearing officer instead of an in-person hearing. Another option is for a hearing on the record with the Hearing Officer, but without the opportunity for oral testimony. Although we believe these rules are procedural rules not subject to notice and comment rulemaking, in the case of this new benefit, we would welcome comments on the sufficiency of these rules and the other options discussed above.

In addition to the appeals process, we have included provisions for reopening and revising an initial or reconsidered determination. We believe the authority to reopen retiree drug subsidy determinations would be in keeping with our authority in section 1860D-22(a)(2)(B) of the Act to “perform audits and other oversight activities necessary to ensure * * * accuracy of payments,” since this audit authority would not be meaningful if we could not reopen payment determinations we later determined to be erroneous. In addition, we believe that sections 1870 and 1871 of the Act provide us with the authority to reopen final determinations of the retiree drug subsidy to such employers. Therefore, in this proposed rule we would include reopening provisions based on those used in Medicare claims reopening, and found in part 405 of the Code of Federal Regulations (subparts G and H). Including reopening provisions would allow us to ensure that any overpayments or underpayments

discovered as a result of oversight or audit could be rectified. Under our proposed provisions, reopening could occur for any reason within one year of the final determination of payment, within four years for good cause, or at any time when the initial, reconsidered, or revised determination was procured by fraud or similar fault. We could initiate a reopening on its own, or an employer could request reopening, but these requests would be at our discretion. The Supreme Court has determined that in the context of reopening cost reports, a fiscal intermediary's decision not to reopen a final determination is not subject to judicial review, (*See Your Home Visiting Nurse Services, Inc. v. Shalala*, 525 U.S. 449, 456 (1999)), and we believe the same reasoning would apply in the context of Part D.

Good cause would be interpreted in the same manner as in Part 405 and as further clarified in the Medicare Carriers Manual (MCM), section 12100. Thus, good cause would exist, if—(a) new and material evidence, not readily available at the time of the determination, is uncovered; (b) there is an error on the face of the evidence on which such determination or decision is based; or, (c) there is a clerical error in determination. In order to meet the standard under (a), the evidence could not have been available at the time the determination was made. A clerical error constitutes such errors as computational mistakes. An error on the face of the evidence exists if it is clear, based upon the evidence that was before us when we reached our initial determination, that the initial determination is erroneous. For example, good cause would exist in cases where it is clear from the files that rebates or administrative costs were not appropriately accounted for, where computation errors had been made, where an employer included non-Part D drugs in their calculations, where individuals not enrolled in the plan were included in calculating payment, and in similar situations. Reopening could occur at any time if the underlying decision was obtained through fraud or similar fault—such as if an employer sponsor—or its subcontractor—knew or should have known that it was claiming erroneous subsidies. We believe it would be necessary to include subcontractors in this standard, since we expect many sponsors will contract with benefit administrators to manage the benefit, and these administrators will be providing data to CMS. We have not included provisions for reopening

hearing officer or Administrator decisions, but are considering allowing for the reopenings as well. We request comments on this issue.

7. Privacy

The HIPAA Privacy Rule at 45 CFR part 160 and subparts A and E of part 164 ("Privacy Rule") applies to "covered entities," which include group health plans and health insurance issuers, as defined in 45 CFR 160.103. Third party administrators would be business associates, as defined in 45 CFR 160.103, of group health plans. Sponsors would not become covered entities by sponsoring a plan and do not have access to claims information or similar Protected Health Information necessary to support the subsidy payment. Much of the data that we would need to support the subsidy payment outlined above would be protected health information held by group health plans, insurers, and "third party administrators" on behalf of self-funded group health plans.

Covered entities may only use or disclose protected health information as permitted or required by the Privacy Rule. A business associate contract generally must limit the business associate's uses or disclosures of protected health information to those the covered entity could make. Permitted uses and disclosures include those for treatment, payment, and health care operations as well as those for public priority purposes, such as those uses and disclosures required by law (45 CFR 164.512(a)).

Section 423.888(b) would require the plan (or the third party administrator on behalf of the plan, as applicable) or the insurer of the plan to disclose certain data to CMS that is related to the retiree drug subsidy when directed by the plan sponsor to do so. We believe we have the authority to mandate the disclosure of this data to CMS pursuant to our oversight authority under section 1860D-22(a)(2)(B) of the Act, which provides that the Secretary shall have the access to such records as necessary to ensure the adequacy of subsidy payments made to sponsors. A sponsor applying for the subsidy can direct the plans that it sponsors (or the third party administrators or the insurers, as applicable) to disclose the protected health information to us, and disclosure will be permitted under the Privacy Rule because the disclosure is required by law, that is, by this regulation. In order to protect the privacy of the information, the protected health information would be provided directly to CMS and would not be shared with the sponsor. (CMS would disclose the

information on the enrollees' Part D eligibility to the sponsors or the plan under § 423.884(b)(6).) We invite comment on the impact this will have on sponsors of retiree plans and on the group health plans, issuers, and third-party administrators of these plans.

8. Change of Ownership (§ 423.892)

Sponsors who apply for a subsidy payment would be required to comply with change of ownership requirements, similar to those set forth in proposed § 423.551 for the MA-PD and PDP plans. However, for purposes of the retiree drug subsidy, we are proposing slightly different change of ownership provisions than those proposed in § 423.551 for PDPs. We request comments regarding how these provisions could be modified to accomplish these objectives. In particular, we seek comments regarding: the situations which constitute a change of ownership, how these provisions should be applied to large companies with multiple business units, the notification requirements related to a change of ownership, and whether sponsors should be subject to novation agreement and facility leasing provisions similar to those proposed in § 423.551.

In § 423.892, we would carry over the three situations that constitute change of ownership (CHOW) in § 423.551 of our proposed rule. We would state that a CHOW includes the following—

- The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law;
- A transfer of substantially all of the assets of the sponsor to another party; or
- The merger of the sponsor's corporation into another corporation, or the consolidation of the sponsor's organization with one or more other corporations, resulting in a new corporate body.

The proposed exception to the three provisions discussed above would be that a transfer of corporate stock or the merger of another corporation into the sponsor's organization, with the sponsor organization surviving, would not usually constitute a CHOW.

We would require a sponsor that has a sponsor agreement in effect and who is considering or negotiating a CHOW, to notify us at least 60 days before the anticipated effective date of the change. In addition, we would also require that when there is a CHOW, and this results in a transfer of the liability for prescription drug costs, the existing subsidy agreement would automatically be assigned to the new owner. We would also require that the new owner

to whom a sponsor agreement is assigned be subject to all applicable statutes and regulations and to the terms and conditions of the subsidy agreement.

We welcome comments on any aspect of the proposed section on change of ownership. We are particularly interested in comments on situations in which a sponsor transfers substantial assets, but substantially less than all of its assets, to another party. Please describe the different scenarios that might develop under such circumstances, especially the extent to which benefits covered by the sponsor agreement might reasonably be expected to be provided by the old or new owner and the best approach for either transferring, issuing or reissuing sponsor agreements. We would also like to receive comments on scenarios that might develop if more than one entity retains or acquires liability for prescription drug costs as the result of the terms of a change in ownership.

9. Construction (§ 423.894)

Sections 423.890(a) through § 423.890(d) are based on section 1860D–22(a)(6) of the Act. It provides that nothing in section 1860D–22 of the Act must be interpreted as preventing—

- An individual who is eligible for Medicare Part D and who is covered under employment-based retiree health coverage from enrolling in a prescription drug plan or in a MA–PD plan;

The sponsor of employment-based retiree health coverage or an employer or other person from paying all or any part of any premium required for coverage under a prescription drug plan or MA–PD plan on behalf of an individual;

Employment-based retiree health coverage from providing coverage that is supplemental to the benefits provided under a prescription drug plan or a MA–PD plan, including benefits to retirees who are not covered under a qualified retiree prescription drug plan, but who are enrolled in a PDP or MA–PD plan;

Employment-based retiree health coverage from providing coverage that is better than the standard prescription drug coverage (as defined in § 423.104(e)) to retirees who are covered under a qualified retiree prescription drug plan; and

Sponsors from providing for flexibility in benefit design and pharmacy access provisions, without regard to the requirements for basic Medicare Part D drug coverage, as long as the actuarial equivalence requirement (as defined in § 423.884(a)) is met.

S. Special Rules for States—Eligibility Determinations for Low-Income Subsidies, and General Payment Provisions

1. Eligibility Determinations (§ 423.904)

The MMA added a new section 1935 to the Act, “Special Provisions Relating to Medicare Prescription Drug Benefit,” which specifies the requirements for States regarding low-income subsidies under the new part D benefit. In accordance with the statute, our proposed regulations at § 423.904(a) and (b) would require States to make initial eligibility determinations for premium and cost sharing subsidies based on applications filed with the States, to conduct periodic redeterminations consistent with the manner and frequency that redeterminations are conducted under Medicaid, and to notify us of eligibility determinations and redeterminations once they are made.

In § 423.904(c), States would be directed to identify individuals who apply for the low-income subsidy who may also be eligible for programs under Medicaid that provide assistance with Medicare cost sharing and to offer enrollment in these programs. This requirement is consistent with existing obligations imposed on States when they make eligibility determinations for Medicaid. We also specify that States notify deemed subsidy eligibles of their subsidy eligibility.

In section § 423.904(d), we would require States to begin accepting application forms for the low-income subsidy no later than July 1, 2005. Our rationale for requiring States to take applications earlier than the open enrollment period for PDP and MA–PD plans would be to allow more time to process the large number of expected subsidy applications at the beginning of the program.

In section § 423.904(d), we would also require States to make available application forms, provide information on the nature of and requirements for the subsidy program, and provide assistance in completing subsidy applications. States also would be required to ensure that applicants or personal representatives attest to the accuracy of the information provided. In verifying application information, we would specify that States may require the submission of statements from financial institutions and may require that information on the application be subject to verification in a manner the State determines to be most cost-effective and efficient. As we discuss under subpart P, we envision a process that will balance the need for program

integrity with the goal of reducing paperwork burden and cost.

In addition, § 423.904(d) would direct States to provide us with necessary information to carry out implementation of the Part D program. This will include information such as income levels for other low-income subsidy eligible individuals under § 423.773 needed to permit PDPs and MA–PDs to determine the amount of sliding scale premium subsidy that a person will receive under § 423.780(b).

In developing this proposed rule, we worked with the Social Security Administration (SSA) on a simplified application form and process for the low-income subsidy program. As a result, we developed uniform criteria for determining resources, income, and family size under the subsidy, which are reflected in the proposed definitions at § 423.772, and the proposed eligibility requirements at § 423.773.

We are considering a number of options to ease the burden on States and to ensure, to the degree permissible under the MMA, a consistent eligibility determination process. We invite comments from States on this issue.

2. General Payment Provisions (§ 423.906)

We specify in § 423.906(a) that States could receive the regular Federal match for administrative costs in determining subsidy eligibility.

Section 1935(d) of the Act contains provisions on Medicaid coordination with Medicare prescription drug benefits. The proposed regulations specify in § 423.906(b) that, in the case of a person who is eligible for Part D and also eligible for full Medicaid benefits, medical assistance is not available for Medicaid covered drugs that could be covered under Part D or for cost sharing related to such drugs. In these cases Medicare is the primary payer. The provision of Part D covered drugs is no longer considered a benefit under the Medicaid program for full benefit dual eligibles, even if such individuals have not enrolled in a Part D plan. Therefore, no payment should be made under Medicaid for covered Part D prescription drugs for full benefit dual individuals.

Also, in our proposed regulations in § 423.906(c), we specify that for individuals enrolled in a drug plan under Part D or in an MA–PD States may elect to cover under Medicaid outpatient drugs, other than Part D covered drugs, in a manner as otherwise provided in their State Plan for individuals who are not full-benefit dual eligible individuals or through

arrangements with the PDP sponsor or MA-PD.

3. Treatment of Territories (§ 423.907)

Low-income Part D eligible individuals residing in the territories are not eligible for premium and cost-sharing subsidies. However, in accordance with section 1935(e) of the Act, territories may submit a plan to the Secretary under which medical assistance is to be provided to low-income individuals for covered Part D drugs. Territories with approved plans will receive increased grants under sections 1108(f) and 1108(g) of the Act. Section 423.907 contains the provisions explaining the territories submittal of plans and the grant funding.

4. State Contribution to Drug Benefit Costs Assumed by Medicare (§ 423.908 through § 423.910)

Medicare will subsidize prescription drug costs for full-benefit dual eligible individuals. However, in accordance with section 1935(c) of the Act, States and the District of Columbia will be responsible for making monthly payments to the Federal government beginning in January 2006 to defray a portion of the Medicare drug expenditures for these individuals. The statute directs, and we would specify, in § 423.910(b)(2) that State payments would be made in a manner similar to the mechanism through which States pay Medicare Part B premiums on behalf of low-income individuals who are eligible for both Medicare and Medicaid, except that those payments will be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

As we are proposing to specify in § 423.908 through § 423.910, to calculate the monthly State contributions, we would first calculate an amount we refer to as the projected monthly per capita drug payment. This amount is based in part on a State's Medicaid per capita expenditures for covered Part D drugs for Medicare beneficiaries eligible for full benefits under Medicaid for 2003, which is equal to the weighted average of gross per capita Medicaid expenditures for prescription drugs for 2003 for Medicaid recipients not receiving drugs through a managed care plan and the estimated actuarial value of prescription drugs benefits provided under a capitated managed care plan for these individuals in 2003. The weighted average would be based on the proportion of individuals who, in 2003, did and did not receive medical assistance for covered outpatient drugs through a Medicaid managed care plan.

The gross per capita Medicaid expenditures for prescription drugs for 2003 is equal to the average (mean) per person expenditures (including dispensing fees) for a State during 2003 for covered Part D drugs provided to Medicare beneficiaries receiving full benefits under Medicaid who are not receiving medical assistance for drugs through a Medicaid managed care plan, based on data from the Medicaid Statistical Information System (MSIS) and other available data, as adjusted by an adjustment factor.

We would apply an adjustment factor to the gross per capita Medicaid expenditures for prescription drugs. The adjustment factor for a State would have to equal the ratio of the aggregate payments to the State in 2003 under rebate agreements under section 1927 of the Act to a State's 2003 gross expenditures for covered Part D drugs not received through a Medicaid managed care plan, based on data contained in the CMS-64 Medicaid expenditure report. We propose to define 2003 as CY 2003 (January 1, 2003, through December 31, 2003). The gross per capita Medicaid expenditures for prescription drugs for 2003 will be reduced by this adjustment factor ratio.

The projected monthly per capita drug payment for a month would be equal to $\frac{1}{12}$ of the product of the State's Medicaid per capita expenditures for covered Part D drugs for Medicare beneficiaries eligible for full benefits under Medicaid for 2003 and a proportion equal to 100 percent minus the Federal medical assistance percentage (as defined in section 1905(b) of the Act) applicable to the State for the year for the month at issue. This amount would be increased by the growth factor for each year beginning in 2004 through the year for the month at issue. The growth factor for years 2004, 2005, and 2006 would be the average percent change from the previous year of the per capita amount of prescription drug expenditures (determined using the most recent National Health Expenditure projections). The growth factor for 2007 and succeeding years would equal the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals for the 12-month period ending in July of the previous year.

The monthly State contributions for each year, beginning in January of 2006, would be the product of the projected monthly per capita drug payment, the total number of full benefit dual eligible individuals for the State in the applicable month, and the applicable ten year phased-down factor for the year

(see Table S-1). As illustrated in Table S-1, State contributions would decline each year until 2015, at which time the applicable 10 year phased-down factor for each year will be fixed at 75 percent.

As specified in § 423.910(b)(3), failure on the part of a State to pay these State contribution amounts would result in interest accruing on those payments at the rate provided under section 1903(d)(5) of the Act, in accordance with section 1935(c)(1)(C) of the Act. In addition, as required by the statute, we would immediately offset unpaid amounts and accrued interest against Federal Medicaid matching payments due to the State under section 1903(a) of the Act. As we specify in § 423.910(e), we would perform periodic data matches to identify full-benefit dual eligibles for purposes of computing State contributions. As we specify in § 423.910(d), States would be required to provide data on full benefit dual eligible enrollees in order to conduct the data match required under section 1935(c)(1)(D) of the Act.

States would make contributions only on behalf of Medicare beneficiaries who would otherwise be eligible for outpatient prescription drug benefits under Medicaid. States would not make contributions on behalf of individuals such as those QMBs who are not otherwise eligible for Medicaid, SLMBs, and QIs for whom the State will pay only Part B premiums or Medicare cost sharing on their behalf. In order to give meaning to the term full benefit dual eligible for purposes of the baseline calculation, we needed to define it in a manner that would permit the baseline calculation to operate. Therefore, we are proposing that Medicaid eligible individuals who receive comprehensive benefits including drug coverage under Medicaid and are also covered under Medicare Part A or Part B to be full benefit dual eligibles for purposes of calculating the baseline. This definition of full benefit dual eligibles excludes Medicare beneficiaries who receive Medicaid drug coverage under a section 1115 Pharmacy Plus demonstration.

As we specify in § 423.910(g), to assist States in their budget planning, we must notify States by October 15 each year of the projected monthly per capita drug payment calculation for the next calendar year.

The ten-year phased-down State contribution factors are identified below in Table S-1.

TABLE S-1.—ANNUAL PHASED—DOWN PERCENTAGES OF STATE CONTRIBUTIONS TO MEDICARE PART D DRUG BENEFIT COSTS

Year	State Percentage
2006	90
2007	88½
2008	86½
2009	85
2010	83½
2011	81½
2012	80
2013	78½
2014	76½
2015 and thereafter	75

T—Part D Provisions Affecting Physician Self-Referral, Cost-Based HMO, PACE, and Medigap Requirements

(If you choose to comment on issues in this section, please include the caption “T—Part D Provisions Affecting Self-Referral, Cost-Based HMO, PACE, and Medigap Requirements” at the beginning of your comments.)

Subpart T includes discussion of several other regulatory areas that would be affected by the proposed provisions implementing the Medicare prescription drug benefit. In the discussion that follows, we specify the revised requirements for physician self-referral prohibition, cost-based HMOs, PACE organizations, and Medigap policies. Any corresponding regulation text appears before or after the section 423 rules in subpart A of our proposed rules.

1. Definition of Outpatient Prescription Drugs for Purposes of Physician Self-Referral Prohibition (§ 411.351)

Section 1877 of the Act, also known as the physician self-referral law, prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which the physician (or an immediate family member) has a financial relationship (ownership or compensation) unless an exception applies. Section 1877 of the Act also prohibits the DHS entity from submitting claims to Medicare for DHS furnished as a result of a prohibited referral.

“Outpatient prescription drugs” are a designated health service under section 1877 of the Act. We have defined in regulation “outpatient prescription drugs” for purposes of the physician self-referral prohibition as “all prescription drugs covered by Medicare Part B” (§ 411.351). However, effective January 1, 2006, additional outpatient

drugs will be covered under Medicare Part D. These additional covered Part D drugs are defined elsewhere in this preamble in II.C.1 of Subpart J, and in regulations text at § 423.100.

As a result of the proposed Medicare prescription drug benefit provisions, we propose to amend the physician self-referral definition of “outpatient prescription drugs” at § 411.351 to include the additional outpatient drugs covered under the new Part D benefit. Specifically, we propose to define “outpatient prescription drugs” for purposes of the physician self-referral prohibition as “all drugs covered under Medicare Part B and Part D.” We believe that referrals for Part D drugs are subject to the same risk of overutilization and anti-competitive behavior as referrals for Part B drugs when a financial relationship exists between the referring physician and the entity furnishing the drugs. We are soliciting comments on this proposed definition.

2. Cost-Based HMOs and CMPS offering Part D coverage (§ 417.440 and § 417.534)

Section 1860D-21(e) of the Act provides that Part D rules will generally apply to reasonable cost reimbursement HMOs and CMPS (Competitive Medical Plans) that contract under section 1876 of the Act and that offer qualified prescription drug coverage to Part D eligible enrollees in the same manner as such rules apply to local MA-PD plans (described in section 1851(a)(2)(A)(i) of the Act). As a result, 42 CFR part 417 must be revised to reflect the treatment of an HMO or CMP as a local MA-PD plan. To codify these changes in regulation we are revising § 417.440(b) specifying that an HMO or CMP may offer qualified prescription drug coverage. In new § 417.534(b)(4), we specify that to the extent that a cost HMO or CMP chooses to participate in the Part D program by offering qualified prescription drug coverage to its members, any costs associated with the offering of Part D benefits may not be claimed on its Medicare cost report.

Section 1860D-21(e)(2) of the Act reinforces the fact that section 1876 reasonable cost contracts that offer Part D of Medicare may do so only as MA-PD plans. This section of the statute stipulates that section 1876 reasonable cost contracts may only offer Part D coverage to individuals also enrolled for Medicare in the reasonable cost contract. In other words, section 1876 reasonable cost HMOs and CMPS are not permitted to operate as “free standing” PDPs.

Section 1860D-21(e)(3) of the Act provides that the Part D bids of section

1876 reasonable cost contracts will not be included in the computation of the national average monthly bid amount and the low-income benchmark premium amount. We discuss the national average monthly bid amount in the subpart F preamble and the low-income benchmark premium amount in the subpart P preamble.

The waiver authority provided in section 1860D-21(c) of the Act would be available to section 1876 reasonable cost HMOs and CMPS in the same manner as it is available to MA-PD plans. We discuss section 1860D-21(c) of the Act and the waiver authority it provides in the subpart J preamble. To the extent that a Part D requirement is in conflict with or duplicative of a section 1876 requirement, or to the extent that a waiver would promote coordination of Part A and Part B benefits with Part D benefits, waiver would also be available to section 1876 reasonable cost HMOs and CMPS. We invite comment on whether there are any Part D requirements otherwise applicable to MA-PD plans that would be uniquely problematic to implement for section 1876 reasonable cost HMOs and CMPS.

3. PACE Organizations Offering Part D Coverage

a. Overview

Section 1860D-1(a)(1) of the Act provides that in general each Part D eligible individual is entitled to obtain qualified prescription drug coverage as a fee-for-service enrollee or a MA enrollee. Although PACE enrollees are neither fee-for-service nor MA beneficiaries, those entitled to benefits under Part A or enrolled under Part B will be Part D eligible individuals. Section 1860D-21(f)(1) of the Act further specifies that a PACE program may elect to provide qualified prescription drug coverage to its Part D eligible enrollees.

Currently, sections 1894 and 1934 of the Act require PACE organizations to provide enrollees with all medically necessary prescription drugs. Drugs covered under Medicare Parts A and B are included in the monthly Medicare capitation rate paid to PACE organizations for Medicare beneficiaries, while outpatient prescription drugs are included as a portion of the monthly Medicaid capitation rate paid to PACE organizations for Medicaid recipients or the Medicaid premium paid by non-Medicaid recipients. The MMA alters the payment structure for covered Part D drugs for PACE organizations by shifting the payer source for PACE enrollees who are full benefit dual eligibles (as defined under section

1935(b)(6) of the Act) from Medicaid to Medicare, and in part from the beneficiary to Medicare in the case of non-full benefit dual eligibles who elect to enroll in Part D. Prescription drug coverage for PACE enrollees enrolled in Medicaid who are not Medicare beneficiaries would continue to be funded by the State through their monthly capitation payment to the PACE organization.

As discussed in proposed § 423.34(d), in accordance with section 1935(d)(1) of the Act, full benefit dual eligibles will no longer be eligible for medical assistance for covered Part D drugs under Medicaid; rather, such individuals may only receive coverage for covered Part D drugs under Part D of Medicare. Consequently, in order for PACE organizations to continue to meet the statutory requirement to provide prescription drug coverage to their enrollees, and ensure that they receive adequate payment for the provision of covered Part D drugs, PACE organizations will need to offer qualified prescription drug coverage to their Part D eligible enrollees.

The MMA provides little specific guidance for implementing the prescription drug benefit for Part D eligible PACE enrollees. Section 1860D–21(f) of the Act indicates that to the extent a PACE program elects to provide qualified prescription drug coverage to Part D eligible individuals, Part D requirements apply to the provisions of such coverage in a manner that is similar to that of MA–PD local plans. Furthermore, the PACE organization may be deemed as an MA–PD local plan.

We believe that Congress did not intend to alter the way in which PACE services, including outpatient prescription drugs, are currently being provided to enrollees. Therefore, we are proposing that PACE organizations not be deemed as MA–PD local plans. Rather, PACE organizations would be treated in a manner that is similar to an MA–PD local plan for purposes of payment under Part D. This approach is consistent with section 1894(d)(1) of the Act that provides that payments will be made to PACE organizations in the same manner and from the same sources as payments are made to a Medicare+Choice (now MA) organization.

In order to account for the shift in payer source for dual eligible and Medicare-only PACE enrollees, we believe that PACE organizations would elect to provide Part D coverage to their enrollees in order to receive payment for prescription drugs. We view the Part D requirements that are associated with

payment as most directly relevant to PACE organizations. However, because all Part D requirements applicable to MA–PD local plans apply in a similar manner to PACE organizations, we also discuss a limited set of non-payment related Part D provisions that would be directly relevant to PACE.

A background of the PACE model is provided below followed by a discussion of Part D requirements as they relate to PACE programs offering qualified prescription drug coverage.

b. Background

Sections 4801 through 4803 of the Balanced Budget Act of 1997 (Pub. L. 105–33) established PACE as a Medicare benefit category and a State plan option under Medicaid. PACE organizations provide services to frail, elderly individuals as an alternative to nursing home placement. The PACE benefit includes all Medicare benefits under Parts A and B, all services in the Medicaid State plan, and any other service(s) deemed necessary by the PACE interdisciplinary team. The PACE benefit currently includes outpatient prescription drugs as well as over-the-counter medications that are indicated by the participant's care plan. Thus, all PACE organizations have been providing the equivalent of qualified prescription drug coverage as described in proposed part 423.

Similar to institutionalized individuals, PACE participants do not acquire their prescription drugs directly from pharmacies, except in unusual circumstances such as when a participant is away from the PACE organization's service area and requires urgent care. Rather, the PACE organization either dispenses prescription drugs directly to participants from its own in-house pharmacy or obtains prescription drugs from a contracted pharmacy that delivers the medications to PACE participants.

PACE organizations are risk-bearing entities that receive a capitated monthly rate from Medicare for Medicare-covered services and from Medicaid for Medicaid-covered services. As required by sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act, the PACE organization pools payments received from all sources in order to provide all services needed by its enrollees, including services covered by neither Medicare nor Medicaid. Most PACE enrollees are dually eligible for Medicare and Medicaid; however, participants may be eligible for Medicare only or Medicaid only. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act require the PACE

organization to provide all covered services to enrollees regardless of source of payment. PACE statutory language further clarifies that deductibles, copayments, coinsurance, or other cost-sharing responsibilities do not apply for PACE participants. Consequently, a PACE organization may not charge its participants any cost-sharing. We note that payment of premiums is permitted under the PACE statutory language.

The PACE Medicare and Medicaid regulations are located in part 460 of title 42 of the CFR. As directed by sections 1894 and 1934 of the Act, these regulatory requirements are a blend of Medicare Advantage (MA) and Medicaid managed care requirements as well as requirements from the PACE Protocol that was created by On Lok, Inc. under a demonstration with the Secretary. Thus, although certain PACE requirements are the same or similar to the proposed MA requirements, most are unique to PACE.

c. Payment Related Requirements for MA–PD Plans and PACE Organizations

i. Part D Bids for Basic Prescription Drug Coverage

Section 1860D–11(b) of the Act requires entities seeking to offer qualified prescription drug coverage under Part D, including MA–PD plans, PDPs, 1876 cost plans, and PACE organizations to participate in a bidding process. As discussed in § 423.279 of the proposed rule, these bids would serve as the basis for establishing a national average monthly bid amount under § 423.780 of our proposed rule that would be applicable to all plans, including PACE organizations. However, section 1860D–21(f)(3) of the Act specifies that the bids of certain plans, including PACE organizations, would not be included in the computation of the national average benchmark amount as well as the low-income benchmark premium amount under § 423.780(a).

In accordance with proposed subpart F, we are proposing that each PACE organization would submit a Part D bid that would reflect its average monthly revenue requirements to provide qualified prescription drug coverage, including enhanced alternative prescription drug coverage, for a Part D eligible individual with a national average risk profile. This bidding process would occur in a similar manner as for MA–PD plans and PDPs. In accordance with § 423.265(c)(3) of our proposed rule, the Part D bids would be prepared according to CMS guidelines on actuarial valuation and actuarially certified.

Plans would use qualified actuaries to prepare their bids in accordance with these principles. However, we are concerned that requiring small PACE organizations to independently contract with actuaries would be costly and burdensome. In order to minimize their cost, PACE organizations may choose to collectively contract with an outside actuary to develop the methodology for establishing a bid, however, each bid would need to be actuarially certified. We note that although each PACE organization's bid would not necessarily be the same, all would follow the same methodology in that they would be required to include the cost of providing basic drug coverage.

Since PACE organizations are required to enroll Medicare-only individuals who meet PACE eligibility requirements, all PACE organization bids would also be required to include the portion of the bid attributable to the cost of providing the enhanced alternative prescription drug coverage discussed later in this section.

ii. Part D Premiums for Prescription Drug Coverage

As stated previously, PACE organizations are required to provide uniform benefits to all enrollees regardless of source of payment. We have reviewed the proposed Title I regulation in conjunction with the PACE regulation and have identified that there would be 3 primary categories of PACE enrollees under the MMA: (1) Individuals enrolled in Medicaid, but not Medicare (Medicaid-only); (2) Individuals enrolled in Medicare and Medicaid (Dual eligibles); and (3) Individuals enrolled in Medicare, but not Medicaid (Medicare-only). Within the Medicare-only category of enrollees would be 3 subcategories: (a) Those individuals with income below 135 percent of the Federal poverty line (FPL) and resources below three times the maximum amount of resources an individual may have and still be eligible for supplemental security income under Title XVI of the Act, (b) those individuals with income below 150 percent of the FPL and resources in 2006 that do not exceed \$10,000 if single, or \$20,000 if married as set forth under proposed § 423.773(d) and, (c) those individuals with income above 150 percent FPL or resources that exceed the amounts set forth under § 423.773(b)(2) or (d)(2).

To ensure that PACE organizations receive payment for the Part D benefit that is consistent with the MMA and PACE statutory requirements, we are proposing policies to address these categories of PACE enrollees. We note

that Medicaid-only PACE enrollees are ineligible for Part D prescription drug coverage. Prescription drug coverage offered by the State would be funded through the Medicaid portion of the monthly capitation rate paid to the PACE organization.

Since section 1894 of the Act precludes cost sharing for PACE enrollees, our only option is to require PACE organizations to offer qualified prescription drug coverage without cost-sharing obligations. Therefore, for dual eligible and Medicare-only PACE enrollees, we are proposing that PACE organizations offer enhanced alternative prescription drug packages with no enrollee cost-sharing. For both dual eligibles and Medicare-only enrollees, CMS would pay PACE organizations a direct subsidy, as calculated under § 423.329(a)(1). In addition, the PACE organization would receive low-income premium and cost sharing subsidy payments or partial subsidy payments for those enrollees who qualify for the low-income subsidy. We note that dual eligible beneficiaries are deemed eligible for the full low-income subsidy under § 423.773(c), which includes a premium subsidy up to the low-income benchmark premium amount under § 423.780(a) or, if greater, the lowest beneficiary premium amount for a PDP offering basic prescription drug coverage in the PDP region where the beneficiary resides. We believe that as compared to larger PDPs and MA-PD plans, PACE organizations may lack the purchasing power to obtain significant discounts and other price concessions for covered Part D drugs. We, therefore, expect that some PACE organizations will submit bids under Part D that on average are higher than those submitted by other Part D plans. Consequently, because the low-income premium subsidy payments are based on regional bid averages, the premium subsidy payments received by PACE organizations might be lower than their Part D basic beneficiary premiums, and thus might not cover the full costs of providing dual eligible beneficiaries coverage for covered Part D drugs. (Section 1860D-13(a)(1) of the Act requires that the enrollee's premium would be increased to cover this discrepancy between the plan bid and the national average monthly bid amount as described under § 423.286(d)(1)).

We are concerned about the impact on low-income PACE enrollees and request public comment on other approaches to handling this premium differential. We note also that Medicare-only beneficiaries who do not qualify for the low-income subsidy or only qualify for

the partial low-income subsidy under § 423.780(b) would also be responsible for paying the difference between the low-income premium subsidy and the plan's beneficiary premium.

The enhanced alternative prescription drug premium amount would be established by the PACE organization during the bidding process and would take into account the additional cost of providing a prescription drug package to enrollees without the application of cost-sharing. Premium amounts actually paid by PACE enrollees would vary for dual eligibles and for Medicare-only PACE enrollees depending on whether the enrollee qualifies for the low-income premium subsidy.

Section 423.104(g)(2) of our proposed rule specifies that a plan may not offer enhanced alternative prescription drug coverage unless it also offers basic prescription drug coverage. In this instance, PACE organizations vary from MA-PD plans in that their enrollees are exempt from cost-sharing. It would be impractical to offer basic prescription drug coverage to PACE enrollees because stand-alone basic prescription drug coverage assumes beneficiary cost-sharing. As codified in § 423.458(d) of our proposed rule, section 1860D-21(c)(2) of the Act establishes authority for CMS to waive Part D provisions for PACE organizations that: (1) Conflict with PACE provisions (2) duplicate PACE requirements; or (3) improve the coordination of benefits between Part D and PACE. Under this authority we are proposing to waive § 423.104(g)(2) for PACE organizations in order to promote coordination of benefits between Part D and PACE.

Section 423.265(b) of our proposed rule specifies that each potential PDP sponsor or MA organization planning to offer an MA-PD plan must submit Part D bids and supplemental information not later than the first Monday in June for each prescription drug or MA-PD plan it intends to offer in the subsequent calendar year.

The start-up of a new PACE organization may take from 2.5–3 years to develop the capacity to offer PACE services, including capital expenditures associated with constructing or renovating space for a PACE Center. In addition, as required by sections 1894 and 1934 of the Act, many activities associated with PACE involve the States. For example, PACE applications are submitted to the State for review prior to CMS review and the PACE program agreement is a 3-party contract; CMS, the State in which the potential PACE program is located, and the PACE organization. We do not believe it would be appropriate for a potential

PACE organization to miss the deadline for submission of bids because of logistical issues associated with PACE. For these reasons, we are proposing to waive our proposed § 423.265(b).

iii. Risk Corridor Payments

Proposed §§ 423.308 and 423.336 define allowable risk corridor costs and outline the risk corridor payment methodology. As stated previously, risk corridor payments allow plans to transition from administratively set payment rates to market based payment rates by limiting some of the risk of bidding. Their purpose is to adjust for significant differences in the projected cost and actual cost of providing basic prescription drug benefits. We have reviewed Part D risk corridor payment provisions and have determined that they do not conflict with the PACE requirement of full financial risk in §§ 1894(f)(2)(B)(v) and 1934(f)(2)(B)(v) of the Act. Therefore, we are proposing that PACE organizations would be eligible to participate in the Part D risk corridor provision.

In accordance with proposed § 423.308, PACE organizations would be required to track allowable risk corridor costs for all Part D eligible PACE enrollees for purposes of risk corridor payments. We note that the costs for Medicare only enrollees (who would be purchasing enhanced alternative prescription drug coverage) must be adjusted not only to exclude any costs attributable to benefits beyond basic coverage, but also to exclude any basic coverage costs determined to be attributable to increased utilization over the standard benefit as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

iv. Reinsurance Payments

Part D reinsurance payments are available to Part D plans for allowable reinsurance costs above the annual out-of-pocket threshold. As discussed in Subpart C, only certain out-of-pocket costs, or true out-of-pocket expenditures (TrOOP), actually incurred by the beneficiary, another person, an SPAP, or paid for by CMS in the form of the low-income cost sharing subsidy count toward the annual out-of-pocket threshold. Because PACE organizations are precluded from imposing cost-sharing on their enrollees, PACE enrollees will not incur any direct cost-sharing that would count toward TrOOP. However, for dual eligibles and other Medicare-only enrollees who qualify for the low-income subsidy, the low-income subsidy amounts received by the PACE programs will count

toward the annual out-of-pocket threshold. Consequently, for enrollees with high drug costs that qualify for the low-income subsidy, PACE programs will be eligible for reinsurance payments. In accordance with proposed § 423.800 PACE organizations would be required to track the application of low-income cost sharing subsidies to be applied to the out-of-pocket threshold for purposes of reinsurance payments. In contrast, PACE organization will not receive any reinsurance payments for Medicare-only enrollees who do not qualify for the low-income subsidy, since these individuals will have no incurred costs that count toward the out-of-pocket threshold.

We request public comment concerning the impact of these rules on PACE organizations. We are particularly interested in receiving drug utilization information from PACE organizations. We also request public comments identifying additional alternatives for providing comparable prescription drug benefits to PACE enrollees.

d. Application of Additional MA–PD Plan Requirements to PACE Organizations

As discussed previously, § 423.458(d) establishes regulatory authority for CMS to waive Part D provisions for PACE organizations. Section 423.458(d) states that PACE organizations may request waivers from CMS. Initially, CMS will identify Part D provisions on behalf of PACE organizations that we believe require waivers. We have identified the non-payment related Part D provisions listed below to waive on behalf of PACE organizations. The provisions identified below do not represent an exhaustive list of all necessary waivers. We request public comment identifying any additional Part D requirements that meet the criteria of section 1860D–21(c)(2) of the Act. We plan to provide this more comprehensive listing of Part D provisions that CMS would waive on behalf of PACE organizations.

i. Requirements for Providing Information About Part D

Sections 423.48 and 423.128 of the proposed regulation specify requirements for providing information about Part D and for the dissemination of plan information. Plans would be required to provide information to CMS regarding benefits, formularies, premiums, cost sharing, and enrollee satisfaction. This information would be published in Medicare's comparative plan brochures and provide key information for beneficiaries to use in making informed decisions about Part D prescription drug coverage.

We believe that the differences between MA–PD plans/PDPs and PACE would complicate comparison and confuse beneficiaries. In addition to specific eligibility requirements for enrollment in PACE, PACE organizations exist only in those States that elect to include PACE in their Medicaid State plan. We are concerned that including PACE information in the comparative plan brochure would be misleading and specifically request public comment on the advantages and disadvantages of including PACE in the MA–PD/PDP comparative brochure. We are proposing that PACE organizations receive a waiver of this requirement in order to promote better coordination of the benefits under PACE and Part D.

ii. Negotiated Prices

Section 423.104(g) of the proposed rule would require MA–PD plans and PDPs to provide enrollees with access to negotiated drug prices. Since PACE enrollees receive the vast majority of their prescription drugs directly from the PACE organization with no cost sharing applied, the negotiated price requirement is already accounted for under part 460. Therefore, we are proposing a waiver of § 423.104(g) in order to promote better coordination of benefits between Part D and PACE.

iii. Access to Pharmacy Networks

Section 423.120(a)(1) of the proposed rule would require that a plan's contracted pharmacy network be located within specified distances from enrollees. Because PACE enrollees receive their prescription drugs directly from their PACE organization as opposed to through a pharmacy, the distance between the enrollee and a network pharmacy is irrelevant. We believe that requiring a PACE organization to set up a pharmacy network would be burdensome, costly, and unnecessary and diverts funds from patient care. Thus, we are proposing to waive this requirement in order to promote better coordination of benefits between PACE and Part D.

iv. Single Card, Standardized Technology

Section 423.120(c) of the proposed rule would require plans to employ the use of a card or other type of standardized technology to assist enrollees in accessing negotiated prices for Part D drugs. Since PACE participants do not routinely acquire their prescription drugs directly from pharmacies, requiring PACE organizations to develop standardized technology would be burdensome, costly, and unnecessary and diverts

funds away from patient care. Therefore, we are proposing to waive proposed § 423.120(c) under the authority of 1860D–21(c)(2) of the Act for PACE organizations to promote better coordination of benefits between Part D and PACE.

v. Out-of-Network Pharmacies

Section 423.124 of the proposed rule specifies access requirements for drugs obtained through out-of-network pharmacies. These provisions would ensure that enrollees residing in long term care facilities have access to drugs in an out-of-network long term care pharmacy and AI/AN enrollees have access to an out-of-network I/T/U pharmacy. Enrollees who obtain their Part D covered drugs from these out-of-network pharmacies would be financially responsible for deductibles or cost-sharing applicable under network pharmacies.

Under the current PACE regulations in §§ 460.90(a) and 460.100, PACE organizations are responsible for all prescription drugs, including those provided to any participants residing in long term care facilities, AI/AN, and those associated with an emergency health event or an approved urgent care need. As noted previously, PACE participants are not responsible for deductibles, co-payments, coinsurance, or other cost sharing associated with prescription drugs. In the PACE program, when participants are out of the service area and need prescription drugs, the PACE organization would arrange payment in full with the pharmacy.

As noted previously, PACE organizations are required to provide all PACE enrollees with prescription drug coverage. Therefore, we view the out of network pharmacy requirements as duplicative of PACE regulations. Thus, we are proposing to waive § 423.124 of the proposed rule for the reasons noted above.

vi. Disclosure of Price Difference Between Part D Drug and Generic Equivalent

Public disclosure requirements in proposed § 423.132 provide that a PDP or MA–PD plan must ensure that its pharmacies inform enrollees of any differential between the negotiated price for a covered Part D drug and the lowest priced generic equivalent. This requirement is inconsistent with the PACE model. PACE participants or their caregivers work with the PACE interdisciplinary team in making care planning decisions and have input into all aspects of their care, including prescription drug use. For this reason,

we are proposing a waiver of the public disclosure requirement in proposed § 423.132 under the authority of section 1860D–21(c)(2) of the Act for PACE organizations in order to promote better coordination of benefits between Part D and PACE.

vii. Privacy, Confidentiality, and Accuracy of Records Requirements

Requirements associated with privacy, confidentiality, and accuracy of enrollees' records under Part D are included in proposed § 423.136. We view these requirements as duplicative of § 460.200(e) of the PACE regulation. We believe that the PACE regulations are providing the same protections as would be provided under proposed § 423.136. For the reasons noted above, we are proposing to waive § 423.136.

viii. Medication Therapy Management Program

The medication therapy management program requirements in proposed § 423.150 would require MA–PDs and PDPs to employ pharmacists to counsel beneficiaries who have chronic conditions and use multiple drugs to ensure they are taking safe combinations of prescription drugs and using the drugs properly. PACE enrollees typically suffer from multiple health conditions that necessitate close monitoring by their interdisciplinary team. Currently, PACE organizations have pharmacists on staff or under contract, working with PACE primary care physicians as they develop the participants' care plans and monitor their drug regimens. In addition, the PACE interdisciplinary team, through its daily interactions with PACE participants and their caregivers, provides counseling to ensure that medication regimens are followed. We believe that the existing PACE regulations satisfy or exceed the medication therapy management program requirements in proposed § 423.150. For the reasons noted above, we are proposing to waive proposed § 423.150 for PACE organizations.

ix. Licensing

Proposed § 423.401 specifies licensing requirements for PDPs. A PDP must be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan. A similar requirement exists for MA–PDs. Organizations that are not licensed under State law would obtain certification from the State that the organization meets financial solvency

and other standards required by the State for it to operate.

We view these requirements as duplicative of PACE requirements. First, sections 1894(e)(2)(iv) and 1943(e)(2)(iv) of the Act require PACE organizations to meet applicable State and local laws and requirements. In addition, sections 1894(f)(2)(B)(v) and 1934(f)(2)(B)(v) of the Act require PACE organizations to be at full financial risk. Therefore, we believe PACE organizations are meeting the intent of these MA requirements. For the reasons noted above, we are proposing to waive § 423.401 for PACE because we believe they are duplicative of PACE requirements.

x. Determinations and Appeals Processes

Proposed process requirements for grievances, coverage determinations, reconsiderations, and appeals under Part D are discussed in Subpart M. We believe the PACE grievance and appeals processes under §§ 460.120 and 460.122 meet the intent of the MMA since they would accommodate complaints regarding prescription drug coverage. Therefore, we are proposing to waive §§ 423.560–423.638 for PACE organizations because we believe they are duplicative of PACE requirements.

xi. Application Process

Subpart K of proposed part 423 includes requirements governing the application process, contracts with PDP sponsors, and reporting requirements. Sections 1894 and 1934 of the Act, as well as PACE regulations in subparts B and C specify application and contract (called a program agreement in accordance with sections 1894 and 1934 of the Act) requirements for PACE that duplicate requirements in subpart K. For this reason, we are proposing to waive the sections in proposed subpart K that address the application process and contract requirements.

We invite comments on the MMA requirements we have proposed to be waived for PACE organizations and ask for comment on additional waivers that may be needed to integrate the Medicare prescription drug benefit and the PACE benefit.

4. Medicare Supplemental Policies

a. Overview and Background

In this proposed rule, we are including two provisions related to Medicare supplemental (Medigap) policies. As required under section 1882(v), as added by section 104 of MMA, we are setting forth standards for the written disclosure notice that Medigap insurers must provide to their

policyholders who have drug coverage. In addition, in order to reflect the addition of the Medicare drug benefit by MMA, we are proposing to revise the definition of a Medigap policy.

i. Medicare Supplemental Policies

A Medicare supplemental (Medigap) policy is a health insurance policy sold by private insurance companies to fill the “gaps” in original Medicare plan coverage. A Medigap policy typically provides coverage for some or all of the deductible and coinsurance amounts applicable to Medicare-covered services and sometimes covers items and services that are not covered by Medicare. Under section 1882 of the Social Security Act (Act), Medigap policies generally may not be sold unless they conform to one of the 10 standardized benefit packages that have been defined, and designated as plans “A” through “J,” by the National Association of Insurance Commissioners (NAIC). Three States (Massachusetts, Minnesota, and Wisconsin) have different standardized Medigap plans and are sometimes referred to in this context as the “waiver” States.

Three of the 10 standardized Medigap plans (Plans H, I, and J) contain coverage for outpatient prescription drugs. In addition, there are Medigap policies issued before the standardization requirements went into effect (“prestandardized” Medigap plans) that cover drugs, as well as Medigap policies in the waiver States, some of which have varying levels of coverage for outpatient prescription drugs.

ii. Legislative Authority and Background

In connection with the addition of a prescription drug benefit to Medicare, the MMA also prescribes changes to the law applicable to Medigap policies. Among other requirements, section 1882(v) of the Social Security Act, as added by section 104 of the MMA, requires Medigap issuers to provide a written disclosure notice to individuals who currently have a policy with prescription drug coverage. (Section 1882(v)(6)(A) specifies that this is to be called a “Medicare Rx policy.”) The MMA also requires that the Secretary establish standards for this disclosure notice in consultation with the National Association of Insurance Commissioners (NAIC).

The purpose of this disclosure notice is to inform an individual who has a Medigap Rx policy about his or her Medigap choices once the new Medicare Prescription Drug Benefit Program (Medicare Part D) goes into effect on

January 1, 2006. Specifically, effective on that date, section 1882(v) will prohibit the sale of new Medigap Rx policies, and require the elimination of drug coverage from Medigap Rx policies held by beneficiaries who enroll under Part D. The statute permits the renewal of Medigap Rx policies if the policy was purchased prior to January 1, 2006, and the individual does not enroll in Part D.

In addition, beneficiaries who do not enroll in Part D during the Initial Enrollment Period, and choose to enroll later, will be charged higher Part D premiums unless they can establish that they had creditable prescription drug coverage prior to enrolling in Part D. Under section 1860D-13(b)(4)(F) of the Act, and § 423.56(a) of this proposed rule, Medigap policies meet the definition of creditable prescription drug coverage if they also meet actuarial equivalence requirements.

Issuers of Medigap insurance policies are required to provide disclosure notices to policyholders with Medigap Rx policies that inform them of their options under the new legislation, as well as informing them whether or not their policies constitute “creditable prescription drug coverage.” As explained in the preamble to Subpart B of this proposed rule, to be considered creditable prescription drug coverage, the coverage must be determined (in a manner specified by the Secretary) to provide prescription drug coverage the actuarial value of which (as defined by the Secretary) equals or exceeds the actuarial value of standard prescription drug coverage under Medicare Part D. Subparts B and F of this proposed rule provide additional detail on creditable coverage and actuarial equivalence.

b. Definition of Medicare Supplemental Policy

Because of the importance of these disclosure notices to beneficiaries, we believe it is necessary to clarify what comes within the scope of a Medigap Rx policy. We are proposing to revise and clarify the definition of a Medicare supplement (Medigap) policy, currently codified at 42 CFR 403.205, to reflect the addition of the Medicare drug benefit by MMA. There was some ambiguity in the past about whether a policy that covered only prescription drugs, either as a separate, “stand-alone” policy or as a rider to another policy, met the definition of a Medigap policy. The ambiguity was created by the fact that there was no Medicare drug benefit to supplement, and has been resolved with the enactment of the Medicare drug benefit. There has also been some confusion about whether a rider attached to a Medigap policy is

considered to be part of the policy, and therefore subject to Medigap requirements.

Accordingly, we propose to revise the definition of a Medigap policy, effective January 1, 2006, to include any insurance policies or riders that contain a prescription drug benefit, and that are primarily designed for, or are primarily marketed and sold to Medicare beneficiaries. We are also proposing to clarify that any rider attached to a Medigap policy is an integral part of the policy. All the requirements that apply to the base policy, such as guaranteed renewability or disclosure requirements, would apply to the rider. Thus, for instance, if an insurer offers an optional prescription drug rider that can be added to any other policies, addition of the rider would make the entire policy a Medigap prescription drug policy (Medigap Rx policy) subject to the disclosure requirements for these policies in section 1882(v) of the Act.

Moreover, any stand-alone drug policies that were not previously considered to meet the definition of a Medigap policy, will meet that definition as of January 1, 2006, when the prescription drug benefit takes effect, and new sales of these policies would be prohibited after that date.

c. Standards for the Disclosure Notice That Medicare Supplemental (Medigap) Issuers Are Required To Provide Current Policy Holders With Drug Coverage

i. General

We believe that the statute is quite clear about the choices that need to be made by beneficiaries who hold Medigap Rx policies. Therefore, we propose to establish standards for the disclosure notice in the form of a required notice that sets forth those choices. The proposed notice is set forth below.

ii. Timing and Content of the Disclosure Notice

The statute requires Medigap issuers to send a written disclosure notice to each individual who is a policyholder or certificate holder of a Medigap Rx policy at the most recent available address of that individual. The issuers must send the disclosure notice during the 60-day period immediately preceding the initial Medicare Part D enrollment period. The initial enrollment period (IEP) for Medicare Part D runs from November 15, 2005 through May 15, 2006. Accordingly, Medigap issuers must send the written disclosure notice between September 16, 2005 and November 15, 2005.

The written disclosure notice must inform the individual of his or her Medigap options if the individual does or does not enroll in Medicare Part D. These include the following:

- If the individual does enroll in Part D, he or she can keep the Medigap policy but the drug coverage must be eliminated.
- If the individual enrolls in a Medicare Part D Prescription Drug Plan (PDP) during the initial enrollment period (IEP), the individual also has the right to buy another Medigap plan, from the same issuer, that does not include drug coverage. The individual has a guaranteed right to buy Plan A, B, C, or F (including the high deductible Plan F) or one of the new Medigap benefit packages mandated by section 104(b) of the MMA (which are expected to be designated K and L), if these plans are offered by the issuer and available to new enrollees. The issuer may also offer other Medigap plans on a guaranteed issue basis.

If the individual does not enroll in Part D, he or she has the option of keeping the Medigap policy with drug coverage.

If the individual does not enroll in Part D during the IEP, the individual may continue enrollment in his or her current Medigap plan without change, but the individual will lose the right to buy another Medigap plan on a guaranteed issue basis. In addition, if the current Medigap plan does not provide creditable prescription drug coverage, there are limitations on the periods in a year in which the individual may enroll in Medicare Part D and any such enrollment may be subject to a late enrollment penalty (increased premium) if the current Medigap plan does not provide creditable prescription drug coverage. We also propose to require that the disclosure notice contain information on the potential impact of an individual's election on his or her Medigap premiums.

It is important to note that the disclosure requirement in section 104 of the MMA that applies to Medigap issuers is separate from the disclosure requirement contained in section 101 of the MMA (section 1860D-13 of the Act). The disclosure requirement in section 104 of the MMA applies exclusively to issuers of Medigap policies and contains very specific statutory criteria for the disclosure notice. The disclosure requirement in section 101 of the MMA applies to various forms of prescription drug coverage, including Medigap. See Subpart B.

The MMA requires that these entities, including Medigap issuers, disclose to

the Secretary, as well as to the Part D eligible individuals, whether the coverage they provide currently meets the actuarial equivalence requirement for creditable coverage. The entities must also notify the individuals if the coverage changes so that it no longer meets the actuarial equivalence requirement. Section 101 of the MMA directs the Secretary to establish procedures for the documentation of creditable prescription drug coverage by these entities. We are developing procedures for the disclosure requirements in section 101 of the MMA. In Subpart B of this proposed rule, we provide a discussion of the disclosure provisions in section 101 of the MMA.

iii. Medigap Policies as Creditable Coverage

Medigap issuers will be responsible for determining whether the drug coverage under their policies is creditable drug coverage in accordance with the final rule implementing the Part D drug benefit. However, The CMS actuaries have determined that, if the final Part D regulations were to reflect the definition of creditable prescription drug coverage in this proposed rule, drug coverage in standardized Medigap Plans H and I would not meet such a standard. Since actuarial equivalence can be demonstrated using a group's experience, it is possible to have a specific group for which the drug coverage in standardized Medigap Plan J would be creditable prescription drug coverage. However, based on the distributions of drug utilization that the actuaries have seen so far, they believe that drug coverage in standardized Medigap Plan J would be unlikely to meet the definition of creditable prescription drug coverage based on this proposed rule. We caution, however, that whether or not coverage is creditable cannot be determined until we have issued a final rule implementing the new Part D drug benefit.

iv. Required Disclosure Notice

The disclosure notice set forth below contains the basic language that would be required to be included in all disclosure notices sent by Medigap issuers. It also proposes specific language to be included for policies that do not provide creditable coverage. We propose to use the same basic model for policies that do provide creditable coverage, but we are not proposing exact language at this time. We are instead inviting comments on how the draft notice could be adapted for the types of policies that might provide creditable

coverage. As noted above, it is highly unlikely, though theoretically possible, that a standardized Plan J could be found to provide creditable coverage. In addition, some pre-standardized policies with drug coverage, as well as policies sold in any of the three "waiver" states of Massachusetts, Minnesota and Wisconsin might qualify. We would, however, note that we expect to require that the notice informing policyholders that they do have creditable coverage must advise them that they may be subject to late enrollment penalties under Part D if they eventually enroll in a Part D plan and have not maintained the creditable drug coverage they have under their Medigap policies.

In addition, we plan to work with the waiver States so that in the event the coverage offered in those States meets the definition of creditable coverage, there will be a required disclosure notice appropriate for use in those States. We are also soliciting comments on what to include in these potential model disclosure notices.

The following is a proposed disclosure notice for Medigap issuers to use for Medigap policies that do not have creditable drug coverage. As stated above, this group likely will include standardized Medigap Plans H, I, and J, as well as prestandardized Medigap plans, or plans sold in waiver states, that do not provide creditable drug coverage. The information shown in brackets represents text that may be modified by the Medigap issuer based on State law or the issuer's own policies. For example, if the Medigap issuer wishes to offer additional plans on a guaranteed issue basis if the individual enrolls in Medicare Part D during the IEP and wants to buy a Medigap plan without drug coverage, the issuer may tailor the required language to add that guaranteed issue offering.

This draft disclosure notice reflects consultation with the NAIC. We provided the NAIC with an earlier draft of the disclosure notice. After having an opportunity to review our disclosure notice, the NAIC's Senior Issues Task Force prepared its own version of the draft disclosure notice. We participated in lengthy discussions of these draft versions of the disclosure notice at NAIC meetings and during conference calls. The disclosure notice largely reflects the disclosure notice developed by the NAIC's Senior Issues Task Force. We have, however, made some changes to ensure that the draft fully complies with the statutory requirements and we will consult further with the NAIC.

The draft model disclosure notice text follows:

Important Notice to Medicare Supplement Policyholders Who Have Prescription Drug Benefits

You have a Medicare Supplement (Medigap) policy from [name of company] that includes an outpatient prescription drug benefit. Please read this entire notice about your Medigap policy and the new Medicare Prescription Drug Program (Medicare Part D). The coverage options that will be available to you under Part D beginning January 1, 2006 will provide greater value than your current coverage. It is important to know this because it will affect the important choices you have to make about your drug coverage.

You can enroll in the new Medicare Prescription Drug Program (Medicare Part D) from November 15, 2005 to May 15, 2006. Medicare Part D is voluntary; you can choose to enroll or not to enroll. There are two ways to enroll in Medicare Part D. If you want to stay in Original Medicare with a Medigap policy, you can enroll in a Prescription Drug Plan (PDP). Or you may choose to enroll in a Medicare Advantage (MA) plan that covers prescription drugs. If you enroll in a Medicare Advantage plan that covers prescription drugs, you will get all your Medicare benefits from that plan and you may get little benefit from a Medigap policy. Call 1-800-MEDICARE (1-800-633-4227) or visit www.medicare.gov on the web for more information about Medicare Advantage or Medicare Part D.

If You Do Not Enroll in Part D

If you decide not to enroll in the new Medicare Prescription Drug Program (Medicare Part D), you can keep your current Medigap policy without changes and you do not need to do anything in reply to this notice. However, because the outpatient prescription drug benefit in your policy is not equal in value to the Medicare Part D benefit, you should keep in mind that you will probably be charged higher Part D premiums if you want to enroll in Medicare Part D after May 15, 2006. Make sure you read the section called "If You Enroll in Medicare Part D After May 15, 2006."

If You Enroll in Part D By May 15, 2006

If you enroll in the new Medicare Prescription Drug Program (Medicare Part D) through a PDP on or before May 15, 2006 and you want to keep a Medigap policy, you have the following options:

You can keep your current Medigap policy, but Federal law requires us to remove the prescription drug coverage, and adjust your premium. [In your case, the new premium will be [issuer insert dollar amount of premium]]; If you choose this option, you must notify us promptly of the effective date of your Part D enrollment so that we can remove the drug coverage from your policy as of that date. [Insert options for notifying issuer]

or

You can cancel your existing policy and enroll in one of our other plans that does not contain outpatient prescription drug coverage [Plans A, B, C, F (including the high

deductible Plan F), and the plans likely to be designated K or L] [issuer insert plans from above list that you currently offer or any others you may want to offer], regardless of your health. [Descriptions of these plans and their current premiums are enclosed—OR—if you would like information about one or more of these plans, please contact us at 1-800-000-0000 or www.issuer.com.] [If you want a new Medigap policy, you must apply for it within 63 days of your enrollment in the new Medicare Prescription Drug Program (Medicare Part D)]. You must notify us promptly of the date your Part D enrollment will begin so that we can start your new policy without drug coverage as of that date.

If you enroll in Part D and you do not apply for a different Medigap policy, you can keep your current Medigap policy but the drug coverage will be removed from the policy, as described in Option #1.

If You Enroll in Medicare Part D After May 15, 2006

If you do not enroll in the Medicare Prescription Drug Program (Medicare Part D) during the initial Medicare Part D enrollment period, but want to do so after May 15, 2006, you need to know [three] things.

1. There are limitations on when you can enroll in Medicare Part D. Generally, you will only be able to enroll between November 15th and December 31st each year.

2. Because you will be enrolling after May 15, 2006, you will have to pay a higher monthly premium for Medicare Part D than if you enrolled by May 15, 2006, unless you have other coverage that qualifies you to enroll without a late enrollment penalty. You will pay this higher premium for as long as you have Part D coverage. Also, the longer you wait to join Part D, the higher your premium will be.

3. You may not be able to enroll in another Medigap policy with our company, as you could have if you had enrolled in Medicare Part D by May 15, 2006. You will be able to keep your current policy with the drug benefit removed.

If you enroll in Medicare Part D after May 15, 2006, please let us know as soon as possible. Federal law requires us to remove the prescription drug benefit from your Medigap policy and adjust your premium.

Effect on Premiums

In making your decision about what to do, please keep in mind that the law requires us to make changes to our plans. These changes, and the decisions that policyholders like you will make, will have an effect on future premiums. Please contact us so we can discuss the likely differences in premiums, depending on which choices you make now and how those premiums may change over time.

Assistance

If you need help understanding your choices, please contact us at 1-800-000-0000 or www.issuer.com for more information [insert issuer phone number and website address].

Your State Health Insurance Assistance Program (SHIP) can help you with information about your Medigap policy and

the new Medicare Prescription Drug Program (Medicare Part D). You can reach the SHIP Program [at insert SHIP number—OR by finding your State's Program number on the next page].

For more information about Medicare Part D, call 1-800-MEDICARE (1-800-633-4227). Information is also available at www.medicare.gov on the web.

III. Collection of Information Requirements

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

Below is a summary of the proposed information collection requirements outlined in this regulation. We are soliciting comment on these proposed requirements, before they are submitted to OMB for PRA approval.

Subpart A—General Provisions

Subpart A does not contain any requirements subject to the PRA.

Subpart B—Eligibility and Enrollment

Section 423.34 Enrollment process

(b) A Part D eligible individual seeking to enroll in a PDP must complete and submit the PDP's enrollment form to the PDP prior to enrollment.

The burden associated with this requirement is the time and effort necessary for an individual to submit the required enrollment application to a PDP sponsor. We estimate that it will take 30 minutes to complete and submit the required application to the PDP. During the first Part D initial enrollment period, it is estimated that 24 million individuals will complete and submit these applications. This estimate is based on preliminary estimates of the number of individuals who will enroll in PDPs in 2006. In 2007, and beyond,

the number of enrollments will be substantially less, since an individual will generally be limited to changing PDPs during the annual coordinated election period, therefore, it is estimated 6 million individuals may change their PDPs annually and that 2 million new beneficiaries will be making first time elections into PDPs.

(c) A PDP sponsor must provide each individual with prompt notice of acceptance or denial of the individual's enrollment request.

The burden associated with this requirement is the time and effort necessary for a PDP sponsor to disclose to an individual notice of acceptance or denial of the individual's enrollment request. Although we have no basis at this time for estimating either the number of regions or the number of participating plans, a rough estimate is that during the first Part D initial enrollment period a total of 24 million notices will be disclosed, affecting approximately 100 PDPs (based upon an estimate of 2 PDPs per 50 states, if each state were to be a region, or alternatively, 4 PDPs for each of 25 regions). Given that each PDP will be creating disclosure notices for mass mailings, we are proposing the following burden estimates. We estimate that it will take each PDP approximately 8 hours to produce each notice—either an acceptance or a denial notice must be provided. We further estimate that on average, it will take each PDP sponsor 1 minute to assemble and disseminate each notice. We further estimate that on average, it will take each sponsor 4,000 hours to disclose 240,000 notices during this first year. In 2007, and beyond, we estimate that 60,000 notices will be disclosed annually at 1,000 hours per sponsor. This assumption is based on that fact that once the notices have been standardized, a PDP sponsor will mass-produce and mail the required notices.

Section 423.36 Enrollment Periods

(c) An individual is eligible to enroll in a Part D plan, enroll in a PDP, or disenroll from a PDP and enroll in another PDP, if the individual demonstrates to CMS, in accordance with guidelines CMS issues, that the PDP sponsor offering the PDP substantially violated a material provision of its contract under this part that meets the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for an individual to submit the required materials to CMS demonstrating that a PDP substantially violated a material provision of its contract. Based on our experience with

the current Medicare+Choice program, we would expect that few, if any, individuals will avail themselves of this option. Generally, in those instances where CMS has found that an M+C organization has substantially violated a material provision of its contract, CMS has taken the necessary action on behalf of these individuals. Thus, we do not estimate any burden on individuals under this provision.

Section 423.42 Coordination of Enrollment and Disenrollment Through PDPs.

(a) An individual may enroll in, or disenroll from a PDP during the enrollment periods specified in § 423.36, by filing the appropriate enrollment form with the PDP sponsor or through other mechanisms CMS determines appropriate.

The burden associated with this is discussed above in §§ 423.34 and 423.36 of the PRA section.

(c) Each PDP sponsor must submit every disenrollment notice to CMS within timeframes CMS specifies. The PDP sponsor must also provide each enrollee with a notice of disenrollment and file and retain disenrollment requests for the period specified in CMS instructions.

The burden associated with these requirements is the time and effort necessary for a PDP sponsor to disclose the disenrollment notice to each enrollee and CMS, and file/retain disenrollment requests for the period specified in CMS instructions. We estimate that on an annual basis there will be approximately 24,000 disenrollments per PDP sponsor. Given that each sponsor will be creating a standardized disclosure notice for mass mailings, we are proposing the following burden estimates. We estimate that it will take each PDP sponsor approximately 8 hours to produce the standardized notice. We further estimate that on average, it will take each PDP sponsor 1 minute to disclose each notice and that on average each PDP sponsor will be required to disclose 24,000 notices on an annual basis for an annual burden of 400 hours. Once the notice has been disclosed to the enrollee the PDP sponsor will forward a copy of the notice to CMS on a batch basis. We estimate that it will require each PDP sponsor 52 hours on an annual basis to send the batch files of disenrollment notices to CMS on an annual basis. In

regard to the record retention requirement we estimate that it will require each of the PDP sponsors 52 hours on an annual basis to maintain the required documentation. While this estimate may appear low, we believe the

retention of the documentation will most likely be an automated process.

Section 423.44 Disenrollment by the PDP.

(c) If the disenrollment is for any of the reasons specified in paragraphs (b)(1), (b)(2)(i), or (b)(iv) of this section, the PDP sponsor must give the individual timely notice of the disenrollment, that meets the requirements set forth in this section, with an explanation of why the PDP is planning to disenroll the individual.

The burden associated with this requirement is the time and effort necessary for a PDP sponsor to disclose to an individual notice of disenrollment. We estimate that on an annual basis it will require a total of 576,100 notices, affecting each PDP sponsors to some degree, as described below. Given that each PDP sponsor will be creating disclosure notices for mass mailings, we are proposing the following burden estimates. We estimate that it will take each PDP sponsor approximately 8 hours to produce the standardized notice. We further estimate that on average, it will take each PDP 1 minute to disclose each notice. Burden estimates for these disenrollments are provided below.

(d) A PDP sponsor may disenroll an individual from the PDP for failure to pay any monthly premium if the PDP sponsor can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount.

The burden associated with this requirement is the time and effort necessary for a PDP sponsor to submit the required materials to CMS demonstrating that the PDP sponsor made reasonable efforts to collect the unpaid premium amount and the time and effort necessary for a PDP sponsor to disclose to an individual the notice of disenrollment. We estimate that it will take a PDP 5 minutes to submit the required documentation to CMS for each occurrence and that each of the PDP sponsors will be required to submit the necessary documentation to CMS 960 times on an annual basis. We estimate that on an annual basis 96,000 individuals will be disenrolled for failure to pay premiums, and it will take each PDP 1 minute to disclose each notice and that each PDP will be required to disclose 960 notices on an annual basis for a annual burden of 16 hours.

To disenroll an individual from its PDP, based on an individual's behavior, the PDP sponsor must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraphs (d)(2)(i) through (d)(2)(iii) of

this section and any extenuating circumstances.

The burden associated with this requirement is the time and effort necessary for a PDP to document and retain the documentation that meets the requirements set forth in this section. We estimate that it will take a PDP 3 hours to capture and retain the required documentation for each occurrence and that each PDP will have 1 occurrence on an annual basis.

The PDP sponsor must disenroll an individual when the individual no longer resides in the PDP's service area. We estimate that on an annual basis 240,000 individuals will be disenrolled for moving out of the service area, and it will take each PDP 1 minute to disclose each notice. It is estimated that each PDP will disclose 24,000 notices on an annual basis for a annual burden of 400 hours.

When a PDP contract terminates as provided in § 423.507 through 423.510 as the PDP sponsor must send a notice to the enrollee before the effective date of the plan termination or area reduction. The notice must provide an effective date of the plan termination and a description of alternatives for obtaining benefits under Part D.

The burden associated with this requirement is the time and effort necessary for a PDP sponsor to disclose to an individual the notice of disenrollment. We estimate that on an annual basis it will require a total of 240,000 notices, affecting approximately 10 PDPs. Given that each PDP will be creating disclosure notices for mass mailings, we are proposing the following burden estimates. We estimate that it will take each PDP sponsor approximately 8 hours to produce the standardized notice. We further estimate that on average, it will take each PDP 1 minute to disclose each notice and that each PDP will be required to disclose 24,000 notices on an annual basis for a annual burden of 400 hours.

Section 423.48 Information About Part D.

Each PDP and MA-PD plan must provide, on an annual basis, and in a format and using standard terminology that CMS may specify in guidance, the information necessary to enable CMS to provide to current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage.

The burden associated with this requirement is the time and effort necessary for a PDP to submit the required materials to CMS. We estimate that on an annual basis it will take 100

PDP sponsors 2 hours to submit the required documentation to CMS.

Section 423.50 Approval of Marketing Materials and Enrollment Forms

(a) 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 PDP sponsor must submit the its marketing materials and forms, as defined in paragraph (b) of this section, to CMS for review.

The burden associated with this requirement is the time and effort necessary for a PDP to submit the required materials to CMS. We estimate that on an annual basis it will take 100 PDP sponsors 2 hours to submit the required documentation to CMS.

Section 423.56 Procedures To Document Creditable Status of Prescription Drug Coverage

(b) Each entity or State that offers prescription drug coverage under any of the types described in § 423.4 must disclose, to all Part D eligible individuals whether such coverage meets the requirements of actuarial equivalence set forth in § 423.265.

The burden associated with this requirement is the time and effort necessary for each of these entities and States to disclose to an individual notice of coverage. We estimate that on an annual basis it will require a total of 5,800,000 notices, affecting slightly over 440,000 entities, including 440,000 employer and union-sponsored group health plans with Medicare-eligible workers, and fewer than 200 other entities including over 100 Medigap plans, State Pharmaceutical Assistance Programs, and a handful of State Pharmacy Plus programs. [Note: A discussion of the costs of the disclosure notices for public and private employer and union sponsored qualified prescription drug plans is in the impact analysis section on payments to sponsors of retiree prescription drug plans.] Given that each entity and State will be creating disclosure notices for mass mailings, we are proposing the following burden estimates. We estimate that it will take each entity or State approximately 8 hours to produce the standardized notice. We further estimate that on average, it will take each entity 1 minute to disclose each notice. It is estimated that the burden per entity will be as follows:

—On average, the 4 State Pharmacy Plus programs will provide 169,118 notices for an annual burden of 2819 hours (these notices are required in 2005 even though, as discussed elsewhere in this preamble, these States may

decide to lower their costs while maintaining equivalent benefits by replacing or reforming these programs).

—On average each of the 440,000 group health plans will provide 4.5 notices for an annual burden of .075 hours.

—On average each of the 20 State Pharmaceutical Assistance Programs will provide 60,000 notices for an annual burden of 1000 hours.

—On average each of an estimated 120 Medigap issuers will provide 15,833 notices for an annual burden of 264 hours.

(c) Each entity must disclose their creditable coverage status to CMS in a form and manner described by CMS.

The burden associated with this requirement is the time and effort necessary for each entity to submit the required creditable coverage status materials to CMS. We estimate that on an annual basis it will take each entity 1 hour to submit the required documentation to CMS.

Subpart C—Benefits and Beneficiary Protections.

(h) A PDP sponsor or an MA organization offering qualified prescription drug coverage is required to disclose to CMS data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers and passed through to beneficiaries, via pharmacies and other dispensers, in the form of lower subsidies, prices, and/or monthly beneficiary prescription drug premiums, in the manner and frequency specified by CMS.

The burden associated with this requirement is the time and effort necessary for PDP sponsor or an MA organization to disclose to CMS the aggregated negotiated price data on concessions to CMS. We estimate that on an annual basis it will take 100 PDPs and 350 organizations 10 hours to submit the required documentation to CMS for total annual burden of 4,500 hours.

Section 423.120 Access to Covered Part D Drugs

(b) A PDP sponsor or MA organization's formulary must be reviewed by a pharmacy and therapeutic committee that committee must maintain written documentation of its decisions regarding formulary development and revision.

The burden associated with this requirement is the time and effort necessary for a PDP or MA committee to document and retain the documentation that meets the requirements set forth in this section.

We estimate that it will take 100 PDPs and 350 providers PDP or MA entity 1 hour each to capture and retain the required documentation on an annual basis for total annual burden of 450 hours.

A PDP sponsor or MA organization offering an MA-PD plan must provide notice of at least 30 days to CMS, affected enrollees, authorized prescribers, pharmacies, and pharmacists prior to removing a covered Part D drug from its formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug.

The burden associated with this requirement is the time and effort necessary for an entity offering an MA-PD PDP plan to provide notice of at least 30 days to CMS, affected enrollees, authorized prescribers, pharmacies, and pharmacists of the removal of a covered Part D drug from its formulary.

Given that each entity will be creating disclosure notices for mass mailings, we are proposing the following burden estimates. We estimate that on an annual basis it will take each entity approximately 1 hour to produce the standardized notice. We further estimate that on average, it will take 100 PDP's and 350 MA organizations 40 hours to disclose the required notice for a total annual burden of 18,450 hours.

(c) A PDP sponsor or MA organization offering an MA-PD plan must issue and reissue, as necessary, a card or other type of technology to its enrollees to use to access negotiated prices for covered Part D drugs.

The burden associated with this requirement is the time and effort necessary for an entity to provide each enrollee a card. The burden associated with this requirement is reflected in section 423.128.

Section 423.128 Dissemination of Plan Information

(a) A PDP sponsor or MA organization offering an MA-PD plan must disclose its plans information as required by this section to each enrollee of a prescription drug plan offered by the sponsor under this part and to Part D eligible individuals.

The burden associated with this requirement is the time and effort necessary for a PDP sponsor or MA organization offering an MA-PD plan to disclose its plans information. We estimate that it will require 100 PDP sponsors and 350 MA organizations 80 hours on an annual basis to prepare the plan materials. We further estimate that on an annual basis, on average, it will require each entity 120 hours on an annual basis to disclose the required

materials to enrollees and eligible individuals for a total annual burden of 90,000 hours.

(e) A PDP sponsor or MA organization offering qualified prescription drug coverage must furnish to enrollees, an explanation of benefits when prescription drug benefits are provided under qualified prescription drug coverage that meets the requirements et forth in this section.

The burden associated with this requirement is the time and effort necessary for 100 PDP sponsors and 350 MA organizations offering an MA-PD plan must disclose an explanation of benefits when prescription drug benefits to enrollees. We estimate that it will require each entity 160 hours on an annual basis disseminate the required materials for total annual burden of 56,000 hours.

Subpart D—Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans

Section 423.153 Cost and Utilization Management, Quality Assurance, Medication Therapy Management Programs, and Programs To Control Fraud, Abuse, and Waste

(d) To become a PDP sponsor an applicant must disclose to CMS and others upon request, the amount of the management and dispensing fees and the portion paid for medication therapy management services to pharmacists.

The burden associated with this requirement is the time and effort necessary for an applicant to submit the required information to CMS upon request. We estimate that it will require 100 applicants, 30 minutes each to provide the required material to CMS for consideration for a total annual burden of 50 hours.

Section 423.168 Accreditation Organizations

(c) An accreditation organization approved by CMS must provide to CMS in written form and on a monthly basis all of the following required by this part.

Since CMS expects to contract with less than 10 organizations on an annual basis, this requirement is not subject to the PRA.

Section 423.171 Procedures for Approval of Accreditation as a Basis for Deeming Compliance

(a) A private, national accreditation organization applying for approval must furnish to CMS all of the information and materials set forth in this part.

Since CMS expects to less than 10 applicants on an annual basis, this requirement is not subject to the PRA.

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

Section 423.265 Submission of Bids and Related Information

(a) An applicant may submit a bid that meets the requirements set forth in this section, to become a PDP sponsor or to become an MA organization offering an MA-PD plan.

The burden associated with this requirement is the time and effort necessary for an entity to submit the required materials to CMS. We estimate we will receive 100 PDP and 350 MA applications on an annual basis and that it will require each entity 80 hours to submit the required documentation to CMS for total annual burden of 26,000 hours.

Subpart G—Payments to PDP Sponsors and MA-PD Plans for All Medicare Beneficiaries for Qualified Prescription Drug Coverage

Section 423.329 Determination of Payment

(b) PDP sponsors must submit data regarding drug claims to CMS that can be linked at the individual level to Part A and Part B data in a form and manner similar to the process provided under § 422.310 and other information as CMS determines necessary.

The burden associated with this requirement is the time and effort necessary for PDP sponsors submit the required claims data to CMS. We estimate that on an annual basis it will take 100 PDPs 52 hours to submit the required documentation to CMS for total annual burden of 5,200 hours.

Section 423.336 Risksharing Arrangements

(a) A PDP sponsor may submit a bid that requests a decrease in the applicable first or second threshold risk percentages or an increase in the percents applied under paragraph (b) of this section.

The burden associated with this requirement is the time and effort necessary for PDP sponsors submit the required bid materials to CMS. We estimate that on an annual basis it will take 10 PDPs 20 hours to submit the required documentation to CMS for total annual burden of 300 hours.

(c) Within 6 months of the end of a coverage year, the PDP sponsor or MA organization offering a MA-PD plan sponsor must provide to CMS the cost data requirements set forth in the paragraph.

The burden associated with this requirement is the time and effort

necessary for PDP sponsors submit the required cost data to CMS. We estimate that on an annual basis it will take 100 PDP sponsors and 350 MA organizations 10 hours to submit the required documentation to CMS for total annual burden of 45,000 hours.

Section 423.343 Retroactive Adjustments and Reconciliations

(c) Within 6 months after the end of a coverage year, the PDP sponsor or MA organization offering a MA-PD plan must provide CMS must provide to CMS the data requirements set forth in the paragraph.

The burden associated with this requirement is the time and effort necessary for PDP sponsors and MA organizations to submit the required data to CMS. We estimate that on an annual basis it will take 100 PDP sponsors and 350 MA organizations 10 hours to submit the required documentation to CMS for total annual burden of 4,500 hours.

(d) Within 6 months after the end of a coverage year, the PDP sponsor or MA organization offering a MA-PD plan must provide CMS the cost data requirements set forth in the paragraph.

The burden associated with this requirement is the time and effort necessary for PDP sponsors and MA organizations to submit the required cost data to CMS. We estimate that on an annual basis it will take 100 PDP sponsors and 350 MA organizations 10 hours to submit the required documentation to CMS for total annual burden of 4,500 hours.

Subpart I—Organization Compliance With State Law and Preemption by Federal Law

Section 423.410 Waiver of Certain Requirements To Expand Choice

(f) Under this section a prospective prescription drug plan (PDP) applicant may submit a waiver application to CMS to waive certain state licensure and fiscal solvency requirements in order to contract with CMS.

The burden associated with this requirement is the time and effort necessary for a PDP applicant to submit a waiver application that meets the requirements of this section. We estimate that on an annual basis it will take 100 applicants 10 hours to submit the required waiver documentation to CMS for total annual burden of 1000 hours.

Subpart J—Special Part D Rules for Organizations Offering MA Plans and Coordination under the Part D Program

Section 423.458 Application of Part D Rules to MA-PD plans on and After January 1, 2006

(c) Organizations offering or seeking to offer a Medicare Advantage-Prescription Drug plan may request from CMS in writing waiver or modification of those requirements under Part D of Medicare that are duplicative of, or that are in conflict with provisions otherwise applicable to the plan under Part C of Medicare.

The burden associated with this requirement is the time and effort necessary for an organization to submit the required waiver information to CMS for consideration. We estimate we will receive 10 waiver applicants, 20 hours to provide the required material to CMS for consideration for a total annual burden of 200 hours.

Section 423.462 Additional Part D Waiver Authority for Prescription Drug Plans

(a) Prescription drug plans may request, in writing, a waiver or modification of those requirements under Part D of Medicare that hinder the design of, the offering of, or the enrollment in, prescription drug plans under contracts between prescription drug plans and employers, labor organizations, or the trustees of funds established by one or more employers or labor organizations to furnish benefits to the entity's employees, former employees, or members or former members of labor organizations.

The burden associated with this requirement is the time and effort necessary for an organization to submit the required waiver information to CMS for consideration. We estimate we will receive 10 waiver applicants, 20 hours to provide the required material to CMS for consideration for a total annual burden of 200 hours.

Subpart K—Application Procedures and Contracts With PDP Sponsors

Section 423.502 Application Requirements

(b) In order to become a PDP sponsor, an entity, or an individual authorized to act for the entity (the applicant), must complete and submit a certified application in the form and manner required by CMS that meets the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for PDP sponsors and MA organizations to submit the required

application materials to CMS. We estimate that on an annual basis it will take 100 PDP sponsors and 350 MA organizations 10 hours to submit the required documentation to CMS for total annual burden of 4,500 hours.

Section 423.505 Contract Provisions

(d) The PDP sponsor agrees must maintain for 6 years books, records, documents, and other evidence of accounting procedures and practices that are sufficient to meet the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for PDP sponsors and MA organizations to maintain the required documentation outlined in this section. We estimate that on an annual basis it will take 100 PDP sponsors and 350 MA organizations 52 hours to maintain the required documentation on an annual basis, for total annual burden of 23,400 hours.

(f) The PDP sponsor must submit to CMS certified financial information that must include the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for PDP sponsors and MA organizations to submit the required certified data to CMS. We estimate that on an annual basis it will take 100 PDP sponsors and 350 MA organizations 8 hours to submit the required documentation to CMS for total annual burden of 3,600 hours.

(g) PDP sponsors must inform all related entities, contractors and subcontractors that payments they receive are, in whole or in part, from Federal funds.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary information to all related entities. We estimate that it will require each of the 100 PDP sponsors 8 hour on an annual basis to disclose the information for a total annual burden of 800 hours.

(j) As a condition for receiving a monthly payment under subpart G of this part, the PDP sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority must request payment under the contract on a document that certifies the accuracy, completeness, and truthfulness of all data related to payment, as stipulated in this section.

The burden associated with this requirement is the time and effort necessary for 100 PDP sponsors to submit the required certified document that meets all of the certification

requirements referenced in this section to CMS. We estimate that on an annual basis it will take 100 PDP sponsors 8 hours to submit the required documentation to CMS for total annual burden of 800 hours.

Section 423.507 Nonrenewal of Contract

(a) If a PDP sponsor does not intend to renew its contract, it must notify CMS in writing by the first Monday of June in the year in which the contract ends and notify, in a manner that meets the requirements of this section, each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective.

The burden associated with this requirement is the time and effort necessary for a PDP sponsor to submit a notice of nonrenewal to CMS. We estimate that on an annual basis it will take 10 PDP sponsors 1 hour to submit the required documentation to CMS for total annual burden of 10 hours.

Section 423.508 Modification or Termination of Contract by Mutual Consent

(b) If the contract is terminated by mutual consent, the PDP sponsor must provide notice to its Medicare enrollees and the general public as provided in paragraph (c) of this section.

Based on our experience with the M+C program CMS does not anticipate that more than 9 of these terminations will occur on an annual basis.

Section 423.509 Termination of Contract by CMS

(b) If CMS notifies the PDP sponsor in writing 90 days before the intended date of their termination the PDP sponsor must notify its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination.

The PDP sponsor must also notify the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the PDP sponsor's service area.

Based on our experience with the M+C program CMS does not anticipate that more than 9 of these terminations will occur on an annual basis.

Section 423.510 Termination of Contract by the PDP Sponsor

(a) If a PDP sponsor terminates its contract because CMS fails to substantially carry out the terms of the contract the PDP sponsor must give advance notice to CMS, its Medicare

enrollees, and the general public in a manner that meets the requirements set forth in the section.

Based on our experience with the M+C program CMS does not anticipate that more than 9 of these terminations will occur on an annual basis.

Section 423.514 Reporting Requirements

(b) Each PDP sponsor must report to CMS or other Federal agencies, on an annual basis the information necessary to meet the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for 100 PDP sponsors to submit the required document that meets all of the requirements referenced in this section to CMS or other federal agencies. We estimate that on an annual basis it will take 100 PDP sponsors 40 hours to submit the required documentation, for total annual burden of 4,000 hours.

(f) Each PDP sponsor must make the information reported to CMS under this section available to its enrollees upon reasonable request.

The burden associated with this requirement is the time and effort necessary for PDP sponsors to disclose the required materials that meet all of the requirements referenced in this section to the public upon request. We estimate that on an annual basis it will take 100 PDP sponsors 20 hours to submit the required documentation, for total annual burden of 2,000 hours.

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

Section 423.551 General Provisions

Paragraph (c) states that a PDP sponsor that has a Medicare contract in effect under § 423.502 of this part and is considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. The PDP sponsor must also provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

The burden associated with this requirement is the time and effort of the PDP sponsor considering or negotiating a change in ownership, to notify CMS and provide the information specified in this section. While this requirement is subject to the PRA, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.4.

Section 423.552 Novation Agreement Requirements

Paragraph (a) discusses the conditions for CMS approval of a novation agreement. This paragraph requires the PDP sponsor to notify CMS at least 60 days before the date of the proposed change of ownership and requires them to provide CMS with updated financial information and a discussion of the financial solvency impact of the change of ownership on the surviving organization.

The burden associated with this requirement is discussed above in § 423.551 of the PRA section.

This paragraph also requires the PDP sponsor to submit to CMS, at least 30 days before the proposed change of ownership date, 3 signed copies of the novation agreement containing the provisions specified in this section, and 1 copy of other relevant documents required by CMS.

The burden associated with this requirement is time and effort of the PDP sponsor to provide CMS with the required documentation. While this requirement is subject to the PRA, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.4.

Subpart M—Grievances, Coverage Determinations, and Appeals

Section 423.562 General Provisions

Paragraph (a). A PDP sponsor must ensure that all enrollees receive written information about the Grievance and appeal procedures that are available to them through the PDP sponsor and that meet the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 PDP sponsors 8 hours on an annual basis to disclose the information for a total annual burden of 800 hours.

Section 423.564 Grievance Procedures

Paragraph (e). The PDP sponsor must maintain records on all grievances received both orally and in writing, including, at a minimum, the date of receipt, final disposition of the grievance, and the date that the PDP sponsor notified the enrollee of the disposition.

The burden associated with this requirement is the time and effort necessary for PDP sponsors to maintain the required documentation outlined in this section. We estimate that on an

annual basis it will take 100 PDP sponsors 52 hours to maintain the required documentation on an annual basis, for total annual burden of 5,200 hours.

Section 423.568 Standard Timeframe and Notice Requirements for Coverage Determinations

Paragraph (a). When a party makes a request for a drug benefit, the PDP sponsor must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after receipt of the request.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 PDP sponsors 8 hours on an annual basis to disclose the information for a total annual burden of 800 hours.

If the PDP sponsor extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the sponsor's decision to invoke an extension.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 PDP sponsors 4 hours on an annual basis to disclose the information for a total annual burden of 400 hours.

Paragraph (b). If a PDP sponsor decides to deny a drug benefit, in whole or in part, it must give the enrollee written notice of the determination.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 PDP sponsors 4 hours on an annual basis to disclose the information for a total annual burden of 400 hours.

Section 423.570 Expediting Certain Coverage Determinations

Paragraph (c). The PDP sponsor must document all oral requests in writing and maintain the documentation in the case file.

The burden associated with this requirement is the time and effort necessary for PDP sponsors to maintain the required documentation outlined in this section. We estimate that on an annual basis it will take 100 PDP sponsors 26 hours to maintain the required documentation on an annual

basis, for total annual burden of 2,600 hours.

Paragraph (d). If a PDP sponsor denies a request for expedited determination, it must give the enrollee prompt oral notice of the denial and subsequently deliver, within 3 calendar days, a written letter that explains the notice requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 PDP sponsors 4 hours on an annual basis to disclose the information for a total annual burden of 400 hours.

Section 423.572 Timeframes and Notice Requirements for Expedited Coverage Determinations

Paragraph (a). Except as provided in paragraph (b) of this section, a PDP sponsor that approves a request for expedited determination must make its determination and notify the enrollee (and the prescribing physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary information to an enrollee and prescribing physician involved. We estimate that it will require each of the 100 PDP sponsors 4 hours on an annual basis to disclose the information for a total annual burden of 400 hours.

(b) When the PDP sponsor extends the deadline, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the sponsor's decision to invoke an extension.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 PDP sponsors 4 hours on an annual basis to disclose the information for a total annual burden of 400 hours.

(c) If the PDP sponsor first notifies an enrollee of an adverse expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary

information to an enrollee. We estimate that it will require each of the 100 PDP sponsors 4 hours on an annual basis to disclose the information for a total annual burden of 400 hours.

§ 423.578 Exceptions process.

Paragraph (a). An enrollee, the enrollee's authorized representative, or the enrollee's prescribing physician may file a request for an exception.

The burden associated with this requirement is the time and effort necessary for an individual to submit a request for exception. We estimate it will require an individual 30 minutes to provide the request and that each of the 100 PDP sponsors will receive 20 requests on an annual basis. Therefore, we estimate a total annual burden of 1000 hours.

Paragraph (b). An enrollee, the enrollee's authorized representative, or the prescribing physician (on behalf of the enrollee) may file an exception request.

The burden associated with this requirement is the time and effort necessary for an individual to submit a request for exception. We estimate it will require an individual 30 minutes to provide the request and that each of the 100 PDP sponsors will receive 20 requests on an annual basis. Therefore, we estimate a total annual burden of 1000 hours.

A PDP sponsor may require a written certification from the enrollee's prescribing physician that the requested prescription drug is medically necessary to treat the enrollee's disease or medical condition.

The burden associated with this requirement is the time and effort necessary for a prescribing physician to submit the required documentation to the PDP sponsor. We estimate it will require a prescribing physician 30 minutes to provide the request and that each of the 100 PDP sponsors will make 10 requests on an annual basis. Therefore, we estimate a total annual burden of 500 hours.

Section 423.582 Request for a Standard Redetermination

Paragraph (a) An enrollee must ask for a redetermination by making an oral or written request with a PDP sponsor that made the coverage determination or a SSA office.

The burden associated with this requirement is the time and effort necessary for an individual to submit a request for redetermination. We estimate it will require an individual 30 minutes to provide the request and that each of the 100 PDP sponsors will receive 20 requests on an annual basis.

Therefore, we estimate a total annual burden of 1000 hours.

(c) If the 60-day period in which to file a request for a redetermination has expired, an enrollee may file a request for redetermination and extension of time frame with the PDP sponsor.

The burden associated with this requirement is the time and effort necessary for an individual to submit a request for extension of redetermination. We estimate it will require an individual 15 minutes to provide the request and that each of the 100 PDP sponsors will receive 10 requests on an annual basis. Therefore, we estimate a total annual burden of 250 hours.

Paragraph (d) The person who files a request for redetermination may withdraw it by filing a written request for withdrawal at one of the places listed in paragraph (a) of this section.

The burden associated with this requirement is the time and effort necessary for an individual to submit a withdraw request. We estimate it will require an individual 15 minutes to provide the request and that each of the 100 PDP sponsors will receive 10 requests on an annual basis. Therefore, we estimate a total annual burden of 250 hours.

Section 423.584 Expediting Certain Redeterminations

Paragraph (c) The PDP sponsor must document all oral requests in writing, and maintain the documentation in the case file.

The burden associated with this requirement is the time and effort necessary for PDP sponsors to maintain the required documentation outlined in this section. We estimate that on an annual basis it will take 100 PDP sponsors 8 hours to maintain the required documentation on an annual basis, for total annual burden of 800 hours.

(d) If a PDP sponsor denies a request for expedited redetermination, it must give the enrollee prompt oral notice, and subsequently deliver, within 3 calendar days, a written letter that explains the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 PDP sponsors 2 hours on an annual basis to disclose the information for a total annual burden of 200 hours.

Section 423.590 Timeframes and Responsibility for Making Redeterminations

Paragraph (a) When the PDP sponsor extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the PDP sponsor's decision to invoke an extension.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 PDP sponsors 2 hours on an annual basis to disclose the information for a total annual burden of 200 hours.

(d) The PDP sponsor must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension.

The burden associated with this requirement is the time and effort necessary for each of the 100 PDP sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 PDP sponsors 2 hours on an annual basis to disclose the information for a total annual burden of 200 hours.

Subpart N—Medicare Contract Determinations and Appeals

This Subpart deals with Contract Determinations and Appeals; therefore, the information collection requirements referenced in this Subpart are exempt from the PRA in accordance with 5 CFR 1320.4(a)(2) during the conduct of an administrative action, investigation, and/or audit.

Subpart O—Intermediate Sanctions

Section 423.756 Procedures for Imposing Sanctions

(a) Before imposing the intermediate sanctions specified in this section, CMS will allow the PDP sponsor to provide evidence that it has not committed an act or failed to comply with the requirements as described. In addition, CMS may allow additional time for the PDP sponsor to provide the evidence if the PDP sponsor sends a written request providing a credible explanation of why additional time is necessary.

These information collection requirements are exempt from the PRA in accordance with 5 CFR 1320.4(a)(2) during the conduct of an administrative action, investigation, and/or audit.

Subpart P—Premiums and Cost-Sharing Subsidies for Low-Income Individuals

Section 423.774 Eligibility Determinations, Redeterminations and Applications

Paragraph (d) of this section discusses the application requirements for individuals applying for low-income subsidy. This paragraph states that individuals applying for low-income subsidy, or a personal representative applying on the individual's behalf, must complete all required elements of the application, provide any statements from financial institutions, as requested, to support information in the application, and certify, as to the accuracy of the information provided on the application form.

The burden associated with this requirement is the time and effort for the individual or personal representative applying on the individual's behalf, to complete the low-income subsidy application, provide financial statements as requested and to certify that the information provided is accurate. These collection requirements are subject to the PRA; however, the burden associated with these requirements is currently approved under OMB# 0938-0467 with a current expiration date of October 31, 2005. We will revise this currently approved PRA package to incorporate the burden being imposed on new enrollees. We estimate that this requirement will impose a burden on 4.5 new enrollees for a total additional burden of 750,000 hours annually (4.5×10 minutes).

Section 423.800 Administration of Subsidy Program

Paragraph (b) of this section requires the PDP sponsor offering the PDP, or the MA organization offering the MA-PD plan, to reduce the individual's premiums and cost-sharing as applicable and provide information to CMS on the amount of such reductions, in a manner determined by CMS. This paragraph also requires the PDP sponsor and MD-PD organization to maintain documentation to track the application of the low-income cost-sharing subsidies to be applied to the out-of-pocket threshold.

The burden associated with these requirements is the time and effort for the PDP sponsor or the MA organization to provide information to CMS and to maintain documentation. We estimate that it will take each of the 100 PDP sponsors and each of the 350 MA organizations approximately 52 hours on an annual basis to provide the information to CMS. We also estimate

that it will take approximately 26 hours for each entity to maintain the information for tracking purposes. Therefore, we estimate that it will take approximately 35,100 total hours annually to comply with these requirements.

Subpart Q—Guaranteeing Access to a Choice of Coverage

Section 423.859 Assuring Access to a Choice of Coverage

(c) states that CMS may waive or modify the requirements of this part if an entity seeking to become a prescription drug plan in a State other than the 50 States or the District of Columbia requests waiver or modification of any Part D in order to provide qualified prescription drug coverage in a State other than the 50 States or the District of Columbia.

The burden associated with this requirement is the time and effort for the PDP to make a request of waiver or modification to CMS. We estimate that approximately 2 PDPs will request a waiver or modification on an annual basis. Since this requirement affects less than 10, it is exempt from the PRA in accordance with 5 CFR 1320.3.

Section 423.863 Submission and Approval of Bids

Paragraph (a) discusses the process CMS uses for the solicitation and approval of bids. CMS solicits bids from eligible fallback entities for the offering in all fallback service areas in one or more PDP regions of a fallback prescription drug plan. CMS specifies the form and manner in which fallback bids are submitted in separate guidance to bidders.

The burden associated with this requirement is the time and effort for the fallback entities to prepare and submit a bid.

We estimate as an upper limit that approximately 20 fallback entities will submit a bid every three years. We also estimate that it will take each fallback entity approximately 80 hours to complete and submit the bid to CMS. Therefore, we estimate it will take a total of $(5 * 80) / 3 = 133.33$ hours on an annual basis to comply with this requirement.

Paragraph (b) discusses the procedures CMS uses to enter into contracts. CMS solicits bids from eligible fallback entities and uses competitive procedures to enter into contracts.

The burden associated with this requirement is the time and effort for the fallback entities to enter into a contract with CMS.

We estimate, again as an upper limit, that approximately 5 fallback entities will enter into a contract with CMS on an annual basis. Since this requirement affects less than 10, it is exempt from the PRA in accordance with 5 CFR 1320.4.

Section 423.871 Contract Terms and Conditions

Paragraph (f) states that each contract for a fallback prescription drug plan requires an eligible fallback entity offering a fallback prescription drug plan to provide CMS with the information CMS determines is necessary to carry out the requirements of this section.

The burden associated with this requirement is the time required of the fallback prescription drug plan to provide CMS with the information CMS determines necessary. We estimate that approximately 5 fallback prescription drug plans will enter into a contract with CMS. Since this requirement affects less than 10, it is exempt from the PRA in accordance with 5 CFR 1320.4.

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

Section 423.884 Requirements for Qualified Retiree Prescription Drug Plans

(a) and (b) In order to qualify for the retiree drug subsidy, the employer or union sponsor shall file an annual application with CMS for each qualified prescription drug plan maintained, including an attestation as to actuarial value. For convenience, these applications may be packaged together.

The burden associated with this requirement is the time and effort necessary for an entity to submit the application to CMS. The requirements of this part state that an application must provide sponsor and plan identification information, together with an actuarially-certified attestation that the actuarial value of the prescription drug coverage in each such plan is at least equal to the actuarial value of standard Medicare Part D prescription drug coverage in accordance with actuarial guidelines established by CMS in accordance with generally accepted actuarial principles. If there is a change during the year that materially affects the actuarial value of their drug coverage, sponsors will need to submit an updated attestation. Sponsors will also be required to collect identifying information on their qualifying covered retirees.

For each entity we estimate an average of 2 hours administrative work

to assemble the application, 31 hours for systems changes to extract identifying information on qualifying covered retirees and about 17 hours for preparation of the actuarial attestations, for a total of approximately 50 hours, for each prescription drug plan. The 17-hour estimate for preparation of actuarial attestations is a weighted average. See the economic impact section of this proposed regulation for the analysis pertaining to the range of time needed for sponsors of various sizes and numbers of plans.

For the number of entities applying for the subsidy, we have used 50,000, our estimate of the total number of public, private, and union sponsors projected to offer retiree prescription drug coverage in 2005. We have estimated on the basis of this figure in order to calculate the highest potential burden.

The total burden for preparation and filing of the 2005 applications for 50,000 sponsors is 2,500,000 hours. We also estimate that 5 percent of the initial applications may have to be refiled due to mid-year changes to drug coverage that materially affect actuarial value. We estimate 125,000 hours for this activity.

If CMS determines that a sponsor of a retiree prescription drug program meets all of the requirements of this section, it will send to the sponsor a written notice of that determination along with two copies of the sponsor agreement outlining the conditions for obtaining a subsidy payment. If the sponsor wishes to participate in the subsidy program, it must return both copies of the agreement, signed by an authorized representative, to CMS.

The burden associated with this requirement is the time and effort necessary for an entity to submit the required signed agreements to CMS. We estimate that on an annual basis it will take 50,000 entities 30 minutes to submit the required agreements to CMS, for a total of 25,000 hours.

(c) Each entity must disclose the creditable coverage status for each prescription drug plan to CMS in a form and manner described by CMS. We estimate this activity to take about 1 hour each for a total of approximately 50,000 hours.

In addition, each entity must notify each Part D eligible individual of the plan's creditable coverage status in a form and manner prescribed by CMS. The burden associated with the sponsor notices is required by § 423.56 of the proposed regulation, as discussed earlier in this analysis.

For the sponsors of retiree drug coverage, we estimate that it will take 50,000 entities approximately 8 hours

each to produce a standardized notice for a total of 400,000 burden hours.

Given that each entity will be creating disclosure notices for mass mailings, we are proposing the following burden estimates. We estimate that it will take each of them 4 hours to disclose, on average, 240 (rounded) notices (or 1 minute per notice), for a total burden of 200,000 hours. This estimate is based on that assumption that once the notices have been standardized, each entity will mass-produce and mail the required notices.

If an individual establishes to CMS that he or she was not adequately informed that he or she no longer had creditable prescription drug coverage or the coverage is involuntarily reduced, the individual may apply to CMS to have the coverage treated as creditable coverage so as to not be subject to the late enrollment fee described in § 423.46. The burden associated with this requirement is the time and effort necessary for an individual to apply to CMS to have such coverage treated as creditable coverage. While we have no way of determining how many individuals will apply to CMS, for the purpose of providing an upper bound estimate for public comment we estimate that on an annual basis it will take 100,000 individuals 15 minutes to apply to CMS, for a total of 25,000 hours.

(d) The employer or union sponsor of the plan must maintain the records outlined in this section for 6 years after the expiration of the plan year in which the costs were incurred.

The burden associated with this requirement is the time and effort necessary for an entity to maintain the required documentation for six years. We estimate that on an annual basis it will take 50,000 entities 20 hours to retain the required documentation, for a total of 1,000,000 burden hours.

Section 423.890 Appeals

The information collection requirements set forth in this section are exempt from the PRA as stipulated in 5 CFR 1320.4.

Section 423.892 Change in Ownership

A sponsor who is contemplating or negotiating a change of ownership must notify CMS. We estimate that approximately 5 percent of sponsors will fall into this category in a given year.

The burden associated with this requirement is the time and effort necessary for a sponsoring entity to submit the required notification to CMS. On an annual basis it will take 2,500 entities (5 percent of 50,000) about 30

minutes to submit the required notification to CMS, for a total of approximately 1,250 burden hours.

Subpart S—Special Rules for States—Eligibility Determinations for Subsidies and General Payment Provisions

Section 423.904 Eligibility Determinations for Low-Income Subsidies

Paragraph (b) of this section states the State agency must inform CMS of cases where eligibility is established or redetermined.

The burden associated with the requirement on State agencies to inform CMS of cases where eligibility is established or redetermined is estimated to total approximately 11,220 annual hours. We estimate that there will be approximately 600,000 of these cases on an annual basis. We also estimate that it will take approximately 10 hours per month for the State agency to inform CMS of these cases.

Paragraph (d) of this section requires States to make available—low-income subsidy application forms, information on the nature of, and eligibility requirements for the subsidies under this section, and offer assistance with the completion of the application forms. States must require an individual or personal representative applying for the low-income subsidy to complete all required elements, provide documents as necessary, and certify as to the accuracy of the information provided. In addition, States must provide CMS with other information as specified by CMS that may be needed to carry out the requirements of the Part D prescription drug benefit.

The burden associated with the requirement on States to make available the information specified in this section is subject to the PRA; however, we believe the burden for this requirement to be a reasonable and customary business practice; therefore, imposes no additional burden on the States.

The burden associated with the requirement on States to require the applicant of the low-income subsidy to complete all required elements, to provide documents, and to certify as to the accuracy of the information is subject to the PRA; however, the burden associated with this requirement is discussed in § 423.774 above.

The burden associated with the requirement on States to provide CMS with other information as specified by CMS is estimated to total approximately 1,020 annual hours. Since it is difficult to determine at this time the volume of information CMS will request, we are estimating that it will take on average 20

hours per State on an annual basis to provide CMS with the specified information.

Section 423.907 Treatment of Territories

Paragraph (a) of this section discusses the requirements on territories to submit plans for approval by the Secretary to receive increased grants. This paragraph states that a territory may submit a plan to the Secretary under which medical assistance is to be provided to low-income individuals for the provision of covered Part D drugs. Paragraph (b) of this section describes what a plan must include.

The burden associated with this requirement is the time and effort of territories to prepare and submit a plan for approval. While this requirement is subject to the PRA, we estimate that this requirement would affect only 5 territories; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.4.

Section 423.908 Phased-Down State Contribution to Drug Benefit Costs Assumed by Medicare

Paragraph (d) of this section discusses the requirements on States to submit MSIS data. This paragraph requires States to provide accurate and complete coding to identify the numbers and types of Medicaid and Medicare dual eligibles in their MSIS data submissions.

The burden associated with the requirement on States to provide accurate and complete coding in their MSIS data submissions is subject to the PRA; however, this requirement is already approved under OMB #0938-0502 with a current expiration date of January 31, 2006.

Paragraph (e) of section requires States to submit an electronic file, in a manner specified by the Secretary, identifying each full benefit dual eligible enrolled in the State for each month with Part D drug coverage who is also determined to be full benefit eligible by the State for full Medicaid benefits.

The burden associated with the requirement on States to submit an electronic file identifying each full benefit dual eligible enrolled in the State for each month with Part D drug coverage is estimated to total approximately 120 hours per State on an annual basis. We estimate that it will take approximately 10 hours for each State to submit an electronic file on a monthly basis. Therefore, we estimate a total burden of 6,120 hours on an annual basis. Startup development effort is estimated at 100 hours per State for a total of 5,100 hours.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Attn: John Burke (CMS-4068-P), Room C5-13-28, 7500 Security Boulevard, Baltimore, MD 21244-1850;

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Christopher Martin, CMS Desk Officer (CMS-4068-P), christopher_martin@omb.eop.gov. Fax (202) 395-6974.

IV. Regulatory Impact Statement

A. Overall Impact

[If you choose to comment on issues in this section, please include the caption "Impact Analysis" at the beginning of your comments.]

We have examined the impacts of this proposed rulemaking under Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 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 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 impact and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any one year). Our estimate is that this rulemaking is "economically significant" as measured by the \$100 million standard, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a regulatory impact analysis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amends Title XVIII of the Social Security Act (the Act) to create a voluntary prescription drug benefit within the Medicare program beginning in 2006. The Medicare prescription drug benefit will make prescription drugs more affordable for beneficiaries by offering subsidized Medicare

prescription drug coverage to all beneficiaries, with even more generous assistance available to low-income beneficiaries. We believe that this is an important step in modernizing the Medicare program to better meet beneficiaries' needs. We anticipate that by giving beneficiaries access to affordable insurance coverage that helps them to pay for their outpatient prescription drugs—which have become a critical component in the delivery of comprehensive, quality health care services—the Medicare prescription drug benefit will help beneficiaries to lead healthier, more productive lives, while also helping to improve the effectiveness of the Medicare program.

The MMA also authorizes Medicare to make retiree drug subsidy payments to employers and unions that provide qualified retiree prescription drug coverage to beneficiaries who do not enroll in a Part D plan. This alternative retiree drug subsidy provides special tax-favored payments to the qualified retiree health plans. The retiree drug subsidy program has highly flexible rules that permit employers and unions to continue providing drug coverage to their Medicare-eligible retirees while retaining their current plan designs that are at least equivalent to the standard Part D benefit and using the drug subsidy to reduce the cost of providing generous coverage.

With the trend toward declining retiree health insurance coverage that has occurred over the past decade, the Medicare alternative retiree drug subsidy is intended to "help employers [to] retain and enhance their prescription drug coverage so that the current erosion in coverage would plateau or even improve" (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Report, p. 53).

Medicare Part D also offers employers a variety of other options for continuing to assist their Medicare retirees. They can also choose to provide enhanced drug coverage to their Medicare-eligible retirees through or in coordination with Part D by encouraging their Medicare-eligible retirees to enroll in Part D (with Medicare subsidizing the costs of their standard Part D benefits), and providing enhanced coverage over and above the standard Part D benefit. This can be achieved by either providing separate supplemental drug coverage that wraps around a Part D plan (similar to policies that wrap around Medicare benefits under Part A and Part B), arranging for a Part D plan (that is, a prescription drug plan (PDP) or Medicare Advantage Prescription Drug Plan (MA-PD)) to provide enhanced benefits to their

retirees, or choosing to become a Part D plan that offers enhanced benefits to their retirees. In all of these cases, financial support from the new Medicare drug subsidy can augment contributions by employers to provide a more generous and less costly drug benefit for retirees than is possible through employer support alone.

We believe that the implementation of Medicare Part D, including the Medicare retiree drug subsidy and the other opportunities it affords employers for providing continued prescription drug assistance to their Medicare retirees, will result in combined aggregate payments by employers and Medicare for drug coverage on behalf of retirees generally being greater—and frequently significantly greater—than they otherwise would have been without the enactment of the MMA. Furthermore, the Medicare prescription drug benefit and retiree drug subsidy represent a particularly important strengthening of health care coverage for future Medicare-eligible retirees, given the erosion in the availability and generosity of employer-sponsored retiree coverage for future Medicare beneficiaries that has already been taking place, as is discussed in further detail subsequently in this impact analysis.

We estimate that in calendar year (CY) 2006 about 41 million Medicare beneficiaries will receive drug coverage either through a Medicare Part D plan (that is, by enrolling in a PDP or MA-PD), including beneficiaries who receive supplemental premium subsidies and enhanced drug coverage as a new retiree benefit, or through an employer or union sponsored retiree plan that is sufficiently generous to qualify for the Medicare retiree drug subsidy. By CY 2010, due to growth in the overall Medicare population, we estimate that nearly 45 million Medicare beneficiaries will be receiving such coverage.

The Medicare drug benefit, including the retiree drug subsidy, will lead to an increase in Federal spending on Medicare benefits and a decrease in Federal spending on Medicaid benefits (as dual eligibles' drug coverage is shifted from Medicaid to Medicare). The net effect of these changes on Federal outlays is estimated to be \$48 billion in CY 2006 and \$67 billion in CY 2010, with the total effect estimated to be \$287 billion over the period from CY 2006–2010. The vast majority of this Federal spending is on Medicare subsidies that defray the cost of the Medicare drug benefit for beneficiaries, that provide substantial additional cost-sharing and premium assistance to low-income beneficiaries, and that make it more

affordable for employers to continue to provide and support high quality retiree drug coverage. We also anticipate that States will save money due to the Medicare drug benefit, as responsibility for drug coverage for full-benefit dual eligibles is shifted from Medicaid to Medicare and as State spending on State prescription drug assistance programs is likely to be at least partly displaced by the Medicare drug benefit. We also estimate that many more eligible low-income beneficiaries will take up Medicaid and other low-income benefits, in addition to the comprehensive Medicare drug benefit, as a result of the additional value of the drug benefit and unprecedented beneficiary outreach activities. Taking all of these considerations together, we estimate that the Medicare drug benefit will lead to net State budgetary savings of about \$500 million in CY 2006 and \$3.0 billion in CY 2010, with total net savings of about \$8.2 billion over the period from CY 2006–2010.

As discussed in more detail in section L of the impact analysis, from both an economic and budgetary accounting perspective, Federal spending on the Medicare drug benefit largely represents transfers of Federal budget revenue from taxpayers to Medicare beneficiaries and retiree plans sponsored by private and public sector employers and unions. Also, from an economic perspective, there is effectively a transfer of Federal budget revenues from taxpayers to State governments, as Medicare pays for some of the costs of drug coverage for full-benefit dual eligibles that had been previously paid for by States and as the Medicare drug benefit displaces some State spending on prescription drug assistance programs. In addition, a portion of the Federal spending on Medicare Part D is for administrative costs incurred by PDPs and MA-PDs to administer the benefit.

B. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a proposed rule (and subsequent final rule) that includes any Federal mandate that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. We anticipate that this rule would not impose costs above the \$110 million UMRA threshold on State, local, or tribal governments. With the exception of the electronic prescribing provisions (for which we are unable to develop a cost estimate because standards are still to be developed), we

have determined that this rule would not impose costs on the private sector exceeding \$110 million.

1. Private Sector

There are two provisions of the MMA that are reflected in this notice of proposed rulemaking that represent mandates on the private sector as defined by the UMRA: Provisions related to disclosure notices of creditable coverage and electronic prescribing.

As discussed elsewhere in this document, certain private sector entities—Medigap plans and private sector employer or union sponsored health plans that provide drug coverage to Medicare beneficiaries who are retired or who are active workers—are required to provide at certain times disclosure notices on whether the coverage provided equals or exceeds the actuarial value of defined standard Part D coverage. Later in the impact analysis we provide a discussion of the costs expected to be borne in providing such notices, including the costs associated with performing the actuarial valuation of the drug benefits. The largest cost for providing these notices is expected to occur in the months preceding the implementation of the drug benefit in January 2006 when the largest volume of notices need to be provided. Following receipt of these notices, beneficiaries will be making choices regarding where they receive their drug coverage.

For private sector employers that provide retiree drug coverage, the implementation of Medicare Part D, including the Medicare retiree drug subsidy program, is expected to produce net savings that far exceed the costs of the disclosure notices. This is true both for employers that choose to obtain the retiree drug subsidy, and for employers and unions that decide to restructure their prescription drug coverage to provide continued assistance by paying Medicare Part D premiums and/or supplementing the Medicare prescription drug benefit.

For those private entities that will not achieve savings—Medigap insurers and group health plans that offer coverage only to beneficiaries who are active workers, not retirees—the cost of providing disclosure notices is estimated to be approximately \$69 million in 2005 (which translates into an average of roughly \$154 per employer that offers drug coverage to Medicare beneficiaries who are active workers and about \$11,050 per Medigap insurer). Thus, the costs associated with the notice requirements are not

expected to reach the \$110 million UMRA threshold.

Another private sector mandate in the MMA is that no later than April 1, 2009, prescriptions for covered Part D drugs for Medicare beneficiaries that are transmitted electronically will have to comply with certain standards. The proposed rule describes the process that will be used to develop these standards, but the actual standards are not yet specified. Moreover, we are seeking comment on a set of approaches to speed the adoption and reduce the cost of more rapid adoption of electronic prescribing, and to maximize the benefits of electronic prescribing on reducing costs and inappropriate care involving the drug benefit. Consequently, at this time it is not possible to estimate the impact. An impact statement on the actual standards will be prepared separately.

We also note that Section 104 of the MMA, which prohibits the sale of new Medigap policies with drug coverage or the renewal of existing Medigap policies that contain drug coverage for Medicare drug benefit enrollees, is not an unfunded mandate as defined by UMRA. This statutory Medigap prohibition does not result in the “expenditure” of funds by the private sector, one part of the statutory test for an unfunded mandate. Moreover, the MMA itself directly restructures the role of Medigap insurance, and it is not the “promulgation of any rule” on our part, the other factor in the statutory test for an unfunded mandate. For a discussion of the effect on Medigap insurers of the MMA prohibition, see section J of the impact analysis.

2. States, Local and Tribal Governments

While States will incur direct costs as a result of this proposed rule, as discussed in greater detail in section H on State impacts, States will achieve net savings under this proposed rulemaking, as now Medicare will be paying for prescription drug costs previously funded under Medicaid, State Pharmacy Assistance Programs (SPAPs), and State sponsored retiree health insurance, or will be providing subsidies for State sponsored qualified retiree prescription drug coverage. There are several sources of the direct costs States will incur. As described below, several of these, taken alone and without consideration of offsetting gains, would reach or exceed the threshold level in UMRA.

In order to defray a portion of the Medicare drug expenditures for full-benefit dual eligibles, States will be responsible for making monthly payments to the Federal government

beginning in January 2006. These payments are estimated to be \$8.5 billion in CY 2006, reaching \$11.1 billion by CY 2010. These payments represent the largest direct cost to States. States will also incur costs associated with assisting in eligibility determinations for the Medicare Part D low-income subsidies. In addition to giving responsibility for eligibility determinations to the Social Security Administration, the MMA also gives States, as a condition of receipt of any Federal financial assistance under Title XIX, responsibility for conducting determinations for eligibility for low-income premium and cost-sharing subsidies under Part D, and as part of those determinations also make determinations related to medical assistance for Medicare cost-sharing under Medicare Parts A and B. Federal matching payments will be available to assist in paying for these administrative costs. Prior to enactment of the MMA, we roughly estimated that the State share of Medicaid administrative costs that might be associated with these low-income eligibility determinations was approximately \$100 million a year, beginning in FY 2005. However, we are undertaking new collaborations with the Social Security Administration, the State Health Insurance Assistance Programs (SHIPs), and other groups to assist in outreach and enrollment, and to help avoid any new administrative burdens for States. We plan to develop an updated estimate of State administrative costs for eligibility determination activities once the operational processes for the eligibility determinations are more fully developed. We also note that there are likely to be some additional costs to States arising from this activity, as discussed in section H of this impact analysis, due to the Medicare Part D low-income eligibility determinations process raising awareness of other benefits available to low-income Medicare beneficiaries through Medicaid and leading to higher enrollment in that program. As noted earlier, however, we believe that overall costs to the States will be reduced due to implementation of the new Medicare drug benefit.

In addition, States will also have revenue losses associated with the MMA prohibition on States imposing taxes on premiums related to Part D coverage. As a result of the shift of beneficiaries from prescription drug coverage subject to State premium taxes to Part D coverage, we estimate that the loss in premium tax revenue to States will be about \$111 million in CY 2006,

and \$129 million by CY 2010, totaling \$598 million over this period.

States will also incur direct costs attributable to required disclosure notices for creditable coverage. Similar to the requirement for private sector employers, State governments that offer retiree health insurance benefits with drug coverage will need to provide disclosure notices to Medicare beneficiaries enrolled in their employer sponsored plans related to that coverage. States will also need to provide disclosure notices to Medicare beneficiaries who receive drug coverage through State Medicaid programs, State Pharmacy Plus programs, and State Pharmacy Assistance Programs. As noted elsewhere in this document, the costs of providing such notices are small and are far more than offset by the savings achieved from receiving the Medicare retiree drug subsidy (because States may also qualify for this subsidy) or through the enrollment of beneficiaries in the Part D benefit.

As discussed in the States section of the impact analysis, the direct and indirect costs and revenue losses to States are more than offset by savings States will achieve as a result of the implementation of the Medicare Part D prescription drug benefit. As noted in that section, the net savings to States increase over time, as the share of drug coverage costs for full-benefit dual eligibles for which States are required to compensate Medicare declines.

Local governments that offer retiree health insurance benefits that include coverage for prescription drugs also will need to provide disclosure notices to Medicare beneficiaries enrolled in their employer sponsored plans related to that coverage. As noted previously, the costs of providing such notices are small, and are far more than offset by the savings achieved either from receiving the Medicare retiree drug subsidy (because local governments may also qualify for this subsidy) or through the enrollment of beneficiaries in the Part D benefit.

We have determined that this proposed rule does not mandate any requirements for Tribal governments.

C. Federalism

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 costs on State and local governments, preempts State law, or otherwise has Federalism implications.

As discussed previously, the MMA and this proposed rule have implications for States. In addition to

the provisions addressed in the UMRA discussion, the statute includes specific provisions prohibiting State regulation of PDP plans, except for licensure and solvency, and permitting the Secretary to waive even State licensure and solvency requirements. The majority of these waivers, however, are temporary and may not exceed 36 months, except in the case of a State that does not have a licensing process for PDP sponsors. As specified in the MMA, we will consult with the National Association of Insurance Commissioners (NAIC) on establishing the financial solvency and capital adequacy standards that will be used in the waiver process.

Because of the national nature of the Medicare Part D benefit, the statute includes provisions that supersede State law relative to the Secretary's final electronic prescribing standards applicable to covered Part D drugs for Part D eligible individuals, and also prohibits States from limiting the amount that a PDP sponsor can recover from liable third parties under Medicare Secondary Payer provisions.

CMS has started routine consultations with States regarding the numerous provisions related to the Medicare prescription drug benefit that have implications for States. Among these, CMS' Center for Medicaid and State Operations has regular meetings with State Medicaid Directors and has used these opportunities to provide our State partners with information about MMA. For example, in March 2004, CMS held conference calls with State representatives to provide them with an overview of the MMA and information on what to expect during implementation, to discuss the provisions in the statute dealing with State payments to the Federal government under Section 103 of the MMA, and to allow States to raise issues about the implementation process. In April and May 2004, CMS held conference calls with State representatives to discuss the calculation of State phased-down contribution, definition of "full-benefit dual eligibles", excluded drugs, enhanced FMAP on family planning drugs, and related State payment issues. CMS is currently working with State Medicaid Directors, State Pharmaceutical Assistance Program staff, and State Health Insurance Assistance Program (SHIP) counseling staff to raise awareness of the Medicare prescription drug discount card program, and we expect to have similar efforts for the implementation of the Medicare Part D prescription drug benefit. We have also consulted with the NAIC on Medigap issues.

The Medicare retiree drug subsidy is an optional program that public or private employers may choose to participate in if they offer qualified retiree prescription drug coverage. Like other employers, State and local governments that offer qualified retiree prescription drug coverage and wish to receive Medicare retiree drug subsidy payments will need to comply with the reporting requirements of this proposed rule, such as attestation of actuarial equivalence and certain data reporting necessary for calculating the retiree drug subsidy payment amount. However, these are not requirements because no public or private employer need apply for Medicare retiree drug subsidy payments. Thus, we have determined that the retiree drug subsidy provisions of this proposed rule would not impose direct costs on State and local governments. As discussed earlier in the preamble, we intend to conduct outreach to prospective applicants for Medicare retiree drug subsidy payments, including State and local governments that sponsor retiree health plans, in an effort to better understand the needs of this segment of the employer community, share information about the Medicare retiree drug subsidy program, and solicit suggestions about how we can best implement the program.

D. Limitations of the Analysis

The following analyses present projected effects of this proposed rule on Medicare beneficiaries, the Federal budget, States, private sector organizations that provide drug coverage to Medicare beneficiaries, and small entities. These impact estimates are generally consistent with the President's fiscal year 2005 budget. Unless otherwise noted, all estimates in this impact analysis are net budgetary spending based on calendar year data.

Because 2006 will be the first year of the Medicare prescription drug benefit and retiree drug subsidy program, we do not have program experience from prior years. In estimating the impact of a completely new program, there are limited data and much greater uncertainty than would be the case with modifications to existing programs. Additionally, there are further policy and administrative issues under consideration in the context of the rule making process. We have explored a wide variety of potential approaches. We believe that these estimates provide a reasonable representation of the likely effects of the policies and potential options discussed. Our analysis generally reflects the broad range of options we have explored and

represents a "mid-range" estimate of the projected possible impacts of the Medicare drug benefit and retiree drug subsidy. We are continuing to work to examine the effects of the issues under consideration and to refine our understanding of the impacts. We would welcome comments on any aspect of the approach, methodology, or assumptions used to develop the estimates presented in this impact analysis.

In addition, we note that analyses in the 2004 Medicare Trustees Report can provide a sense of the range of uncertainty inherent in these types of estimates. Because the methodology used in our estimates is fairly similar to the one used by the Medicare Trustees, we believe that the Trustees Report provides relevant information on the potential range of uncertainty in these types of estimates (see the "2004 Annual Report of the Boards of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds" available on the CMS Web site).

E. Enrollment Estimates

1. Summary

We estimate that in CY 2006 about 41 million Medicare beneficiaries will receive drug coverage either through a Medicare Part D plan (that is, by enrolling in a PDP or MA-PD) or through an employer or union sponsored retiree plan that is eligible for the Medicare retiree drug subsidy. By CY 2010, as a result of growth in the overall Medicare population, we estimate that nearly 45 million Medicare beneficiaries will be receiving such coverage.

As mentioned previously, Medicare Part D offers additional assistance with Medicare drug benefit cost-sharing and premiums to low-income beneficiaries who meet certain income and assets requirements. We estimate that about 10.9 million beneficiaries would enroll in the Medicare Part D low-income subsidy program in CY 2006. Among low-income subsidy participants, we estimate that about 6.4 million would be full-benefit dual eligibles.

2. Projection Assumptions

We project that there will be 43.3 million beneficiaries entitled to or enrolled in Medicare Part A or enrolled in Medicare Part B in 2006 who will be eligible for Medicare Part D. We estimate that roughly 95 percent of these beneficiaries, 41.2 million, will receive drug coverage either through a Medicare Part D plan (that is, a PDP or MA-PD) or through an employer sponsored

retiree plan that is eligible for the Medicare retiree drug subsidy.

First, we assume that Medicare beneficiaries who are active workers and who have employer-sponsored insurance as their primary payer with Medicare as a secondary payer (MSP), will not participate in Medicare Part D at this time. Since these beneficiaries are active workers, not retirees, they would be ineligible for the Medicare retiree drug subsidy. In addition, we believe that it is unlikely that these beneficiaries will enroll in the Medicare drug benefit at this time. These beneficiaries are likely to already have creditable drug coverage from their employer and that coverage would be the primary payer regardless of enrollment in the Medicare drug benefit. In the future, when Medicare becomes the primary payer for these beneficiaries, they will have an opportunity to enroll in Medicare Part D without a late enrollment penalty as long as they had creditable drug coverage from their previous primary insurer.

Second, we assume that all beneficiaries who are full-benefit dual eligibles will enroll in the Medicare drug benefit. As discussed in the preamble, there will be automatic processes put in place to ensure that any beneficiary who is a full-benefit dual eligible who does not enroll in the Medicare drug benefit will be automatically enrolled in a Medicare Part D plan.

Third, among all other eligible beneficiaries, we assume that roughly 99 percent receive prescription drug coverage either through a Medicare Part D plan (that is, a PDP or MA-PD) or through an employer or union sponsored retiree plan that is eligible for the Medicare retiree drug subsidy. This assumption is based in part on the experience of high participation rates in Medicare Part B, but on other factors as well. The standard Medicare Part D benefit shares several similar features with Medicare Part B that encourage enrollment. Both are subsidized benefits, where the beneficiary premium is set at roughly 25 percent of the cost of the insurance, with the government providing a subsidy to cover the remaining 75 percent.

In addition, under both Part B and Part D, beneficiaries face a late enrollment penalty or surcharge (in the form of higher premiums) unless they enroll within the initial enrollment period, have met creditable coverage requirements in the case of Medicare Part D, or have met certain other requirements that occur in a limited number of circumstances. We believe

that the late enrollment penalty is a strong incentive for beneficiary enrollment. The statute provides that the penalty is the greater of either 1 percent of the base beneficiary premium for each month of late enrollment or an amount that CMS determines is actuarially sound for each month of late enrollment that is subject to the penalty (that is, when the beneficiary did not have other creditable coverage). As discussed elsewhere in the preamble, during the first several years of the program, we currently expect that we would specify a penalty amount of 1 percent of the base beneficiary premium per month of late enrollment. In future years once we have sufficient data and experience under the program, we anticipate being able to determine the appropriate penalty amount (that is, either one percent or a greater amount that is actuarially sound). This late enrollment penalty begins after the close of the open enrollment period in May 2006 for those beneficiaries without other creditable coverage. Prescription drug costs are a major concern for Medicare beneficiaries. There will be extensive educational and outreach efforts prior to implementation of Medicare Part D to educate beneficiaries about the coverage available to them through the Medicare drug benefit and about enrollment processes, including the presence of the late enrollment penalty. We think that beneficiaries' concern about current prescription drug costs and the likelihood that as an elderly or disabled individual they will have even greater need for prescription drugs as they age, in combination with the substantial late enrollment penalty, will result in high initial enrollment in the Medicare drug benefit.

We also note that we believe it is likely that some beneficiaries who have not enrolled in Medicare Part B will choose to enroll in the Medicare prescription drug benefit. Many beneficiaries who currently have not enrolled in Part B would face a late enrollment surcharge should they want to enroll in Part B at this time. These same beneficiaries would not face a late enrollment penalty if they chose to enroll in the Medicare Part D drug benefit during the initial enrollment period, and we believe their experience with the Part B late enrollment surcharge may influence their decision-making regarding Part D.

Other features of the Medicare drug benefit are also likely to encourage high enrollment. In addition to the Federal subsidy of the beneficiary premium (which is a part of the standard benefit), a subset of beneficiaries, specifically those who meet certain income and

assets requirements, are eligible for additional low-income subsidies. We expect that States over the next 18 months will also be doing aggressive outreach particularly related to the lower income population. For example, many States have been working with CMS to facilitate enrollment (including for some States auto-enrollment arrangements) of beneficiaries participating in State Pharmaceutical Assistance Programs into the Medicare drug discount card program. In addition, as discussed elsewhere in the preamble, the MMA also provides for transitional grants to States with Pharmaceutical Assistance Programs in each of fiscal years 2005 and 2006, to among other things, help facilitate enrollment in Part D.

Also, in the months preceding the implementation of the Part D benefit, the approximately 76 percent of beneficiaries who have drug coverage (based on 2001 Medicare Current Beneficiary Survey data) will receive separate specific disclosure notices from the entities from which they get that coverage regarding enrollment in the Medicare prescription drug benefit and the applicability of the late enrollment penalty. These notices from other sources are in addition to the extensive outreach efforts that CMS and SSA will conduct over the next 18 months. We also expect that Medicare Advantage plans will work with their members to facilitate enrollment into MA-PD plans.

Another feature of the Medicare Part D program that factors into our expectations regarding participation is the availability of the Medicare retiree drug subsidy. The Medicare retiree drug subsidy lowers the cost of providing drug benefits for employers that sponsor qualified retiree plans, making it more affordable for employers to provide this coverage. We anticipate that most beneficiaries with employer or union sponsored retiree drug coverage will receive their prescription drug coverage through an employer or union plan that is eligible for the Medicare retiree drug subsidy.

It is important to note, though, that in addition to the ability to obtain Medicare retiree drug subsidy payments, Medicare Part D also gives employers a variety of other options for providing their retirees with assistance with prescription drug costs. Employers can choose to provide enhanced drug coverage to their Medicare-eligible retirees through or in coordination with Part D by encouraging their retirees to enroll in Part D (with Medicare subsidizing the costs of their standard Part D benefits), and providing enhanced coverage over and above the

standard Part D benefit. This can be achieved by either arranging for a PDP or MA-PD Part D plan to provide enhanced benefits to their retirees, choosing to become a Part D plan that offers enhanced benefits to their retirees, or providing separate supplemental drug coverage that wraps around a Part D plan (similar to policies that wrap around Medicare benefits under Parts A and B). Thus, some beneficiaries with employer sponsored drug coverage are likely to receive enhanced prescription drug benefits by enrolling in Part D and receiving employer sponsored enhanced Part D benefits or wraparound coverage and/or premium assistance.

The advantages and disadvantages to employers of choosing among the various options for providing employer prescription drug assistance (for example, taking the Medicare retiree drug subsidy versus offering enhanced prescription drug benefits through a Part D plan) will in many cases be influenced by a number of factors, including current benefit design, employer and retiree contributions and other financial considerations, tax status, labor relations, and contractual agreements. Because of these factors and because employers have several options that are advantageous to their retirees and to them in terms of both costs and labor relations, it is difficult to accurately predict which specific choices they will make in many cases. We expect that some employers will choose to provide prescription drug assistance in the form of enhanced benefit packages through Part D plans or separate wraparound coverage. Employers commonly do this relative to Medicare Part A and Part B coverage, either through separate supplemental policies or through arrangements with Medicare Advantage plans. In fact, the Medicare retiree drug subsidy represents a new type of arrangement for employers relative to the interaction of their retiree coverage with Medicare. Thus, we expect that some employers may prefer to interface with the new Medicare prescription drug benefit in a manner similar to their supplementation of the basic Medicare Part A and Part B benefits. In addition, we anticipate that providing enhanced Part D benefits or separate wraparound coverage may be an attractive option to those employers that may not be eligible for the Medicare retiree drug subsidy because their retiree drug benefits, as currently structured, are not as generous as the standard Medicare Part D benefit. Regardless of whether employers seek the Medicare retiree drug subsidy or provide drug coverage to retirees by

encouraging them to participate directly in the Medicare prescription drug benefit and providing enhanced benefits or wraparound coverage, Medicare Part D is estimated to significantly lower employers' cost of providing drug coverage, thus making the provision of that coverage much more affordable and thus more likely. The variety of choices available to employers means that there is some uncertainty around specific choices on the part of employers. An example of the complexity of the issues surrounding employer decision making related to the Medicare retiree drug subsidy is the tax-advantaged status of the 28 percent subsidy. This provides a substantially different incentive to three groups of employers: (a) those for-profit employers paying 35 percent on the margin in corporate income tax rates, (b) those for-profit employers paying far lower rates for a variety of reasons (including not earning a profit), and (c) governmental and non-profit sponsors who do not pay corporate income taxes to begin with. These different incentives, in turn, could affect whether plan sponsors choose the alternative Medicare retiree drug subsidy or choose to enhance benefits provided through Part D.

A fourth participation assumption concerns enrollment in the low-income subsidy portion of the program. We estimate that approximately 14.5 million beneficiaries will be eligible for the low-income subsidy in 2006. We assume that a portion of beneficiaries who are eligible for the low-income subsidy (while receiving prescription drug coverage under Part D) will not take up the low-income assistance. While we assume 100 percent uptake among full-benefit dual eligibles (as discussed previously), we assume that roughly 56 percent of other beneficiaries who are eligible for the low-income subsidy will choose to enroll in it. We assume less than full uptake of the low-income subsidy among these beneficiaries based on experience with other means tested programs such as Medicaid and Medicare Savings (QMB/SLMB) programs, which suggests that full take up does not generally occur.

There are several limitations inherent in the assumptions to predict the specific impacts of a major new program like the Medicare drug benefit. For example, it can be difficult to project enrollment rates in this entirely new program, and there is uncertainty about how employers will respond to the multiple approaches available to augment Medicare prescription drug coverage including the retiree drug subsidy. The assumptions discussed previously reflect our current best

estimates, considering the structure of the program, the wide variety of new efforts to educate beneficiaries and facilitate enrollment, and information about participation rates in other types of similar programs where available. In addition, the estimates do not take into account the possibility that some beneficiaries may have creditable drug coverage through pre-standardized Medigap plans. To the extent that such situations exist and beneficiaries choose to remain in such coverage, our estimates for Medicare Part D may be slightly overstated.

F. Anticipated Effect of Medicare Part D on Beneficiaries

Included in the following section are discussions of: the anticipated positive effects of the Medicare prescription drug benefit on beneficiaries, a recap of the Medicare drug benefit's structure, estimates of the average amount of drug spending covered by the Medicare drug benefit and average beneficiary premiums, and a discussion of the benefits of the Medicare retiree drug subsidy and the other opportunities Medicare Part D affords employers for providing continued prescription drug assistance to retirees.

1. Qualitative Discussion of Positive Effects of the Medicare Drug Benefit

The purpose of the Medicare prescription drug benefit is to provide all of the nation's Medicare beneficiaries with the opportunity to enroll in a prescription drug benefit that is subsidized by the Medicare program. Outpatient prescription drugs have become an integral component in the delivery of comprehensive, high-quality health care services. Giving beneficiaries access to affordable drug coverage that helps them to pay for their outpatient prescription drugs and helps beneficiaries and their health professionals use prescription drugs more effectively as part of their overall health care, will enable beneficiaries to lead healthier, more productive lives, while improving the effectiveness of the Medicare program.

a. Enhancement of the Medicare Benefit Package

When the Medicare program was first enacted, outpatient prescription drug coverage was generally not included in private sector health benefit packages. However, over the last two decades, prescription drugs have played an increasingly critical role in health care delivery. For example, currently, at least one medication is ordered, provided, or continued in approximately 65 percent of all visits to office-based physicians by

persons 65 years and over (2001 National Ambulatory Medical Care Survey, National Center for Health Statistics). Prescription drugs have significantly improved the treatment and management of many major conditions—including life-threatening diseases such as stroke (anticoagulant or clot-blocking therapy), heart disease and coronary artery disease (antihypertensive medications, cholesterol-lowering drugs), and cancer (targeted biologics and other agents that modify the course of illness and can be taken orally), as well as disorders that have fundamental impacts on quality of life like psychiatric illnesses (antipsychotics and antidepressants), osteoporosis (bone-strengthening drugs), and arthritis (anti-inflammatory drugs and other disease-modifying agents)—thereby contributing to longer and healthier lives as well as reductions in other types of medical expenditures such as inpatient admissions and lengths of stay ("The Price of Progress: Prescription Drugs in the Health Care Market," J.D. Kleinke, *Health Affairs* 20:5, September/October 2001, available at <http://www.healthaffairs.org>). Many other significant diseases have seen improvements in treatment and management and thus in patient health as a result of new medications. Examples include: AIDS/HIV, complex infections, diabetes, asthma and chronic lung diseases, Parkinson's disease, and many less common but serious disorders. With more new medicines in development than ever before, potential future health benefits from better drug therapies are even greater. Medicare Part D will augment the Medicare program benefit package by making drug coverage, which is currently offered in most private sector health plans, available to all beneficiaries. This represents an important step in modernizing the Medicare program to better meet beneficiaries' needs and respond to changes in health care delivery.

b. Access to Subsidized Prescription Drug Coverage

The Medicare prescription drug benefit will make subsidized prescription drug coverage available to the estimated 24 percent of Medicare beneficiaries that currently do not have any prescription drug coverage at all (based on 2001 Medicare Current Beneficiary Survey data). Additionally, the Medicare prescription drug benefit will make subsidized coverage available to many other beneficiaries who may have less generous, costly drug coverage—including those who currently receive drug coverage through

Medigap policies or through "access-only" group health plans (group health plans that are available through their former employers which require retirees to pay the premiums for such coverage), and those retirees who may currently be paying a large share of the cost of their retiree coverage.

By providing a substantial subsidy to defray the cost of Medicare drug coverage, including new subsidies for the retiree coverage and Medicare Advantage coverage that many beneficiaries receive today, the Medicare prescription drug benefit will make prescription drug coverage more accessible and affordable for many beneficiaries. As discussed in more detail elsewhere in the preamble, the Medicare program will make payments to PDPs and MA-PDs (through a direct subsidy and government reinsurance payments) that will amount to roughly 75 percent of the total cost of the Medicare Part D prescription drug benefit for all beneficiaries. Medicare Part D will also offer low-income beneficiaries additional assistance by reducing or eliminating beneficiary premiums and by providing very low cost-sharing requirements.

c. Improved Compliance With Treatment Regimens

Available data suggest that not having drug coverage, combined with high drug expenses, may cause some beneficiaries to either not have their prescriptions filled or have them filled less often because they are not financially able to purchase outpatient prescription drugs. Because the Medicare prescription drug benefit will reduce affordability barriers associated with obtaining outpatient prescription drugs by reducing both the costs of drug treatment and beneficiaries' payments, we believe it will help to improve beneficiaries' compliance with their drug treatment regimens.

There is evidence that some beneficiaries, particularly those without drug coverage, do not fill some prescriptions ordered by their physicians and skip doses to make their drugs last longer due to cost concerns. For example, a study of Medicare beneficiaries in eight States found that among those without drug coverage, 25 percent reported not filling a prescription due to cost, while 27 percent reported skipping doses to make drugs last longer. These rates of "noncompliance" with physician prescribing orders were more than double the rates reported among beneficiaries with drug coverage (Dana G. Safran, *et. al.*, "Prescription Drug Coverage And Seniors: How Well Are

States Closing the Gap?" *Health Affairs* Web Exclusive W253, July 2002, <http://content.healthaffairs.org/cgi/reprint/hlthaff.w2.253v1.pdf>).

Furthermore, analysis of data from the 2001 Medicare Current Beneficiary Survey (MCBS), a nationally representative sample of Medicare beneficiaries shows that Medicare beneficiaries without drug coverage fill fewer prescriptions than those with drug coverage. Overall, beneficiaries without drug coverage, on average, self-report filling 37 percent fewer prescriptions (18) than those with drug coverage (29). While some of this difference in utilization likely reflects differences in health status and other beneficiary characteristics, this phenomenon holds true even among groups of beneficiaries with large numbers of chronic conditions. For beneficiaries with five or more chronic conditions, those without drug coverage self-report, on average, filling approximately 38 prescriptions a year compared to beneficiaries with drug coverage, who self-report filling, on average, 50 prescriptions.

Finally, a study in the December 2001 issue of the *Journal of General Internal Medicine* found that certain characteristics, such as minority ethnicity, and low income (defined as income less than \$10,000) significantly increase the risk that individuals without drug coverage will restrict their use of medications by, for example, skipping doses or avoiding taking medication altogether. For example, the odds of medication restriction in minority subjects were higher among those with no drug coverage than among those with full drug coverage. Similarly, the odds of medication restriction were higher in low-income subjects with no drug coverage than in those with full drug coverage. (Michael A. Steinman, *et al.*, "Self-restriction of Medications Due to Cost in Seniors without Prescription Coverage," 16 *Journal of General Internal Medicine* 793-799, Dec. 2001). Thus, comprehensive coverage is particularly likely to have an impact on prescription drug use among disadvantaged populations.

d. Improved Health and Reduction of Adverse Health Effects

Not filling prescriptions, skipping doses, or cutting pills in half are referred to in the medical literature as "medication noncompliance," and can have adverse health effects. We believe that by reducing financial barriers associated with obtaining outpatient prescription drugs and encouraging beneficiary compliance with their drug treatment regimens, the Medicare

prescription drug benefit will reduce the occurrence of adverse health events and lead to overall improvements in beneficiaries' health.

Medication noncompliance can lead to worsening health problems and the need for additional health care services. For example, a study of prescription drug noncompliance among disabled adults found that about half of the individuals reporting medication noncompliance due to cost reported experiencing one or more health problems as a result, including pain, discomfort, disorientation, change in blood pressure or other vital signs, having to go to a doctor or emergency room, or being hospitalized. (Jae Kennedy and Christopher Erb, "Prescription Noncompliance Due to Costs Among Adults with Disabilities in the United States," *American Journal of Public Health*, July 2002). This same study cited other research indicating that medication noncompliance is a clinical problem, particularly related to chronic illnesses such as hypertension, and has been found to be a predictor of hospital admissions and emergency room visits in other studies.

Similarly, another study found that limiting access to medications among low-income, elderly Medicaid patients increased rates of admission to nursing homes. The study analyzed Medicaid recipients aged 60 years or older who took three or more medications per month and at least one maintenance drug for chronic diseases. Limiting affordable access to prescription drugs for this population (through a reimbursement cap on medications) increased rates of admission to nursing homes. The authors concluded that for the sicker patients in the study, the limitation on medication more than "double[d] the rate" of admission in comparison to a group whose medications were not limited. (Stephen B. Soumerai *et al.*, "Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes," 325 *New England Journal of Medicine* 1072, 1074, 1991).

There is also evidence suggesting that the use of specific drugs may reduce adverse health events, utilization of other health care services, and related costs for certain groups of patients. For example, a recent study found that the use of statins in cholesterol-lowering drug therapy reduced the incidence of coronary disease-related deaths by 24 percent in elderly men and women (ages 70 to 82) with a history of, or risk factors for, vascular disease, and also reduced the incidence of non-fatal heart attacks and fatal or non-fatal strokes in these patients ("Pravastatin in Elderly

Individuals at Risk of Vascular Disease (PROSPER): A Randomised Controlled Trial," *Lancet* 2002, 360:9346, 1623–1630.

Similarly, the Heart Outcomes Prevention Evaluation (HOPE) study has found that antihypertensive drug therapy reduced the combined risk of cardiovascular death, heart attack and stroke by 22 percent in approximately 9,000 high-risk middle-aged and elderly patients (ages 55 and older), with \$871,000 in net estimated savings over 4 years, and also significantly reduced the risk of adverse cardiovascular outcomes by 25 to 30 percent in a broad range of high-risk middle-aged and elderly patients with diabetes mellitus (See "Drug Therapy and Heart Failure Prevention," Editorial, Jennifer V. Linseman, PhD, and Michael R. Bristow, MD PhD, *Circulation* 107:1234, American Heart Association, 2003; "Economic Impact of Ramipril on Hospitalization of High-Risk Cardiovascular Patients, Cathryn A. Carroll, PhD MA MBA BSPharm, *The Annals of Pharmacotherapy*, Volume 37, No. 3, pp. 327–331; and "Effects of Ramipril on Cardiovascular and Microvascular Outcomes in People With Diabetes Mellitus: Results of the HOPE Study and MICRO-HOPE Substudy, Evaluation (HOPE) Study Investigators, *Lancet* 355 (9200):253–259, 2000).

While there is evidence that the use of certain prescription drugs may be cost-effective for specific groups of patients (in the sense that they result in net health care cost savings or produce health improvements at relatively low cost), thus far it has been difficult to generalize the results of these drug-specific studies more broadly to estimate the potential health care cost savings or morbidity or mortality reductions in the context of an overall Medicare prescription drug benefit. First, the findings from available cost-effectiveness analyses in the literature suggest that while some prescription drugs may lead to short-term or long-term reductions in net health care costs, other prescription drugs may lead to net increases in health costs. Second, the Medicare prescription drug benefit will improve access to prescription drugs for a broader patient population than is typically included in the available studies in the literature, which may affect the potential cost-effectiveness of certain drugs. For example, while the literature suggests that the use of statin drugs for lowering blood cholesterol levels in patients with existing heart disease is relatively cost-effective, using these drugs to preventively lower blood cholesterol levels in patients that do not have heart disease may be less cost-

effective (see "Are Pharmaceuticals Cost-Effective? A Review Of The Evidence," Peter J. Neumann, Eileen A. Sandberg, Chaim M. Bell, Patricia W. Stone, and Richard H. Chapman, *Health Affairs* 19:2, November/December 2000; and "The Price of Progress: Prescription Drugs in the Health Care Market," J. D. Kleinke, *Health Affairs* 20:5, September/October 2001 available at <http://www.healthaffairs.org>).

In addition to the anticipated reductions in adverse health events associated with anticipated improvements in prescription drug compliance, we believe that many elements of the Medicare prescription drug benefit—including quality assurance, electronic prescribing, better beneficiary information on drug costs and ways to reduce drug costs (for example, through generic substitution), and medication therapy management which are designed to improve medication use and reduce the risk of adverse events, including adverse drug interactions—will also improve beneficiaries' health outcomes. We believe that these improvements will occur through enhanced beneficiary education, health literacy and compliance programs; improved prescription drug-related quality and disease management efforts; and ongoing improvements in the information systems that are used to detect various kinds of prescribing errors—including duplicate prescriptions; drug-drug, drug-allergy and drug-food interactions; incorrect dosage calculations, and problems relating to coordination between pharmacies and health providers. We also believe that additional reductions in errors and additional improvements in prescription choices based on the latest available evidence will occur over time as the electronic prescribing provisions of the MMA are implemented (*To Err is Human: Building A Safer Health System*, Institute of Medicine of the National Academies, 1999, pp. 191–193, <http://www.iom.edu> or <http://www.nap.edu>).

Ultimately, we believe that the evidence supports our conclusion that making prescription drugs more available and affordable will help beneficiaries to live healthier, more productive lives. We also believe that expanding prescription drug coverage will reduce adverse health events and Medicare program spending on more costly services for some beneficiaries, and will be particularly important for beneficiaries with limited means who are more likely to forego beneficial prescription drugs when they do not have coverage. However, the effect on

aggregate Medicare program spending across all beneficiaries is difficult to ascertain. At this time, there have not been studies that have found evidence that expansions of drug coverage across a large population, as will occur under the Medicare drug benefit, yields aggregate health care cost savings. Furthermore, there have been mixed results on the impact of coverage on the cost-effectiveness of care involving certain individual drugs in general, and in differing patient populations. Thus, the extent to which the Medicare drug benefit may lead to reductions in Medicare spending for other health care services in the aggregate across all beneficiaries is difficult to predict. Additional research will be needed to further examine and quantify these potential effects. For example, we are currently conducting a demonstration study on the extent to which coverage of oral medicines reduces the use of professionally-delivered medicines and the associated physician and health care services that are currently covered in Part B. We are very interested in developing further evidence on the best ways to encourage outcome improvements and overall health care cost reductions through drug coverage, and would welcome comments in this area and how this can be incorporated into the implementation of the drug benefit. For example, CMS is currently collaborating with AHRQ and other experts to identify priorities for developing better evidence and increasing value in the use of outpatient medications, and intends to develop further evidence as part of the implementation of the drug benefit.

2. Recap of the Structure of the Medicare Part D Drug Benefit

As discussed in more detail elsewhere in the preamble, standard prescription drug coverage under Medicare Part D for 2006 consists of a \$250 deductible, 25 percent cost-sharing (or an actuarially equivalent cost-sharing structure) up to an initial coverage limit of \$2,250, 100 percent cost-sharing after the initial coverage limit until an out-of-pocket threshold of \$3,600 is reached, and nominal cost-sharing for expenditures beyond the out-of-pocket threshold (that is, the greater of 5 percent coinsurance or a copayment of \$2 for a generic or preferred multiple source drug and \$5 for any other drug in 2006, or an actuarial equivalent cost-sharing structure). For each year after 2006, the deductible, initial coverage limit, out-of-pocket threshold, and nominal copayment amounts are indexed to per capita growth in prescription drug expenditures for Part D enrollees, as

described in more detail in the preamble.

While we model all of our impact estimates on the defined standard benefit structure, we note that PDP and MA-PD plans have the option of offering actuarially equivalent standard or alternative coverage. In addition, plans may offer enhanced alternative coverage where for an additional premium they offer supplemental drug coverage such as coverage for benefits above the initial coverage limit (that is, coverage of the so-called "doughnut hole"), and we anticipate that some plans will offer this coverage.

Beneficiaries who meet certain income and assets requirements qualify for low-income subsidy assistance with cost-sharing and premiums. While the out-of-pocket threshold level is the same for all enrollees, the beneficiary cost-sharing liability covered by the low-income subsidy counts towards the Part D out-of-pocket threshold. Therefore, subsidy-eligible individuals will pay substantially less than all other enrollees before the catastrophic coverage begins. Institutionalized full-benefit dual eligibles pay no cost-sharing. Other full-benefit dual eligibles with income not in excess of 100 percent of the Federal Poverty Level (FPL) face no deductible, have nominal cost sharing of \$1 for generic drugs or preferred multiple source drugs and \$3 for any other drug up to the out-of-pocket threshold, and receive full coverage for drug costs beyond the out-of-pocket threshold. Other full-benefit dual eligibles with income above 100 percent of FPL and beneficiaries who are not full benefit dual eligibles, but who have income less than 135 percent of FPL and assets up to \$6,000 per individual (or \$9,000 per couple) in 2006, face no deductible, have nominal cost sharing of \$2 and \$5 for the respective drugs up to the out-of-pocket threshold, and receive full coverage for costs beyond the out-of-pocket threshold. For other beneficiaries with income less than 150 percent of FPL and assets up to \$10,000 per individual (or \$20,000 per couple) in 2006, there is a reduced deductible of \$50, cost-sharing of 15 percent for costs up to the out-of-pocket threshold, and nominal cost sharing of \$2 and \$5 for the respective drugs for costs beyond the out-of-pocket threshold. For years after 2006, all aspects of the benefit structure related to the low-income subsidy are indexed to growth in per capita drug spending, except for the nominal copayment amounts for full-benefit dual eligibles with income not in excess of 100 percent of FPL and the low-incomes

assets tests, which are indexed to the Consumer Price Index.

The low-income subsidy also offers beneficiaries substantial help with premiums. Many beneficiaries who receive the low-income subsidy will pay no premium for Medicare drug coverage. Full-benefit dual eligibles and beneficiaries who have incomes up to 135 percent of FPL and who meet the assets test receive a full Federal subsidy of the beneficiary premium—that is, beneficiaries pay no premium as long as they select a PDP or MA-PD that has a premium that does not exceed the greater of the low-income benchmark premium or the lowest PDP premium for basic coverage for the region and as long as they sign up for Medicare Part D within the initial enrollment period or have met creditable coverage requirements. Other beneficiaries receiving a low-income subsidy—those with income between 135 percent and 150 percent of FPL and meeting asset requirements—would face a sliding scale premium based on income.

Medicare Part D also has implications for beneficiaries enrolled in the Program of All Inclusive Care for the Elderly (PACE). PACE programs already provide a comprehensive drug benefit to dual eligible enrollees and to enrollees who only have Medicare coverage. For the dual eligible enrollees, PACE programs will now be receiving funding for prescription drugs through Medicare Part D instead of through the State Medicaid program. PACE enrollees who only have Medicare coverage are today paying the full cost of their drug coverage. As a result of the Federal subsidization of Part D coverage, they will receive substantial premium relief. This lowering of premiums for beneficiaries who only have Medicare coverage may lead to an increase in enrollment in PACE organizations.

3. Estimated Total Drug Spending, Spending Paid by the Medicare Drug Benefit, and Premiums

a. Summary

Table V-1 presents estimates for Medicare Part D enrollees of average total drug spending, average drug spending paid for by the Medicare drug benefit, and the average premium associated with Medicare Part D drug coverage. Since beneficiaries who are eligible for the low-income subsidy receive additional assistance with cost-sharing and premiums, we present estimates separately for beneficiaries who do and do not receive the low-income subsidy.

For Medicare Part D enrollees who do not receive the low-income subsidy, we

estimate that average per capita drug spending in CY 2006 would be \$2,936. This projection of drug spending includes cost-management savings discussed in the next subsection, such as price concessions and generic substitution, or utilization effects resulting from the Medicare drug benefit. The Medicare drug benefit would be expected to pay for on average about \$1,437 of prescription drug costs, or on average nearly half of total beneficiary drug spending in CY 2006.³ Beneficiary premiums for defined standard coverage will vary across PDPs and MA-PDs. We estimate that the beneficiary premium to obtain defined standard coverage would be on average about \$428 per year in CY 2006. Thus, we estimate that the average monthly premiums would be in the range of about \$35. A beneficiary may pay more or less depending upon which PDP or MA-PD the beneficiary selects. For these non-low-income beneficiaries, the government is estimated to contribute \$1,231 of the \$1,659 total cost of the standard Medicare Part D benefit (including PDP and MA-PD administrative costs). In CY 2010, drug spending for Part D enrollees who do not receive the low-income subsidy is projected to be \$3,852 on average, with the Medicare drug benefit paying for on average \$1,890 of prescription drug costs. The average premium in CY 2010 for these beneficiaries is projected to be \$564 per year or roughly \$47 per month for defined standard coverage.

For enrollees who receive the low-income subsidy, we estimate that average per capita drug spending in 2006 would be \$3,649.⁴ We estimate that on average the Medicare drug benefit would be expected to pay for about \$3,476 of prescription drug costs, or approximately 95 percent of total drug spending. In 2010, these beneficiaries would be expected to spend on average \$4,794 per capita on prescription drugs, with the Medicare

³ We note that \$1,437 reflects the average payout of the Medicare drug benefit for non-low-income beneficiaries in 2006. This is different from what the payout would be for a beneficiary with total drug spending equal to average total drug spending for all enrollees. For example, standard coverage under Medicare Part D would payout \$1500 for a beneficiary with total spending of \$2936. The difference between the average payout versus the payout for a beneficiary with average total drug spending is due to the interaction between the distribution of drug spending and the deductible and cost-sharing structure of the Medicare drug benefit.

⁴ Average drug spending for enrollees eligible for the low-income subsidy is higher than for enrollees not eligible for the subsidy because a substantial portion of those eligible for the low-income subsidy are full-benefit dual eligibles, who on average tend to be sicker.

drug benefit paying for on average about \$4,518 of those drug costs. As discussed in the preamble, the low-income cost-sharing amounts vary depending upon a beneficiary's income and assets. Consequently, the share of drug spending paid for by the Medicare drug benefit would vary by subsidy eligibility category, ranging from an average of about 85 percent for the highest-resource subsidy eligibility category (that is, those beneficiaries who qualify for the subsidy under the criteria that they have income less than 150 percent of FPL and assets up to \$10,000 per individual (or \$20,000 per couple) in CY 2006) to more than 95 percent for the most generous subsidy category (that is, full-benefit dual eligibles with income not in excess of 100 percent of FPL). As discussed in the following methodology section, these estimates do not take into account the waiver of cost sharing for institutionalized full-benefit dual eligibles, which further enhances the drug subsidy for this category of beneficiaries.

As noted previously, many beneficiaries who receive the low-income subsidy receive a full Federal subsidy of the beneficiary premium (that is, the beneficiary pays no premium at all), as long as they enroll in a PDP or MA-PD with a premium that does not exceed the greater of the low-income benchmark premium or the lowest PDP premium for basic coverage for the region and as long as they enroll during the initial enrollment period or have met creditable coverage requirements. For low-income enrollees with income between 135 percent and 150 percent of FPL who face a sliding scale premium based on income, we estimate that the premium will average \$214 per year or roughly \$18 per month in 2006, and \$282 per year or roughly \$24 per month in 2010.⁵ The government contribution to the cost of Medicare Part D prescription drug coverage for low-income subsidy enrollees is estimated to average almost \$3,500 in CY 2006.

b. Methodology and Assumptions Underlying Estimates

To estimate beneficiary drug spending for the period CY 2006–2010, we use drug spending data from the Medicare Current Beneficiary Survey (MCBS) adjusted for underreporting and trended forward based on projected growth in per capita drug spending based on the

National Health Expenditures projections.

In projecting drug spending for enrollees in Medicare Part D, we assume that PDPs and MA-PDs will achieve a certain level of savings due to cost management activities such as negotiation of manufacturer rebates and discounts and other price concessions, and promotion of generic substitution. We assume discounts and cost-management savings of 15 percent in 2006, 17 percent in 2007, 19 percent in 2008, 21 percent in 2009, and 23 percent in 2010. To take into account that some enrollees in the Medicare Part D drug benefit are likely to have had previous drug coverage from other sources and received some level of discounts and cost-management savings through that coverage, we adjusted the MCBS spending data upward to reflect the full retail price by backing out any assumed discounts and cost management savings and then applied the Part D savings factor. We note that some beneficiaries without drug coverage are currently receiving discounts through the Medicare-approved drug card program. Conceptually, those discounts should also be backed out of drug spending before applying the Part D savings factor; however, because the drug spending data on which our projections are based predate the Medicare-approved drug card program, such an adjustment was not necessary.

Our assumptions related to the cost management savings take into account several factors. Insured products generally obtain lower drug prices than those available to cash paying customers. For example, an April 2000 study prepared by HHS entitled, "A Report to the President: Prescription Drug Coverage, Spending, Utilization and Prices," indicated a significant price differential between individuals paying cash for prescriptions at a retail pharmacy versus individuals with insurance. This difference held true for both the Medicare and non-Medicare populations. According to the study, in 1999 the price paid by cash customers was nearly 15 percent more than the total price paid under prescription drug insurance, including the enrollee cost sharing. For 25 percent of the most commonly prescribed drugs, this price difference was higher—over 20 percent. Such price concessions are envisioned to be an important part of the Medicare drug benefit, as the statute specifically requires PDPs and MA-PDs to provide beneficiaries with access to negotiated prices, which would reflect manufacturer rebates and discounts and other price concessions. Besides these

types of price concessions, we also anticipate that PDPs and MA-PDs will achieve savings as a result of other cost management activities such as promotion of generic substitution, which Medicare will help support as well through providing information on opportunities for cost savings to beneficiaries and their health providers. As discussed elsewhere in the preamble, the statute requires PDPs and MA-PDs to put in place a cost-effective drug utilization management program that would include incentives to reduce costs when medically appropriate. We believe that these various efforts are likely to increase use of generics relative to brand-name drugs among Medicare Part D enrollees.

Furthermore, in developing our cost management savings assumptions, we also considered the nature of the drug price negotiations occurring under the Medicare prescription drug benefit. We expect that the private price negotiations between PDP sponsors and drug manufacturers would achieve comparable or better savings than direct price negotiation between the government and manufacturers, as well as coverage options that better reflect beneficiary preferences. This expectation reflects the strong incentives to obtain low prices and pass on the savings to beneficiaries resulting from competition, relevant price and quality information, Medicare oversight, and beneficiary assistance in choosing a drug plan that meets their needs. This is similar to the conclusion of other analyses, for example, CBO's recent statement that "Most single-source drugs face competition from other drugs that are therapeutic alternatives. CBO believes that there is little, if any, potential savings from negotiations involving those single-source drugs. We expect that risk-bearing private plans will have strong incentives to negotiate price discounts for such drugs and that the Secretary would not be able to negotiate prices that further reduce federal spending to a significant degree." It also reflects Medicare's recent experience with drug price regulation for currently-covered drugs, in which regulated prices for many drugs have significantly exceeded market averages.

In addition, our drug spending projections assume that changes in beneficiary out-of-pocket costs resulting from the Medicare drug benefit would affect beneficiaries' utilization of drugs. For example, as discussed previously, beneficiaries without drug coverage fill fewer prescriptions and spend less in total on prescription drugs than beneficiaries with drug coverage. Under

⁵ We note that to estimate the average sliding scale premium we assume a uniform distribution of income between 135 percent and 150 percent of FPL. If the income distribution is not uniform, the average sliding scale premium could differ somewhat from our estimates.

the Medicare drug benefit, we would expect that drug utilization and spending would increase for beneficiaries without prior drug coverage. Our estimates assume that aggregate beneficiary drug spending (that is, total drug spending for all beneficiaries including those with and without drug coverage prior to 2006) would be 10.6 percent greater in CY 2006 than it otherwise would be, due to reduced out-of-pocket costs resulting from the Medicare drug benefit.

Using our estimates of projected drug spending for enrollees in Medicare Part

D, we estimate the amount of drug spending that would be paid for by the Medicare drug benefit, separately for enrollees who would and would not receive the low-income subsidy. For enrollees who receive the low-income subsidy, these estimates take into account the differential cost-sharing by income and assets within the low-income group. However, due to data limitations, our estimates do not take into account the fact that beneficiary cost-sharing is waived entirely for institutionalized full-benefit dual eligibles.

For the purposes of this impact analysis, those beneficiaries who are assumed to enroll in Medicare Part D are assumed to do so within their initial enrollment period and face no late enrollment penalty. We also assume that all low-income beneficiaries with income under 135 percent of FPL select PDP and MA-PD plans with a premium that does not exceed the greater of the low-income benchmark premium or the lowest PDP premium for basic coverage for the region, and thus face no beneficiary premium.

TABLE V-1.—ESTIMATED AVERAGE ENROLLEE TOTAL DRUG SPENDING, DRUG SPENDING PAID FOR BY MEDICARE DRUG BENEFIT, AND DRUG BENEFIT PREMIUM, CY 2006 AND CY 2010

		Estimated average annual drug spending paid for by the medicare drug benefit*	Estimated average annual premium
2006:			
	Enrollees Not Receiving Low-Income Subsidy	\$2,936	\$428.
	Enrollees Receiving Low-Income Subsidy	3,649	0 or \$214**.
2010:			
	Enrollees Not Receiving Low-Income Subsidy	3,852	\$564.
	Enrollees Receiving Low-Income Subsidy	4,794	0 or \$282**.

* Average annual drug spending paid for by the Medicare drug benefit reflects on average how much the Medicare drug benefit will payout per beneficiary. This is different from the amount of drug costs the Medicare drug benefit would payout for a beneficiary with average total drug spending, due to the interaction between the distribution of drug spending and the deductible and cost-sharing structure of the Medicare drug benefit. We also note that the average drug spending paid for by the Medicare Part D plan reflects drug costs reimbursed by the plan and does not include PDP or MA-PD administrative costs.

** Low-income subsidy enrollees with income between 135 percent and 150 percent of FPL face a sliding scale premium based on income, which is estimated to average \$214 per year in 2006 (\$282 in 2010). Other enrollees in the low-income subsidy pay no beneficiary premium at all, as long as they select a PDP or MA-PD with a premium that does not exceed the greater of the low-income benchmark premium or the lowest PDP premium for basic coverage for the region and as long as they enroll within the initial enrollment period or have met creditable coverage requirements.

4. Positive Effects of the Medicare Retiree Drug Subsidy and Other Employer Options for Providing Prescription Drug Assistance

The Medicare prescription drug benefit and retiree drug subsidy represent additional funding sources that can help employers and unions continue to provide high quality drug coverage for their retirees. We anticipate that these new sources of support will have many important positive benefits for the quality and security of drug coverage for retirees. In this section, we describe the Medicare retiree drug subsidy and several other ways that Medicare Part D offers financial assistance with retiree prescription drug costs to employers and unions.

a. Overview of the Medicare Retiree Drug Subsidy

The positive benefits for retiree coverage from the new retiree drug subsidy are the result of the subsidy itself, the special tax-favored status of the subsidy payments to the qualified retiree health plans, and the flexibility

in using the subsidy to support retiree coverage. The retiree drug subsidy program has highly flexible rules and stands as an additional option that permits employers and unions to continue providing drug coverage to their Medicare-eligible retirees while retaining their current plan designs that are at least equivalent to the standard Part D benefit, and receiving a Federal subsidy that reduces the cost of providing this coverage. Employers retain the option of delivering regular supplementation to Medicare Part A and Part B benefits through arrangements with Medicare Advantage organizations offering a MA only plan without the Part D benefit, but then still participate in the retiree drug subsidy program and through a separate private contract with the MA organization arrange for an employer-sponsored retiree drug benefit.

The intent of the Medicare retiree drug subsidy is to offer qualified retiree prescription drug plans financial assistance with a portion of their prescription drug costs and thereby

“help employers [to] retain and enhance their prescription drug coverage so that the current erosion in coverage would plateau or even improve” (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Report, p. 53). By making a tax-free subsidy for 28 percent of allowable prescription drug costs (that is, drug spending between \$250 and \$5,000 for 2006) available to qualified retiree prescription drug plans, the Medicare retiree drug subsidy significantly reduces financial liabilities associated with employers’ retiree drug coverage and encourages employers to continue assisting their retirees with prescription drug coverage.

To provide a rough estimate of the per capita retiree drug subsidy, we used MCBS data on prescription drug spending for retirees with employer-sponsored coverage, adjusted for under-reporting, and trended these data forward based on the projected growth rate in prescription drug spending from the National Health Expenditures projections. We then applied 28 percent

to annual allowable costs between the cost threshold and cost limit (\$250 and \$5,000, respectively, in 2006). This calculation yielded an estimated per capita retiree drug subsidy amount of \$611 in 2006. The per capita subsidy amount was calculated across all beneficiaries in qualified retiree prescription drug plans, including both those who do and do not have spending high enough to qualify for a Medicare retiree drug subsidy payment. We are aware that there are other sources of information on the value of current and projected retiree coverage, and we seek comment on the completeness and accuracy of our MCBS-based projections for valuing the retiree subsidy.

The Medicare retiree drug subsidy is excluded from the taxable income of the employer (just as the Medicare subsidy provided to beneficiaries through the Medicare prescription drug benefit is excluded from the taxable income of the beneficiary). The tax-free nature of the Medicare retiree drug subsidy generally increases its value to employers. As indicators of the value of this tax subsidy, we provide some estimates of the equivalent values of a taxable subsidy for employers at several corporate income tax rates. For corporations with taxable incomes, marginal tax rates generally range from 15 percent to 35 percent. According to estimates by the Congressional Research Service, the weighted average effective tax rate for corporations that pay taxes is approximately 28.5 percent. Combining this tax rate and the estimated \$611 average per capita subsidy amount for 2006, we estimate that the \$611 tax-free retiree drug subsidy amount would be equivalent to a taxable subsidy of \$855 for employers subject to taxation. The equivalent taxable subsidy for any particular employer with taxable income would, of course, vary depending on its specific marginal tax rate. For example, the tax-free \$611 average retiree drug subsidy amount would be equivalent to about \$815 of taxable income for employers with a marginal tax rate of 25 percent and about \$940 of taxable income for employers with a marginal tax rate of 35 percent. We request comments on the effect of the tax-favored treatment of the subsidy payments for employers and retirees, including further evidence on the distribution of marginal tax rates among employers offering or likely to offer retiree coverage.

Another important factor in whether employers or unions will use the retiree subsidy is whether their contribution to the retiree coverage is sufficient to qualify for coverage, and if it is not currently sufficient, whether they will

increase the generosity of their contribution in order to receive the cash and tax value of the subsidy. As we note below, we intend to implement the retiree drug subsidy in a manner that avoids "windfalls" to employers that are not making contributions to retiree coverage that reflect the value of the retiree subsidy. Because some employers appear to contribute less than the value of the retiree subsidy to the coverage they provide now, we seek comment on the current levels and trends of such limited employer contributions, and on how the new Medicare payments may affect decisions by firms to increase the generosity of their retiree health contributions. Such increased contributions are likely to be in the financial interest of some employers, because they could qualify for the value of the full subsidy by making an additional incremental contribution of less than the full value of the subsidy, thereby achieving net savings.

b. Additional Options Available to Employers Through Medicare Part D

As indicated earlier, in addition to the ability to obtain Medicare retiree drug subsidy payments for sufficiently generous drug coverage, Medicare Part D also gives employers a variety of other options for continuing to assist their Medicare-eligible retirees in obtaining more generous drug coverage. For example, employers that are supporting retiree coverage now could also choose to provide enhanced drug coverage by using the new Medicare Part D subsidy directly (that is, encouraging their retirees to enroll in an enhanced Medicare Part D plan which includes a 75 percent government subsidy for the standard benefit) and employers providing enhanced coverage over and above the standard Part D benefit that maintains or exceeds the generosity of their current benefit designs. This can be achieved by either arranging for a PDP or MA-PD Part D plan to provide enhanced benefits to their retirees, choosing to become a Part D plan that offers enhanced benefits to their retirees, or providing separate supplemental drug coverage that wraps around a Part D plan (similar to the typical employer and union policies that wrap around Medicare benefits under Part A and Part B).

Based on published employer surveys, reports from employers and benefit consultants, and other sources of evidence including the fact that some employers are not making contributions to coverage sufficient to qualify for the retiree drug subsidy, we expect that some employers will choose to provide

prescription drug assistance to their Medicare-eligible retirees in the form of enhanced benefit packages through Part D plans or separate wraparound coverage. In both cases, the employer contributions would augment the Medicare's subsidized coverage under Part D. Employers currently do this relative to Medicare Part A and Part B coverage, either through separate supplemental policies or through arrangements with Medicare Advantage plans. In fact, the Medicare retiree drug subsidy represents a new type of arrangement for employers relative to the interaction of their retiree coverage with Medicare. Thus, some employers may prefer to interface with the new Medicare prescription drug benefit in a manner similar to their supplementation of the basic Medicare Part A and Part B benefits. In addition, we anticipate that providing enhanced Part D benefits or separate wraparound coverage may be an attractive option to those employers that may not be eligible for the Medicare retiree drug subsidy because their retiree drug benefits, as currently structured, are not actuarially equivalent to the standard Medicare Part D drug benefit. We also expect that many of the employers and unions that choose to provide drug coverage through or in coordination with Part D will also choose to pay some or all of their retirees' Part D premiums. Since the Medicare Part D drug benefit includes a direct Federal subsidy, these approaches would allow employers to continue to provide a benefit package of similar or greater generosity compared to their existing arrangements while potentially lowering their prescription drug costs.

Although the Medicare prescription drug benefit and retiree drug subsidy represent additional funding sources for employer-sponsored retiree drug coverage that can help employers to retain drug coverage for their retirees, there are also a number of economic forces unrelated to Medicare that play a role in employers' decision making regarding both the availability and the generosity of employer-sponsored retiree health coverage. Many of the economic forces behind the ongoing erosion of retiree health benefits that are discussed subsequently in this impact analysis may continue to give employers a financial incentive to reduce the costs associated with providing retiree health coverage. The Employee Benefit Research Institute (EBRI) has estimated that additional declines in retiree drug coverage could potentially continue to occur, particularly for future retirees, "due to existing business, accounting,

and cost trends," regardless of changes in the Medicare program ("EBRI Special Analysis: How Many Medicare Beneficiaries Will Lose Employment-Based Retiree Health Benefits if Medicare Covers Outpatient Prescription Drugs?" Dallas L. Salisbury and Paul Fronstin, Employee Benefit Research Institute, July 18, 2003, available at <http://www.ebri.org>).

c. Anticipated Effects of the Medicare Retiree Drug Subsidy Program and Part D Assistance for Retirees

While there is considerable uncertainty about the choices that employers will make regarding the form of prescription drug assistance that they may choose to provide for their Medicare-eligible retirees, we believe that employers will generally continue to provide prescription drug assistance to their retirees and that Medicare Part D will make it more affordable for them to do so.

First, with the decline over the years in the number of employers offering retiree health insurance coverage, the remaining employers who continue to offer such coverage directly are likely those employers who have a contractual commitment or other interest in maintaining that coverage.

Second, although employers' responses to Medicare Part D and the retiree drug subsidy are expected to play out over the next few years, initial signals suggest that there has been a positive response to the Medicare retiree drug subsidy. Several major employer associations, including the Employers' Coalition on Medicare, American Benefits Council, and the U.S. Chamber of Commerce, have praised the MMA for giving businesses flexibility in deciding how their retiree health plans will interact with the Medicare prescription drug benefit, and for offering employers a 28 percent Medicare retiree drug subsidy payment that would not be taxed for employers who continue to provide high-quality retiree coverage ("ECOM Applauds Historic Passage of Medicare Reform Legislation," Employers' Coalition on Medicare press release, November 25, 2003, <http://www.employersandmedicare.org>; "Senate Passes Medicare, Prescription Drug Reform Bill," press release, American Benefits Council, November 25, 2003, <http://www.americanbenefitscouncil.org>, "Chamber Praises Congressional Action on Medicare Reforms," U.S. Chamber of Commerce, November 25, 2003, <http://www.uschamber.com>).

Additionally, several major corporations have recently issued 2003 annual reports that include estimates of

the reduction in their accumulated benefits obligation that will occur over time due to the Medicare subsidy payments they anticipate receiving under the Medicare retiree drug subsidy program. Eighteen companies have estimated that they would collectively save \$11.8 billion in long-term postretirement benefit costs, which are expected to be amortized over the full working life of the employees that are eligible for these benefits ("Expected Cost Savings From Medicare Act May Top \$11.8 Billion", Lingling Wei, Dow Jones Newswires, The Wall Street Journal, March 22, 2004, available at <http://www.wsj.com>). However, we are aware that some of these companies may need to revise their initial estimates to reflect: (1) The Financial Accounting Standards Board's (FASB) recently-issued Final Staff Position on accounting for the effects of the Medicare retiree drug subsidy payments, which is effective for financial statements for periods beginning after June 15, 2004 ("FASB Staff Position Number FAS 106-2, Accounting and Disclosure Requirements Related to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003," posted May 19, 2004, available at http://www.fasb.org/fasb_staff_positions/fsp_fas106-2.pdf), and (2) the regulations for the retiree drug subsidy.

Although most publicly traded companies have chosen to defer recognizing the effects of the Medicare retiree drug subsidy payments pending receipt of additional accounting and regulatory guidance, these sources suggest that numerous large companies that offer employment-based retiree prescription drug coverage anticipate continuing to provide this coverage and accepting the Medicare retiree drug subsidy payments. However, some employers have not yet decided whether they will apply for the Medicare retiree drug subsidy, and are considering the various other options that are available for providing prescription drug assistance to their Medicare-eligible retirees (See Press Releases and Statements, Press Room of the Employers' Coalition on Medicare, available at <http://www.employersandmedicare.org>).

Overall, we believe that the implementation of Medicare Part D, including the Medicare retiree drug subsidy and the other opportunities it affords employers for providing continued prescription drug assistance to their Medicare retirees, will result in combined aggregate payments by employers and Medicare for drug coverage on behalf of retirees generally

being greater—and frequently significantly greater—than they otherwise would have been without the enactment of the MMA. Furthermore, we believe that the Medicare prescription drug benefit and retiree drug subsidy represent a particularly important strengthening of health care coverage for future Medicare-eligible retirees, given the erosion in the availability and generosity of employer-sponsored retiree coverage for future Medicare beneficiaries that has already been taking place. In addition to comments on how employers are likely to view each choice of coverage, we also seek comment on how the several options available to employers to continue or increase the generosity of their retiree coverage can be designed together to maximize the increase in availability of high-quality drug benefits for retirees. This includes a request for comments on modeling not just the choice by employers and unions of retiree drug subsidy, wrapping around Part D coverage, qualifying as an enhanced Part D plan directly, or using an enhanced PDP or MA plan, but also the impact of these choices on premium reductions and additional drug benefits for retirees and thus the impact on reducing retirees' net payments for drugs and other health services.

d. Historical Trends in the Availability and Generosity of Retiree Drug Coverage

As additional background, we provide a discussion of trends in the availability and generosity of employer-sponsored retiree drug coverage, based on data from several different sources. We note that there are a limited number of data sources relating to retiree coverage, and some of these data sources may not be directly comparable to one another due to differences in the scope of analysis (for example, overall retiree health benefits versus specific information on retiree drug coverage), unit of analysis (for example, retirees versus firms, or firms versus establishments), as well as differences in the age groups, types of retirees (current versus future), and employer sizes that are being analyzed. For these reasons, caution should be exercised in making comparisons across the various data sources that are cited in this section.

As noted previously, employer-sponsored insurance has been an important source of drug coverage for many Medicare beneficiaries. However, for well over a decade, the availability and generosity of employer-sponsored retiree health coverage has been eroding, particularly for future retirees. The level of employer-sponsored retiree health coverage has been relatively

stable for the nation's current retirees during recent years. However, the apparent stability of benefits has been changing for future retirees.

For example, the trend in retiree health coverage for older Medicare beneficiaries (ages 70 and older) was essentially flat between 1996 and 2000 ("Employer-Sponsored Health Insurance and Prescription Drug Coverage for New Retirees: Dramatic Declines in Five Years," Bruce Stuart et al, Health Affairs, July 23, 2003, available at <http://www.healthaffairs.org>).

From 1988 to 1991, the percentage of firms with 200 or more workers offering health benefits to active workers that also offered retiree health benefits declined substantially from 66 percent to 46 percent (KPMG Survey of Employer-Sponsored Health Benefits: 1988, 1991, cited in Kaiser/HRET 2003 Annual Survey of Employer-Sponsored Health Benefits, available at <http://www.kff.org>) due to the implementation of Financial Accounting Statement No. 106 (FAS 106) as well as increasing costs. FAS 106, which was published in December 1990, required companies to make significant changes in the way that they accounted for future retiree health benefits on their balance sheets for fiscal years ending after December 15, 1992 ("Retiree Health Benefits: Trends and Outlook," Paul Fronstin, Employee Benefit Research Institute (EBRI) Issue Brief No. 236, August 2001; "Statement of Financial Accounting Standards No. 106: Employers' Accounting for Postretirement Benefits Other Than Pensions," Financial Accounting Standards Board, December 1990, available at <http://www.fasb.org/pdf/fas106.pdf>). The percentage of large employers offering retiree health coverage has continued to decline during the past decade (General Accounting Office (GAO), "Retiree Health Benefits: Employer-Sponsored Benefits May Be Vulnerable To Further Erosion," May 2001, available at <http://www.gao.gov>). However, the recent declines have been more gradual than what occurred during the early 1990s, with slightly less than 40 percent of the nation's large firms with 200 or more workers that offer health benefits to active workers also offering retiree health benefits in 2003 (Kaiser/HRET 2003 Annual Survey of Employer-Sponsored Health Benefits, available at <http://www.kff.org>).

Many of the changes in availability of retiree health coverage in the past decade have primarily affected future retirees, rather than current retirees. (Fronstin, August 2001). For example, the percentage of large employers with 500 or more employees offering retiree

health benefits to new Medicare-age (that is, ages 65 and older) retirees decreased from 40 percent in 1993 to 21 percent in 2003 (data from the National Survey of Employer-Sponsored Health Plans, 2003 cited in a press release entitled "Surprise slow-down in U.S. health benefit cost increase," Mercer Human Resource Consulting, December 8, 2003, available at <http://www.mercerhr.com>). As a result, new retirees are less likely to have employer-sponsored retiree drug coverage than current retirees.

Availability of retiree health coverage varies depending on the type of employer. Employers with union workers are more likely to offer retiree coverage than employers without union workers. Similarly, public sector employers are more likely to offer coverage to retirees than private sector employers. (Kaiser/HRET 2003 Annual Survey of Employer-Sponsored Health Benefits, available at <http://www.kff.org>; "How States Are Responding to the Challenge of Financing Health Care for Retirees," Jack Hoadley, Henry J. Kaiser Family Foundation, September 2003, available at <http://www.kff.org>.)

Availability of retiree health coverage also varies according to the size of the employer. Larger employers are more likely to offer retiree health coverage than smaller employers. For example, in 2003, 38 percent of the nation's private sector firms with 200 or more workers that offered health benefits to active workers also offered retiree health coverage to pre-age 65 and/or Medicare-age retirees (Kaiser/HRET, 2003). However, very few smaller employers offer retiree health insurance. Recent surveys have found that only 3 to 10 percent of the nation's smaller private sector firms (3 to 199 workers) that offer health benefits to active workers also offer retiree health coverage (Kaiser/HRET 2001, 2002 and 2003 Annual Surveys of Employer-Sponsored Health Benefits, available at <http://www.kff.org>).

Larger employers account for the majority of the beneficiaries with employer-sponsored retiree coverage. In 2001, data from the Medical Expenditures Panel Survey indicate that less than 1 percent of the nation's smallest private establishments (those with a "firm size," or total number of employees for the entire firm, of less than 50 employees) offered health insurance to Medicare-age retirees, compared with 37 percent of the nation's largest private sector establishments (those with a firm size of 1,000 or more employees). As a result, within the private sector, the largest firms (1,000 or more employees)

covered approximately 90 percent of the Medicare-age retirees who had employer-sponsored retiree coverage, while smaller firms (fewer than 1,000 employees) covered only 10 percent of these retirees.

In an effort to control costs, many employers have been changing their benefit packages (for example, reducing the benefit that is offered and/or increasing the amount that the retiree has to pay), resulting in gradual erosion in the generosity of this coverage over time. For example, since the mid-1990s, some employers have made changes in eligibility for retiree health coverage (for example, age and service requirements), reduced their subsidization of retiree health costs (by increasing retirees' share of premiums and increasing retirees' co-payments and deductibles), placed caps on the employer contribution to retiree health costs (aggregate or per beneficiary), or moved to offering a defined contribution health benefit (Fronstin, August 2001; GAO, May 2001). Because many employers have identified prescription drug costs as a major contributor to rising retiree health benefit costs, they have adopted cost control measures in an effort to manage their retiree prescription drug costs (Kaiser/HRET, 2003).

The intent of Medicare Part D and the retiree drug subsidy is to provide employers and unions with a set of highly flexible options that are designed to make it more affordable for them to continue providing high-quality prescription drug assistance to their Medicare-eligible retirees. As discussed earlier, the MMA Conference Report indicates that by lowering the cost of providing retiree drug benefits and providing financial incentives for employers to maintain this coverage for their Medicare-eligible retirees through Medicare Part D and the retiree drug subsidy, it is hoped that the erosion in the availability of employer-sponsored retiree drug coverage will plateau or even improve.

Overall, we expect that the implementation of Medicare Part D, including the Medicare retiree drug subsidy and the other opportunities it affords employers for providing continued prescription drug assistance to their Medicare retirees, will result in combined aggregate payments by employers and Medicare for drug coverage on behalf of retirees generally being greater—and frequently significantly greater—than they otherwise would have been without the enactment of the MMA. Furthermore, the Medicare prescription drug benefit and alternative retiree drug subsidy represent a particularly important

strengthening of health care coverage for future Medicare-eligible retirees, given the erosion in the availability and generosity of employer-sponsored retiree coverage for future Medicare beneficiaries that has been taking place.

G. Anticipated Effect on the Federal Budget

The following section presents estimates of the effect of Medicare Part D on net Federal budgetary spending. As indicated previously there is a great deal of uncertainty related to making these estimates, including the implications of outstanding policy and administrative issues that are the subject of this rule making. These represent our current best mid-range estimates of the net Federal budgetary effects. We have explored various potential approaches. We believe that these estimates provide a reasonable representation of the likely effects of a variety of proposed policies and potential options.

We expect that the Medicare drug benefit will affect several components of the Federal budget. Specifically, we anticipate that it will increase Federal spending on Medicare benefits and decrease Federal spending on Medicaid benefits (as dual eligibles' drug coverage is shifted from Medicaid to Medicare). The net effect of these changes on Federal spending is estimated to be about \$48 billion in CY 2006 and \$67 billion in CY 2010, with the total effect estimated to be about \$287 billion over the period from 2006–2010. Table V–2 provides year-by-year estimates of the net Federal budgetary effects⁶ of Medicare and Medicaid benefit spending. We discuss these effects subsequently, as well as the expected impacts of the Medicare drug benefit on Federal administrative costs for Medicare, Medicaid, and the Social Security Administration.

1. Federal Medicare Spending

We estimate that the net Federal budgetary effect of Medicare benefit spending related to Medicare Part D, including the Medicare retiree drug subsidy program, will be nearly \$59 billion in CY 2006 and \$353 billion over the five-year period from CY 2006–2010. The estimated \$353 billion in additional net Federal spending over the five-year period is made up of approximately \$401 billion in net Federal spending on direct government subsidies, government reinsurance payments, low-income subsidies, and retiree drug

subsidies, with an offset of nearly \$49 billion in additional Medicare revenues received from States to partially compensate for Medicare coverage of dual eligibles' drug costs (overall, we estimate States will save due to reduced Medicaid spending, as is explained subsequently).⁷

In addition, CMS expects to incur administrative expenses related to the Medicare drug benefit. Implementing a new program of the size and scope of the Medicare drug benefit requires substantial implementation expenses, including extensive computer and other systems changes. We are in the process of developing estimates of these administrative costs as the policies and operational framework for the program are developed through the rulemaking process and other efforts.

2. Federal Medicaid Spending

As a result of Medicare Part D, there is expected to be a reduction in net Federal spending on Medicaid benefits for the period CY 2006–2010, with the reduction estimated to be about \$10 billion in CY 2006 and about \$66 billion over the five-year period from CY 2006–2010.

With the Medicare program providing drug coverage to dual eligibles who had previously received drug coverage through Medicaid, State Medicaid spending on prescription drugs will be reduced, and as a result Federal spending on Medicaid matching payments will also be reduced. We estimate reduced Federal Medicaid spending on prescription drugs for full-benefit dual eligibles of about \$12 billion in CY 2006 and about \$76 billion during the five-year period from CY 2006–2010.

The reduction in Federal spending for Medicaid prescription drug benefits will be partially offset by an increase in Federal Medicaid spending for newly enrolled dual eligibles. As discussed in more detail in the State impacts section, the additional benefits available to low-income beneficiaries through Medicare Part D and our outreach activities are likely to raise awareness of other benefits available to such individuals through Medicaid, including Medicare Savings (QMB/SLMB) programs, and lead to higher enrollment in these programs. We assume that 1.1 million more Medicare beneficiaries will enroll in Medicaid, including Medicare Savings (QMB/SLMB) programs, in CY 2006 as a result of the Medicare drug

benefit. As discussed later in the State impacts section, we estimate that a larger share of these beneficiaries will receive benefits as QMB/SLMB individuals than will receive full Medicaid benefits. Among beneficiaries that are eligible for, but not enrolled in Medicaid, we assume a smaller Medicaid uptake rate among those beneficiaries that are eligible for full Medicaid benefits, because we believe that if these beneficiaries were likely to sign up for the richer full Medicaid benefit package, most would have done so already. We assume a somewhat higher uptake rate for those beneficiaries that are eligible for QMB/SLMB benefits. We estimate Federal matching payments for State Medicaid expenditures for these beneficiaries will be about \$1.7 billion in CY 2006, and total about \$10 billion during the five-year period from CY 2006–2010.

In addition, the Medicare drug benefit has implications for Federal spending on Medicaid administrative costs. The statute gives responsibility to State Medicaid programs as well as the Social Security Administration for conducting eligibility determinations for low-income benefits under Part D. In addition, States are required to provide CMS with data for the purposes of calculating the amounts States are required to pay Medicare to compensate for a portion of full-benefit dual eligibles' drug costs. These activities will generate State administrative costs. Just prior to enactment of the MMA, the State share of costs for these determinations was estimated at roughly \$100 million per year beginning in FY 2005. The Federal share of costs would be expected to be roughly the same in any year, and we have projected about \$106 million in Federal matching payments for these State administrative activities in the FY 2005 budget. We plan to develop an updated estimate of State administrative costs for eligibility determination activities once the operational processes for the eligibility determinations are more fully developed, including accounting for any efficiency gains resulting from SSA participation.

3. SSA Administrative Costs

As noted previously, the Social Security Administration (SSA) is one of the entities given responsibility by the MMA for making eligibility determinations for low-income benefits under Part D as well as conducting outreach activities. In addition, SSA will be involved in premium collection via withholdings from Social Security checks. SSA's administrative costs associated with these functions will be

⁶ We note that the estimated net Federal budgetary effect of Medicare subsidy payments excludes changes to governmental receipts (that is, tax collections) because we do not have sufficient data to estimate these effects at this time.

⁷ For the purposes of this impact analysis, we do not assume any additional Medicare costs or savings related to risk corridors. We also do not assume any savings on Part A and Part B benefits.

paid out of the Medicare trust funds. Estimates of these administrative costs

will be developed as the policies and operational framework for the program

are formulated through the rulemaking process and other efforts.

TABLE V-2.—ESTIMATED NET FEDERAL BUDGETARY EFFECTS OF MEDICARE AND MEDICAID BENEFIT SPENDING, CY 2006–2010
[billions of dollars]

	2006	2007	2008	2009	2010	2006–2010
Net Effect of Medicare Benefit Spending Related to Medicare Part D						
Federal Spending Related to Medicare Part D, including the Retiree Drug Subsidy	67.2	73.1	79.7	86.8	94.7	401.4
State Payments to Partially Offset Medicare Drug Costs for Dual Eligibles	−8.5	−9.1	−9.7	−10.4	−11.1	−48.7
Subtotal	58.7	64.0	70.0	76.4	83.6	352.6
Net Effect of Medicaid Benefit Spending						
Additional Federal Matching Payments for Newly Enrolled Dual Eligibles	1.7	1.9	2.1	2.2	2.4	10.4
Reduction in Federal Matching Payments for Medicaid Drug Expenditures for Dual Eligibles	−12.0	−13.5	−15.1	−16.9	−18.9	−76.3
Subtotal	−10.2	−11.6	−13.0	−14.6	−16.4	−65.9
Net Federal Budgetary Effects of Medicare and Medicaid Benefit Spending	48.4	52.4	56.9	61.8	67.1	286.7

NOTE: Positive numbers denote increased spending; negative numbers denote reduced spending (that is, savings). Numbers may not sum to totals due to rounding and exclude effects on Federal revenues.

H. States

1. Overall State Budgetary Impacts

We estimate that, as a result of Medicare Part D, States will realize net savings of \$8.2 billion over the CY 2006–2010 period. Estimated State savings range from approximately \$500 million in CY 2006, increasing each year during the five-year period, to reach about \$3 billion by CY 2010. The estimated \$8.2 billion in net State savings over the five-year period are made up of \$65.3 billion in State savings related to Medicare Part D that are partially offset by \$57.1 billion in State costs related to Medicare Part D.

We estimate that States will save approximately \$65 billion as the Medicare Part D drug benefit and Medicare retiree drug subsidy provide financial support for prescription drug costs of full-benefit dual eligibles, State retirees, and participants in State prescription drug assistance programs. The vast majority of these State savings are the result of Medicare Part D replacing drug coverage for full benefit dual eligibles that would otherwise be paid for by Medicaid. States will also achieve savings due to Medicare retiree drug subsidies that will be available to State governments that provide qualified prescription drug coverage for their retirees. States that operate prescription drug assistance programs, as well as states with Pharmacy Plus programs, will also realize additional savings as Medicare Part D displaces a portion of their spending on

prescription drug coverage for enrollees. Savings for State prescription drug programs are discussed in more detail in a separate section later in this analysis.

The estimated \$65 billion in State savings, discussed previously, will be partially offset by approximately \$57 billion in State costs related to Medicare Part D over the period CY 2006–2010. Those costs include State payments to the Federal government to partially offset Medicare Part D costs for full-benefit dual eligibles, additional Medicaid benefit spending resulting from an anticipated increase in Medicaid enrollment, and reduced State premium tax revenues as some beneficiaries shift from drug coverage that is subject to State taxation to Medicare Part D which is exempt from taxation.

The largest component of these costs are State payments to the Federal government to defray a portion of the Medicare drug expenditures for full-benefit dual eligibles, estimated at about \$48.7 billion from CY 2006–2010. As discussed in the preamble, the States and the District of Columbia are required to make these monthly payments beginning January 1, 2006. It is important to note that the data sources and methodology used to estimate these State payments for the purposes of this impact analysis differ somewhat from those that will be used, as stipulated by statute and described in more detail in Subpart S of the preamble, to calculate the actual State payment amounts for 2006. The

expenditure data that will be used to calculate the actual State payment amounts are not yet available, and thus for the purposes of this impact analysis we relied on MCBS as the data source to produce an estimate of aggregate State payments.

Another component of these costs is increased State Medicaid spending due to increased Medicaid enrollment. We anticipate that in the process of outreach and applying for the Part D low-income subsidy, some beneficiaries will learn of their eligibility for other low-income assistance such as Medicaid or Medicare Savings (QMB/SLMB) programs and choose to enroll in these programs. We estimate that about 1.1 million additional beneficiaries will enroll in Medicaid or the Medicare Savings programs in CY 2006; with 23 percent of those beneficiaries estimated to receive full Medicaid, 19 percent to receive QMB benefits, and 58 percent to receive SLMB benefits. We estimate that State Medicaid spending on benefits for these individuals will be about \$7.8 billion over the five-year period from CY 2006–2010.

Also included in our estimate of State costs is the effect of the MMA's prohibition on States imposing taxes on premiums related to Part D coverage. As a result of this prohibition, we estimate that States will realize reduced premium tax revenues of approximately \$535 million over the period CY 2006–2010.

In addition, the statute gives responsibility to State Medicaid

programs as well as the Social Security Administration for conducting eligibility determinations for low-income benefits under Part D. We have not included these costs in our above estimates of net State savings. However, prior to enactment of the MMA, we roughly estimated the State share of costs for these determinations at approximately \$100 million a year, beginning in FY 2005. We plan to develop an updated estimate of these costs once the operational processes for the eligibility determinations are more fully developed. Given that our net savings estimate averages \$1.5 billion per calendar year and exceed \$500 million in every year, we do not believe that these administrative costs significantly affect the level of savings States will realize from implementation of Medicare Part D.

We also note that States are generally responsible for issuing licenses to health insurers. While some new PDP plans will require new licenses, the States charge fees for licensing and the States already have the mechanisms in place to handle these new license applications. Furthermore, licensing would not affect current insurers that want to become PDPs if these insurers are already licensed as insurers in a given State; the PDP would simply be a new line of business for these insurers. Thus, we do not estimate any cost implications for the States associated with licensing insurers.

2. State Prescription Drug Assistance Programs

As mentioned previously, one of the components of our estimate of net State savings resulting from Medicare Part D is savings on State Pharmaceutical Assistance Programs (SPAPs). We estimate that SPAPs spend roughly \$1.45 billion of State only resources on prescription drug assistance for 1.2 million individuals, based largely on FY 2002 data. Five States account for approximately 87 percent of the SPAP spending, and have approximately 77 percent of the enrollment. For Medicare beneficiaries who have income less than 135 percent of the Federal Poverty Level (FPL) and assets valued up to \$6,000 per individual (or \$9,000 per couple), Part D offers comprehensive drug coverage with a full Federal subsidy for the beneficiary premium and only nominal cost-sharing. Thus, SPAP expenditures on this group of Medicare beneficiaries will be mostly displaced by the Medicare prescription drug benefit. We estimate that the savings that will accrue to States as a result of Medicare Part D displacing SPAP expenditures for low-income beneficiaries will be

approximately \$600 million per year, or about \$3 billion over the five-year period from CY 2006–2010.

States with SPAPs have shown a commitment to assisting their low-income residents with drug costs. As of Spring 2004, nineteen States were operating SPAPs that provide subsidized drug coverage to individuals who will be eligible for Medicare Part D. CMS anticipates that many of these States will choose to continue providing financial assistance with drug expenditures, because they can achieve the same or greater level of assistance for their beneficiaries at a lower cost to the States. Part D provides States with a number of options for continuing their provision of prescription drug assistance to Medicare beneficiaries, if they choose to do so. States, for example, have the flexibility to restructure their SPAP programs to wrap around the Part D benefit and pay deductibles and cost sharing for beneficiaries with the State's assistance counting toward the Medicare Part D annual out-of-pocket threshold triggering protection against catastrophic drug costs. States can also provide assistance by paying for Part D premiums for beneficiaries. As part of their SPAPs, States also have the flexibility to make arrangements with PDPs and MA-PDs to provide enhanced Part D benefits.

We believe that we are presenting a conservative estimate of the displacement of SPAP expenditures, because our assessment does not include any potential State savings for SPAP enrollees at income levels above 135 percent of FPL. States that choose to restructure their programs to complement Medicare Part D can still achieve savings because of the substantial Medicare displacement of SPAP spending for low-income beneficiaries as well as for individuals who enroll in Part D and do not qualify for the low-income subsidy.

We also note that, as discussed elsewhere in the preamble, Section 1860D–23(d) of the Act provides for the payment of transitional grants to States with Pharmaceutical Assistance Programs of up to \$62.5 million in each of fiscal years 2005 and 2006. In addition, the statute provides the authority (Section 1860D–23(a) of the Act) for the Secretary to establish requirements for effective coordination between Part D plans and SPAPs. For further discussion related to coordination of benefits see the section on coordination of benefits under Administrative Costs.

To estimate potential SPAP savings resulting from Medicare Part D

expenditures, we focus our analysis on SPAP expenditures that may be spent on individuals with income below 135 percent of FPL. We are primarily relying on State-published data that describe SPAPs and their eligibility standards (sources such as State government websites, program annual reports, and Governor's budget documents). Our ongoing work with States also provides us with certain information regarding enrollment and expenditures under SPAPs. Unless we have adequately detailed State-published data on SPAP expenditures for enrollees by income, we use the Census Bureau's Current Population Survey (CPS) data to help us estimate SPAP spending on beneficiaries with income under 135 percent of FPL.

We recognize that our methodology has significant limitations and that our estimates are imprecise. For example, our analysis does not take into account the effect of the Medicare Part D assets test and does not include an estimate of potential savings for SPAP enrollees with income greater than 135 percent of FPL. We believe that States, with their own internal data and resources, are in the best position to project individual State-level impacts. Therefore, we invite States to provide specific enrollment and expenditure data by FPL for their State and any State-specific savings estimates they may have developed, as well as comments on improvements in our methodology.

3. Pharmacy Plus Waiver Programs

Four States under Medicaid section 1115 waivers operate Pharmacy Plus demonstration programs that provide assistance to Medicare beneficiaries with the cost of prescription drugs. Expenditures for these services receive Federal matching payments in the same manner as do services for full benefit Medicaid beneficiaries. Similar to the impact on State only funded SPAPs, we expect that the new Medicare drug benefit will be assuming a large share of the costs for prescription drugs previously financed through Pharmacy Plus waiver programs and consequently we believe States will achieve savings as a result. To be conservative, State savings estimates for these four Pharmacy Plus programs have not been included in our estimates of overall State savings, and would be in addition to net State savings presented in this analysis.

As noted elsewhere in the preamble the statute affords State only funded SPAP expenditures special treatment relative to the application of the TrOOP, in that the SPAP expenditures can be counted toward the out-of-pocket

protection threshold. However, as previously discussed, Pharmacy Plus waiver programs are not considered to be SPAPs. Due to the special treatment SPAPs receive relative to the TrOOP, our analysis of the States with Pharmacy Plus waivers indicates that States that operate Pharmacy Plus programs and beneficiaries enrolled in those programs could benefit financially by States restructuring their Pharmacy Plus programs to use a State only SPAP design to wrap around Medicare Part D. Under such an approach, we believe that generally States could realize savings relative to their current Pharmacy Plus spending levels and that program participants would face lower out-of-pocket costs due to the generous Medicare Part D catastrophic coverage. We welcome comments on this, and as indicated previously we would welcome further data and analyses from States.

I. Administrative Costs

There are four major areas of administrative costs associated with Medicare Part D that will be incurred by the private and public sector that merit separate discussion. These areas include the costs for PDPs and MA-PDs for administering the Medicare prescription drug benefit, the cost of creditable coverage disclosure notices that the MMA requires be provided to Medicare beneficiaries, the administrative costs associated with certain coordination of benefits as required by the MMA, and the administrative costs associated with obtaining the Medicare retiree drug subsidy. The following provides a detailed discussion of each of these areas.

1. Prescription Drug Plans and MA-PD Plans

The administrative cost estimates are based on taking into account the normal fixed costs associated with administering a prescription drug benefit, for example, such functions as claims processing, responding to customer inquiries, information dissemination, appeals processes, pharmacy network negotiations and contracting, and drug manufacturer negotiations and contracting. In addition, we assume "risk-premium" costs associated with risk-based insurance products that require companies to maintain certain levels of financial reserves. The other factor taken into account when developing our estimate is that PDPs and MA-PDs will likely incur slightly higher administrative costs during the initial few years of the Part D benefit due to start-up costs related to implementation

and initial operations for a new benefit, for example more marketing and enrollment activities. We also assume that entities that will participate as PDPs will have already made the necessary changes to be HIPAA compliant because of the other business arrangements they will have been functioning in prior to choosing to participate as a PDP under the Medicare drug benefit program.

As is typically done with insurance products, we express the average administrative costs as a percentage relative to net standard benefit expenses. This percentage is commonly referred to as the "administrative load." We estimate that the average administrative load will be 12.7 percent in CY 2006, with this declining slightly over time, and reaching 11.5 percent in CY 2010. The administrative load is expected to decline slightly over the period for two reasons: (1) administrative costs are expected to grow at a somewhat slower rate than PDP and MA-PD plans' prescription drug costs and (2) initial administrative start-up costs associated with implementation are expected to phase out in the first few years of operations.

Our estimates for administrative costs are similar to those seen in the general insurance market. Our administrative load of 12.7 percent in 2006 translates into administrative costs being about 11.2 of total Part D plan expenditures (including both benefits and administrative costs). This is similar to the share of total health plan spending accounted for by administrative costs in the private sector. For example, as CMS reported in its "Health Care Industry Market Update on Managed Care" Blue Cross Blue Shield health plans had average sales, general and administrative (SG&A) expenses ranging from 12 percent in 1999, 11.7 percent in 2000, 11.3 percent in 2001, and 10.9 percent in the first half of 2002. Similarly, in examining our Medicare Advantage plans data we see variation in administrative costs, for example newer plans (less than 5 years) seem to have higher administrative costs (11 percent) than older plans (7 percent).

The MMA also requires PDPs and MA-PDs to pay a user fee to help offset ongoing beneficiary education and enrollment costs relating to the Medicare prescription drug benefit, which represents an expansion of the user fees that are currently required of MA plans. As discussed earlier in this preamble, the MMA authorizes up to \$200 million for beneficiary education and enrollment activities in FY 2006 and thereafter, reduced by the fees that will be collected from MA organizations

and PDP sponsors in that fiscal year. Our rough estimates of the user fees for beneficiary education and enrollment costs in CY 2006 are approximately \$22 million for PDPs and \$50 million for MA organizations, with the remainder (approximately \$128 million) being the government's share. While the user fees will actually be collected on a fiscal year basis, we believe that these estimates, which are based on calendar year data, provide a reasonable estimate of what the magnitude of these user fees will be during a given fiscal year. We assume that the cost of these user fees will be built into the administrative cost structure of the PDPs and MA-PDs, and will therefore be reflected in bids. We note that these user fees represent a minuscule percentage of the estimated total payments to MA organizations and PDP sponsors under the Medicare program.

2. Disclosure Notice Requirements

A number of entities that provide prescription drug coverage to Medicare beneficiaries—Medigap plans, private and public sector employer or union sponsored plans that provide drug coverage to Medicare beneficiaries who are retired or who are active workers, State Medicaid programs including State Pharmacy Plus programs, and State Pharmacy Assistance programs (SPAPs)—are required to provide at certain times disclosure notices to beneficiaries on whether the coverage provided equals or exceeds the actuarial value of standard coverage. The largest cost for providing these notices is expected to occur in the months preceding the implementation of the drug benefit in January 2006. Thereafter, notices will generally only need to be provided by these entities if there is a change in creditable coverage status. Also, firms that provide drug coverage to active workers will have to provide disclosure notices in the future to those active workers who become new Medicare beneficiaries.

With the exception of Medigap insurers and group health plans that provide drug coverage only to Medicare beneficiaries who are active workers (and not retirees), implementation of the Medicare prescription drug benefit and the retiree drug subsidy is expected to produce net savings to public and private sector entities that provide drug coverage to Medicare beneficiaries. For State Medicaid programs, SPAPs, State Pharmacy Plus programs, and private and public sector employer sponsored plans that provide retiree drug coverage, we estimate that the cost of disclosure notices will be about \$29 million in 2005, with anticipated savings from the

implementation of Medicare Part D expected to far exceed the disclosure notice costs for each of these entities.

For Medigap insurers and group health plans that offer coverage only to beneficiaries who are active workers, not retirees, the cost of providing disclosure notices is estimated to be approximately \$69 million in 2005 (which translates into an average of roughly \$154 per employer that offers drug coverage to Medicare beneficiaries who are active workers and about \$11,050 per Medigap insurer).

We anticipate that disclosure notice costs in years after 2005 will generally be minimal. However, employer sponsored health plans that provide drug coverage to active workers are likely to expend some time in future years for disclosure notices for the more limited number of new beneficiaries who age into the Medicare program. These employer plans would also incur costs in the event that their plan has a substantial change in its benefit structure that makes a reconfirmation of their creditable coverage status appropriate. We estimate administrative costs of roughly \$5 million to \$6 million per year for these employers during the period 2006–2010.

In brief, we take the following approach to estimate the cost of disclosure notices. For the various entities that are required to provide disclosure notices, the circumstances of these different types of coverage and how they will relate to the new Medicare prescription drug benefit differ. Consequently the nature of the disclosure notice and any associated actuarial valuation will vary. Beyond the cost of the actuarial valuation are the costs of preparing and mailing the notices. We generally base our cost estimates on 2005 wage data for an actuary and administrative personnel loaded for compensation, overhead, general administration, and fee.

In terms of the basic costs of preparing and mailing the disclosure notice, we assume that each entity required to provide these notices expends 8 hours for developing the notice (with one exception), 1 hour per 60 notices for producing and disseminating the notices to beneficiaries, and 1 hour for providing a copy of the notice to CMS. The one exception to this is group health plans that provide drug coverage only to Medicare beneficiaries who are active workers, not retirees. We assume these entities expend less time developing the notice (2 hours) because we expect that this service is likely to be provided to them by insurers or health plan administrators who we anticipate will

spread the cost of this service across many employers.

In terms of the time involved in performing the actuarial valuation that forms the basis of the disclosure notices, we anticipate that it will vary somewhat by the type of entity providing the notice. In the case of Medicaid, we assume that the actuarial valuation costs will be negligible as Medicare Part D will be assuming primary responsibility for drug coverage for full benefit dual eligibles and we assume that any supplemental coverage States may provide (for example, coverage for drugs not covered under Medicare Part D) would not be creditable. With respect to SPAPs and State Pharmacy Plus programs, we expect that the actuarial assessment is not likely to be complex, and that the disclosure notice will likely focus on how the State program will work with the new Medicare drug benefit. We assume that each SPAP and State Pharmacy Plus program would expend on average 2 hours for actuarial work.

The notice requirement related to Medigap drug policies we believe will be relatively straightforward. In accordance with section 104 of the MMA, CMS is developing a model disclosure notice for Medigap insurers in consultation with the NAIC. For standardized Medigap plans, we anticipate that the actuarial work involved in developing these notices will be negligible. As discussed elsewhere in the preamble, we believe that standard Medigap plans H and I are not creditable and that it is very unlikely that plan J would be creditable. In the case of the pre-standardized policies the nature of the actuarial valuation and the level of effort involved will likely vary with the nature of the benefit package. For the purposes of this analysis, we assume that on average an actuarial valuation for an insurer offering pre-standardized Medigap policies would involve 6 hours of an actuary's time. For the three Medigap waiver states, we assume that the actuarial valuation would be fairly straightforward since these States have generally prescribed a fixed benefits structure for Medigap drug coverage. Consequently, we have assumed an average of 3 hours of an actuary's time per insurer serving the waiver States.

Employer sponsored retiree health plans that apply for the Medicare retiree subsidy will have to perform an actuarial valuation for the purposes of their application. We assume that those plans will simply use the actuarial valuation developed for the subsidy application also for the disclosure notices. Thus, we assume negligible

costs for the actuarial valuation related to the disclosure notices. Estimates of the administrative costs related to applying for the Medicare retiree subsidy, including the actuarial valuation, are discussed elsewhere in this document.

Disclosure notices are also required of group health plans that provide drug coverage to active workers who are Medicare beneficiaries (that is, beneficiaries where Medicare is the secondary payer). It is very difficult to know how many firms that provide health insurance to their active workers have a Medicare beneficiary in their workforce. We have estimated roughly as an upper bound that there may be as many as 440,000 firms that provide drug coverage to at least one Medicare beneficiary who is an active worker. We emphasize that this is a very rough estimate that extrapolates from data from a number of sources (including an IRS, SSA, CMS data match, Census data, BLS data, and a Kaiser survey).

We anticipate that many of these employers are purchasing standard health insurance products from insurers that sell these plans to numerous purchasers and that the cost of the actuarial valuation will be spread across a relatively large number of employers or third party purchasers. While self-insured employers may have more distinct health plan benefit structures, we believe that it is likely that their health plan administrators would be able to achieve economies of scale by building actuarial models that can serve a number of clients. In addition, the cost of the valuation for those employers that also offer retiree drug coverage could be incorporated into the costs required to do an actuarial valuation for both types of coverage and thus there may be some economies of scale. For these reasons, we assume that each of these employers will on average incur expenses for one-quarter of an hour of actuarial time. This relatively low number reflects our assumption that insurers will spread the cost of these valuations across a large number of purchasers.

In years after 2005, employers that provide drug coverage to Medicare beneficiaries who are active workers are likely to expend some additional time related to disclosure notices, but we anticipate this time will be substantially less than in 2005. In subsequent years, we anticipate that these employers will provide disclosure notices to their workers who age into the Medicare program and continue working. In addition, it is possible that a portion of employers may alter their drug benefit design to such an extent that a reconfirmation of their creditable

coverage status may be appropriate. We assume that those active workers who become new Medicare beneficiaries each year require notices, that about 25 percent of firms per year obtain a new actuarial valuation on their benefit design, and that about 1 percent of firms per year have a change in creditable coverage status that requires a notice.

As discussed previously, we anticipate that the disclosure notice cost per employer that offers drug coverage to Medicare beneficiaries who are active workers (and not retirees) will be relatively small—\$154 per employer on average in 2005 and substantially less in future years. However, we are concerned about these expenditures in relation to their benefits to employers and Medicare beneficiaries who are active workers and the number of firms that could potentially be affected. We seek comment on ways to minimize burden on these employers and whether other approaches could lower these costs.

3. Coordination of Benefits Under Employer-Sponsored Plans and SPAPs

CMS is required under the statute to establish requirements for coordination of benefits between Medicare PDPs and MA-PDs and other insurers including SPAPs, Medicaid programs, group health plans, FEHBP, military coverage including TRICARE, and other coverage CMS may specify. Ensuring accurate and timely coordination of benefits is important for tracking the true out-of-pocket limit, a cornerstone of the benefit design. This will necessitate that an efficient and effective operational framework be established to track beneficiary out-of-pocket expenditures. As discussed elsewhere in the preamble, CMS is considering and seeking comment on a wide range of options related to coordination of benefits. For example, one of the fundamental issues is who should have responsibility for developing the systems infrastructure needed to track beneficiary out-of-pocket expenditures—PDPs and MA-PDs or the government. If the government were to develop a system to facilitate tracking beneficiary out-of-pocket expenditures, there is the additional question of how this system should be set up operationally and how data flow should be structured into and out of the system from pharmacies, supplemental insurers, and Part D plans. Given that such a wide range of approaches is under consideration for coordination of benefits, it is not possible to estimate the administrative costs associated with coordination of benefits at this time. We seek comment on the cost implications of various

options discussed in the preamble and will be working to develop a cost estimate of coordination of benefits activities for the final rule.

4. Estimated Administrative Costs in Applying for Retiree Drug Subsidy

Qualified retiree prescription drug plans that choose to accept the Medicare retiree subsidy will incur some administrative costs associated with obtaining the subsidy. As discussed earlier in the preamble, sponsors will have to submit to CMS an application for the Medicare retiree drug subsidy, including an attestation that the actuarial value of the prescription drug coverage under their retiree plan or plans is at least equal to the actuarial value of standard prescription drug coverage under Medicare Part D, which must be signed by the plan sponsor (or a plan administrator designated by the sponsor). As part of this application, employers are also required to provide other information including data about the eligible covered Medicare retirees in their plan or plans. In addition, entities accepting the Medicare retiree drug subsidy payments will have to comply with certain reporting requirements and maintain records for purposes of audit and oversight by CMS. We also note that employer and union sponsored health plans that provide drug coverage to beneficiaries are required to provide, at certain times, creditable coverage disclosure notices to beneficiaries. These notices are required regardless of whether the plan sponsor applies for a subsidy, and consequently the costs of these notices are discussed in the section of this analysis on disclosure notices.

In developing the proposed rule, we have tried to minimize the administrative burden associated with the operation of the retiree subsidy program, and we seek comments regarding our proposed administrative approaches and reporting requirements. We want to establish an efficient administrative structure that provides maximum flexibility for qualified retiree prescription drug plans, while at the same time providing for an appropriate level of financial accountability that assures the accuracy of payments and safeguards the interests of beneficiaries, consistent with our fiduciary responsibility. Thus, we are seeking public comment on appropriate approaches for achieving this objective.

For purposes of the “Collection of Information Requirements” section and the accounting statement in this proposed rule, we have developed an estimate of the time and aggregate employer costs involved in the various

administrative functions associated with employers obtaining the Medicare retiree subsidy including: subsidy application requirements, including performing the actuarial valuation; preparing the plan(s)’ enrollment files to identify the eligible Medicare retiree population and other relevant information; assembling the application; and record retention. We base our cost estimates on 2005 wage data for an actuary and administrative personnel loaded for compensation, overhead, general administration, and fee.

a. Application for Retiree Drug Subsidy Including Actuarial Attestation

In applying for the subsidy, sponsors of qualified retiree prescription drug plans are required to provide to CMS an attestation that the actuarial value of the prescription drug coverage in each such plan is at least equal to the actuarial value of standard Medicare Part D prescription drug coverage. Sponsors of qualified retiree prescription drug plans will need to submit this attestation on an annual basis, and submit an updated attestation if there is a change during the year that materially affects actuarial value of their drug coverage. As discussed earlier in the preamble, a material change means any change that potentially causes a plan to no longer meet the actuarial equivalence test (these submissions would not be required when non-material changes are made to the coverage).

We are aware that many employers purchase retiree health coverage by paying premiums to insurance companies. Thus, one insurance company may be offering the same prescription drug benefit design to numerous employers, and consequently be able to spread the cost of the actuarial valuation across a number of purchasers. Similarly, many employers use pharmacy benefit managers (PBMs) to administer their prescription drug benefits, and again the same benefit design may be used by multiple employer plans, generating economies of scale.

We are also aware that any given sponsor may be offering more than one qualified retiree prescription drug plan in which Medicare beneficiaries are enrolled and for which Medicare retiree drug subsidy payments are sought. Another factor in the cost of actuarial attestations, however, is that employers can potentially use one actuarial model to analyze multiple plans’ benefit designs that, for example, are similar in design but use different co-payments. Thus, there may also be economies of scale in conducting the analyses for employers that have multiple plans.

Because of these factors, the total time involved in preparing the actuarial valuation is likely to vary across qualified retiree plans. To develop assumptions, we had discussions with actuaries in CMS' Office of the Actuary and other industry experts. From these discussions, we developed a range of time estimates for preparing actuarial models, taking into consideration: The use of actual plan data if it is available and credible, the time to conduct the analyses, the issue of economies of scale in the use of one model to analyze multiple plans, and the time involved in preparing the written attestation report. Based on these discussions, our preliminary estimate is that total time involved in developing one actuarial model and preparing an analysis and report on one plan could range from 6 to 40 hours. For the purposes of this analysis, we assume that average time involved in the actuarial valuation per firm ranges from one-third of an hour for very small firms (where the actuarial valuation is performed by an insurance company and its cost is spread across a large number of purchasers) to 100 hours for very large firms that offer multiple plans. Based on these assumptions and taking into account the time involved for firms of different sizes, we estimate that the cost of the actuarial valuation would on average be in the range of about 1.8 percent of the value of the retiree subsidy.

In addition to the actuarial valuation, plans sponsors applying for the retiree subsidy will need to prepare the application and related enrollment data and information on retirees, and ultimately sign the agreement if approved to receive the subsidy. We anticipate that the time involved in preparing the application and required enrollment information will vary by firm size, with the average time ranging from 5 hours for the smallest firms with 6 retirees on average to 382 hours for the largest firms with more than 1,500 retirees on average. As discussed elsewhere, some of the information needed on eligible beneficiaries may not be routinely available to plan sponsors and consequently for initial start-up some level of effort may be needed to obtain this information. We have been conservative in our assumptions to reflect this possibility. It is important to note that a significant portion of the time involved would be a one-time expense. In addition, we estimate that each firm will expend one-half hour signing and submitting the final agreement. Based on these assumptions, we estimate that on average across large and small firms, the cost involved in

preparing the application and related enrollment information (excluding the actuarial work) and ultimately signing the agreement would be in the range of about 3.2 percent of the value of the subsidy. It is important to note that after the first year, we believe these costs will decline as the initial work associated with identifying the eligible population will have been accomplished and as employers and their agents gain more experience with the program.

b. Reporting

In order to obtain the subsidy, sponsors of qualified retiree prescription drug plans will need to submit certain data to CMS and maintain certain records. This proposed rule outlines a number of different options we are considering in terms of data reporting. At this time, we have not determined which option is the most efficient and effective method of obtaining the data and information necessary for administering this program and we seek public comment on the various options.

As discussed in detail in the preamble and the alternatives considered section, the options that we are considering related to data reporting vary in terms of their scope, level of detail, and frequency of data reporting activities. Consequently, at this time it is not possible to estimate the administrative costs of reporting requirements under this proposed rule. However, we anticipate that the administrative costs associated with the data reporting will be small relative to the Medicare retiree drug subsidy payments received by employers. Because prescription drug data and records are highly automated, there are significant economies of scale related to reporting and audit requirements. In addition, one of our primary objectives in establishing the data reporting requirements will be to do so in as cost effective a manner as possible while upholding our fiduciary responsibilities. We seek public comment on the administrative costs associated with any of the data reporting options under consideration in this rule, as well as any other approaches for minimizing such costs.

In addition to data reporting, employers that receive the subsidy will also be required to retain data and records for six years. For the purposes of this analysis, we assume that the time involved in record retention would vary by firm size, with the average time ranging from 4 hours for the smallest firms to 20 hours for the largest firms. Based on these assumptions and taking into account the varied time involved across firms of different sizes, we

estimate that on average the record retention would be in the range of about 0.5 percent of the value of the subsidy.

c. Conclusion

Based on our analyses, we estimate that the administrative costs associated with obtaining the retiree subsidy (excluding the data reporting requirements not yet determined) will represent on average in the range of about 5.5 percent of the value of the subsidy in 2006 and are expected to decline significantly in subsequent years. After the first year, we believe these costs will decline as the initial work associated with identifying the eligible population will have been accomplished and as employers and their agents gain more experience with the program.

J. Medigap Provisions

The MMA prohibits Medigap insurers from selling new Medigap policies that cover prescription drugs after December 31, 2005 and prohibits the renewal of existing Medigap policies with drug coverage for beneficiaries who enroll in Medicare Part D. Part D enrollees with current Medigap drug coverage have the choice of renewing their existing Medigap policy without drug coverage or buying certain other Medigap plans that do not have drug coverage if they enroll in a Part D plan in the initial enrollment period. We emphasize that the MMA itself directly restructures the role of Medigap insurance, and that it is not the result of this rulemaking.

We estimate that about 1.9 million beneficiaries would be enrolled in Medigap plans with drug coverage in 2006, absent the law change. As discussed elsewhere in this analysis, we assumed nearly all of these beneficiaries will enroll in Medicare Part D. As a result of the statutory prohibition on the sale of Medigap policies with drug coverage to Part D enrollees, we expect these beneficiaries will move from Medigap policies that contain prescription drug coverage to Medigap policies that do not contain such coverage. We expect that the policies without drug coverage will have lower premiums. If all beneficiaries with Medigap drug coverage enrolled in the Medicare drug benefit, we estimate that the reduction in Medigap insurers revenues associated with MMA prohibition on the sale or renewal of policies with drug coverage would be approximately \$2.5 billion in 2006, \$2.6 billion in 2007, \$2.8 billion in 2008, \$3.0 billion in 2009, and \$3.2 billion in 2010. We note, however, that some Medigap insurers may choose to enter the PDP or MA-PD market and offer

those products. This market entry might mitigate the revenue impacts on these insurers, and could even possibly produce a revenue gain for these insurers, as the Medicare prescription drug benefit would be subsidized and likely attract more enrollees. In addition, we believe that the movement of beneficiaries from Medigap drug coverage to Medicare Part D will generate substantial savings for these beneficiaries on prescription drug costs. The standard Medicare Part D benefit provides a 75 percent subsidized benefit, catastrophic coverage, and cost savings from discounts and other cost management activities. It also is not likely to suffer from the substantial adverse selection, and resulting increased premiums, that are seen in Medigap plans with drug coverage.

Our estimates of Medigap enrollment in policies with drug coverage and the premiums associated with that drug coverage were developed using data from NAIC on standardized Medigap plans, and information gathered by a CMS contractor on pre-standardized Medigap plans and waiver State plans. While our estimates do not take into account standalone Medigap drug policies, these policies represent substantially less than 1 percent of the Medigap market and would not affect the estimates.

K. Small Business Analysis

The Regulatory Flexibility Act (RFA) requires agencies to determine whether a proposed rule will have a "significant economic impact on a substantial number of small entities."

If a rule is expected to have a significant economic impact on a substantial number of small entities the RFA requires that an Initial Regulatory Flexibility Analysis (IRFA) be performed. Under the RFA, a "small entity" is defined as a small business (as determined by the Small Business Administration (SBA)), a non-profit entity of any size that is not dominant in its field, or a small government jurisdiction. HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

With respect to the Medicare prescription drug benefit and retiree drug subsidy, there are three areas that we believe merit discussion related to small business impacts: (1) Pharmacies, (2) insurers and PBMs, and (3) employers. We anticipate that the pharmacy industry, which is comprised of both chains and a large number of independent pharmacies, will play a critical role in the Medicare drug benefit

as it furnishes prescription medicines and pharmacy services to beneficiaries enrolled in Medicare Part D. While the Medicare prescription drug benefit is expected to have several effects on pharmacy revenues, both positive and negative, our estimate is that the impact on the overall pharmacy industry, including small pharmacies, will be positive.

Since PDPs and MA-PDs are the principal vehicles through which the Medicare prescription drug benefit is administered, we also examine whether there are any small business impacts on the types of businesses expected to apply to be prescription drug plans—that is, insurers and PBMs. Our analysis suggests that while the statutorily created Medicare Part D program would increase drug utilization and thus be favorable to insurers and PBMs, this proposed rule as such will have little overall effect on the insurance and PBM industry, and certainly not a significant adverse impact.

In the case of the small employers who continue to provide qualified prescription drug coverage for their retirees, we estimate that savings obtained from the Medicare retiree drug subsidy will greatly exceed the employer's administrative costs associated with obtaining the subsidy, and thus the result of the retiree drug subsidy provision is a net positive impact. We would like to make participation in the retiree drug subsidy program as simple as possible for small entities.

While we believe that we could certify that this proposed rule will not have a significant economic impact on a substantial number of small entities, we provide an Initial Regulatory Flexibility Analysis (IRFA) and request comment on this conclusion as well as any aspects of the rule that might adversely affect small businesses, or that could be modified to increase positive impacts.

In addition, in accordance with Section 1102(b) of the Social Security Act, we also address whether this rule will have an impact on the operations of small rural hospitals.

1. Pharmacies

The RFA requires us to determine whether this rule will have a significant economic impact on a substantial number of small pharmacies. SBA considers pharmacies with firm revenues of less than \$6 million to be small businesses. The 1997 Economic Census (the latest available detailed data) indicates that there were about 21,000 firms operating about 41,000 retail pharmacies and drug store

establishments (NAICS code 44661) continuously through 1997. Of these firms, about 20,000 had revenues under \$5 million (which was the small business size standard in 1997) and operated a total of about 21,000 establishments. Since over 95 percent of pharmacy firms are small businesses (as defined by the SBA size standards), we do expect that the statutorily-created Medicare prescription drug benefit will have some effect on a substantial number of small pharmacies. However, we estimate that overall the revenue effect on the retail pharmacy industry, including small pharmacies, will be positive. Furthermore, we emphasize that this effect is really a result of the statutorily-created Medicare prescription drug benefit, and not this rulemaking.

We anticipate that, although the Medicare prescription drug benefit will lead to both revenue increases and decreases for pharmacies, the increase in revenues is estimated to more than offset the decrease in revenues. First, we expect that the vast majority of beneficiaries currently without prescription drug coverage will choose to enroll in Medicare Part D. The extension of drug coverage to these individuals, and the resulting lower out-of-pocket costs they face when purchasing prescription drugs, is expected to lead to higher drug utilization and total expenditures, and consequently higher revenues for pharmacies. At the same time, some of these beneficiaries without prior drug coverage, as well as some beneficiaries with Medigap drug coverage, would be expected to realize new pharmacy discounts under Medicare Part D that they otherwise would not obtain. We note that the Medicare prescription drug benefit would not lead to any additional pharmacy discounts for the majority of beneficiaries who currently have drug coverage as they already obtain pharmacy discounts through their current insurers (for example, employer-sponsored health plans, Medicare Advantage plans, and State plans). In addition, we have examined the potential for increased use of mail order pharmacies among some beneficiaries, and its potential impact on retail pharmacies. As described in more detail subsequently, we estimate that the countervailing effects of increased utilization and new pharmacy discounts and possibly new use of mail order pharmacies among some beneficiaries would result in a net increase in retail pharmacy revenues ranging from a lower bound of 1.7 percent to an upper bound of 3.0 percent.

Second, since State Medicaid programs typically pay higher reimbursement rates to pharmacies than private sector insurers. We expect that pharmacies would experience some reduction in revenues due to the movement of full-benefit dual eligibles from Medicaid drug coverage to Medicare drug coverage (through PDPs and MA-PDs). As discussed in more detail subsequently, our upper bound estimate of the average reduction in pharmacy revenues that could result from full-benefit dual eligibles receiving drug coverage from Medicare is 1.1 percent. We believe this is an overestimate of the revenue reduction because it does not take into account the effect of the Federal Upper Payment Limit on reducing Medicaid reimbursement rates for many multi-source drugs. Also, to the extent that a State Medicaid program has adopted managed care arrangements to lower the cost of drugs for dual eligibles, our estimate of the revenue impact of pharmacy reimbursement changes for full-benefit dual eligibles would be overstated.

Considering together the effect of increased utilization, new pharmacy discounts and possibly new use of mail order pharmacies among some beneficiaries, and reimbursement changes for full-benefit dual eligibles, we estimate that retail pharmacy revenues would experience a net increase ranging from 0.6 percent to 1.9 percent, as a result of the Medicare prescription drug benefit. Furthermore, while we are not able to provide a quantitative estimate at this time, we expect that pharmacies may realize additional revenues from the MMA requirement that PDPs and MA-PDs offer medication therapy management programs to targeted enrollees, which may be furnished by pharmacists. Our estimates also do not take into account that increased use of prescription drugs resulting from the Medicare drug benefit may lead to increased foot traffic in pharmacies and increased sales for pharmacies' other goods in addition to prescription medicines.

We note that our estimate of the overall impact on small pharmacies represents the average effect. We recognize that the effect on any specific pharmacy will likely vary to some extent around the average. While we have estimated that the average effect on small pharmacies would range from 0.6 percent to 1.9 percent, it is possible that some individual pharmacies could experience smaller positive effects and even in some cases negative revenue effects. While it is possible that a specific pharmacy because of unique

circumstances could experience a negative revenue impact, we believe that this will be uncommon. For example, it is likely that pharmacies that serve a large population of full-benefit dual eligibles (for which pharmacies would experience a revenue decrease) would tend to be located in low-income areas that also serve a large population of beneficiaries without drug coverage (for which pharmacies would experience a revenue increase). This would suggest that pharmacies that experience larger than average revenue reductions for full-benefit dual eligibles would also tend to be those that experience larger than average revenue increases for beneficiaries without prior drug coverage. However, lack of data makes estimating the distributional effects among small pharmacies speculative. We seek comments and data that can help inform this issue.

a. Expansion of Drug Coverage and Increased Access to Pharmacy Discounts Among Beneficiaries Previously Lacking Such Coverage or Discounts

A substantial portion of beneficiaries (about 24 percent as of 2001) lack drug coverage. As discussed in Section E, we project that nearly all beneficiaries without drug coverage will enroll in the Medicare drug benefit. The expansion of drug coverage to these individuals is likely to have countervailing effects on pharmacy revenues. First, it is likely to lead to increased drug utilization and spending among beneficiaries without prior drug coverage, and thus increased pharmacy revenues. Second, it is likely to lead to increased access to pharmacy discounts for some beneficiaries who previously did not receive such discounts (specifically, many beneficiaries without drug coverage and beneficiaries with Medigap drug coverage), and thus decreased revenues for pharmacies. Because many beneficiaries that currently have prescription drug coverage (for example, those in employer sponsored retiree health plans or Medicare Advantage plans) already receive pharmacy discounts through those insurers, we do not expect the Medicare prescription drug benefit to generate any new pharmacy discounts for these beneficiaries. In addition, it is possible that the Medicare drug benefit may lead to new use of mail order pharmacies among beneficiaries without prior drug coverage and beneficiaries with Medigap drug coverage, potentially having some effect on retail pharmacy revenues. Overall, we estimate that increased utilization for beneficiaries without prior drug coverage and new pharmacy discounts and possibly new

use of mail order pharmacies among some beneficiaries will result in a net positive revenue impact for retail pharmacies.

Medicare beneficiaries without prior drug coverage who enroll in the Medicare drug benefit will face a substantial reduction in out-of-pocket costs for prescription medicines, and consequently we expect that their drug utilization and expenditures will increase. Beneficiaries with drug coverage fill more prescriptions and have higher total drug spending than beneficiaries without drug coverage. Based on 2001 MCBS data, beneficiaries with drug coverage have average total drug spending that is 109 percent greater than beneficiaries without drug coverage. These spending differences hold true even among beneficiaries with similar numbers of chronic conditions. For example, average spending for beneficiaries with drug coverage was higher than for beneficiaries without drug coverage among beneficiaries with no chronic conditions (247 percent higher), 1–2 chronic conditions (107 percent higher), 3–4 chronic conditions (76 percent higher), and 5 or more chronic conditions (53 percent higher). Thus, we expect that the expansion of drug coverage to beneficiaries who previously did not have such coverage will lead to increased drug utilization and spending, and thus higher pharmacy revenues. For the purposes of this analysis, we assume that beneficiaries without prior drug coverage who enroll in the Medicare drug benefit will experience a 76 percent increase in total drug spending. We base this assumption on the fact that most beneficiaries without drug coverage fall into the category of having 1–2 chronic conditions or 3–4 chronic conditions, and we have chosen the more modest use difference seen in the 3–4 chronic condition group. Furthermore, we believe that this is a conservative assumption because the average difference across the population in drug spending for beneficiaries with and without coverage is 109 percent. Since beneficiaries without drug coverage account for about 13 percent of all drug spending by Medicare beneficiaries (based on 2001 MCBS data), if we assume that all of these previously uninsured beneficiaries enroll in the Medicare drug benefit and experience a 76 percent increase in drug expenditures due to a use effect, this would represent about a 9.9 percent increase in total drug spending by Medicare beneficiaries.

At the same time, to the extent that beneficiaries without drug coverage did not receive pharmacy discounts prior to

Medicare Part D, we would expect that pharmacy discounts negotiated by PDPs and MA-PDs could result in some reduction in pharmacy revenues. While the vast majority of beneficiaries who currently have drug coverage are likely to already be receiving pharmacy discounts, and thus the Medicare drug benefit would not result in any change in pharmacy discounts for these beneficiaries, this may not be the case for beneficiaries without drug coverage. As mentioned previously, the April 2000 HHS Report "Prescription Drug Coverage, Spending, Utilization, and Prices" found that on average individuals with drug coverage paid a 15 percent lower price for prescription drugs at the point of sale than individuals without drug coverage. The discount insured individuals receive at the point of sale reflects a combination of pharmacy and manufacturer discounts. However, to take a conservative approach, we assume that Medicare Part D enrollees without prior drug coverage realize 15 percent price discounts at the point of sale, all of which reflect pharmacy discounts. This assumption is conservative not only because it assumes that the entire 15 percent discount comes from pharmacies, but also because some of these beneficiaries are likely to have received pharmacy discounts previously through the Medicare drug discount card, which began offering discounts in June 2004 and which includes substantial discounts from drug manufacturers, and through senior pharmacy discounts previously offered by many pharmacies. Thus, our assumption that all Part D enrollees without prior drug coverage would receive new pharmacy discounts of 15 percent under Medicare Part D overstates the negative revenue impact on pharmacies. With these beneficiaries accounting for about 13 percent of all drug spending by Medicare beneficiaries, we estimate that extending a 15 percent discount to these beneficiaries would result in about a 2 percent decrease in total drug spending by Medicare beneficiaries.

Another group of beneficiaries who we believe may obtain new pharmacy discounts under Medicare Part D are beneficiaries with Medigap drug coverage. Some Medigap plans do not actively negotiate prescription drug discounts for enrollees. As a result, these beneficiaries who enroll in Medicare Part D may also realize new pharmacy discounts. As discussed elsewhere in this impact analysis, we estimate that 1.9 million beneficiaries would have Medigap drug coverage in

2006, absent the law change. To be conservative, we assume that all of these beneficiaries with Medigap drug coverage obtain new pharmacy discounts under the Medicare drug benefit. With these beneficiaries accounting for about 4 percent of prescription drug spending by all beneficiaries, we estimate that extending pharmacy discounts to these beneficiaries could result in about a 0.6 percent decline in total Medicare drug spending by beneficiaries.

It is also possible that the Medicare prescription drug benefit may result in new use of mail order pharmacies by some beneficiaries. We believe that the new Medicare benefit is unlikely to affect the use of mail order pharmacies among beneficiaries currently with employer sponsored or Medicare Advantage drug coverage as mail order is an option currently available to these beneficiaries and the implementation of Medicare Part D makes no changes in this regard. We also believe that there is likely to be no effect on mail order use by beneficiaries who qualify for the low-income subsidy because nominal cost sharing exists regardless of where the beneficiary purchases the prescriptions (and as noted above, for those without prior drug coverage or less generous prior drug coverage, we expect that these beneficiaries will fill significantly more prescriptions). The two groups where it is possible that mail order usage may increase are beneficiaries without prior drug coverage and beneficiaries with Medigap drug coverage. The effect of Medicare Part D on mail order use by these beneficiaries, however, is uncertain. For example, Medicare Part D includes a provision that allows retail pharmacies (subject to state pharmacy laws) to provide a 90-day supply, putting them on equal footing with mail order pharmacies in this regard.

To estimate the potential effect of new mail order use among beneficiaries without prior drug coverage and beneficiaries with prior Medigap drug coverage, we take the approach of making estimates based on two alternate assumptions. As a lower bound, we assume that there is no additional mail order use. As an upper bound, we assume that the percent of beneficiaries using mail order pharmacies among these two groups of beneficiaries increases to be similar to the rate of use among beneficiaries with private employer-based drug coverage. There is limited publicly available data related to mail order utilization. To supplement publicly available data we tried to obtain information from proprietary sources to help inform our upper bound

estimates. For our upper bound assumptions, we use data from the Medical Expenditure Panel Survey (MEPS) to assign higher rates of mail order use (that is, the percentage of population that fills at least one prescription through mail order) to the population that gains drug coverage and to beneficiaries with prior Medigap drug coverage. We also tried to obtain data on the share of drug spending through mail order pharmacies that occurs among individuals who use these pharmacies. However, we were unable to obtain this type of information. We were able to obtain some proprietary information regarding the share of total plan spending occurring through mail order and retail pharmacies for a commercially insured over 65 population. Using this information in combination with the recognition that a number of prescriptions are unlikely to be filled through mail order (for example such as antibiotics and pain medication used to treat acute conditions, or newly prescribed medications), we developed an upper bound assumption that as much as 50 percent of drug spending among new users of mail order might occur through mail order pharmacies. We do not expect mail order use to approach this level; we use it simply for purposes of estimating the maximum potential impact. Under this upper bound assumption, we estimate that as a result of mail order effects, aggregate Medicare drug spending in retail pharmacies could decrease by as much as 1.9 percent. Thus, based on our lower bound and upper bound assumptions, we estimate that possible new use of mail order pharmacies among some beneficiaries could result in a decrease in retail pharmacy revenues of somewhere between 0 to 1.9 percent. If a shift in mail order use were to occur, our prior estimates of utilization and discount effects would be altered slightly since they are based on the assumption of no change in mail order use. We estimate that under our upper bound assumptions related to mail order, our previous estimates of the combined effect of utilization increases and new pharmacy discounts for some beneficiaries would need to be adjusted downward by as much as 1.2 percentage points. We note that even with these adjustments based on a very high upper bound assumption, the net effect for retail pharmacies remains positive. We welcome additional data that could help inform our assumptions and analysis related to new mail order use by beneficiaries who previously did not have drug coverage.

Taken together, we estimate that the effect of expanding access to prescription drug coverage among beneficiaries without prior drug coverage and the effect of new pharmacy discounts and possibly new use of mail order pharmacies by some beneficiaries will result in a net increase in total prescription drug spending by Medicare beneficiaries at retail pharmacies of between 4.1 percent and 7.3 percent. We estimate that this would represent an average increase in retail pharmacy revenues of between 1.7 percent and 3.0 percent, as Medicare beneficiaries account for about 40.5 percent of outpatient prescription drug spending for the non-institutionalized population according to 1999 MEPS data (Stagnitti MN et al., AHRQ, "Outpatient Prescription Drug Expenses, 1999", 2003). Furthermore, while not quantifiable at this time, we expect that pharmacies may realize additional revenues from the MMA requirement that PDPs and MA-PDs offer medication therapy management programs to targeted enrollees, which may be furnished by pharmacists. In addition, it is likely that increased use of prescription drugs by Medicare beneficiaries will lead to increased foot traffic in pharmacies and increased pharmacy revenues from non-pharmaceutical products as well.

b. Medicare's Assumption of Drug Coverage for Full-Benefit Dual Eligibles

Because State Medicaid programs typically pay higher reimbursement rates to pharmacies than private sector insurers, the movement of full-benefit dual eligibles from Medicaid drug coverage to Medicare drug coverage (through PDPs and MA-PDs) has potential implications for pharmacy revenues. Our upper bound estimate of the average reduction in pharmacy revenues that could result from full-benefit dual eligibles receiving drug coverage from Medicare is 1.1 percent. We believe that this is an overestimate because it does not take into account the effect the Federal Upper Payment Limit has in reducing Medicaid reimbursement rates for multi-source drugs with at least three generic equivalents. Also, to the extent that a State Medicaid program has adopted managed care arrangements to lower the cost of drugs for dual eligibles, our estimate of the revenue impact of pharmacy reimbursement changes for full-benefit dual eligibles would be overstated.

We conducted the following analysis to estimate how the transfer of dual eligibles' drug coverage from Medicaid to Medicare would affect pharmacy

revenues. First, we developed an estimate of the average Medicaid drug reimbursement rate across States. To begin, we considered how Medicaid reimburses pharmacies for drugs. Medicaid reimburses pharmacies for drugs based on the estimated acquisition costs (EAC) plus a dispensing fee. There is variation across States in how they define and the level at which they set EAC and the dispensing fee. The vast majority of States define EAC as the average wholesale price (AWP) less a certain percentage discount, while a small number define it as wholesale acquisition cost (WAC) plus a certain percentage or the lower of an AWP-based or WAC-based payment amount. Dispensing fees also vary by State and typically range from \$3 to \$5. Some States use the same reimbursement formula for brand and generic drugs, while others institute a greater discount off of AWP for generic drugs or a higher dispensing fee for generic drugs, and in some cases both. In addition, Medicaid reimbursement rates for multi-source drugs with 3 or more generic equivalents are generally capped by the Federal Upper Payment Limit.

Based on information on the Medicaid EAC and dispensing fee for each State for brand and generic drugs as of January 2004, we estimated the overall drug reimbursement rate (EAC plus dispensing fee) as a percent of AWP separately for brand and generic drugs. We did this by estimating the dispensing fee as a percent of the average AWP, using unpublished Express Scripts data on the average AWP for brand drugs (\$77.42) and generic drugs (\$32.57) in 2002.⁸ (It should be noted that under this methodology the total reimbursement rate for generic drugs (including the ingredient cost and the dispensing fee) as a percent of AWP is much greater than the reimbursement rate as a percent of AWP for the ingredient cost alone, because the dispensing fee represents a fairly high percentage of AWP for low cost generic drugs.) For States that set EAC based on WAC rather than AWP, we express their reimbursement formula in AWP terms by assuming that WAC is equivalent to roughly 20 percent of AWP, based on information about the typical relationship between WAC and AWP in

the 2000 HHS Prescription Drug study. After estimating an overall Medicaid reimbursement amount for brand and generic drugs for each State, we estimate the weighted average reimbursement rate across States, using the number of full-benefit dual eligibles with drug coverage in each State for weights. Based on this method, we estimate that average Medicaid reimbursement to pharmacies (for ingredient cost and dispensing fee combined) is roughly equivalent to AWP minus 7 percent for brand drugs and AWP for generic drugs. It should be noted that this likely overstates the Medicaid reimbursement rate for generic drugs because it does not take into account that Medicaid reimbursement for multi-source drugs with 3 or more generic equivalents is generally capped by the Federal upper payment limit.

We then estimated an average Medicaid reimbursement rate across all drugs (brand and generic) by weighting the average reimbursement estimates for brand and generic drugs by the percent of Medicaid expenditures we assume they comprise. According to a survey of State Medicaid programs by the Kaiser Family Foundation, States estimate that 80 percent of State Medicaid drug expenditures are on brand drugs and 20 percent on generics. Using these figures for weights, we estimate an overall average Medicaid drug reimbursement rate (including dispensing fee) of roughly 5 percent off of AWP.

Second, for the purposes of this analysis, we make assumptions about the average pharmacy reimbursement rate for brand and generic drugs under PDPs and MA-PDs. We base these assumptions on available literature about typical pharmacy reimbursement rates under private sector insured products. It must be noted that these assumptions are not meant to convey our expectation of the actual pharmacy reimbursement rates negotiated by PDPs and MA-PDs with pharmacies under the Medicare drug. Instead, they are assumptions made solely for this regulatory flexibility analysis.

According to a survey sponsored by Takeda Lilly of employer sponsored insurance plans covering more than 17 million lives, the average reimbursement for ingredient cost for a brand drug in 2002 was about 14 percent off of AWP (Takeda, "The Prescription Drug Benefit Cost and Plan Design Survey Report," 2003). In addition, according to a report by Express Scripts, there tends to be about a three times greater discount off of AWP for generic drug ingredient cost than for brand drug ingredient cost (Express Scripts, "Drug Trends 2002

⁸These unpublished Express Scripts estimates of average AWP for brand and generic drugs in 2002 reflect the average AWP for a 30-day equivalent weighted by the number of scripts, based on utilization data from a commercially insured population age 65 and older, with employer sponsored insurance and with an integrated benefit (network and mail prescription coverage).

Report," June 2003). Based on these studies, we assume reimbursement for ingredient costs of 14 percent off of AWP for brand drugs and 42 percent off of AWP for generic drugs. In terms of dispensing fees, the Novartis Pharmacy Benefit Reports, which is a survey of HMO plans, finds an average dispensing fee of \$1.79 for brand drugs and \$2.08 for generic drugs as of 2002 (Novartis, "Pharmacy Benefit Report: Facts and Figures," 2003). The Takeda Lilly survey of employer-sponsored plans indicates an average dispensing fee of \$2.13 for brand and \$2.22 for generic drugs. For the purposes of this analysis, we average the findings from the two studies and assume a dispensing fee of \$1.96 for brand drugs and \$2.11 for generic. Similar to the Medicaid reimbursement analysis, we estimate these dispensing fees as a percent of average AWP for brand and generic drugs and then add them to our ingredient cost reimbursement assumptions to arrive at average reimbursement estimates—11 percent off of AWP for brand drugs and 35 percent off of AWP for generic drugs. We then weight the average reimbursement estimates for brand and generic drugs by the percent of expenditures they are assumed to comprise to arrive at an overall average reimbursement estimate (including dispensing fee) of 16 percent off AWP for all drugs.

Third, we estimated the share of national retail prescription drug spending accounted for by Medicaid drug expenditures on dual eligibles. According to a special analysis by the Kaiser Commission on Medicaid and the Uninsured, Medicaid prescription drug spending on dual eligibles was \$9.5 billion in 2000, including fee-for-service and managed care and netting out manufacturer rebates (Kaiser Commission on Medicaid and the Uninsured, "The Proposed Medicare Prescription Drug Benefit: A Detailed Review of Implications for Dual Eligibles and Other Low-Income Medicare Beneficiaries," September 2003). In addition, national retail prescription drug spending, net of manufacturer rebates, was \$121.5 billion in 2000 according to National Health Expenditures projections by our Office of the Actuary. (<http://www.cms.hhs.gov/statistics/nhe/projections-2003/t11.asp>). Based on the above figures, we estimate Medicaid drug spending on dual eligibles comprised about 7.8 percent of total national retail prescription drug spending net of rebates in 2000. While this estimate is based on drug spending

adjusted for rebates, drug spending without adjustments for rebates would be a better measure of the actual amount of revenues flowing through pharmacies. Manufacturer rebates typically occur on the back end between manufacturers and third party insurers and do not impact pharmacy revenues. Therefore, we adjust our estimate to pre-rebate levels of drug spending using the following method. We take national retail prescription drug spending net of rebates and inflate it based on our Office of the Actuary's estimate that national retail prescription drug spending in 2000 would be 6 percent higher without the adjustments for rebates. We also take our estimate of Medicaid prescription drug spending for dual eligibles and inflate it based on information from the Kaiser Study, which indicates that rebates reduced Medicaid fee-for-service drug spending in 2000 by an average of about 19 percent. Absent information on the percent of Medicaid drug spending for dual eligibles that is under fee-for-service versus managed care, we take an extremely conservative approach and inflate Medicaid drug spending to pre-rebate as though all spending had been fee-for-service. It should be noted that we strongly believe this overstates the amount of Medicaid drug spending on dual eligibles, and thus overstates any negative revenue impact on pharmacies. Based on the above, we estimate that Medicaid drug spending on dual eligibles is about 9.1 percent of total national retail prescription drug spending. Finally, we estimate the potential impact on pharmacy revenues of transferring responsibility for drug coverage of full benefit dual eligibles from Medicaid to Medicare.

Based on our previous estimates of average pharmacy drug reimbursement rates under Medicaid and private insurers, we estimate that prescription drug spending on dual eligibles would account for about 8.1 percent of national retail prescription drug spending if drugs were reimbursed at rates typical of private sector insurer rates rather than Medicaid.⁹ Thus, our upper bound estimate of the average reduction in pharmacy revenues that could result from full-benefit dual eligibles receiving drug coverage from Medicare is about 1.1 percent.¹⁰ As mentioned previously,

we believe that this is an overestimate of the impact on pharmacies because it does not take into account existing policies that reduce Medicaid reimbursement rates such as the Federal Upper Payment limit for multi-source drugs with at least three generic equivalents.

c. Conclusion

Considering together the effect of increased utilization, new pharmacy discounts and possibly new use of mail order pharmacies among some beneficiaries, and reimbursement changes for full-benefit dual eligibles, we estimate that retail pharmacy revenues would increase on average by between 0.6 percent and 1.9 percent as a result of the Medicare prescription drug benefit. This is the result of an increase in prescription drug revenues ranging from 1.7 percent to 3.0 percent due to the net effect of increased utilization, new pharmacy discounts, and possibly new use of mail order pharmacies among some beneficiaries, and a 1.1 percent decrease in pharmacy revenues (upper bound estimate) due to drug coverage for full-benefit dual eligibles shifting from Medicaid to Medicare.

In addition, we believe that these estimates underestimate the degree to which pharmacy revenues increase as a result of the Medicare prescription drug benefit for several reasons. Our estimate of the revenue reduction resulting from the transfer of drug coverage for full benefit dual eligibles from Medicaid to Medicare is likely to be overstated because it does not take into account the effect of the Medicaid upper payment limit on reducing Medicaid reimbursement rates for some multi-source drugs. In addition to revenue effects we have estimated, the Medicare prescription drug benefit is likely to provide other sources of revenue increases for pharmacies; for example, through targeted medication therapy management programs under Medicare Part D which may be furnished by pharmacists, or through increased foot traffic in pharmacies leading to increased pharmacy sales of other goods in addition to prescription medicines. For these reasons, we estimate that the Medicare prescription drug benefit will have a positive revenue impact on the pharmacy industry overall.

We believe that the program's effect on small pharmacies specifically will also be positive. We expect that small pharmacies will participate in the networks of Medicare Part D plans and consequently will share in the positive revenue impacts. We believe that given the current industry practice of broad

⁹The 8.1 percent figure is computed by multiplying our estimate of drug spending for dual eligibles as a percent of NHE (9.1 percent) by our estimate of pharmacy reimbursement rates typical of private sector insurers (AWP—16 percent, or 84 percent of AWP) and dividing by our estimate of average Medicaid pharmacy reimbursement (AWP—5 percent, or 95 percent of AWP).

¹⁰The 1.1 percent decrease does not equal 9.1 percent – 8.1 percent due to rounding.

pharmacy networks, together with the special any willing provider provision for pharmacies under Medicare Part D, all pharmacies that wish to participate in the program will be able to do so. As shown previously, over 95 percent of pharmacy firms are small businesses, and these firms operate about half of all retail pharmacies. The general practice of PBM companies is to build large networks that encompass both chains and independents in an area. According to a study by PricewaterhouseCoopers, the average PBM has 42,000 pharmacies in its network and the two largest PBM networks contain approximately 57,000 pharmacies, 98 percent of all pharmacies in the United States (PricewaterhouseCoopers report "Study of Pharmaceutical Benefit Management" at <http://www.cms.hhs.gov/researchers/reports/2001/cms.pdf>). Furthermore, a survey by the Pharmaceutical Care Management Association of five Medicare drug discount card programs found that on average the card program networks contained about 80 percent of pharmacies, with one of the five programs surveyed including nearly 95 percent of pharmacies. While broad pharmacy networks are typical of current industry practice, the MMA includes a special "any willing provider" provision that further promotes inclusiveness in pharmacy networks under the Medicare drug benefit. The MMA requires that a PDP or MA-PD must accept a pharmacy into its network if the pharmacy is willing to agree to contractual terms offered by the sponsor. This type of arrangement is not typical of standard industry practice, and was not required in the Medicare Drug Discount Card program. We believe that it helps ensure that all pharmacies that wish to do so have the ability to participate in the Medicare prescription drug benefit. Finally, according to the PricewaterhouseCoopers study, independent pharmacies also have the ability to participate in pharmacy networks through a Pharmacy Services Administrative Organization, which gives them group purchasing leverage and the ability to secure PBM reimbursement rates that are comparable to those attained by chains. For these reasons, we would expect the great majority of small business pharmacies to share in the increased business created by the Part D drug benefit.

Although we believe that the revenue effects on small pharmacies will be positive, we seek comments on this conclusion and on any aspect of this

proposed rule that may adversely affect pharmacies of any size.

2. Insurers and Pharmacy Benefit Managers (PBMs)

This proposed rule sets forth the terms and conditions that must be met by firms to be approved to offer the Medicare prescription drug benefit. Organizations sponsoring the Medicare prescription drug benefit can be either stand alone Prescription Drug Plans (PDPs) or Medicare Advantage Prescription Drug Plans (MA-PDs). The requirements for Medicare Advantage are discussed in our separate proposed rule. That proposed rule includes an IRFA specific to the Medicare Advantage program. Consequently the discussion here will focus on PDP sponsors. As discussed previously in the preamble, in order to be approved to offer the Medicare prescription drug benefit as a PDP an entity must be organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan, or have secured a time-limited Federal waiver. The SBA size standard for "small entity" health insurance firms is annual revenue of \$6 million or less.

Our IRFA for the Medicare Advantage proposed rule includes an extensive discussion related to insurance firms that might potentially be eligible to be MA plans. That analysis is also applicable to insurance firms that might be interested in being a PDP. As noted for the MA market and equally applicable to the PDP market, essentially all of the insurance firms affected by the statute and our proposed rule exceed size standards for "small entities" within the meaning of the RFA and implementing SBA guidelines, which state that an insurance firm is "small" only if its revenues are below \$6 million annually. Standalone drug insurance policies are not a typical product in the insurance market today. Thus, the range of insurance companies that may choose to enter this market is uncertain. However, we anticipate that a portion of the insurance firms that might be interested in being a PDP and thus affected by these proposed rules are "small entities" by virtue of their non-profit status.

PDP eligibility provisions in the MMA rely on the Medicare Advantage enrollment provision (continued unchanged from prior law) that no health insurance plan is normally eligible to participate unless it already serves at least 5,000 enrollees. Section 1860D-12(b)(3) of the Act provides that this minimum shall be waived during

the first contract year in a region, since PDPs in the context of Part D are new entities. While there is also a 1,500 minimum standard enrollment for plans that predominantly serve rural populations, in the context of PDP services areas designed on a regional basis, we do not believe a predominantly rural situation would occur. Consequently, we have not considered this level of enrollment in our analysis. We welcome comment on this issue. At the 5,000-enrollee level, no insurance plan would fall below the SBA revenue cutoff assuming estimated average per enrollee revenue of approximately \$1,675 in 2006, a revenue level similar to that of prescription drug plans under the standard Medicare Part D benefit. Therefore, the statutory limits generally prevent any insurance firm defined as "small" pursuant to the RFA's size standards from participating in the program. It is also important to note that PDPs will only operate on a regional basis. The MMA specifically states that there will be no fewer than 10 regions and no more than 50 regions, not including the territories. Thus, the statute itself envisions risk-bearing entities that are operating on a fairly large-scale basis.

In our IRFA for the Medicare Advantage program, we include a detailed analysis on regional Medicare Advantage market and small entities. That discussion is applicable to the PDP market, and therefore we are not repeating that same discussion here. That analysis also reviews the local Medicare Advantage market. As is noted in that analysis the option to be a local MA-PD plan provides opportunity for health insurance entities of all types and sizes (but probably not below the "small" insurance entity cutoff level defined by the SBA, which is lower than appears viable for a Part D risk-bearing insurance plan) to participate in offering the Medicare prescription drug benefit, albeit as part of a comprehensive benefit offered on a local basis. We point out that many HMOs are non-profit entities, as are several dozen Blue Cross and Blue Shield plans, and conclude that on balance Medicare Advantage provide favorable opportunities for them, although regional boundaries may pose problems for some. We note that a number of HMOs and other insurers including a number of Blue Cross plans are sponsoring Medicare-endorsed drug discount cards under that new program, which suggests their future ability to participate as PDP or MA-PD participants, regardless of profit status. While this proposed rule extends

certain requirements related to the provision of Part D benefits to Medicare Advantage plans (for example, network adequacy standards and any willing pharmacy provisions), we believe that these requirements will not result in consequential additional costs for MA-PD plans. We believe that any well-designed plan would already meet or readily be able to accommodate these standards. For example, we believe that competition among plans for enrollees will necessitate that they have a pharmacy network that is at least as broad as those stipulated by our network adequacy standards.

The other organizations that we think potentially may be interested in being PDP sponsors, or most certainly working closely with PDP and MA-PD sponsors to administer all or part of their drug programs, are pharmacy benefit managers (PBMs). PBMs are a relatively new player in the health care market. A major limitation on PBMs being PDP sponsors, however, is the statutory requirement for State licensure as a risk bearing entity, a status PBMs have not historically achieved. As discussed in section C (Federalism) of this Regulatory Impact Analysis, the MMA provides for a time-limited waiver to obtain State licensure, during which an organization can be approved by CMS to be a PDP sponsor. Since the Part D benefit is new, we do not currently have information on whether PBMs are considering becoming PDP sponsors, and would welcome comment regarding this issue.

There are basically two types of PBMs in the market today. Some are subsidiaries of health plans (that is, managed care organizations or insurance companies), and others are independent PBMs. PBMs have evolved over time in the nature of services they provide. In the late 1970s and early 1980s they offered claims processing services. In the late 1980s and early 1990s their services evolved to include pharmacy network design and management, formulary design and manufacturer rebate negotiations, mail order pharmacy services, drug utilization review, and enrollee services (for example, call centers). During the 1990s, PBMs generally expanded to become managers of a wide array of pharmacy services as plan sponsors sought to control drug costs. For example, some PBMs now also provide clinical services such as disease management, and physician and patient education.

Under the "carve-out" trend by which pharmacy benefits are administered separately from medical benefits in employer-sponsored insurance, PBMs are now believed to administer roughly

half of all pharmacy benefits for employer health plans, and this share is rising rapidly. The primary reasons are analyzed in a 2003 General Accounting Office report ("Federal Employees Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies" available at <http://www.gao.gov>; see also the CMS study on PBMs cited above). These reports and others conclude that PBMs help insurance plans achieve significant savings in their drug coverage, for example, through use of discounts and rebates to lower prices, through drug utilization review, and through shifting sales from name brands to generics. Obviously, insurance plans can do these things for themselves, but most find that PBMs substantially improve their ability to achieve savings.

Because PBMs rely heavily on computerized systems to manage pharmacy records, they also provide safeguards against many kinds of medication errors through drug utilization review. Which services a PBM provides to a particular plan sponsor is negotiated between the PBM and the sponsor. Selection of a PBM (usually one, but sometimes two, one for mail order and one for retail) by plan sponsors is strongly influenced by the expected cost of drug benefits, with PBMs gaining a competitive advantage in contractual negotiations by offering lower average costs per prescription.

There are believed to be about one hundred PBM firms. Some are standalone companies, but most are subsidiaries of health insurance firms (for example, Wellpoint and Anthem) or owned by drug store chains (for example, Walgreens). Although a handful of particularly large firms account for most of the "covered lives" and industry revenue, the industry is regarded by analysts as highly competitive. We have no information on the size of the smaller firms in the industry, but it is likely that none of them, or at most a very small number, would fall below the \$6 million annual revenue threshold used by the SBA for defining "small entities" in the insurance industry. (The smallest companies are in any event most likely to be subsidiaries or components of health insurance companies and other large firms). This is an industry in which there appear to be marked advantages to larger size, through both economies of scale and bargaining power. Nor do we believe that a substantial number, if any, are non-profit entities. We do, however, request additional information on the characteristics of this industry and its firms.

The MMA will expand PBM business in two ways. First, assuming that all or most PDPs and many MA-PDs will use PBMs, and that nearly all beneficiaries without drug coverage will enroll in a plan providing drug coverage, we anticipate that millions of beneficiaries will start purchasing their drugs using PBM-managed benefits. Second, all or most of those currently enrolled in plans that cover drug purchases on an indemnity basis (rather than through PBMs), and who sign up for PDP or MA-PD plans, will start using PBM services. This latter group includes most of the 1.9 million persons we estimate are currently enrolled in Medigap plans that offer drug coverage. Thus, drug insurance plans using PBMs are likely to enroll millions of new covered lives. Because these enrollees are on average much higher utilizers of drugs than most covered lives in the private sector, this will create positive and significant economic impact on the future volume of business for these firms.

Obviously, the scope, timing, and nature of additional PBM business will depend on the future decisions of PDP and MA-PD sponsors, and the PBMs themselves, and ultimately on the decisions of Medicare beneficiaries as they make choices among their various insurance options. Nothing in this rule directly regulates PBMs, positively or negatively, or directly encourages or discourages their use over alternative methods of managing drug benefits. Furthermore, there are many other influences on the role of PBMs and on the amount of drug spending that they manage. Chief among these is the continuing growth in spending on prescription drugs and the incentives this creates to control costs.

It is possible that decisions on regional boundaries (not part of this proposed rule) may affect the ability of some PBM firms to compete for PDP and MA-PD contracts, but we believe that most if not all PBMs that are not plan-specific will compete in broad regions or the entire nation. We welcome information on any possible problems that regional boundary decisions could create.

For all the reasons given above, we conclude that while the statutorily-created Part D and Medicare Advantage programs will be largely favorable to PBMs, this proposed rule as such will have little or no direct effect on the PBM industry, and certainly not a significantly adverse effect on a substantial number of small entity PBMs. However, we request comments on this conclusion and on any provisions that might adversely affect such firms.

3. Small Employers

In the case of the small employers, public and private, who provide qualified prescription drug coverage for their retirees, we estimate that savings obtained from the Medicare retiree drug subsidy will exceed by several-fold the employer's administrative costs associated with obtaining the subsidy, and thus the result of the retiree drug subsidy provision is a net positive impact. We would like to make participation in the retiree drug subsidy program as simple as possible for small entities. Accordingly, we request comments on any provisions of this proposed rule that may be particularly difficult for small entities, and on any alternatives that might lessen such burdens.

As noted earlier, we estimate that the administrative costs associated with obtaining the Medicare retiree drug subsidy (excluding data reporting costs, which are not yet quantifiable) will represent on average about 5.5 percent of the Medicare retiree drug subsidy payments in 2006 (declining in subsequent years after initial start-up costs), and that the bulk of these costs will be associated with preparing the actuarial valuation, retiree drug subsidy application, and related enrollment information. It is important to note that this estimate reflects an average across all employers. While administrative costs for small employers as a percent of retiree subsidy dollars are likely to be somewhat higher than the average, we believe that subsidy payments to small employers are still likely to exceed the administrative costs of obtaining the subsidy by more than several-fold. Although smaller employers will spread their administrative costs across fewer qualifying retirees for whom they will be receiving Medicare retiree drug subsidy payments than larger employers, they are expected to have lower costs associated with identifying their Medicare retirees and related enrollment information than large employers. Additionally, we expect that small employers that purchase retiree coverage from insurance companies are likely to have lower direct costs associated with the actuarial valuation due to the spreading of these costs across many employers that are purchasing the same insurance product. Alternatively, as discussed elsewhere in this document, employers (both small and large) may decide to restructure their prescription drug coverage to provide continued coverage by providing enhanced benefits or providing supplemental wraparound coverage, and thus will be positively

impacted as a result of beneficiaries now receiving contributions to their drug coverage from Medicare.

We believe that affected small businesses are unlikely to experience increased revenues of the magnitude that would approach 3 to 5 percent of revenues due to the Medicare retiree drug subsidy payments. We arrive at this conclusion as follows. First, we estimate the number of covered lives per firm offering retiree coverage. To make this estimate, we use 2001 data from the Medical Expenditure Panel Survey (MEPS) on the number of establishments (by firm size), with retiree coverage for the over 65 population, and the number of retirees covered by these establishments. As a conservative approach, we assume two covered lives per retiree to estimate the number of covered lives in these establishments. This assumption overstates the number of covered lives as not all Medicare beneficiaries will be married, or are married to an individual who is also a Medicare beneficiary. Second, we convert the number of establishments offering age 65 and over retiree coverage to a firm based count using the ratio of the number of establishments to the number of firms, based on the U.S. Census Bureau's Statistics on U.S. Businesses for 2001 (see <http://www.census.gov/epcd/www/smallbus.htm#EmpSize>). Using this firm based count we then estimate the average number of age 65 and over covered lives per firm. For firms with fewer than 100 employees our estimated average number of 65 and older covered lives was 6.15; the corresponding figure for firms with a firm size of 100 to 999 employees was 44.7. Data for 2001 on the overall number of establishments, the overall estimated number of firms, the number of estimated firms with retiree coverage for retirees aged 65 and over, the number of covered retirees, and the estimated number of retirees and covered lives per firm, are shown in Table V-3.

As an extreme example, we assume the absolute maximum subsidy per person that an employer can receive in 2006 is \$1,330 (that is, 28 percent of the difference between \$250 and \$5,000, and assuming no further adjustment related to netting out discounts, chargebacks or rebates). As discussed earlier, we estimated an average per capita Medicare retiree drug subsidy amount at \$611 in 2006 (which, for example, would be equivalent to about \$815 of taxable income for employers with a marginal tax rate of 25 percent and about \$940 of taxable income for employers with a marginal tax rate of 35 percent). Using the \$1,330 value, the

retiree drug subsidy payments would be about \$8,178 per firm with less than 100 employees and \$59,456 for firms with 100 to 999 employees. These amounts almost certainly are overstated because they assume that every qualifying covered retiree would have annual allowable prescription drug costs of at least \$5,000 in 2006, and that each firm would thus receive the maximum retiree drug subsidy payment for every covered individual, which is unlikely.

We compare these estimates with revenues for firms of these respective sizes. We trend forward 1997 revenue data by firm size, from the U.S. Census, to 2001 based on the annual change in the average Consumer Price Index (CPI). While revenues would likely grow at a faster rate than the CPI due to increases in the quantity of items and/or services sold, we take a conservative approach by only accounting for increases in prices from 1997 to 2001 via the annual changes in the average CPI. The most recent year that data on revenues are available is for 1997. We used U.S. Census Bureau data for 2001 for estimating the number of firms. The estimated per firm average revenues for 2001 are about \$1.2 million for firms with a firm size of less than 100 employees and \$28 million for firms with a firm size of 100 to 499 employees.

The Medicare retiree drug subsidy payments, therefore, represent only 0.7 percent of total revenues for firms with a firm size of less than 100 employees, and 0.2 percent for firms with a firm size of 100 to 999 employees. Because revenue data are not available for firms with 100 to 999 employees, we conservatively use the per-firm revenues for firms with a firm size of 100 to 499 employees to represent the per firm revenues for firms with a firm size of 100 to 999 employees. For further illustrative purposes, Table V-4 shows by different firm sizes the revenue impacts using the maximum assumption on retiree drug subsidy payments. Even for the smallest firms, the revenue impacts of the subsidy would be less than 2 percent. The table shows that, as the firm size increases, the percentage of the revenues accounted for by the subsidy decreases. We therefore conclude that this proposed rule will not have a significant economic impact on a substantial number of small employers. This conclusion applies equally to non-profit employers and small local government employers, though we do not have detailed data on these groups (had we the data, the comparison would have been on a cost rather than revenue basis, but the relationships of retirees to active

employees would have been similar.) Because of the likely interest in the Medicare retiree drug subsidy program, however, we present some additional background information related to the number of small entities that might potentially be eligible to receive the Medicare retiree drug subsidy payments.

To estimate the number of potentially eligible small businesses for RFA purposes, we need to determine the appropriate standards for identifying a small business. In general, the Small Business Administration (SBA) has size standards that define small businesses within a given industry based on either the average annual receipts (millions of dollars) or average employment (number of employees) of a firm ("Table of Size Standards Matched To North American Industry Classification System Codes, January 28, 2004," U.S. Small Business Administration, available at <http://www.sba.gov>). However, we did not have data available on retiree coverage among either establishments or firms by annual revenues, but these data are available by employee size. We used an alternative size standard for RFA purposes based on our consultation with the Office of Advocacy at the Small Business Administration (SBA). The alternative size standards are based on the number of the firm's employees, rather than the firm's annual revenues.

Because our data from the Medical Expenditure Panel Survey (MEPS) on the number of establishments providing retiree drug coverage are at the 2-digit North American Industry Classification System (NAICS) code level and the MEPS industry group level (which is based on rolling-up 2-digit NAICS codes), while the SBA size standards are at the 6-digit NAICS code level, we developed an approach for rolling up the size standards to the 2-digit NAICS code level. For the purpose of our

analysis, we classified a business within a 2-digit NAICS code as small business based on the largest SBA employment size standard among all the six-digit NAICS codes that comprised that two-digit NAICS code. It is likely that this methodology overstates the number of small businesses because some large businesses are likely counted as small businesses. Our employee firm size standards ranged from 150 to 1,500 employees.¹¹

We estimate the number of small businesses who offer retiree drug coverage based on an analysis of 2001 MEPS data. We mapped the 19 two-digit NAICS codes to nine MEPS industry groups. Where the MEPS industry group consisted of two or more two-digit NAICS codes, we defined a small business using the largest employee size standard among the two-digit NAICS codes that crosswalked to the MEPS industry code. However, for each of nine MEPS industry groups, the MEPS data do have the number of establishments offering retiree health insurance coverage by the number of employees in the firm. We estimate that in 2001, there were 399,751

establishments offering retiree coverage to their retirees age 65 and older. Of this total, 65,208 (not shown in Table V-3) were small businesses, based on the small business size standards (that is, 150 to 1,500 as noted earlier). These businesses represented 1.3 percent of all small establishments. These businesses also accounted for 16 percent of all establishments offering retiree coverage to their retirees that were age 65 and over.

While in the case of small businesses the number of establishments is very similar to our estimate of number of firms, this relationship is not the case for the largest firms; that is, those firms with more than 1,000 employees. As a result, from a firm perspective, we

estimate that firms with less than 1,000 employees account for 93 percent of all firms offering coverage to retirees age 65 and over, but account for only 10 percent of all retirees with employer-sponsored coverage.

While we have data on the number of small employers who offer retiree coverage, by industry sector, we do not have data on the number of retirees covered by small employers by industry sector. The only analysis we are able to do is the distribution of age 65 and over retirees between large firms with 1,000 or more employees and firms with less than 1,000 employees that offer retiree health coverage to this population. Most covered retirees receive their drug coverage from large employers, both because these large employers are more likely to provide coverage, and large employers have a large number of retirees. According to data from MEPS, in 2001 the largest private sector firms (1,000 or more employees) covered 90 percent of all the retirees who had employer-sponsored retiree coverage, with only 10 percent of retirees being covered in firms of less than 1,000 employees.

As discussed previously, we expect that Medicare Part D will also positively impact those small employers that had provided retiree drug coverage prior to implementation of the Medicare prescription drug benefit but choose not to obtain the Medicare retiree drug subsidy payments. For example, some of these employers may choose to provide alternate forms of prescription drug coverage by either offering enhanced Medicare Part D benefits for their retirees or providing wraparound coverage. These employers would see reductions in their spending on retiree drug coverage, as the Medicare prescription drug benefit would partially offset their spending on drug coverage.

TABLE V-3.—ESTIMATED NUMBER OF COVERED RETIREES IN PRIVATE SECTOR ESTABLISHMENTS AND FIRMS, 2001

Firm size	Number of private sector establishments, 2001 *	Number of private sector firms, 2001 *	Ratio of number of establishments to number of firms	Number of private sector establishments that offer coverage to retirees aged 65 and over, 2001 **	Estimated number of private sector firms that offer coverage to retirees 65 and Over, 2001	Number of covered retirees aged 65 and over **, 2001	Estimated average number of retirees per private sector firm	Estimated number of covered lives, per private sector firm (assuming 2 covered lives per retiree)
Less 100 than employees	5,058,525	4,851,266	1.04	39,308	37,697	115,899	3.1	6.15
100 to 999 employees	418,085	93,876	4.45	29,438	6,610	147,745	22.4	44.70
1,000 or more employees	913,080	8,795	103.82	331,006	3,188	2,432,542	763.0	1,525.91

¹¹ We used the following alternative size standards for the purpose of this RFA: less than 150

employees (NAICS codes 42 and 44), less than 500 employees (NAICS codes 11, 23, 56, 71, 72, and 81),

and less than 1,500 employees (NAICS codes 21, 22, 31, 48, 51, 52, 53, 54, 55, 61, and 62).

TABLE V-3.—ESTIMATED NUMBER OF COVERED RETIREES IN PRIVATE SECTOR ESTABLISHMENTS AND FIRMS, 2001—Continued

Firm size	Number of private sector establishments, 2001 *	Number of private sector firms, 2001 *	Ratio of number of establishments to number of firms	Number of private sector establishments that offer coverage to retirees aged 65 and over, 2001 **	Estimated number of private sector firms that offer coverage to retirees aged 65 and over, 2001	Number of covered retirees aged 65 and over **, 2001	Estimated average number of retirees per private sector firm	Estimated number of covered lives, per private sector firm (assuming 2 covered lives per retiree)
Total	6,389,690	4,953,937	n/a	399,751	47,496	2,696,186	56.8	113.53

Sources: *U.S. Census Bureau, Statistics of U.S. Businesses, 2001, <http://www.census.gov/epcd/www/smallbus.htm#EmpSize>.

**Medical Expenditure Panel Survey (MEPS), 2001.

TABLE V-4.—ANALYSIS OF MEDICARE RETIREE DRUG SUBSIDY IMPACTS FOR DIFFERENT PRIVATE SECTOR FIRM SIZES

Firm size	Number of private sector firms, 2001	Total revenues, 2001 (in 000s)	Estimated per firm revenues, 2001	Estimated number of covered lives per firm	Maximum per person subsidy	Total estimated retiree drug subsidy amount	Estimated subsidy as percent of revenues (percent)
1 to 9 employees	3,716,934	\$1,815,857,996	\$488,535	6.15	\$1,330	\$8,178	1.7
10 to 19 employees	616,064	1,049,691,336	1,703,867	6.15	1,330	8,178	0.5
20 to 99 employees	518,258	2,781,101,533	5,366,249	6.15	1,330	8,178	0.2
100 to 499 employees	85,304	2,385,814,720	27,968,380	44.70	1,330	59,456	0.1

Sources: Number of Firms, Revenues: U.S. Census Bureau, Statistics of U.S. Businesses, <http://www.census.gov/epcd/www/smallbus.htm#EmpSize>.

4. Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory flexibility impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. This rule will not affect small rural hospitals since the program will be directed at outpatient prescription drugs, not drugs provided during a hospital stay. Prescription drugs provided during hospital stays are covered under Medicare as part of Medicare payments to hospitals. Therefore, we are not providing an analysis.

5. Other Requirements in the Regulatory Flexibility Act

The RFA lists five general requirements for an IRFA and four categories of burden reducing alternatives to be considered. We know of no relevant Federal rules that duplicate, overlap, or conflict with the proposed rule (which in any event establishes a new program). The analysis above, taken together with the rest of this preamble, addresses all these general requirements.

We have not, however, addressed the various categories of burden reducing alternatives listed in the RFA as appropriate in IRFAs. These alternatives, such as an exemption from coverage of the rule for small entities, establishment of less onerous requirements for small entities, or use of performance rather than design standards, simply do not apply to a situation in which a program beneficial to entities both large and small is being created, and in which the regulations do not create economically “significant” burdens. Furthermore, the consumer choice-driven Medicare prescription drug benefit is overwhelmingly a “performance” system rewarding plans that operate at lower costs, provide better services as evaluated by enrollees and potential enrollees. For Part D benefits, CMS operates in a stewardship role, not as the promulgator of detailed design standards (except in a few areas, such as protections for enrollees). As to the retiree drug subsidy program, we likewise propose no detailed design standards, restricting our regulations to the minimum necessary to meet statutory requirements and to assure that benefits are actuarially qualified and payments to employers soundly administered. However, throughout the preamble we identify issues and options for attention by affected entities. We welcome comments on these and suggestions for additional steps we can

take, consistent with the underlying statute, to minimize any unnecessary burdens on plans, pharmacies, employers, or other affected entities.

L. Accounting Statement

In accordance with the OMB A-4 circular on regulatory impact analyses, we have included an accounting statement in Table V-5. The Medicare prescription drug benefit and retiree drug subsidy represents a transfer of revenues from taxpayers to Medicare beneficiaries, States, and retiree plans sponsored by employers and unions. The table provides an estimate of the annualized amount of transfers from taxpayers to these entities over the five-year period from 2006–2010. For the purposes of the accounting statement, these estimates are shown separately with a 3 percent and 7 percent discount rate in 2001 dollars.

The table also indicates that there will be some “off-budget” administrative costs associated with the Medicare prescription drug benefit, specifically the costs associated with disclosure notices, coordination of benefits, and the Medicare retiree drug subsidy. Costs associated with these activities are discussed in the respective sections of this impact analysis.

The accounting statement also provides a summary of the effects of the proposed rule on State and local governments and small businesses, as

discussed in the relevant sections of the analysis.

TABLE V-5.—ACCOUNTING STATEMENT ANNUALIZED ESTIMATES FOR MEDICARE PRESCRIPTION DRUG BENEFIT AND RETIREE DRUG SUBSIDY, 2006–2010
(2001 dollars in billions)

	3 percent discount rate	7 percent discount rate
Transfers		
Monetized Transfers: "on budget": From Taxpayers to Beneficiaries, States, and Employers.	\$45.9	\$40.9
Administrative Costs: "off budget": Notice Requirement	\$0.02	\$0.02
Coordination of Benefits	Not quantifiable at this time	Not quantifiable at this time
Administrative Costs Incurred by Employers to Obtain the Medicare Retiree Drug Subsidy (Excluding Data Reporting Costs).	5.5 percent of subsidy in 2006 and declining in subsequent years.	5.5 percent of subsidy in 2006 and declining in subsequent years
Category	Effects	
Effect on State and Local Governments	Net positive effect on State and Local Governments: \$1.9 billion (3 percent discount rate) and \$1.7 billion (7 percent discount rate).	
Effect on small business	Small Pharmacies: Positive impact. Estimated economic impact is not expected to reach the threshold for significant (3 to 5 percent of revenues). Small PBMs: Impact favorable for PBM industry, and no significant adverse impact on a substantial number of small entities. Small Insurers: Impact favorable on insurance industry, and no significant adverse impact on a substantial number of small entities as defined by SBA. Small Employers: Positive impact. Estimated economic impact is not expected to reach the threshold for significant (3 to 5 percent of revenues).	

M. Alternatives Considered

1. Designation of Regions

The MMA requires that we establish between 10 to 50 PDP regions within the 50 States and District of Columbia and at least one PDP Region covering the territories. These regions will define PDP service areas. PDPs that provide service in a particular region must cover that region entirely. PDPs can submit bids to provide services in anywhere from one to all regions.

The MMA stipulates that, to the extent practicable, PDP regions must be consistent with MA regions. However, if we determine that access to Part D benefits would be improved by establishing PDP regions that are different than MA regions, we may do so. As discussed in the preamble, we anticipate designating PDP and MA regions before January 1, 2005. The designation of regions will be made after the market study required by the MMA and the opportunity for public discussion and comment on this study.

In designating PDP regions, our primary objective will be to ensure that all beneficiaries have reliable access to PDP plans at the lowest possible cost. The law requires that beneficiaries have a choice of enrolling in at least 2 qualifying plans, at least one of which is a PDP. If it is not possible to achieve that with PDP plans undertaking the standard level of risk, the law makes

provision for limited risk PDPs, and in cases where that does not occur a fallback plan that is paid based on cost.

For several reasons, we believe it is beneficial to have several PDP plans operating in a region. Most importantly, more plans means greater beneficiary ability to obtain coverage that meets their needs and greater competitive pressure to provide high quality and low costs. We also believe that PDPs that assume some financial risk, as opposed to a fallback plan that is paid based on cost, are likely to negotiate larger price concessions for beneficiaries. In addition, more competition for enrollees between PDPs, as well as MA-PDs, is likely to generate higher quality service for beneficiaries.

Given the goal of providing beneficiary access to risk-bearing PDP plans in as many areas as possible, an important question is what type of regional configuration, or method of configuring regions, has the greatest likelihood of achieving this. One of the principal questions is whether regions should be comprised of the largest possible number (the 50 States, or a close approximation), or a smaller number of regions covering much larger geographic areas. Designating a smaller number of regions that cover large geographic areas might be desirable in the sense that areas that might be less likely to attract market interest could be

grouped with other more sought after areas. Large regions might also offer PDPs a larger potential enrollee market that would provide more leverage in negotiating rebates and discounts with manufacturers. On the other hand, regions of too large a size could deter participation if there are concerns by PDPs about providing uniform benefits and bearing financial risk across large and possibly diverse health care markets. In addition, large regions may make it more difficult for small organizations to participate as PDPs, although there is nothing to preclude small organizations from forming joint ventures to participate.

We recognize that there are a number of other factors that would affect any decision on the designation of regions, including State licensure issues for insurers and size and capital requirements for plans, as well as other potential barriers to initial or subsequent market entry; the number of competitors that are likely to operate in an area; and the goal of initiating and sustaining competition. We seek public comment on the various factors that may influence potential PDP plans' participation decisions and on how we can design regions in such a way to best ensure access to PDP plans.

The experience of the Medicare drug discount card program may provide some preliminary information that has

relevance to the designation of regions and ensuring access to PDPs under the Medicare drug benefit. The MMA required that beneficiaries have a choice of at least 2 Medicare endorsed drug discount cards. Card sponsors were allowed to designate their own service area, which could be as small as one State. If any portion of a State was included in a card sponsor's service area, the entire State must be included.

In total, 73 drug discount card programs were originally approved by Medicare. Forty of these programs were national in scope, available in every State and the District of Columbia (with three of these cards also available in the territories), exceeding the MMA requirement of choice of at least two discount cards per State. While there were numerous national cards, we believe it is uncertain whether this level of market entry would occur in the context of the Medicare drug benefit since PDPs are required to assume some financial risk unlike Medicare-approved drug card programs. Furthermore, it is possible that some discount card sponsors that entered the Medicare market at the national level did so with the intention of gathering information and experience about Medicare beneficiaries' prescription drug expenditures to guide their decision making about what regions to focus on under the Medicare drug benefit.

The remaining Medicare-approved drug cards were regional or State cards being offered in 42 States, including the District of Columbia. There was one additional card serving exclusively the territories. There were 25 regional cards that entered an individual State, the smallest possible market area. The 7 remaining regional cards entered at least two States. Nine States had no regional discount cards: Massachusetts, Rhode Island and Vermont (contiguous States); Washington and Oregon (contiguous States); Arkansas and Mississippi (contiguous States) and Alaska and Hawaii. In addition, three of these States—Alaska, Mississippi, and Vermont—did not have Medicare Advantage drug card sponsors in operation. This might suggest that in the context of the Medicare drug benefit if regions were defined at the individual State level there could be a lack of PDP participation in some regions. However, we note that it is difficult to generalize from the experience of market entry in the Medicare drug discount card program to the Medicare drug benefit, and we note that PDP sponsors with national market interests can participate in multiple regions. The large number of national Medicare-approved discount cards may also have influenced market

entry by potential regional card sponsors. If there are fewer national plans under the Medicare drug benefit, it is possible that more regional market entry might occur. However, the requirement that PDPs bear some financial risk, which is not the case with the Medicare-approved drug card program, may result in different market entry behavior at both the national and regional level.

Also noteworthy in considering the regional boundaries for the prescription drug benefit would be the number of risk bearing companies that entered the Medicare drug discount card market. There were 23 drug cards that were sponsored by insurance companies (21 of which are distinct companies). We counted Anthem and BlueCross BlueShield companies separately, due to the distinct drug card markets they serve, as well as their legal status as separate companies; but other insurance companies that were offering more than one national card were counted only once. There were 33 cards sponsored by PBMs (17 of which are distinct companies). While PBMs administer drug benefits, they historically have not been licensed as risk bearing entities although they are not precluded from doing so in the future. Thus, only 21 of the drug card sponsors were risk-bearing companies. Three of the 21 risk bearing insurance companies developed national drug cards, two others entered markets of either three or five States, and the remaining companies were sponsoring drug cards in single States.

Another issue to be considered in designating PDP regions is whether they should be the same as Medicare Advantage (MA) regions. The statute stipulates that to the extent practicable, PDP and MA regions should be the same. However, because of the nature of health plan markets for physician and provider services, as opposed to the kind of product that PDPs will be offering and the uncertainty related to configuring insurance pools for risk-based drug only products, we believe potentially it may not be feasible to have the same regional configurations for each of these programs. For example, as shown in the regional market entry for the Medicare drug discount card, there are States in which there are no entrants by regional based drug card programs, yet these are markets in which there are MA plans. Also, there were States in which there was market entry by regional card programs but in which no MA plans participate. This might suggest that different regions may be appropriate for PDPs and MA plans. However, as noted previously, it is uncertain the extent to which

experience with market entry by Medicare-approved discount card sponsors foreshadows what might occur under the Medicare drug benefit. We welcome comments on issues that should be considered in determining whether or not PDP and MA regions should be the same.

As discussed in the Medicare Advantage proposed rule, we have conducted a preliminary market survey (through Research Triangle Institute) to inform the designation of PDP and MA regions. We are providing opportunity for public input during the course of that work.

2. Bid Level Negotiations

As mentioned previously, the FEHBP standard in 5 U.S.C. 8902(i) requires us to ascertain that a PDP's or MA-PD's bid "reasonably and equitably reflects the costs of benefits provided." In addition, we note that section 1860D-11(e)(2)(c) of the Act requires that the portion of the bid attributable to basic prescription drug coverage must "reasonably and equitably" reflect revenue requirements * * * for benefits provided under that plan, less the sum * * * of the actuarial value of reinsurance payments." Analogous to the manner in which FEHBP views its management responsibilities, we see this requirement as imposing the fiduciary responsibility to evaluate the appropriateness of the overall bid amount.

In general, we expect to evaluate the reasonableness of bids submitted by at-risk plans by means of the actuarial valuation analysis. This would require evaluating the plan's assumptions regarding the expected distribution of costs, including average utilization and cost by drug coverage tier, for example, in the case of standard coverage—(1) those with no claims; (2) those with claims up to deductible; (3) those with claims between the deductible and the initial coverage limit; (4) those with claims between the initial coverage limit and the catastrophic limit; and (5) those with claims in excess of the catastrophic limit. We could test these assumptions for reasonableness through actuarial analysis and comparison to industry standards and other comparable bids. Bid negotiation could take the form of negotiating changes upward or downward in the utilization and cost per script assumptions underlying the bid's actuarial basis.

As discussed in greater detail in the preamble, we considered the circumstances and manner under which we would need to use our authority to carry out bid level negotiations. We anticipate that market forces will generally lead to efficient and

appropriate bid prices. In areas where there is competition for enrollees among a number of PDPs and MA-PDs that are at-risk for the provision of Part D drug coverage to beneficiaries, our strong expectation is that we will be able to rely on the incentives provided by competitive bidding, and we would use our authority for bid level negotiations only on the rare occasion we find that a plan's data differs significantly from its peers without any indication as to the factors accounting for this result. If there are any Regions with minimal competition (for example, just two Part D plans) or less financial risk (for example, just limited risk PDPs), we anticipate that it is possible that bid-level negotiations might be slightly more common.

A second issue we considered is to what extent we could negotiate aggregate bid prices with fallback plans. As mentioned elsewhere in the preamble, similar to at-risk and limited-risk plans, we will evaluate whether a fallback plan bid is reasonably justified, and if the price reference points appear too high or low, we may request an explanation of the bidder's pricing structure and the nature of their arrangements with manufacturers. We would also ensure that there is no conflict of interest leading to higher bids.

In addition, since fallback plans are paid on a cost basis, there is significantly less incentive for them to negotiate lower drug prices and take other steps to reduce drug expenditures. Consequently, we also considered options through the contracting process to provide fallback plans with some incentives to control cost. We are proposing to tie fallback plan performance payments to the plan's ability to keep drug costs below a certain level. We believe that this carries out Congress' requirement under 1860D-11(g)(5)(B)(i) of the Act that payments to fallback plans take into account the plan's ability to contain costs through mechanisms such as generic substitution or price discounts. Under this approach, we might include performance incentives similar to those used in many pharmacy benefit management contracts today, such as the plan achieving certain targets such as an average discount (including manufacturer discounts) off of AWP (or other pricing reference points chosen by CMS), average cost per script, average generic substitution rate, average dispensing fee per script, or average administrative fee per script. However, because these incentives would apply only to fallback plan performance fees, they would not provide as strong

incentives for drug cost control as the incentives faced by risk-bearing plans to keep overall costs down.

3. Coordination of Benefits

The MMA requires that beneficiaries' incurred costs be tracked to determine when a Medicare beneficiary enrolled in Part D is eligible for catastrophic coverage. The MMA provides that with respect to out-of-pocket expenditures: "such costs shall be treated as incurred only if they are paid by the part D eligible individual (or by another person, such as a family member, on behalf of the individual), under section 1860D-14, or under a State Pharmaceutical Assistance Program and the part D eligible individual (or other person) is not reimbursed through insurance or otherwise, a group health plan or other third party arrangement (other than under such section or such a Program) for such costs." This means that beneficiary prescription drug expenditures covered by supplemental insurers (other than SPAPs) are not considered incurred costs that count toward the true out-of-pocket cost limit (TrOOP) that triggers catastrophic coverage. Consequently, the MMA requires coordination between Part D plans and other insurers with respect to payment of claims for any prescription drug coverage that is supplemental to Medicare Part D coverage. This will necessitate that an efficient and effective operational framework be established to track beneficiary out-of-pocket expenditures. Elsewhere, the preamble of this rule discusses and seeks comment on a number of options that could be considered for developing such a framework.

There are a number of issues to be considered. One of the principal issues is what entity or entities should be responsible for creating any infrastructure needed to track TrOOP incurred costs. Should it be the responsibility of PDPs and MA-PDs or should the government be responsible for developing a system that can collect and distribute information on costs reimbursed by all payors in order to facilitate accurate calculation of TrOOP? If the government took responsibility for developing such a system, there is the additional question of whether that system should operate in such a way that pharmacies query the system or that the system provides information to Part D plans which in turn provide information to pharmacies. Another issue is whether reporting of information by supplemental insurers to a coordination of benefits system should be mandatory or voluntary. We are also considering whether or not we should

mandate that Part D plans collect information related to coordination of benefits under the Part D program, and whether or not we should mandate that beneficiaries enrolling in Part D provide third party payment information as part of their enrollment application (which might be validated through a HIPAA compliant beneficiary release of information).

In considering these various options, we believe there are a number of issues to be considered. One is the extent to which the various alternatives would advance the goal of accurately tracking beneficiary out-of-pocket expenditures. Another is the cost-effectiveness and efficiency of various options under consideration. We also think it is important to consider the cost that any coordination of benefits approach may place on various entities and the degree to which the burden is shared. We seek public comment on all of the coordination of benefits options and issues under consideration.

4. Charitable Assistance and TrOOP

We also consider the issue of whether beneficiary cost-sharing for Medicare Part D enrollees paid for by charities should be considered incurred costs that count toward the true out-of-pocket threshold (TrOOP) that triggers Medicare Part D comprehensive coverage. The MMA States with regard to out-of-pocket expenditures: "such costs shall be treated as incurred only if they are paid by the part D eligible individual (or by another person, such as a family member, on behalf of the individual), under section 1860D-14, or under a State Pharmaceutical Assistance Program and the part D eligible individual (or other person) is not reimbursed through insurance or otherwise, a group health plan or other third party arrangement (other than under such section or such a Program) for such costs." This raises the question of how cost-sharing paid for by private charities relates to the true-out-of-pocket threshold.

We believe that the statute provides discretion in terms of whether a charity's payment of a Part D enrollee's cost-sharing should be considered incurred costs that count toward the TrOOP. Many laws define "person" to include corporate entities or organizations. Since private charities tend to be corporate entities or organizations that likely do not fall into the categories of "insurance or otherwise, group health plan, or other third party arrangement," we believe there is statutory discretion to count a charity as "another person" for purposes of the TrOOP calculation.

We have proposed in this rule that payment of Part D cost-sharing by a charity should be considered incurred costs that count toward the TrOOP, provided that charitable organization does not meet the definition of "insurance or otherwise, group health plan, or other third party arrangement," as outlined in the preamble. By allowing charitable payment of Part D cost-sharing to count toward the TrOOP, we believe this will help beneficiaries who are most in need of financial assistance in affording prescription drugs. While this decision to allow charitable dollars to count toward TrOOP would increase Medicare program expenditures slightly by allowing more beneficiaries to qualify for catastrophic coverage, we would expect the additional Medicare costs to be quite small. The number of people helped by charity organizations will likely be rather modest and the impact on Medicare costs would be only for the subset of these people with catastrophic expenses. Given the very small effect on Medicare program spending and that many beneficiaries will have incomes or assets that exceed the criteria for the low-income subsidy, we feel that promoting the maintenance of charitable assistance to beneficiaries by counting charitable payments of beneficiary cost-sharing toward the TrOOP is important.

5. Actuarial Equivalence of Retiree Drug Subsidy and Interactions With Other Means of Enhancing Retiree Drug Coverage

As mentioned previously, the MMA provides the Secretary with the authority to determine the standards and methods for actuarial equivalence. In considering the issues related to actuarial equivalence we have been very cognizant that the Congress has clearly and repeatedly articulated four key policy objectives for the Medicare retiree drug subsidy program and for securing and enhancing retiree drug coverage more generally. The first goal involves maximizing the number of retirees retaining employer-based drug coverage, primarily through the retiree drug subsidy program created by Section 1860D-22 of the Act but also through the other means of assuring high-quality retiree drug coverage that are provided by the Act (including, as described above, employer wraparound coverage and employer support for enhanced Part D plans). The second goal entails not creating windfalls, where retirees might receive a smaller subsidy from sponsors of their retiree drug plans than Medicare would pay on their behalf. The third goal is to minimize the administrative burdens on beneficiaries,

employers, and unions. The final goal is to minimize costs to the government of providing retiree drug subsidies (and not exceed the budget estimates). While the first, third and fourth goals received extensive discussion during the creation of the MMA, the second goal has also emerged in response to the possibility that the MMA might create the potential for an unintended windfall.

As discussed previously in the preamble, our consideration of various alternatives reflects the four objectives of maximizing the number of beneficiaries who receive high-quality retiree drug coverage, avoiding windfalls, minimizing administrative burden, and not exceeding budget estimates. The MMA provisions creating Part D provide multiple options for plan sponsors, ranging from participating in the retiree drug subsidy to various mechanisms for enrolling retirees in Part D prescription drug plans while offering enhanced benefits. Our goal is not only to protect but also to enhance coverage offered retirees. As discussed elsewhere in this document, prior to enactment of the MMA, employers have been systematically restricting drug coverage for future retirees. Taken together, these legal and behavioral factors introduce substantial uncertainty about how plan sponsors will assess their options and react to the new Part D benefit.

We believe the Secretary has authority to achieve these goals. One key element of this authority is the requirements that plans qualifying for the retiree drug subsidy must offer at least actuarially equivalent benefits to those offered by standard Part D prescription drug plans (PDPs). We seek comments on how best to use the Secretary's statutory authority in setting the specific actuarial equivalence requirements to qualify for the retiree drug subsidy, recognizing any tradeoffs and interactions among our key goals and that our implementation of this definition must be consistent with the statutory authority provided the Secretary. As discussed previously in the preamble, there is a range of aspects of the actuarial equivalence definition, each of which may have an impact on achieving the key objectives.

a. Alternative 1: Gross Value Test

One possible definition would stipulate that plans must meet the same test as for "creditable coverage." The test for creditable coverage requires that the total or "gross" value of the benefit package offered by the employer at least equal that of the standard Part D benefit offered by PDPs, without regard to the financing of this benefit package. More

specifically, under this approach the sponsor of a retiree prescription drug plan would be eligible for a subsidy if the expected amount of paid claims under the retiree prescription drug plan is at least equal to the expected amount of paid claims under standard Medicare Part D prescription drug coverage.

However, this "single prong" approach to defining actuarial equivalence could not by itself preclude the existence of windfalls. This is because, without considering financing, an employer theoretically could impose as much as the full cost of the benefit package on the employee through employee premiums, and still be eligible for a subsidy payment if the package the employee was buying met the actuarial equivalence test. That is, the employer could contribute a smaller amount toward the financing of the package than it would receive in a subsidy payment. We seek comments on whether additional steps associated with this approach could preclude windfalls. In particular, some observers have argued that the forces in a competitive labor market, collectively bargained contracts, and constraints on changing state, local and other public sector retiree health plans obviate the likelihood of windfalls. We have serious reservations about the adequacy of such forces in precluding the existence of any windfalls without significant additional administrative monitoring by Medicare or others to assure that benefit subsidy payments are passed on to augment benefits received by retirees. Such approaches may create excessive administrative burdens on retirees, employers, and unions, and thus alternative approaches to precluding windfalls are likely to be preferable.

b. Alternative 2: Gross Value Test With Subsidy Not To Exceed Plan Sponsor Contribution

Another possible policy option would combine the gross value test with a requirement that the amount of the retiree drug subsidy could not exceed the amount paid by plan sponsors on behalf their retirees. This approach would assure the elimination of windfalls: The subsidy provided by the employer or union to the retiree's drug coverage would have to exceed the Medicare subsidy payment to the employer or union. While this approach is simple both to describe and operationalize, we have questions about the adequacy of the legal basis underpinning such a policy.

c. Alternative 3: Two-Prong Actuarial Equivalence

A third approach, which could be implemented in a variety of ways, would establish a “two-prong” test of actuarial equivalence: The “gross” test assures the total value of benefits, and the “net” test reflects only the value of benefits not financed by beneficiaries. This third approach is also structured to preclude windfalls.

Under this approach, in order to qualify for the subsidy a sponsor’s plan would have to meet both prongs of the actuarial equivalence standard. The first prong would again be a test based strictly on plan design, as described in more detail previously. The second prong would be a “net value” test in which the gross value of the plan design would be reduced to account for the level of benefits financed solely by the beneficiary. For instance, the net value of the coverage could be calculated by subtracting the retiree premium from the expected amount of paid claims under the retiree drug program.

The “net” prong of the two-prong test of actuarial equivalence has several variants. While each variant of the two-prong test precludes windfalls, each presents a different balance among potentially competing objectives. At a minimum, we believe as a policy matter that the net value of the creditable coverage should at least equal the per capita amount that Medicare would expect to pay as the retiree drug subsidy. As noted above, using MCBS data, we roughly estimate this value at \$611 in 2006, though we acknowledge that other data sources may produce other estimates. While there may be policy advantages to this approach, we have questions about the adequacy of the legal basis underpinning such a policy. We specifically invite comment on the question of whether the language could reasonably be interpreted to support this approach.

Alternatively, a higher threshold might be required, though as the threshold is raised, it would be more difficult for retiree plans to qualify that do not provide windfalls and that offer coverage that is at least as generous in overall actuarial value as the Medicare subsidy. Two other benchmarks are conceptually possible as alternative values for the net test. These two conceptually possible values would be tied either to a specified fraction of the expected value of the Medicare payment to standard Part D PDPs for retirees with enhanced coverage or to the value of the \$611 retiree drug subsidy after taking

taxes into account.¹² Determining the appropriate amount for the threshold value poses a significant data problem because of the heterogeneity of the plan sponsors. For example, we estimate that at least 60 percent of retirees that are age 65 and older receive retiree health benefits from entities that are exempt from taxation (including both public and nonprofit entities, based on data from the 2001 Medical Expenditure Panel Survey); for those plan sponsors subject to taxation, their rates of taxation vary markedly. In addition, as mentioned above, we have questions about the adequacy of the legal basis underpinning this approach.

Similarly, the value of benefits offered by plans providing creditable coverage varies widely, ranging from being only marginally more generous than standard Part D benefits to being extremely generous. (Some retiree plans provide less generous coverage, but as noted previously, they would not be creditable for purposes of the subsidy.) As a result, it could be challenging to calculate appropriate reinsurance payments and equitably operationalize the subsidies for these plans.

As noted above, adopting a two-prong test with the higher value for the net test could arguably provide greater protection to beneficiaries but might drive more sponsors out of participating in the retiree drug subsidy and toward using the Part D-based options for supporting and enhancing drug coverage. Conversely, adopting a lower value for the net test might qualify more plan sponsors to participate in the retiree drug subsidy, but it might also discourage some employers and unions from increasing their contributions to reach the higher threshold level, and thereby increasing generosity of coverage.

Finally, the employer’s decision about using the retiree subsidy versus continuing to provide enhanced retiree coverage through other means (offering supplemental drug coverage that wraps around Part D, qualifying directly for the Part D subsidy as a Part D enhanced plan, and/or paying the additional costs on top of the Medicare Part D subsidy for enhanced benefits in PDPs or in MA plans) depends on the attractiveness of each of these options. We note that none of these alternatives permit employer windfalls. We intend for these additional approaches to providing generous retiree coverage to be attractive to employers who may not make

sufficient contributions or provide sufficiently generous coverage on their own to qualify for the retiree drug subsidy. This combination of approaches will maximize the number of beneficiaries who receive additional drug coverage as a result of adding together Medicare contributions and contributions from employers and unions.

Public comment would help limit uncertainty by clarifying the likely responses of plan sponsors to these different approaches. In addition, we solicit comments not just on desirability of the different options, but as noted above on the legal bases for possible options, and on the impact of the combination of approaches on increasing the overall generosity of drug coverage available to retirees.

6. Payment Methodology—Method and Frequency of Medicare Retiree Drug Subsidy Payments

We believe that the MMA gives us broad discretion to determine the methodology for distributing the Medicare retiree drug subsidy payments. We wish to develop a payment methodology that is least burdensome to employers, technologically feasible, and cost-efficient. Additionally, our payment methodology must accommodate the exclusion of rebates from retiree drug subsidy payments.

As discussed earlier in the preamble, we are considering four potential approaches for making Medicare retiree drug subsidy payments. The first alternative that we are considering is our proposed approach, which combines monthly payments based on actual experience with monthly adjustments for price concessions as they are received. We are also considering three potential alternatives to our proposed approach: annual retroactive retiree drug subsidy payments, interim payments throughout the year with a settlement after the end of the plan or calendar year, and lagged payments based on actual experience on a periodic basis throughout the year with a settlement after the end of the year. We discuss the pros and cons of these four alternatives further below.

a. Alternative 1: Monthly Retiree Drug Subsidy Payments Based on Actual Experience With Monthly Adjustments for Price Concessions

Under the first alternative, CMS would make monthly Medicare retiree drug subsidy payments to employers based on actual claims experience throughout the year, with monthly adjustments for price concessions as

¹² There is special tax treatment available for the retiree drug subsidy. Plan sponsors get to deduct all the associated expenses but the value of the subsidy payments is not recognized as income.

they are received, along with any adjustments to actual expenditures for prior months, and a final reconciliation no later than 45 days after the end of the calendar year (excluding outstanding rebates and discounts).

Specifically, by the 15th day of each month, each qualified plan sponsor would submit information to CMS certifying the total amount by which actual retiree-beneficiary gross drug spending (based on actual claims experience) exceeded the cost threshold yet remained below the cost limit for the preceding month, and Medicare would pay 28 percent of the certified amount to the sponsor by the 30th of that month. As part of their monthly data submission to CMS, plan sponsors would also apply the appropriate share of any discounts, rebates, or other price concessions, along with any adjustments to the actual expenditures for prior months. Any amounts owed to the government would offset the retiree drug subsidy payment for that month, and to the extent that the amount owed to the government exceeds any applicable monthly payment, the plan sponsor would pay that amount to CMS. No later than 45 days after the end of the calendar year, the plan sponsor would submit a final reconciliation to CMS for payment by or, if applicable, to CMS (excluding any outstanding rebates and discounts, which may not be received until after the close of the their plan year). Plan sponsors or plan administrators would be required to maintain detailed records of claims payment and other matters.

While this alternative is arguably the most data intensive of the four alternatives that we are considering here, we believe that it is the most straightforward option, minimizing reliance on projections and actuarial representations. This option would also facilitate ensuring that sponsors receive expeditious payment of the full retiree drug subsidy amounts to which they are entitled. As discussed previously, we are considering and seek comment on whether to require a surety bond type of instrument or preferred creditor status in order to address situations related to businesses that may terminate or experience bankruptcy prior to completion of a final reconciliation.

b. Alternative 2: Annual Retroactive Retiree Drug Subsidy Payments

Under the second alternative, CMS would make an annual retroactive Medicare retiree drug subsidy payment to each employer after the end of the year. By the beginning of the fourth month after the end of the year, each employer would submit information to

CMS on the number of months of coverage for each qualifying covered retiree and their gross and allowable costs. These costs would be based on data derived directly from claims payments and retiree cost-sharing for prescriptions dispensed during the year and discounts, chargebacks and rebates for that year. CMS would review this submission and make a payment for the year by the end of the following month. This alternative would be the simplest to administer of the four alternatives considered here and would obviate the need for interaction between CMS and employers other than during the review process. From the perspective of employers, however, this alternative may be problematic since payment would not be received until after the end of the year.

c. Alternative 3: Interim Retiree Drug Subsidy Payments With Year End Settlement

Under the third alternative, CMS would make interim payments throughout the year with a settlement after the end of the year. Employers that sponsor qualified retiree plans would estimate the per capita Medicare retiree drug subsidy payments they would expect to receive, based on historical data on prescription drug claims for their qualifying covered retirees, along with rebates or discounts that the employer has received from drug manufacturers. Employers would submit their estimated per capita retiree drug subsidy payment and any supporting documentation to CMS at the same time that they submit their attestation of their qualified retiree prescription drug plan's actuarial equivalence to standard Medicare Part D coverage. CMS would review each employer's estimate and related documentation, and would determine an interim monthly per capita amount.

In order to minimize the possibility of having to recoup large amounts of money at the time of settlement, CMS would pay each plan sponsor a percentage of this interim monthly per capita amount on a periodic basis for each of their qualifying covered retirees. We are proposing under this alternative to pay 70 percent of the interim monthly per capita amount in 2006 and 2007, given the significant uncertainty that will exist in estimating Medicare retiree drug subsidy payments. This alternative is more administratively complex than the second alternative because it entails calculating an interim payment amount for each employer; making periodic payments during the year; and conducting a settlement with each employer after the end of the year with

actual claims data. It would, however, provide Medicare retiree drug subsidy payments to employers during the year, which could be beneficial to employers from a cash flow perspective.

d. Alternative 4: Lagged Interim Retiree Drug Subsidy Payments

Under the fourth alternative, CMS would make lagged Medicare retiree drug subsidy payments to employers based on actual claims experience, on a periodic basis throughout the year, with a settlement after the end of the year that would be limited to reconciling estimated versus actual discounts, chargebacks, and rebates. By the 15th day of the month after the end of the payment period, each qualified employer would submit information to CMS on gross and allowable costs for the previous payment period for each of their qualifying covered retirees whose gross costs to date exceeded the cost threshold, but did not exceed the cost limit. Employers would base the cost data that they submit to CMS on their actual claims experience, adjusted on a percentage basis for estimated discounts, chargebacks and rebates (each employer would also submit a justification for the percentage used).

By the 15th of the following month, CMS would review the submission and make a Medicare retiree drug subsidy payment to the employer. By the beginning of the fourth month after the close of the year, the employer would submit documentation on actual discounts, chargebacks and rebates that were received for the plan, with a comparison to the estimated discounts, chargebacks and rebates that were used in calculating the payments. We would correct any underpayment or overpayment by adjusting the employer's subsequent periodic payments.

Similar to the first, this fourth alternative is more administratively complex than the second and third alternatives considered here, but as with the first alternative it would provide employers with a payment stream that comes closer to subsidizing their actual plan expenditures as they occur. However in contrast to the first alternative, it relies on projected amounts related to retrospective discounts, chargebacks, and rebates, with a reconciliation process, and thus does not come as close as the first alternative to ensuring that sponsors receive expeditious payment of the full retiree drug subsidy amounts to which they are entitled. Compared with the first and third alternatives, this fourth alternative would reduce somewhat the risk to the government and employers

that substantial overpayments or underpayments would need to be redeemed.

e. Frequency of Retiree Drug Subsidy Payments

If an interim payment process is chosen, then there would be the additional question of the frequency of the Medicare retiree drug subsidy payments. One could envision a system of bi-annual, quarterly or monthly payments under either of these alternatives. The advantage of making more frequent retiree drug subsidy payments is that it would provide a more even cash flow for employers. On the other hand, a disadvantage of more frequent payments may be increased administrative costs for both CMS and employers. This may particularly be the case for the first and fourth alternatives, which would require employers to submit actual cost data to CMS following the end of each payment period in order to receive the retiree drug subsidy payments.

We are also considering a variable payment alternative in which the frequency of payment would vary in accordance with the size of the employer's plan. Under this scenario, employers with 10,000 or more qualifying covered retirees would receive monthly Medicare retiree drug subsidy payments while employers with fewer than 10,000 qualifying covered retirees would receive quarterly payments, and very small employers could choose to minimize their reporting burden by receiving payments on an annual basis. This alternative would enable employers that have very large numbers of qualifying covered retirees, for whom the Medicare retiree drug subsidy payments would potentially represent a large amount of money, to receive their periodic subsidy payments on a more frequent basis. Making more frequent Medicare retiree drug subsidy payments to employers that provide drug coverage to large numbers of qualifying covered retirees would balance the administrative workload considerations that are associated with more frequent payments with the desire to assist these employers by matching the distribution of their Medicare retiree drug subsidy payments more closely with the timeframe during which the related expenses were incurred. However, we are concerned that this alternative may be too administratively complex for CMS to implement. We are also seeking comment on whether to use more than one of the payment alternatives described above, while determining which payment method would apply

based on the size of the sponsor's plan (for example, in order to minimize administrative burden on small businesses, sponsors with fewer than 100 qualifying covered retirees could receive an annual retroactive payment, while sponsors with larger plans could have access to one of the other payment alternatives).

7. Data Collection—Aggregate vs. Individual Level

Qualified retiree prescription drug plan sponsors (or the plan administrators that have been designated by the sponsors) will need to submit cost data relating to their qualifying covered retirees so that CMS will be able to accurately calculate each sponsor's Medicare retiree drug subsidy payment. As discussed earlier, in addition to certain beneficiary identifying and eligibility information, each plan sponsor (or plan administrator that has been designated by the sponsor) will be required to submit cost data for each of their qualifying covered retirees (including information about the period of time when these costs was incurred). We are considering three alternatives relating to the level of detail of this cost data: (1) Submission of aggregate allowable costs data, (2) submission of beneficiary-level total allowable costs data, and (3) submission of actual claims data. We discuss these three alternatives further below.

a. Alternative 1: Submission of Aggregate Level Cost Data

Under this alternative, CMS would require the plan sponsor (or the plan administrator designated by the sponsor) to submit the aggregate total of all allowable drug costs for all of the qualifying covered retirees that were enrolled in the plan during the time period in question. These costs would represent the allowable costs incurred between the cost threshold and cost limit for each qualifying covered retiree, with a reduction for the anticipated rebates and discounts (which would be calculated based upon historical data).

Under this alternative, the plan sponsors would not submit separate cost data for each qualifying covered retiree. However, each plan sponsor (or their administrator) would have to maintain the individual-level claims data that support its submission for audit purposes. While this alternative would probably be easier for the sponsors and would be the most protective of the individual's privacy, it may be the most problematic in terms of accurately calculating the Medicare retiree drug subsidy payments.

b. Alternative 2: Submission of Beneficiary Level Cost Data

Under this alternative, the plan sponsor (or its plan administrator) would submit the total allowable costs for each individual qualifying covered retiree during the time period in question. This alternative would be more complex for the sponsor and would raise some privacy questions, but it would be more reliable in terms of calculating the Medicare retiree drug subsidy payments.

c. Alternative 3: Submission of Actual Claims Data

Under this third alternative, each plan sponsor (or its plan administrator) would submit the actual claims data for each qualifying covered retiree during the time period in question. However, this alternative would be the most complex in terms of calculating the Medicare retiree drug subsidy payments and would be the most problematic in terms of privacy concerns. Accordingly, we have ruled out this alternative.

N. Conclusion

We estimate that about 41 million Medicare beneficiaries will receive drug coverage either through a Medicare Part D plan (that is, by enrolling in a PDP or a MA-PD) or through an employer or union sponsored retiree plan that is eligible for the Medicare retiree drug subsidy in calendar year (CY) 2006. By CY 2010, due to growth in the overall Medicare population, we estimate that nearly 45 million Medicare beneficiaries will be receiving such coverage. The net Federal budgetary effect of the Medicare prescription drug benefit and retiree drug subsidy is estimated to be about \$287 billion during CY 2006–2010. Medicare Part D is estimated to generate about \$8.2 billion in net savings for States over the five-year period from 2006–2010.

All Medicare beneficiaries will have access to a benefit that protects against catastrophic drug costs. On average, for non-low-income beneficiaries the benefit will cover approximately half their costs, and for beneficiaries with very high drug costs it covers substantially more. For low-income beneficiaries coverage is comprehensive covering on average about 95 percent of their prescription drug costs.

Medicare beneficiaries who have no drug coverage today will now be able to obtain an affordable benefit that provides substantial assistance with prescription drug costs. Those beneficiaries with existing private coverage through retirement benefits and Medicare Advantage plans will

receive the benefits of new Medicare subsidies to maintain and enhance their coverage. Beneficiaries with public coverage through Medicaid and State programs will have more secure (and potentially more generous) benefits because of the comprehensive low-income Medicare benefit. Beneficiaries who pay the full costs for limited Medigap drug coverage will now be able to obtain highly-subsidized, more generous coverage.

Overall, we anticipate that by giving beneficiaries access to affordable insurance coverage that helps them to pay for their outpatient prescription drugs—which have become a critical component in the delivery of comprehensive, quality health care services—the Medicare prescription drug benefit will help beneficiaries to lead healthier, more productive lives.

List of Subjects

42 CFR Part 403

Grant programs—health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements

42 CFR Part 411

Kidney diseases, Medicare, Reporting and recordkeeping requirements

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, Reporting and recordkeeping requirements

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professions, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements

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

PART 403—SPECIAL PROGRAMS AND PROJECTS

1. The authority citation for part 403 continues to read as follows:

Authority: 42 U.S.C. 1359b-3 and secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart B—Medicare Supplemental Policies

2. Section 403.205 is revised to read as follows:

§ 403.205 Medicare supplemental policy.

(a) Except as specified in paragraph (e) of this section, Medicare supplemental (or Medigap) policy means a health insurance policy or other health benefit plan that—
 (1) A private entity offers to a Medicare beneficiary; and
 (2) Is primarily designed, or is advertised, marketed, or otherwise purported to provide payment for expenses incurred for services and items that are not reimbursed under the Medicare program because of deductibles, coinsurance, or other limitations under Medicare.

(b) The term policy includes both policy form and policy as specified in paragraphs (b)(1) and (b)(2) of this section.

(1) *Policy form.* Policy form is the form of health insurance contract that is approved by and on file with the State agency for the regulation of insurance.

(2) *Policy.* Policy is the contract—
 (i) Issued under the policy form; and
 (ii) Held by the policy holder.

(c) Medicare supplemental policy includes—

(1) An individual policy;
 (2) A group policy;
 (3) A rider attached to an individual or group policy; or

(4) As of January 1, 2006, a stand-alone limited health benefit plan or policy that supplements Medicare benefits and is sold primarily to Medicare beneficiaries or that otherwise meets the definition of a Medicare supplemental policy as defined in this section.

(d) Any rider attached to a Medicare supplemental policy becomes an integral part of the basic policy.

(e) Medicare supplemental policy does not include a Medicare Advantage plan, a Prescription Drug plan under Part D, or any of the other types of health insurance policies or health benefit plans that are excluded from the definition of a Medicare supplemental policy in section 1882(g)(1) of the Act.

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

3. The authority citation for part 411 is revised 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 J—Financial Relationships Between Physicians and Entities Furnishing Designated Health Services

4. In § 411.351, the definition of “Outpatient prescription drugs” is revised to read as follows:

* * * * *

§ 411.351 Definitions

* * * * *

Outpatient prescription drugs means all drugs covered by Medicare Part B and Part D.

* * * * *

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

5. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e-5, and 300e-9), and 31 U.S.C. 9701.

6. In § 417.440, add paragraph (b)(1)(iii) to read as follows:

§ 417.440 Entitlement to health care services from an HMO or CMP.

* * * * *

(b) * * *

(1) * * *

(iii) Medicare Part D services, to the extent the HMO or CMP offers qualified prescription drug coverage under Part D, and the enrollee is entitled to benefits under Part D.

* * * * *

7. In § 417.534, add paragraph (c) to read as follows:

§ 417.534 Allowable costs.

* * * * *

(c) *Medicare Part D program costs.* To the extent that an HMO or CMP provides qualified prescription drug coverage to enrollees under Part D, no costs related to the offering or provision of Part D benefits will be reimbursed under this part. These costs will be reimbursed solely under the applicable provisions of part 423 of this chapter.

8. Part 423 is added as set forth below:

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

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Sec.

423.1 Basis and Scope.

423.4 Definitions.

423.6 Cost-Sharing in beneficiary education and enrollment.

Subpart B—Eligibility and Enrollment

423.30 Eligibility to enroll.

423.34 Enrollment process.

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423.38 Effective dates.	423.336 Risk-sharing arrangements.	423.590 Timeframes and responsibility for making redeterminations.
423.42 Coordination of enrollment and disenrollment through PDPs.	423.343 Retroactive adjustments and reconciliations.	423.600 Reconsideration by an independent review entity.
423.44 Disenrollment by the PDP.	423.346 Reopenings.	423.602 Notice of reconsideration determination by the independent review entity.
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423.48 Information about Part D.		423.610 Right to an ALJ hearing.
423.50 Approval of marketing materials and enrollment forms.		423.612 Request for an ALJ hearing.
423.56 Procedures to determine and document creditable status of prescription drug coverage.		423.620 Medicare Appeals Council review
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423.100 Definitions.		423.634 Reopening and revising determinations and decisions.
423.104 Requirements related to qualified prescription drug coverage.		423.636 How a PDP sponsor must effectuate standard predeterminations, reconsideration determinations, or decisions.
423.112 Establishment of prescription drug plan service areas.		423.638 How a PDP sponsor must effectuate expedited redeterminations or reconsidered determinations.
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423.124 Special rules for access to covered Part D drugs at out-of-network pharmacies.		
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423.279 National average monthly bid amount.		
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423.308 Definitions and terminology.		
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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 A—General Provisions

§ 423.1 Basis and scope.

(a) *Basis.* (1) This part is based on the indicated provisions of the following sections of the Social Security Act:
 1860D–1. Eligibility, enrollment, and information.
 1860D–2. Prescription drug benefits.
 1860D–3. Access to a choice of qualified prescription drug coverage.
 1860D–4. Beneficiary protections for qualified prescription drug coverage.
 1860D–11. PDP regions; submission of bids; plan approval.
 1860D–12. Requirements for and contracts with prescription drug plan (PDP) sponsors.
 1860D–13. Premiums; late enrollment penalty.
 1860D–14. Premium and cost-sharing subsidies for low-income individuals.

1860D–15. Subsidies for Part D eligible individuals for qualified prescription drug coverage.
 1860D–16. Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

1860D–21. Application to Medicare Advantage program and related managed care programs.
 1860D–23. State pharmaceutical assistance programs.

1860D–24. Coordination requirements for plans providing prescription drug coverage.
 1860D–31. Medicare prescription drug discount card and transitional assistance program.

1860D–41. Definitions; treatment of references to provisions in Part C.
 1860D–42. Miscellaneous provisions.

(2) The following specific sections of the Medicare Modernization Act also address the prescription drug benefit program:

Sec. 102 Medicare Advantage conforming amendments.
 Sec. 103 Medicaid amendments.
 Sec. 104 Medigap.
 Sec. 109 Expanding the work of Medicare Quality Improvement Organizations to include Parts C and D.

(b) *Scope.* This part establishes standards for beneficiary eligibility, access, benefits, protections, and low-income subsidies in Part D, as well as establishes standards and sets forth requirements, limitations, procedures and payments for organizations participating in the Voluntary Medicare Prescription Drug Program.

§ 423.4 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Actuarial equivalence means a state of equivalent value demonstrated through the use of generally accepted actuarial principles and in accordance with section 1860D–11(c) of the Act and with CMS guidelines described at § 423.265(c)(3).

Brand name drug means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)), including an application referred to in section 505(b)(2) of the Act (21 U.S.C. 355(b)(2)).

Fallback prescription drug plan means a prescription drug plan offered by a fallback entity that—

(1) Offers only standard prescription drug coverage;

(2) Provides access to negotiated prices; and

(3) Meets other requirements as specified by CMS in subpart Q of this part.

Formulary means the entire list of Part D drugs covered by a PDP sponsor's or Medicare Advantage organization's drug plan.

Full-benefit dual eligible beneficiary means an individual who meets the criteria established in § 423.772, regarding coverage under both Part D and Medicaid.

Generic drug means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is approved.

Insurance risk means, for a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitutions, nor does it include elements potentially in the control of the pharmacy (for example, labor costs or productivity).

MA stands for Medicare Advantage, which refers to the program authorized under Part C of the Act.

MA plan means health benefits coverage offered under a policy or contract with Medicare by an MA organization as defined in § 422.2.

MA-PD plan means an MA plan that provides qualified prescription drug coverage.

Medicare prescription drug account means the account created within the Federal Supplementary Medical Insurance Trust Fund for purposes of Medicare Part D.

Part D eligible individual means an individual who is entitled to or enrolled in Medicare benefits under Part A and/or Part B.

PDP region means a prescription drug plan region as determined by CMS under § 423.112.

PDP sponsor means a nongovernmental entity that is certified under this part as meeting the requirements and standards of this part that apply to entities that offer prescription drug plans.

Prescription drug plan or PDP means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in § 423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the contract requirements under subpart K of this part.

Service area means, for purposes of eligibility to enroll to receive Part D benefits, (1) for a prescription drug plan, an area established in § 423.112(a)

within which access standards under § 423.120 are met; and (2) for an MA-PD plan, an area that meets the definition of MA service area as described in § 422.2, and within which access standards under § 423.120 are met.

State Pharmaceutical Assistance Program (SPAP) means a program (other than the Medicaid program) operated by a State (or under contract with a State) that—

(1) Provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals;

(2) Provides assistance to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls;

(3) Meets the benefit coordination requirements specified in subpart J of this part; and

(4) Does not change or affect the primary payor status of a Part D plan.

Subsidy-eligible individual means a Part D eligible individual who is enrolled in a PDP or MA-PD plan and who has an income below 150 percent of the poverty level as applicable to a family of the size involved and who meets the resource requirements specified in subpart P of this part.

Tiered cost-sharing means a process of grouping Part D drugs into different cost sharing levels within a PDP sponsor's formulary.

§ 423.6 Cost-sharing in beneficiary education and enrollment-related costs.

The requirements of section 1857(e)(2) of the Act and § 422.6 with regard to the payment of fees established by CMS for cost sharing of enrollment related costs apply to PDP sponsors under Part D.

Subpart B—Eligibility and Enrollment.

§ 423.30 Eligibility to enroll.

(a) *Enrollment in a PDP.* Except as otherwise provided in paragraph (b) of this section, a Part D eligible individual is eligible to enroll in a PDP or fallback plan if he or she lives in the plan's service area.

(b) MA enrollees are not eligible to enroll in a PDP except as follows:

(1) A Part D eligible individual is eligible to enroll in a PDP if the individual is enrolled in a MA private fee-for-service plan (as defined in section 1859(b)(2) of the Act) that does not provide qualified prescription drug coverage; and

(2) A Part D eligible individual is eligible to enroll in a PDP if the

individual is enrolled in a MSA plan (as defined in section 1859(b)(3) of the Act).

(c) *Enrollment in a MA-PD Plan.* A Part D eligible individual enrolled in a MA-PD plan must obtain qualified prescription drug coverage through that plan.

§ 423.34 Enrollment process.

(a) *General Rule.* A PDP sponsor must enroll in its PDP all Part D eligible individuals who are eligible to enroll in its plan under § 423.30(a) and who elect to enroll in the plan during the individual's initial enrollment period, the annual coordinated election period, or a special enrollment period as specified in § 423.36.

(b) *Enrollment.* (1) A Part D eligible individual seeking to enroll in a PDP must complete the PDP's enrollment form or other enrollment process permitted by CMS.

(2) The PDP sponsor must process an individual's enrollment request in accordance with CMS enrollment guidelines.

(c) *Notice requirement.* The PDP sponsor must provide the individual with prompt notice of acceptance or denial of the individual's enrollment request, in a format and manner specified by CMS.

(d) *Enrollment requirement for full benefit dual eligibles.* (1) *General rule.* Full benefit dual eligible individuals who fail to enroll in a PDP or a MA-PD plan during their initial enrollment period or special enrollment period under § 423.36(c)(4) will be automatically enrolled into—

(i) A PDP offering basic prescription drug coverage in the PDP region where the individual resides that has a monthly beneficiary premium that does not exceed the premium subsidy amount, or,

(ii) In the case of an individual enrolled in an MA plan without qualified prescription drug coverage, a MA-PD plan offered by the same MA organization that has a monthly beneficiary premium that does not exceed the premium subsidy amount, in accordance with procedures established by CMS.

(2) *When there is more than one PDP in a PDP region.* In the event that there is more than one PDP in a PDP region with a monthly beneficiary premium at or below the premium subsidy amount, full benefit dual eligible individuals subject to automatic enrollment under this paragraph will be enrolled in such PDPs on a random basis.

(3) *Declining enrollment & disenrollment.* Nothing in this paragraph shall be deemed to prevent

these full benefit dual eligible individuals from—

(i) Affirmatively declining enrollment in a PDP or MA-PDP, or
(ii) Disenrolling from the PDP or MA-PDP in which they have been automatically enrolled and electing a new PDP or MA-PD plan, pursuant to the special election period, as provided for under § 423.42.

§ 423.36 Enrollment periods.

(a) *Initial enrollment period for Part D—Basic rule.* The initial enrollment period is the period during which an individual is first eligible to enroll in a Part D plan.

(1) *In 2005.* An individual who is first eligible to enroll in a Part D plan on or prior to January 31, 2006, has an initial enrollment period from November 15, 2005 through May 15, 2006.

(2) *February 2006.* An individual who is first eligible to enroll in a Part D plan in February 2006 has an initial enrollment period from November 15, 2005 through May 31, 2006.

(3) *March 2006 and subsequent months.* (i) Except as provided in (3)(ii) below, the initial enrollment period for an individual who is first eligible to enroll in a Part D plan on or after March 2006 is the same as the initial enrollment period for Medicare Part B under § 407.14.

(ii) *Exception.* For those individuals who are not eligible to enroll in a Part D plan at any time during their initial enrollment period for Medicare Part B, their initial enrollment period under this Part will be the 3 months before becoming eligible for Part D, the month of eligibility, and the three months following eligibility to Part D.

(b) *Annual coordinated election period.* (1) *For 2006.* This period begins on November 15, 2005 and ends on May 15, 2006.

(2) *For 2007 and subsequent years.* For coverage beginning 2007 or any subsequent year, the annual coordinate election period is November 15th through December 31st for coverage beginning the following calendar year.

(c) *Special enrollment periods.* An individual eligible to enroll in a Part D plan enroll in a PDP or disenroll from a PDP and enroll in another PDP, as applicable, at any time under any of the following circumstances—

(1) The individual involuntarily loses creditable prescription drug coverage or such coverage is involuntarily reduced so that it is no longer creditable coverage under § 423.56(a). Loss of credible prescription drug coverage due to failure to pay any required premium shall not be considered involuntary loss of such coverage.

(2) The individual was not adequately informed, as required by standards established by CMS under § 423.56, that he or she has lost his or her creditable prescription drug coverage, never had credible prescription drug coverage, or the coverage is involuntarily reduced so that it is no longer creditable prescription drug coverage.

(3) The individual's enrollment or nonenrollment in Part D is unintentional, inadvertent, or erroneous because of the error, misrepresentation, or inaction of a Federal employee, or any person authorized by the Federal government to act on its behalf.

(4) The individual is a full-benefit dual eligible individual as defined under section 1935(c)(6) of the Act.

(5) The individual elects to disenroll from a MA-PD plan and elects coverage under Medicare Part A and Part B in accordance with § 422.62(c).

(6) The PDP sponsor's contract is terminated by the PDP sponsor or by CMS, as provided under § 422.507 through § 422.510.

(7) The individual is no longer eligible for the PDP because of a change in his or her place of residence to a location outside of the PDP region(s) in which the PDP is offered.

(8) The individual demonstrates to CMS, in accordance with guidelines issued by CMS, that—

(i) The PDP sponsor offering the PDP substantially violated a material provision of its contract under this part in relation to the individual, including, but not limited to the following—

(A) Failure to provide the individual on a timely basis benefits available under the plan;

(B) Failure to provide benefits in accordance with applicable quality standards; or

(C) The PDP (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in marketing the plan to the individual.

(ii) The individual meets other exceptional circumstances as CMS may provide.

§ 423.38 Effective dates.

(a) *Initial enrollment period.* An enrollment made prior to the month of entitlement to or enrollment in Medicare benefits under Part A and/or enrollment in Part B is effective the first day of the month the individual is entitled to or enrolled in Part A or enrolled in Part B. An enrollment made during or after the month of entitlement to or enrollment in Part A and/or enrollment in Part B is effective the first day of the calendar month following the month in which the enrollment in Part

D is made. If the individual is not eligible to enroll in Part D on the first day of the calendar month following the month in which the election to enroll in Part D is made, the enrollment in Part D will be effective the first day of the month the individual is eligible for Part D. In no case will an enrollment in Part D be effective before January 1, 2006 or before entitlement to or enrollment in Part A and/or Part B.

(b) *Annual coordinated election periods.* (1) *General Rule.* Except as provided under paragraph (b)(2) of this section, for an enrollment or change of enrollment in Part D made during an annual coordinated election period as described in § 423.36(a)(2), the coverage or change in coverage is effective as of first day of the following calendar year.

(2) *Exception for January 1, 2006–May 15, 2006.* Enrollment elections made during the annual election period between January 1, 2006 and May 15, 2006 will be effective the first day of the calendar month following the month in which the enrollment in Part D is made.

(c) *Special enrollment periods.* For an enrollment or change of enrollment in Part D made during a special enrollment period specified in § 423.36(a)(3), the effective date shall be determined by CMS, which, to the extent practicable, will be determined in a manner consistent with protecting the continuity of health benefits coverage.

§ 423.42 Coordination of enrollment and disenrollment through PDPs.

(a) *Enrollment.* An individual who wishes to enroll in a PDP may enroll during the enrollment periods specified in § 423.36, by filing the appropriate enrollment form with the PDP or through other mechanisms CMS determines are appropriate.

(b) *Disenrollment.* An individual who wishes to disenroll from a PDP may disenroll during the periods specified in § 423.36 in either of the following manners:

(1) Enroll in a different PDP plan;
 (2) Submit a disenrollment request to the PDP in the form and manner prescribed by CMS; or

(3) File the appropriate disenrollment request through other mechanisms as determined by CMS.

(c) *Responsibilities of the PDP sponsor.* The PDP sponsor must—

(1) Submit a disenrollment notice to CMS within timeframes CMS specifies;

(2) Provide the enrollee with a notice of disenrollment as CMS determines and approves; and

(3) File and retain disenrollment requests for the period specified in CMS instructions.

(d) *Retroactive disenrollment.* CMS may grant retroactive disenrollment in the following cases:

(1) There never was a legally valid enrollment;

or, (2) A valid request for disenrollment was properly made but not processed or acted upon.

(e) *Maintenance of Enrollment.* An individual who is enrolled in a PDP will remain enrolled in that PDP until one of the following occurs:

(i) The individual successfully enrolls in another PDP;

(ii) The individual voluntarily disenrolls from the PDP;

(iii) The individual is involuntarily disenrolled from the PDP or;

(iv) The PDP is discontinued and no longer serves the area in which the individual resides.

§ 423.44 Disenrollment by the PDP.

(a) *General Rule.* Except as provided in paragraphs (b) through (d) of this section, a PDP sponsor may not—

(1) Involuntarily disenroll an individual from any PDP it offers; or

(2) Orally or in writing, or by any action or inaction, request or encourage an individual to disenroll.

(b) *Basis for disenrollment.* (1)

Optional involuntary disenrollment. A PDP sponsor may disenroll an individual from a PDP it offers in any of the following circumstances:

(i) Any monthly premium is not paid on a timely basis, as specified under paragraph (d)(1) of this section; or

(i) The individual has engaged in disruptive behavior, as specified under paragraph (d)(2) of this section.

(2) *Required involuntary disenrollment.* A PDP sponsor must disenroll an individual from a PDP it offers in any of the following circumstances:

(i) The individual no longer resides in the PDP's service area.
 (ii) The individual loses entitlement or enrollment to Medicare benefits under Part A and/or Part B.

(iii) Death of the individual.
 (iv) The PDP sponsor's contract is terminated by CMS or that terminates a PDP. The PDP sponsor must disenroll affected enrollees in accordance with the procedures for disenrollment set forth at § 423.507 through § 423.510.

(v) The individual materially misrepresents information, as determined by CMS, to the PDP sponsor that the individual has or expects to receive reimbursement for third-party coverage.

(c) *Notice Requirement.* (1) If the disenrollment is for any of the reasons specified in paragraphs (b)(1), (b)(2)(i), or (b)(iv) of this section (that is, other

than death or loss of entitlement or enrollment to benefits under Part A and/or enrollment in Part B), the PDP sponsor must give the individual timely notice of the disenrollment with an explanation of why the PDP is planning to disenroll the individual.

(2) Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) and (b)(2)(iv) of this section must—

(i) Be provided to the individual before submission of the disenrollment notice to CMS; and

(ii) Include an explanation of the individual's right to a hearing under the PDP's grievance procedures.

(d) *Process for Disenrollment.* (1) *Monthly PDP premiums that are not paid timely.* A PDP sponsor may disenroll an individual from the PDP for failure to pay any monthly premium under the following circumstances:

(i) The PDP sponsor can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount.

(ii) The PDP sponsor gives the enrollee notice of disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) *Reenrollment in the PDP.* If an individual is disenrolled from the PDP for failure to pay monthly PDP premiums, the PDP sponsor has the option to decline future enrollment by such individual in any of its PDPs until the individual has paid any past premiums due to the PDP sponsor.

(2) *Disruptive or threatening behavior.* (i) *Basis for disenrollment.* A PDP sponsor may disenroll an individual from its PDP if the individual's behavior is disruptive, unruly, abusive, uncooperative or threatening. Disruptive behavior may not be based upon noncompliance with medical advice. An individual may be deemed to engage in disruptive or threatening behavior if the individual exhibits any of the following:

(A) Behavior that jeopardizes his or her health or safety, or the health and safety of others; or

(B) Behavior that impairs the PDP sponsor (or a network pharmacy's) ability to furnish services to either the individual or other individuals enrolled in the plan; or

(C) An individual with decision-making capacity who refuses to comply with the material terms of the enrollment agreement.

(ii) *Effort to resolve the problem.* The PDP sponsor must make a good faith effort to resolve the problems the individual presents, including the use (or attempted use) of the PDP's grievance procedures. The beneficiary has a right to submit any information or explanation that he or she may wish to submit to the PDP.

(iii) *Documentation.* The PDP sponsor must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraphs (d)(2)(i) through (d)(2)(iii) of this section and any extenuating circumstances. The PDP sponsor must also submit to CMS such documentation, as well as any documentation received by the beneficiary.

(iv) *CMS review of the proposed disenrollment.* CMS decides after reviewing the documentation submitted by the PDP sponsor whether the sponsor has met the criteria for disenrollment for disruptive or threatening behavior.

(v) *Effective date of disenrollment.* If CMS permits a PDP to disenroll an individual for disruptive behavior, the termination is effective the first day of the calendar month after the month in which the PDP gives the individual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(vi) *Reenrollment in the PDP.* Once an individual is disenrolled from the PDP for disruptive behavior, the PDP sponsor has the option to decline future enrollment by the individual in any of its PDPs for a period of time CMS specifies.

(vii) *Expedited process.* In the event that an individual's disruptive or threatening behavior is so extreme as to have caused harm to others or prevented the PDP from providing services, CMS may consider allowing an expedited disenrollment process in accordance with procedures established by CMS.

(3) *Loss of entitlement or enrollment in Part A and Part B benefits.* If an individual is no longer entitled or enrolled to Medicare benefits under Part A and enrolled in Part B, CMS will notify the PDP that the disenrollment is effective the first day of the calendar month following the last month of entitlement or enrollment to benefits under Part A or Part B.

(4) *Death of the individual.* If the individual dies, disenrollment is effective the first day of the calendar month following the month of death.

(5) *Plan termination.*

(i) When a PDP contract terminates as provided in § 423.507 through 423.510 as the PDP sponsor must give each affected PDP enrollee notice of the effective date of the plan termination and a description of alternatives for obtaining benefits under Part D, as specified by CMS.

(ii) The notice must be sent before the effective date of the plan termination or area reduction, and in the timeframes specified by CMS.

(6) *Misrepresentation of third-party reimbursement.* (i) If CMS determines

an individual has materially misrepresented information to the PDP regarding whether the individual has or expects to receive reimbursement from group health plans, insurers or otherwise, or similar third party arrangements for incurred costs for covered Part D drugs under § 423.44(b)(2)(v), the termination is effective the first day of the calendar month after the month in which the PDP gives the individual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(ii) *Reenrollment in the PDP.* Once an individual is disenrolled from the PDP for misrepresentation of third party reimbursement, the PDP sponsor has the option to decline future enrollment by the individual in any of its PDPs for a period of time CMS specifies.

(iii) *Ineligibility for SEP.* An individual who is disenrolled for misrepresentation of third party reimbursement is not eligible for an SEP. The individual may enroll in a PDP during the next annual coordinated election period as provided in § 423.36(b).

§ 423.46 Late enrollment penalty.

(a) *General.* A Part D eligible individual must pay the late penalty described under § 423.286(d)(3) if there is a continuous period of 63 days or longer at any time after termination of the individual's initial enrollment period during all of which the individual meets the following conditions:

(1) The individual was eligible to enroll in a PDP or MA-PD plan;

(2) The individual was not covered under any creditable prescription drug coverage; and

(3) The individual was not enrolled in a PDP or MA-PD plan.

(b) [Reserved]

§ 423.48 Information about Part D.

Each PDP and MA-PD plan must provide, on an annual basis, and in a format and using standard terminology that CMS may specify in guidance, the information necessary to enable CMS to provide to current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage.

§ 423.50 Approval of marketing materials and enrollment forms.

(a) *CMS review of marketing materials.* (1) Except as provided in paragraph (a)(2) of this section, a PDP may not distribute any marketing materials (as defined in paragraph (b) of

this section), 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 marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution, the PDP sponsor submits the material or form to CMS for review under the guidelines in paragraph (c) of this section; and

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

(2) If the PDP sponsor is deemed by CMS to meet certain performance requirements established by CMS, the PDP sponsor may distribute designated marketing materials 5 days following their submission to CMS.

(b) *Definition of marketing materials.* Marketing materials include any informational materials targeted to Medicare beneficiaries which—

(1) Promote the PDP;

(2) Inform Medicare beneficiaries that they may enroll, or remain enrolled in a PDP;

(3) Explain the benefits of enrollment in a PDP, or rules that apply to enrollees;

(4) Explain how Medicare services are covered under a PDP, including conditions that apply to such coverage;

(5) 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.

(c) *Guidelines for CMS review.* In reviewing marketing material or enrollment forms under paragraph (a) of this section, CMS determines (unless otherwise specified in additional guidance) that the marketing materials—

(1) 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—

(i) 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.

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

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

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

(3) Include in the written materials notice that the PDP 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 PDP.

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

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

(d) *Deemed approval.* If CMS has not disapproved the distribution of a marketing materials or form submitted by a PDP sponsor with respect to a PDP plan in a region, CMS is deemed not to have disapproved the distribution of the marketing material or form in all other regions covered by the PDP, with the exception of any portion of the material or form that is specific to the particular region.

(e) *Standards for PDP marketing.* (1) In conducting marketing activities, a PDP may not—

(i) 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 PDP.

(ii) 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.

(iii) Solicit Medicare beneficiaries door-to-door.

(iv) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the PDP sponsor or its PDP. The PDP 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 PDP. It may, however, explain that the organization is approved for participation in Medicare.

(v) Use providers or provider groups to distribute printed information comparing the benefits of different PDPs unless the materials have the concurrence of all PDP sponsors involved and have received prior approval by CMS.

(vi) Accept PDP enrollment forms in provider offices or other places where health care is delivered.

(vii) Employ PDP plan names that suggest that a plan is not available to all Medicare beneficiaries.

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

(2) In its marketing, the PDP organization must—

(i) 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.

(ii) 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.

§ 423.56 Procedures to determine and document creditable status of prescription drug coverage.

(a) *Definition.* *Creditable prescription drug coverage* means any of the following types of coverage, but only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage as demonstrated through the use of generally accepted actuarial principles and in accordance with the requirements of § 423.265(c)(3):

(1) Prescription drug coverage under a PDP or MA-PD plan.

(2) Medicaid coverage under title XIX of the Act or under a waiver under section 1115 of the Act.

(3) Coverage under a group health plan, including the Federal employees health benefits program, and qualified retiree prescription drug plans as defined in section 1860D-22(a)(2) of the Act.

(4) Coverage under programs that provide financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals.

(5) Coverage of prescription drugs for veterans, survivors and dependents under chapter 17 of title 38, USC.

(6) Coverage under a Medicare supplemental policy (Medigap policy) under section 1882 of the Act, and as specified in 42 CFR 403.205, that provides prescription drug benefits, whether or not the coverage was issued pursuant to standardization requirements under section 1882(p)(1) of the Act.

(7) Military coverage under chapter 55 of title 10, U.S.C., including TRICARE.

(8) Individual health insurance coverage (as defined in section 2791(b)(5) of the Public Health Service Act) that includes coverage for outpatient prescription drugs and that does not meet the definition of an excepted benefit (as defined in section 2791(c) of the Public Health Service Act).

(9) Coverage provided by the medical care program of the Indian Health Service, Tribe or Tribal organization, or Urban Indian organization (I/T/U).

(b) *General.* With the exception of PDPs and MA-PD plans under 423.56(a)(1), each entity that offers prescription drug coverage under any of the types described in § 423.56(a), must disclose to all Part D eligible individuals enrolled in or seeking to enroll in such coverage whether such coverage meets the requirements of actuarial equivalence of § 423.265.

(c) *Disclosure of non-creditable coverage.* In the case that the coverage does not meet the actuarial equivalence requirements at § 423.265 the disclosure described in paragraph (b) of this section to Part D eligible individuals must include:

(1) The fact that the coverage does not meet the actuarial equivalence requirement under 423.265;

(2) That there are limitations on the periods in a year in which the individual may enroll under a PDP or MA-PD plan; and

(3) That the individual may be subject to a late enrollment penalty, under § 423.46.

(d) *Disclosure to CMS.* Each entity must disclose the creditable coverage status to CMS in a form and manner described by CMS.

(e) *Notification.* Notification to Part-D eligible individuals must be provided in a form and manner prescribed by CMS.

(f) *When an individual is not adequately informed of coverage.* If an individual establishes to CMS that he or she was not adequately informed that his or her prescription drug coverage was not creditable, the individual may apply to CMS to have such coverage treated as creditable coverage for purposes of applying § 423.46.

Subpart C—Benefits and Beneficiary Protections.

§ 423.100 Definitions.

As used in this subpart, unless otherwise specified—

Alternative prescription drug coverage means coverage of covered Part D drugs other than standard prescription drug coverage that meets the requirements of § 423.104(f). The term “alternative prescription drug coverage” must be either—

(1) *Basic alternative coverage* (alternative coverage that is actuarially equivalent to defined standard coverage), as determined through processes and methods established under § 423.265; or

(2) *Enhanced alternative coverage* (alternative coverage that meets the requirements of § 423.104(g)(1)).

Basic prescription drug coverage means coverage of covered Part D drugs that is either standard prescription drug coverage or basic alternative coverage.

Bioequivalent has the meaning given such term in section 505(j)(8) of the Food, Drug, and Cosmetic Act.

Covered Part D drug means—

(1) Unless excluded under number (2) of this definition, any of the following if used for a medically accepted indication (as defined in section 1927(k)(6) of the Act)—

(i) A drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act;

(ii) A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act;

(iii) Insulin described in section 1927(k)(2)(C) of the Act;

(iv) The following medical supplies associated with the injection of insulin:

syringes, needles, alcohol swabs, and gauze; or

(v) A vaccine licensed under section

351 of the Public Health Service Act.

(2) Does not include—

(i) Drugs for which payment as so prescribed and dispensed or administered to an individual is available with respect to that individual under Parts A or B (even though a deductible may apply, or even though the individual is eligible for coverage under Parts A or B but has declined to enroll in Parts A or B); and

(ii) Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid pursuant to sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents.

Group health plan has the meaning given such term in § 411.101 of this chapter.

Incurred costs means costs incurred by a Part D enrollee for covered part D drugs covered under (or treated as covered under) a prescription drug plan or MA-PD plan—

(1) That are not paid for under the prescription drug plan or MA-PD 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(e)(5)(iii), including any price differential for which the Part D enrollee is responsible under § 423.120(a)(6) and § 423.124(b)(2); 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 described in § 423.454; or

(iii) Under § 423.782.

Insurance or otherwise means a plan (other than a group health plan) or program that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the Public Health Service Act, 42 U.S.C. 300gg-91(a)(2)), including any of the following:

(1) Health insurance coverage as defined in 42 U.S.C. 300gg-91(b)(1);

(2) An MA plan as described in § 422.2 of this chapter.

(3) A program of all-inclusive care for the elderly (PACE) under titles XVIII and XIX of the Act;

(4) An approved State child health plan under title XXI of the Act providing benefits for child health assistance that meet the requirements of section 2103 of the Act;

(5) The Medicaid program under title XIX of the Act or a waiver pursuant to section 1115 of the Act;

(6) The veterans health care program under chapter 17 of title 38 of the U.S.C.

(7) Any other government-funded program whose principal activity is the direct provision of health care to individuals.

I/T/U pharmacy means a pharmacy operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603.

Long-term care facility means a skilled nursing facility, as defined in

section 1819(a) of the Act, or nursing facility, as defined in section 1919(a) of the Act.

Long-term care pharmacy means a pharmacy owned by or under contract with a long-term care facility to provide prescription drugs to the facility's residents.

Long-term care network pharmacy means a long-term care pharmacy that is a network pharmacy.

Negotiated prices means prices for covered Part D drugs that—

(1) Are available to beneficiaries at the point of sale at network pharmacies; and

(2) Take into account discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remunerations and include any dispensing fees.

Network pharmacy means a licensed pharmacy that is not a mail order pharmacy and that is under contract with a PDP sponsor or MA organization offering an MA-PD plan to provide negotiated prices to its prescription drug plan or MA-PD plan enrollees.

Non-preferred pharmacy means a network pharmacy that offers Part D enrollees higher cost-sharing for covered Part D drugs than a preferred pharmacy.

Out-of-network pharmacy means a licensed pharmacy that is not under contract with a PDP sponsor or MA organization offering an MA-PD plan to provide negotiated prices to its prescription drug plan or MA-PD plan enrollees.

Person means a natural person, corporation, mutual company, unincorporated association, partnership, joint venture, limited liability company, trust, estate, foundation, not-for-profit corporation, unincorporated organization, government or governmental subdivision or agency.

Plan allowance means the amount prescription drug plans and MA-PD plans use to determine their payment and Part D enrollees' cost-sharing for covered Part D drugs purchased at out-of-network pharmacies in accordance with the requirements of § 423.124(b).

Preferred drug means a covered part D drug on a prescription drug plan or MA-PD plan's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug in the plan's formulary.

Preferred pharmacy means a network pharmacy that offers Part D enrollees lower cost-sharing for covered Part D drugs than a non-preferred pharmacy.

Qualified prescription drug coverage means any standard prescription drug coverage or alternative prescription drug coverage that meets the requirements of § 423.104(d).

Required prescription drug coverage means coverage of covered Part D drugs under an MA-PD plan that consists of either—

(1) Basic prescription drug coverage; or

(2) Enhanced alternative coverage, provided there is no MA monthly supplemental beneficiary premium applied under the plan due to the application of a credit against the premium of a rebate under § 422.266(b) of this chapter.

Rural means a five-digit ZIP code in which the population density is less than 1,000 individuals per square mile.

Standard prescription drug coverage means coverage of covered Part D drugs that meets the requirements of § 423.104(e). The term "standard prescription drug coverage" must be either—

(1) *Defined standard coverage* (standard prescription drug coverage that provides for cost-sharing as described in §§ 423.104(e)(2)(i)(A) and (e)(5)(i)); or

(2) *Actuarially equivalent standard coverage* (standard prescription drug coverage that provides for cost-sharing as described in § 423.104(e)(2)(i)(B) or cost-sharing as described in § 423.104(e)(5)(ii), or both).

Suburban means a five-digit ZIP code in which the population density is between 1,000 and 3,000 individuals per square mile.

Supplemental benefits means benefits that meet the requirements of § 423.104(g)(1)(ii).

Therapeutically equivalent refers to drugs that are rated as therapeutic equivalents under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations."

Third party payment arrangement means any contractual or similar arrangement under which a person has a legal obligation to pay for covered Part D drugs.

Urban means a five-digit ZIP code in which the population density is greater than 3,000 individuals per square mile.

Usual and customary (U&C) price means the price that a pharmacy charges a customer who does not have any form of prescription drug coverage.

§ 423.104 Requirements related to qualified prescription drug coverage.

(a) *General.* Subject to the conditions and limitations set forth in this subpart, a PDP sponsor offering a prescription drug plan or an MA organization offering an MA-PD plan must provide enrollees with coverage of the benefits described in paragraph (c) of this

section. The benefits may be provided directly by the PDP sponsor or MA organization or through arrangements with other entities. CMS reviews and approves these benefits consistent with § 423.272, and using written policy guidelines and requirements in this part and other CMS instructions.

(b) *Availability of plans.* Except as provided in § 422.60(b) of this chapter, a PDP sponsor offering a prescription drug plan must offer that plan to all Part D eligible beneficiaries residing in the plan's service area.

(c) *Types of benefits.* A prescription drug plan or MA-PD plan must include qualified prescription drug coverage.

(d) *Qualified prescription drug coverage.* Qualified prescription drug coverage includes—

(1) Standard prescription drug coverage consistent with paragraph (e) of this section; or

(2) Alternative prescription drug coverage consistent with paragraph (f) of this section.

(e) *Standard prescription drug coverage.* Standard prescription drug coverage includes access to negotiated prices as described under paragraph (h)(1) of this section, provides coverage of covered Part D drugs, and must meet the following requirements—

(1) *Deductible.* An annual deductible equal to—

(i) *For 2006.* \$250; or

(ii) *For years subsequent to 2006.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (e)(5)(iv) of this section, and rounded to the nearest multiple of \$5.

(2) *Cost-sharing under the initial coverage limit.*

(i) *25 Percent coinsurance.*

Coinsurance for costs for covered Part D drugs covered under the plan above the annual deductible specified in paragraph (e)(1) of this section, and up to the initial coverage limit under paragraph (e)(3) of this section, that is—

(A) Equal to 25 percent for defined standard coverage; or

(B) Actuarially equivalent to an average expected coinsurance of no more than 25 percent, as determined through processes and methods established under § 423.265, for actuarially equivalent standard coverage.

(ii) *Tiered copayments.* A prescription drug plan or MA-PD plan may apply tiered copayments without limit, provided that any tiered copayments are consistent with paragraph (e)(2)(i)(B) of this section and are reviewed as described in § 423.272(b)(2).

(3) *Initial coverage limit.* The initial coverage limit is equal to—

(i) For 2006. \$2,250.

(ii) For years subsequent to 2006. The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (e)(5)(iv) of this section, and rounded to the nearest multiple of \$10.

(4) *Cost-sharing between the initial coverage limit and the annual out-of-pocket threshold.* Coinsurance for costs for covered Part D drugs covered under the plan above the initial coverage limit described in paragraph (e)(3) of this section and annual out-of-pocket threshold described in paragraph (e)(5)(iii) of this section that is equal to 100 percent.

(5) *Protection against high out-of-pocket expenditures.* (i) After an enrollee's incurred costs exceed the annual out-of-pocket threshold described in paragraph (e)(5)(iii) of this section, cost-sharing equal to the greater of—

(A) *Copayments.* (1) In 2006, \$2 for a generic drug or preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i) of the Act) and \$5 for any other drug; and

(2) For subsequent years, the copayment amounts specified in this paragraph for the previous year increased by the annual percentage increase described in paragraph (e)(5)(iv) of this section and rounded to the nearest multiple of 5 cents; or

(B) *Coinurance.* Five percent coinsurance.

(ii) As determined through processes and methods established under § 423.265, a prescription drug plan or MA-PD plan may substitute for cost-sharing under paragraph (e)(5)(i) of this section an amount that is actuarially equivalent to expected cost-sharing under paragraph (e)(5)(i) of this section.

(iii) *Annual out-of-pocket threshold.* For purposes of this part, the annual out-of-pocket threshold equals—

(A) For 2006. \$3,600.

(B) For years subsequent to 2006. The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (e)(5)(iv) of this section, and rounded to the nearest multiple of \$50.

(iv) *Annual percentage increase.* The annual percentage increase for each year is equal to the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals and is based on data for the 12-month period ending in July of the previous year.

(f) *Alternative prescription drug coverage.* Alternative prescription drug coverage includes access to negotiated prices as described under paragraph

(h)(1) of this section, provides coverage of covered Part D drugs, and must meet the following requirements—

(1) Has an annual deductible that does not exceed the annual deductible specified in paragraph (e)(1) of this section;

(2) Imposes cost-sharing no greater than that specified in paragraph (e)(5)(i) or (ii) of this section once the annual out-of-pocket threshold described in paragraph (e)(5)(iii) is met;

(3) Has an unsubsidized value that is at least equal to the unsubsidized value of standard prescription drug coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage exceeds the actuarial value of the subsidy payments under § 423.782 with respect to such coverage; and

(4) Provides coverage that is designed, based upon an actuarially representative pattern of utilization, to provide for the payment, with respect to costs incurred that are equal to the initial coverage limit under paragraph (e)(3) of this section, of an amount equal to at least the product of—

(i) The amount by which the initial coverage limit described in paragraph (e)(3) of this section for the year exceeds the deductible described in paragraph (e)(1) of this section; and

(ii) 100 percent minus the coinsurance percentage specified in paragraph (e)(2)(i) of this section.

(g) *Enhanced alternative coverage.* (1) Enhanced alternative coverage must meet the requirements under paragraph (f) of this section and includes—

(i) Basic prescription drug coverage, as defined in § 423.100; and

(ii) Supplemental benefits, which include—

(A) Coverage of drugs other than covered Part D drugs; and/or

(B) Any of the following changes or combination of changes that increase the actuarial value of benefits above the actuarial value of defined standard prescription drug coverage, as determined through processes and methods established under § 423.265—

(1) A reduction in the annual deductible described in paragraph (e)(1) of this section;

(2) A reduction in the cost-sharing described in paragraphs (e)(2) or (e)(5) of this section, or

(3) An increase in the initial coverage limit described in paragraph (e)(3) of this section.

(2) *Restrictions on the offering of enhanced alternative coverage by PDP sponsors.* A PDP sponsor may not offer enhanced alternative coverage in a service area unless the PDP sponsor also

offers a prescription drug plan in that service area that provides basic prescription drug coverage.

(3) *Restrictions on the offering of enhanced alternative coverage by MA organizations.* Effective January 1, 2006, an MA organization—

(i) May not offer an MA coordinated care plan, as defined in § 422.4 of this chapter, in an area unless either that plan (or another MA plan offered by the MA organization in that same service area) includes required prescription drug coverage; and

(ii) May not offer prescription drug coverage (other than that required under Parts A and B of Title XVIII of the Act) to an enrollee—

(A) Under an MSA plan, as defined in § 422.2 of this chapter; or

(B) Under another MA plan (including a private fee-for-service plan, as defined in § 422.4 of this chapter) unless the drug coverage under such other plan provides qualified prescription drug coverage and unless the requirements of paragraph (g)(3)(i) of this section are met.

(h) *Negotiated prices.* (1) *Access to negotiated prices.* Under qualified prescription drug coverage offered by a PDP sponsor or an MA organization, the PDP sponsor or MA organization is required to provide its enrollees with access to negotiated prices for covered Part D drugs included in its 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.

(2) *Interaction with Medicaid best price.* Prices negotiated with a pharmaceutical manufacturer, including discounts, subsidies, rebates, and other price concessions, for covered Part D drugs by the following entities will not be taken into account in establishing Medicaid's best price under section 1927(c)(1)(C) of the Act—

(i) A prescription drug plan;

(ii) An MA-PD plan; or

(iii) A qualified retiree prescription drug plan (as defined in § 423.882) for Part D eligible individuals.

(3) *Disclosure.* (i) A PDP sponsor or an MA organization offering qualified prescription drug coverage is required to disclose to CMS data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers and passed through to beneficiaries, via pharmacies and other dispensers, in the form of lower subsidies paid by CMS on behalf of low-income individuals described in § 423.782, or in the form of lower monthly beneficiary premiums

and/or lower covered Part D drug prices at the point of sale, as specified in § 423.336(c)(1) and § 423.343(c)(1).

(ii) Information on negotiated prices disclosed to CMS under paragraph (h)(3) of this section is protected under the confidentiality provisions applicable under section 1927(b)(3)(D) of the Act.

(4) *Audits.* CMS may conduct periodic audits of the financial statements and all records of PDP sponsors and MA organizations pertaining to any qualified prescription drug coverage they may offer under either a prescription drug plan or an MA–PD plan.

§ 423.112 Establishment of prescription drug plan service areas.

(a) *Service area for prescription drug plans.* The service area for a prescription drug plan consists of one or more PDP regions as established under paragraphs (b) and (c) of this section.

(b) *Establishment of PDP regions.* (1) *General.* CMS establishes PDP regions in a manner consistent with the requirements for the establishment of MA regions as described at § 422.455 of this chapter.

(2) *Relation to MA regions.* To the extent practicable, PDP regions are the same as MA regions. CMS may establish PDP regions that are not the same as MA regions if CMS determines that the establishment of these regions improves access to prescription drug plan benefits for Part D eligible individuals.

(c) *Authority for territories.* CMS establishes a PDP region or regions for States that are not within the 50 States and the District of Columbia.

(d) *Revision of PDP regions.* CMS may revise the PDP regions established under paragraphs (b) and (c) of this section.

(e) *Regional or national plan.* Nothing in this section prevents a prescription drug plan from being offered in two or more PDP regions in their entirety or in all PDP regions in their entirety.

§ 423.120 Access to covered Part D drugs.

(a) *Assuring pharmacy access.* (1) *Convenient access to network pharmacies.* Except as provided in paragraph (a)(3) of this section, a prescription drug plan or MA–PD plan must have a contracted pharmacy network, consisting of pharmacies other than mail-order pharmacies, sufficient to ensure that for beneficiaries residing in the prescription drug plan's service area, as described in § 423.112, or the MA–PD plan's service area, as described in § 422.2 of this chapter, the following requirements are satisfied:

(i) At least 90 percent of Medicare beneficiaries, on average, in urban areas served by the prescription drug plan or

MA–PD plan live within 2 miles of a network pharmacy;

(ii) At least 90 percent of Medicare beneficiaries, on average, in suburban areas served by the prescription drug plan or MA–PD plan live within 5 miles of a network pharmacy; and

(iii) At least 70 percent of Medicare beneficiaries, on average, in rural areas served by the prescription drug plan or MA–PD plan live within 15 miles of a network pharmacy.

(2) *Access to mail-order pharmacies.* A prescription drug plan's or MA–PD plan's contracted pharmacy network may be supplemented by pharmacies offering home delivery via mail-order, provided the requirements of paragraph (a)(1) of this section are met.

(3) *Waiver of pharmacy access requirements.* CMS waives the requirements under paragraph (a)(1) of this section in the case of—

(i) An MA–PD plan that provides its enrollees with access to covered Part D drugs through pharmacies owned and operated by the MA organization, provided the organization's pharmacy network is sufficient to provide access to its enrollees that is comparable to the standard set forth under paragraph (a)(1) of this section.

(ii) An MA private fee-for-service plan described in § 422.4 of this chapter that—

(A) Offers qualified prescription drug coverage;

(B) Provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies and without charging cost-sharing in excess of that described in §§ 423.104(e)(2) and (5).

(4) *Pharmacy network contracting requirements.* In establishing its contracted pharmacy network, a PDP sponsor or MA organization offering qualified prescription drug coverage—

(i) Must contract with any pharmacy that meets the prescription drug plan's or MA–PD plan's terms and conditions; and

(ii) May not require a pharmacy to accept insurance risk as a condition of participation in the PDP plan's or MA–PD plan's network.

(5) *Discounts for preferred pharmacies.* A PDP sponsor or MA organization offering a prescription drug plan or an MA–PD plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs (relative to the copayments or coinsurance applicable when those covered Part D drugs are obtained through a non-preferred pharmacy) when a Part D eligible individual

enrolled in its prescription drug plan or MA–PD plan obtains the covered Part D drug through a preferred pharmacy. If the prescription drug plan or MA–PD plan provides actuarially equivalent standard coverage, the plan must still meet the requirements under §§ 423.104(e)(2) and (5). Any cost-sharing reduction must not increase CMS payments under § 423.329.

(6) *Level playing field between mail-order and network pharmacies.* A PDP sponsor or MA organization must permit its prescription drug plan or MA–PD plan enrollees to receive benefits, which may include a 90-day supply of covered Part D drugs, at a network retail pharmacy instead of a network mail-order pharmacy, provided an enrollee obtaining a covered Part D drug at a network retail pharmacy pays for any differential in the negotiated price for the covered Part D drug at the network retail pharmacy and network mail-order pharmacy.

(b) *Formulary requirements.* A PDP sponsor or MA organization that uses a formulary under its qualified prescription drug coverage must meet the following requirements—

(1) *Development and revision by a pharmacy and therapeutic committee.* A PDP sponsor or MA organization's formulary must be reviewed by a pharmacy and therapeutic committee that—

(i) Includes a majority of members who are practicing physicians and/or practicing pharmacists.

(ii) Includes at least one practicing physician and at least one practicing pharmacist who are independent and free of conflict with respect to the PDP sponsor and prescription drug plan, or MA organization and MA–PD plan, and who are experts regarding care of elderly or disabled individuals.

(iii) Bases clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmaco-economic studies, outcomes research data, and other such information as it determines appropriate.

(iv) Considers whether the inclusion of a particular covered Part D drug in a formulary or formulary tier has any therapeutic advantages in terms of safety and efficacy.

(v) Documents in writing its decisions regarding formulary development and revision.

(2) *Inclusion of drugs in all therapeutic categories and classes.* A prescription drug plan's or MA–PD plan's formulary must include at least two covered Part D drugs within each therapeutic category and class of

covered Part D drugs, with different strengths and doses available for those drugs. Only one covered Part D drug must be included in a particular category or class of covered Part D drugs if the category or class includes only one covered Part D drug.

(3) *Limitation on changes in therapeutic classification.* Except as CMS may permit to account for new therapeutic uses and newly approved covered Part D drugs, a PDP sponsor or MA organization offering an MA–PD plan may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year.

(4) *Periodic evaluation of protocols.* A PDP sponsor or MA organization offering an MA–PD plan must periodically evaluate and analyze treatment protocols and procedures related to its plan's formulary.

(5) *Provision of notice regarding formulary changes.* A PDP sponsor or MA organization offering an MA–PD plan must provide at least 30 days notice to CMS, affected enrollees, authorized prescribers, pharmacies, and pharmacists prior to removing a covered Part D drug from its plan's formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug.

(6) *Limitation on formulary changes prior to the beginning of a contract year.* A PDP sponsor or MA organization offering an MA–PD plan may not remove a covered Part D drug from its plan's formulary, or make any change in the preferred or tiered cost-sharing status of a covered Part D drug, between the beginning of the annual coordinated election period described in § 423.36(b) and 30 days after the beginning of the contract year associated with that annual coordinated election period.

(7) *Provider and patient education.* A PDP sponsor or MA organization offering an MA–PD plan must establish policies and procedures to educate and inform health care providers and enrollees concerning its formulary.

(c) *Use of standardized technology.* A PDP sponsor or MA organization offering an MA–PD plan must issue and reissue, as necessary, a card or other type of technology that its enrollees may use to access negotiated prices for covered Part D drugs as provided under § 423.104(h). The card or other technology must comply with standards CMS establishes.

§ 423.124 Special rules for access to covered Part D drugs at out-of-network pharmacies

(a) *Out-of-network access to covered part D drugs.* A PDP sponsor or MA

organization offering an MA–PD plan must assure that Part D enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when such enrollees cannot reasonably be expected to obtain such drugs at a network pharmacy.

(b) *Financial responsibility for out-of-network access to covered Part D drugs.* A Part D enrollee is financially responsible for the sum of the following costs of a covered Part D drug obtained as provided in paragraph (a) of this section—

(1) Any deductible or cost-sharing (relative to the plan allowance, as described in § 423.100, for that covered Part D drug); and

(2) Any differential between the out-of-network pharmacy's usual and customary price and the PDP sponsor or MA organization's plan allowance (including any applicable beneficiary cost-sharing) for that covered Part D drug.

§ 423.128 Dissemination of plan information.

(a) *Detailed description.* A PDP sponsor or MA organization offering an MA–PD plan must disclose the information specified in paragraph (b) of this section—

(1) To each enrollee of a prescription drug plan offered by the PDP sponsor or the MA–PD plan offered by the MA organization under this part;

(2) In a clear, accurate, and standardized form; and

(3) At the time of enrollment and at least annually thereafter.

(b) *Content of plan description.* The plan description must include the following information about the qualified prescription drug coverage offered under a prescription drug plan or an MA–PD plan—

(1) *Service area.* The plan's service area.

(2) *Benefits.* The benefits offered under the plan, including—

(i) Applicable conditions and limitations.

(ii) Premiums.

(iii) Cost-sharing (such as copayments, deductibles, and coinsurance), and cost-sharing for subsidy eligible individuals.

(iv) Any other conditions associated with receipt or use of benefits.

(3) *Cost-sharing.* A description of how a Part D eligible individual may obtain more information on cost-sharing requirements, including tiered or other copayment levels applicable to each drug (or class of drugs), in accordance with paragraph (d) of this section.

(4) *Formulary.* The manner in which any formulary (including any tiered

formulary structure) functions, including—

(i) The process for obtaining an exception to a prescription drug plan's or MA–PD plan's tiered cost-sharing structure;

(ii) A description of how a Part D eligible individual may obtain additional information on the formulary, including the formulary itself, in accordance with paragraph (d) of this section.

(5) *Access.* The number, mix, and distribution (addresses) of network pharmacies from which enrollees may reasonably be expected to obtain covered Part D drugs and how the prescription drug plan sponsor or MA organization meets the requirements of § 423.120(a)(1) for access to covered Part D drugs;

(6) *Out-of-network coverage.* Provisions for access to covered Part D drugs at out-of-network pharmacies, consistent with § 423.124(a).

(7) *Grievance, coverage determinations, reconsideration, exceptions, and appeals procedures.* All grievance, coverage determination, reconsideration, exceptions, and appeal rights and procedures required under § 423.564 et. seq.

(8) *Quality assurance program.* A description of the quality assurance program required under § 423.153(c), including the medication therapy management program required under § 423.153(d).

(9) *Disenrollment rights and responsibilities.*

(c) *Disclosure upon request of general coverage information, utilization, and grievance information.* Upon request of a Part D eligible individual, a PDP sponsor or MA organization offering an MA–PD plan must provide the following information—

(1) *General coverage information.* General coverage information, including—

(i) *Enrollment procedures.*

Information and instructions on how to exercise election options under this part;

(ii) *Rights.* A general description of procedural rights (including grievance, coverage determination, reconsideration, exceptions, and appeals procedures) under this part;

(iii) *Potential for contract termination.* The fact that a PDP sponsor or MA organization may terminate or refuse to renew its contract, or, in the case of an MA organization, reduce the service area included in its contract, and the effect that any of those actions may have on individuals enrolled in a prescription drug plan or MA–PD plan;

(iv) *Benefits.* (A) Covered services under the prescription drug plan;

(B) Any beneficiary cost-sharing, such as deductibles, coinsurance, and copayment amounts, including cost-sharing for subsidy eligible individuals;

(C) Any maximum limitations on out-of-pocket expenses;

(D) The extent to which an enrollee may obtain benefits from out-of-network providers;

(E) The types of pharmacies that participate in the prescription drug plan's or MA-PD plan's network and the extent to which an enrollee may select among those pharmacies; and

(F) Out-of-network pharmacy access.

(v) Premiums;

(vi) The prescription drug plan's or MA-PD plan's formulary;

(vii) The prescription drug plan's or MA-PD plan's service area; and

(viii) Quality and performance indicators for benefits under a plan as determined by CMS.

(2) The procedures the PDP sponsor or MA organization offering an MA-PD plan uses to control utilization of services and expenditures.

(3) The number of disputes, and the disposition in the aggregate, in a manner and form described by CMS. These disputes are categorized as—

(i) Grievances according to § 422.564 of this chapter;

(ii) Rights to a reconsideration according to § 422.578 *et. seq.* of this chapter.

(4) Financial condition of the PDP sponsor or MA organization, including the most recently audited information regarding, at a minimum, a description of the financial condition of the PDP sponsor or MA organization offering the prescription drug plan or MA-PD plan.

(d) *Provision of specific information.*

Each PDP sponsor or MA organization offering qualified prescription drug coverage must have mechanisms for providing specific information on a timely basis to current and prospective enrollees upon request. These mechanisms must include—

(1) A toll-free customer call center that—

(i) Is open during usual business hours.

(ii) Provides customer telephone service, including to pharmacists, in accordance with standard business practices.

(2) An Internet Website that—

(i) Includes, at a minimum, the information required in paragraph (b) of this section.

(ii) Includes a current formulary for its PDP plan or MA-PD plan, updated at least weekly.

(iii) Provides current and prospective Part D enrollees with at least 30 days

notice regarding the removal or change in the preferred or tiered cost-sharing status of a covered Part D drug on its prescription drug plan's or MA-PD plan's formulary.

(3) The provision of information in writing, upon request.

(e) *Claims information.* A PDP sponsor or MA organization offering qualified prescription drug coverage must furnish to enrollees, in a form easily understandable to such enrollees, an explanation of benefits when prescription drug benefits are provided under qualified prescription drug coverage. The explanation of benefits must—

(1) List the item or service for which payment was made and the amount of the payment for each item or service.

(2) Include a notice of the individual's right to request an itemized statement.

(3) Include the cumulative, year-to-date total amount of benefits provided, in relation to—

(i) The deductible for the current year.

(ii) The initial coverage limit for the current year.

(iii) The annual out-of-pocket threshold for the current year.

(4) Include the cumulative, year-to-date total of incurred costs to the extent practicable.

(5) Include any applicable formulary changes as described in § 423.120(b)(5).

(6) Be provided during any month when prescription drug benefits are provided under this part.

§ 423.132 Public disclosure of pharmaceutical prices for equivalent drugs.

(a) *General requirements.* Except as provided under paragraph (c) of this section, a PDP sponsor or an MA organization offering an MA-PD plan must require a pharmacy that dispenses a covered Part D drug to inform an enrollee of any differential between the price of that drug and the price of the lowest priced generic version of that drug available at that pharmacy, unless the particular covered Part D drug being purchased is the lowest-priced generic version of that drug available at that pharmacy.

(b) *Timing of notice.* Subject to paragraph (d) of this section, the information under paragraph (a) of this section must be provided at the point of sale or, in the case of dispensing by mail order, at the time of delivery of the drug.

(c) *Waiver of public disclosure requirement.* CMS waives the requirement under paragraph (a) of this section in the case of—

(1) An MA private fee-for-service plan described in § 422.4 of this chapter that—

(i) Offers qualified prescription drug coverage and provides plan enrollees

with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies; and

(ii) Does not charge additional cost-sharing for access to covered Part D drugs dispensed at out-of-network pharmacies.

(2) An out-of-network pharmacy;

(3) An I/T/U network pharmacy; and

(4) A network pharmacy that is located in any of the U.S. territories; and

(5) Such other circumstances where CMS deems compliance with the requirements of paragraph (a) of this section to be impossible or impracticable.

(d) *Modification of timing requirement.* CMS modifies the requirement under paragraph (b) of this section as follows—

(1) For long-term care network pharmacies, which must meet the requirement in paragraph (a) of this section within a time period specified by CMS; and

(2) Under such other circumstances where CMS deems compliance with the requirement under paragraph (b) of this section to be impossible or impracticable.

§ 423.136 Privacy, confidentiality, and accuracy of enrollee records.

The provisions of § 422.118 of this chapter apply to a PDP sponsor and prescription drug plan in the same manner as they apply to an MA organization and an MA plan.

Subpart D—Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans

§ 423.150 Scope.

The regulations in this subpart specify requirements relating to the following:

(a) Cost and utilization management programs, quality assurance programs, medication therapy management programs (MTMP), and programs to control fraud, abuse, and waste for PDP sponsors and MA organizations offering MA-PD plans.

(b) CMS consumer satisfaction surveys of prescription drug plan and MA-PD.

(c) Electronic prescription program.

(d) Compliance deemed on the basis of accreditation.

(e) Accreditation organizations.

(f) Procedures for the approval of accreditation organizations as a basis for deeming compliance.

§ 423.153 Cost and utilization management, quality assurance, medication therapy management programs, and programs to control fraud, abuse, and waste.

(a) *General rule.* Each PDP sponsor or MA organization offering an MA-PD plan must have established, for covered Part D drugs, furnished through a prescription drug plan or MA-PD plan, a cost-effective drug utilization management program, a quality assurance program, an MTMP, and a program to control fraud, abuse, and waste as described in § 423.153(b), § 423.153(c), § 423.153(d), and § 423.153(e) of this section.

(b) *Cost-effective drug utilization management.* A cost-effective drug utilization management program must—

(1) Include incentives to reduce costs when medically appropriate; and

(2) Maintain policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications.

(c) *Quality assurance program.* A quality assurance program must include measures and systems to reduce medication errors and adverse drug interactions and improve medication use. The program must establish processes for—

- (1) Drug utilization review;
- (2) Patient counseling; and
- (3) Patient information record-keeping

(d) *Medication therapy management program.* (1) *General rule.* A medication therapy management program—

(i) Must assure that drugs prescribed to targeted beneficiaries described in paragraph (d)(2) of this section are appropriately used to optimize therapeutic outcomes through improved medication use;

(ii) Must, for the targeted beneficiaries described in paragraph (d)(2) of this section, reduce the risk of adverse events, including adverse drug interactions;

(iii) May be furnished by a pharmacist; and

(iv) May distinguish between services in ambulatory and institutional settings.

(2) *Targeted beneficiaries.* Targeted beneficiaries for the medication therapy management program described in paragraph (d)(1) of this section are enrolled Part D eligible individuals who—

- (i) Have multiple chronic diseases;
- (ii) Are taking multiple covered Part D drugs; and

(iii) Are likely to incur annual costs for covered Part D drugs that exceed a predetermined level that CMS determines.

(3) *Use of experts.* The MTMP must be developed in cooperation with licensed

and practicing pharmacists and physicians.

(4) *Coordination with care management plans.* The MTMP must be coordinated with any care management plan established for a targeted individual under a chronic care improvement program under section 1807 of MMA.

(5) *Considerations in pharmacy fees.* An applicant to become a PDP sponsor or an MA organization wishing to offer an MA-PD plan must—

(i) Describe in its application how it will take into account the resources used and time required to implement the MTMP it chooses to adopt in establishing fees for pharmacists or others providing medication therapy management services for covered Part D drugs under a prescription drug plan.

(ii) Disclose to CMS upon request the amount of the management and dispensing fees and the portion paid for medication therapy management services to pharmacists and others upon request. Reports of these amounts are protected under the provisions of section 1927(b)(3)(D) of the Act.

(e) *Program to control fraud, abuse, and waste.* PDP sponsors and MA organizations offering MA-PD plans must develop performance standards to evaluate, prevent, and investigate fraud, abuse, and waste. These standards will apply to the PDP sponsor's or MA organization's evaluation of PDPs, MA-PDs, pharmacy benefit managers, or other subcontractors managing or coordinating the benefit for the organization or sponsor, pharmacies, physicians, and any other providers with whom the PDP sponsor or MA organizations does business.

(f) *Exception for private fee-for-service MA plans offering qualified prescription drug coverage.* In the case of an MA plan described in § 422.4(a)(3) of this chapter, the requirements under paragraphs (b) and (d) of this section do not apply.

§ 423.156 Consumer satisfaction surveys.

CMS conducts consumer satisfaction surveys of PDP and MA-PD enrollees similar to the surveys it conducts of MA enrollees under § 422.152 (b) of this chapter.

§ 423.159 Electronic prescription program.

(a) *Electronic prescription standards.* PDP sponsors and MA organizations offering qualified prescription drug coverage must have the capacity to support and must comply with electronic prescription standards relating to covered Part D drugs, for Part D eligible individuals, developed by CMS, once final standards are effective.

(b) *Promotion of electronic prescribing by MA-PD plans.* An MA organization offering an MA-PD plan may provide for a separate or differential payment to a participating physician that prescribes covered Part D drugs in accordance with electronic prescription standards, including voluntary standards promulgated by CMS as well as final standards established by CMS once final standards are effective.

§ 423.162 Quality Improvement Organization activities.

(a) *General rule.* Quality Improvement Organizations (QIOs) are required to offer providers, practitioners, MA organizations, and PDP sponsors quality improvement assistance pertaining to health care services, including those related to prescription drug therapy. QIOs offer assistance according to contracts established with the Secretary.

(b) *Collection of information.*

Information collected, acquired, or generated by a QIO in the performance of its responsibilities under this section is subject to the confidentiality provisions of 42 CFR Part 480. PDP sponsors and MA organizations offering MA-PD plans are required to provide specified information to CMS for distribution to the QIOs as well as directly to QIOs.

(c) *MA organizations and PDP sponsors.* For purposes of 42 CFR Parts 476 and 480, MA organizations and PDP sponsors are included in the definition of "health care facility."

§ 423.165 Compliance deemed on the basis of accreditation.

(a) *General rule.* A PDP sponsor or MA organization offering an MA-PD plan is deemed to meet all of the requirements of any of the areas described in paragraph (b) of this section if—

(1) The PDP sponsor or MA organization is fully accredited (and periodically reaccredited) for the standards related to the applicable area under paragraph (b) of this section by a private, national accreditation organization approved by CMS; and

(2) The accreditation organization uses the standards approved by CMS for the purposes of assessing the PDP sponsor or MA organization's compliance with Medicare requirements.

(b) *Deemable requirements.* The requirements relating to the following areas are deemable:

(1) Access to covered drugs, as provided under § 423.120 and § 423.124.

(2) Cost and utilization management, quality assurance, medication therapy management programs, and programs to

control fraud, abuse, and waste, as provided under § 423.153.

(3) Privacy, confidentiality, and accuracy of enrollee records, as provided under § 423.136.

(c) *Effective date of deemed status.*

The date the PDP sponsor or MA organization offering an MA-PD plan is deemed to meet the applicable requirements is the later of the following:

(1) The date the accreditation organization is approved by CMS.

(2) The date the PDP sponsor or MA organization is accredited by the accreditation organization.

(d) *Obligations of deemed PDP sponsors and MA organizations offering MA-PD plans.* A PDP sponsor or MA organization offering an MA-PD plan deemed to meet Medicare requirements must—

(1) Submit to surveys by CMS to validate its accreditation organization's accreditation process; and

(2) Authorize its accreditation organization to release to CMS a copy of its most recent accreditation survey, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(e) *Removal of deemed status.* CMS removes part or all of a PDP sponsor or MA organization's deemed status for any of the following reasons—

(1) CMS determines, on the basis of its own investigation, that the PDP sponsor or MA organization does not meet the Medicare requirements for which deemed status was granted.

(2) CMS withdraws its approval of the accreditation organization that accredited the PDP sponsor or MA organization.

(3) The PDP sponsor or MA organization fails to meet the requirements of paragraph (d) of this section.

(f) *Enforcement authority.* CMS retains the authority to initiate enforcement action against any PDP sponsor or MA organization offering an MA-PD plan that it determines, on the basis of its own survey or the results of an accreditation survey, no longer meets the Medicare requirements for which deemed status was granted.

§ 423.168 Accreditation organizations.

(a) *Conditions for approval.* CMS may approve an accreditation organization for a given standard under this part if it meets the following conditions:

(1) In accrediting PDP sponsors and MA organizations offering MA-PD plans, it applies and enforces standards that are at least as stringent as Medicare

requirements for the standard or standards in question.

(2) It complies with the application and reapplication procedures set forth in § 423.171.

(3) It ensures that—

(i) Any individual associated with it, who is also associated with an entity it accredits, does not influence the accreditation decision concerning that entity;

(ii) The majority of the membership of its governing body is not comprised of managed care organizations, PDP sponsors or their representatives; and

(iii) Its governing body has a broad and balanced representation of interests and acts without bias.

(b) *Notice and comment.* (1) *Proposed notice.* CMS publishes a notice in the **Federal Register** whenever it is considering granting an accreditation organization's application for approval. The notice—

(i) Announces CMS's receipt of the accreditation organization's application for approval;

(ii) Describes the criteria CMS uses in evaluating the application; and

(iii) Provides at least a 30-day comment period.

(2) *Final notice.* (i) After reviewing public comments, CMS publishes a final notice in the **Federal Register** indicating whether it has granted the accreditation organization's request for approval.

(ii) If CMS grants the request, the final notice specifies the effective date and the term of the approval that may not exceed 6 years.

(c) *Ongoing responsibilities of an approved accreditation organization.*

An accreditation organization approved by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS in written form and on a monthly basis all of the following:

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to deemed PDP sponsors or MA organizations.

(iv) Information about any PDP sponsor or MA organization against which the accrediting organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the PDP sponsor's or MA organization's accreditation. (The accreditation organization must provide this information within 30 days of taking the remedial or adverse action.)

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 days of a change in CMS requirements, submit the following to CMS—

(i) An acknowledgment of CMS's notification of the change.

(ii) A revised crosswalk reflecting the new requirements.

(iii) An explanation of how the accreditation organization plans to alter its standards to conform to CMS's new requirements, within the timeframes specified in the notification of change it receives from CMS.

(3) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 3 days of identifying, in an accredited PDP sponsor or MA organization, a deficiency that poses immediate jeopardy to the organization's enrollees or to the general public, give CMS written notice of the deficiency.

(5) Within 10 days of CMS's notice of withdrawal of approval, give written notice of the withdrawal to all accredited PDP sponsors and MA organizations.

(6) On an annual basis, provide summary data specified by CMS that relate to the past year's accreditation activities and trends.

(d) *Continuing Federal oversight of approved accreditation organizations.* Specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization include the following:

(1) *Equivalency review.* CMS compares the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when—

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new standards or changes in its survey process; or

(iii) The term of an accreditation organization's approval expires.

(2) *Validation review.* CMS or its agent may conduct a survey of an accredited organization, examine the results of the accreditation organization's own survey, or attend the accreditation organization's survey to validate the organization's accreditation process. At the conclusion of the review, CMS identifies any

accreditation programs for which validation survey results indicate—

- (i) A 20 percent rate of disparity between certification by the accreditation organization and certification by CMS or its agent on standards that do not constitute immediate jeopardy to patient health and safety if unmet;
- (ii) Any disparity between certification by the accreditation organization and certification by CMS or its agent on standards that constitute immediate jeopardy to patient health and safety if unmet; or
- (iii) That, regardless of the rate of disparity, there are widespread or systematic problems in an organization's accreditation process that accreditation no longer provides assurance that the Medicare requirements are met or exceeded.

(3) *Onsite observation.* CMS may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to the following:

- (i) Reviewing documents.
- (ii) Auditing meetings concerning the accreditation process.
- (iii) Evaluating survey results or the accreditation status decision-making process.

(iv) Interviewing the organization's staff.

(4) *Notice of intent to withdraw approval.* If an equivalency review, validation review, onsite observation, or CMS's daily experience with the accreditation organization suggests that the accreditation organization is not meeting the requirements of this subpart, CMS will give the organization written notice of its intent to withdraw approval.

(5) *Withdrawal of approval.* CMS may withdraw its approval of an accreditation organization at any time if CMS determines that—

(i) Deeming, based on accreditation, no longer guarantees that the PDP sponsor or MA organization meets the requirements for offering qualified prescription drug coverage, and failure to meet those requirements may jeopardize the health or safety of Medicare enrollees and constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations under this section or under § 423.158 or § 423.162.

(6) *Reconsideration of withdrawal of approval.* An accreditation organization dissatisfied with a determination to

withdraw CMS approval may request a reconsideration of that determination in accordance with subpart D of part 488 of this chapter.

§ 423.171 Procedures for approval of accreditation as a basis for deeming compliance.

(a) *Required information and materials.* A private, national accreditation organization applying for approval must furnish to CMS all of the following information and materials (when reapplying for approval, the organization need furnish only the particular information and materials requested by CMS):

(1) The types of prescription drug plans and MA-PD plans that it reviews as part of its accreditation process.

(2) A detailed comparison of the organization's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk).

(3) Detailed information about the organization's survey process, including the following:

(i) Frequency of surveys and whether surveys are announced or unannounced.

(ii) Copies of survey forms, and guidelines and instructions to surveyors.

(iii) Descriptions of—

(A) The survey review process and the accreditation status decision making process;

(B) The procedures used to notify accredited PDP sponsors and MA organizations of deficiencies and to monitor the correction of those deficiencies; and

(C) The procedures used to enforce compliance with accreditation requirements.

(4) Detailed information about the individuals who perform surveys for the accreditation organization, including the—

(i) Size and composition of accreditation survey teams for each type of plan reviewed as part of the accreditation process;

(ii) Education and experience requirements surveyors must meet;

(iii) Content and frequency of the in-service training provided to survey personnel;

(iv) Evaluation systems used to monitor the performance of individual surveyors and survey teams; and

(v) Organization's policies and practice for the participation, in surveys or in the accreditation decision process by an individual who is professionally or financially affiliated with the entity being surveyed.

(5) A description of the organization's data management and analysis system

for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(6) A description of the organization's procedures for responding to and investigating complaints against accredited organizations, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs.

(7) A description of the organization's policies and procedures for the withholding or removal of accreditation for failure to meet the accreditation organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

(8) A description of all types (for example, full or partial) and categories (for example, provisional, conditional, or temporary) of accreditation offered by the organization, the duration of each type and category of accreditation, and a statement identifying the types and categories that serve as a basis for accreditation if CMS approves the accreditation organization.

(9) A list of all currently accredited PDP sponsors and MA organizations and the type, category, and expiration date of the accreditation held by each of them.

(10) A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization as requested by CMS.

(11) The name and address of each person with an ownership or control interest in the accreditation organization.

(b) *Required supporting documentation.* A private, national accreditation organization applying or reapplying for approval also must submit the following supporting documentation—

(1) A written presentation that demonstrates its ability to furnish CMS with electronic data in CMS compatible format.

(2) A resource analysis that demonstrates that its staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(3) A statement acknowledging that, as a condition for approval, it agrees to comply with the ongoing responsibility requirements of § 423.168(c).

(c) *Additional information.* If CMS determines that it needs additional information for a determination to grant or deny the accreditation organization's request for approval, it notifies the organization and allows time for the

organization to provide the additional information.

(d) *Onsite visit.* CMS may visit the accreditation organization's offices to verify representations made by the organization in its application, including, but not limited to, review of documents and interviews with the organization's staff.

(e) *Notice of determination.* CMS gives the accreditation organization, within 210 days of receipt of its completed application, a formal notice that—

(1) States whether the request for approval has been granted or denied;

(2) Gives the rationale for any denial; and

(3) Describes the reconsideration and reapplication procedures.

(f) *Withdrawal.* An accreditation organization may withdraw its application for approval at any time before it receives the formal notice specified in paragraph (e) of this section.

(g) *Reconsideration of adverse determination.* An accreditation organization that has received a notice of denial of its request for approval may request a reconsideration in accordance with subpart D of part 488 of this chapter.

(h) *Request for approval following denial.* (1) Except as provided in paragraph (h)(2) of this section, an accreditation organization that has received notice of denial of its request for approval may submit a new request if it—

(i) Has revised its accreditation program to correct the deficiencies on which the denial was based.

(ii) Can demonstrate that the PDP sponsors and MA organizations that it has accredited meet or exceed applicable Medicare requirements; and

(iii) Resubmits the application in its entirety.

(2) An accreditation organization that has requested reconsideration of CMS' denial of its request for approval may not submit a new request until the reconsideration is administratively final.

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

§ 423.251 Scope.

This section sets forth the requirements and limitations on submission, review, negotiation and approval of competitive bids for prescription drug plans and MA–PD plans; the calculation of the national average bid amount; and the determination of enrollee premiums.

§ 423.258 Definitions.

For the purposes of this part, the following definitions apply:

Full risk plan means a prescription drug plan that is not a limited risk plan or a fallback prescription drug plan.

Limited risk plan means a prescription drug plan that provides basic prescription drug coverage and for which the PDP sponsor includes a modification of risk level described in § 423.265(d) in its bid submitted for the plan. This term does not include a fallback prescription drug plan.

Standardized bid amount means, for a prescription drug plan that provides basic prescription drug coverage, the PDP approved bid; for a prescription drug plan that provides supplemental prescription drug coverage, the portion of the PDP approved bid that is attributable to basic prescription drug coverage; for a MA–PD plan, the portion of the accepted bid amount that is attributable to basic prescription drug coverage.

§ 423.265 Submission of bids and related information.

(a) *Eligibility for bidding.* (1) *Eligible entities.* With the exception set forth in paragraph (a)(2) of this section, an applicant may submit a bid to become a PDP sponsor or to become an MA organization offering an MA–PD plan

(2) *Limitation on entities offering fallback prescription drug plans.* CMS will not accept a bid from a potential PDP sponsor for the offering of a full risk or limited risk prescription drug plan in a PDP region for a year if the applicant—

(i) Submitted a bid under § 423.863 for the year (as the first year of a contract period under § 423.863) to offer a fallback prescription drug plan in any PDP region;

(ii) Offers a fallback prescription drug plan in any PDP region during the year; or

(iii) Offered a fallback prescription drug plan in that PDP region during the previous year.

(3) *Construction.* For purposes of this paragraph, an entity is treated as submitting a bid for a prescription drug plan or offering a fallback prescription drug plan if the entity is acting as a subcontractor of a PDP sponsor that is offering a plan. The previous sentence does not apply to entities that are subcontractors of an MA organization except insofar as the MA organization is applying to act as a PDP sponsor of a prescription drug plan.

(b) *Bid Submission.* Not later than the first Monday in June, each potential PDP sponsor or MA organization planning to offer an MA–PD plan must

submit bids and supplemental information described in this section for each prescription drug or MA–PD plan it intends to offer in the subsequent calendar year.

(c) *Basic rule for bid.* Each potential PDP sponsor or MA organization must submit a bid in a format to be specified by CMS for each prescription drug plan or MA–PD plan it offers. Each bid must reflect a uniform benefit package, including premium (except as provided for the late enrollment penalty described in § 423.286(d)(3)) and all applicable cost sharing, for all individuals enrolled in the plan. Each bid must reflect the applicant's estimate of its average monthly revenue requirements to provide qualified prescription drug coverage (including any supplemental coverage) for a Part D eligible individual with a national average risk profile for the factors described in § 423.329(b)(1).

(1) *Included costs.* The bid includes costs (including administrative costs and return on investment/profit) for which the plan is responsible in providing basic and supplemental benefits.

(2) *Excluded costs.* The bid does not include costs associated with payments by the enrollee for deductible, copayments, coinsurance, payments projected to be made by CMS for reinsurance, or any other costs for which the sponsor is not responsible.

(3) *Actuarial valuation.* The bid must be prepared in accordance with CMS actuarial guidelines based on generally accepted actuarial principles. A qualified actuary must certify the plan's actuarial valuation (which may be prepared by others under his/her direction or review), and must be a member of the American Academy of Actuaries to be deemed qualified. Applicants may use qualified outside actuaries to prepare their bids.

(d) *Specific requirements for bids.* The bid submission must include the following information:

(1) *Coverage.* A description of the coverage to be provided under the plan, including any supplemental coverage and the deductible and other cost sharing.

(2) *Actuarial value of bid components.* The applicant must provide the following information on bid components, as well as actuarial certification that the values are calculated according to CMS guidelines on actuarial valuation, including adjustment for the effect that providing alternative prescription drug coverage (rather than defined standard prescription drug coverage) has on drug utilization, if applicable.

(i) The actuarial value of the qualified prescription drug coverage to be offered under each plan for a Part D eligible individual with a national average risk profile for the factors described in § 423.329(b)(1) and the basis for the estimate.

(ii) The portion of the bid attributable to basic prescription drug coverage and the portion (if any) attributable to supplemental benefits.

(iii) The assumptions regarding reinsurance amounts payable under § 423.329(c) used in calculating the bid.

(iv) The assumptions regarding low-income cost-sharing payable under § 423.329(d) used in calculating the bid.

(v) The amount of administrative costs and return on investment or profit included in the bid.

(3) *Service area.* A description of the service area of the plan.

(4) *Level of risk assumed.* For a potential PDP sponsor, the level of risk assumed in the bid specified in paragraph (e) of this section.

(5) *Plan Average Risk Score.* An estimate of the plan's average prescription drug risk score (as established under § 423.329(b)) for all projected enrollees for purposes of risk adjusting any supplemental premium.

(6) *Additional information.*

Additional information CMS requests to support bid amounts and facilitate negotiation.

(e) *Special rule for PDP sponsors.* Bids for all plans offered by a potential PDP sponsor in a region, but not those of potential MA organizations offering MA-PD plans, may include a uniform modification of the amount of risk assumed (based on a process to be specified) as described in one or more of the following paragraphs. Any such modification will apply to all plans offered by the PDP sponsor in a PDP region.

(1) *Increase in Federal percentage assumed in initial risk corridor.* An equal percentage point increase in the percents applied for costs between the first and second threshold limits under § 423.336(b)(2)(i) and (b)(2)(ii)(A) and § 423.336(b)(3)(i) and (b)(3)(ii)(A). This provision does not affect the application of a higher percentage for plans in 2006 or 2007 under § 423.336(b)(2)(iii).

(2) *Increase in Federal percentage assumed in second risk corridor.* An equal percentage point increase in the percents applied for costs above the second threshold upper limit or below the second threshold upper limit under paragraphs § 423.336(b)(2)(ii)(B) and (b)(3)(ii)(B).

(3) *Decrease in size of risk corridors.* A decrease in the size of the risk corridors by means of reductions in the

threshold risk percentages specified in § 423.336(a)(2)(ii)(A) and/or (a)(2)(ii)(B).

(f) *Special rule for fallback plans.* Fallback plan bids are not subject to the rules in this section. They must follow requirements specified in § 423.863.

§ 423.272 Review and negotiation of bid and approval of plans submitted by potential PDP sponsors or MA organizations planning to offer MA-PD plans.

(a) *Review and negotiation regarding information, terms and conditions.* CMS reviews the information filed under § 423.265(c) in order to conduct negotiations regarding the terms and conditions of the proposed bid and benefit plan using authority similar to that of the Director of the Office of Personnel Management for health benefit plans under Chapter 89 of title 5, U.S.C.

(b) *Approval of proposed plans.* CMS will approve the prescription drug plan or MA-PD plan only if the plan and the PDP sponsor or MA organization offering the plan comply with all applicable CMS Part D requirements, including those related to the provision of qualified prescription drug coverage and actuarial determinations.

(1) *Application of revenue requirements standard.* CMS only approves a bid if it determines that the portions of the bid attributable to basic and supplemental prescription drug coverage are supported by the actuarial bases provided and reasonably and equitably reflect the revenue requirements (as used for purposes of section 1302(8)(C) of the Public Health Service Act) for benefits provided under that plan, less the sum (determined on a monthly per capita basis) of the actuarial value of the reinsurance payments under section § 423.329(c).

(2) *Plan design.* CMS does not approve a bid if it finds that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan. If the design of the categories and classes within a formulary is consistent with the model guidelines (if any) established by the United States Pharmacopeia, that formulary may not be found to discourage enrollment on the basis of its categories and classes alone.

(c) *Limited risk plans.* (1) *Application of limited risk plans.* There is no limit on the number of full risk plans that CMS approves under paragraph (b) of this section. CMS only approves a limited risk plan in accordance with paragraphs (c)(2) and (c)(3) of this section if the access requirements under

§ 423.859 are not otherwise met for a PDP region.

(2) *Maximizing assumption of risk.* CMS gives priority in approval for those limited risk plans bearing the highest level of risk, but may take into account the level of the bids submitted by the plans and is not required to accept the plan with the highest assumption of risk. In no case does CMS approve a limited risk plan under which the modification of risk level provides for no (or a minimal) level of financial risk.

(3) *Limited exercise of authority.* CMS only approves the minimum number of limited risk plans needed to meet the access requirements.

(d) *Special rules for private fee-for-service (PFFS) plans that offer prescription drug coverage.* PFFS plans choosing to offer prescription drug coverage are subject to all MA-PD bid submission and approval requirements with the following exceptions:

(1) *Exemption from negotiations.*

These plans are exempt from the review and negotiation process in paragraph (a) of this section, and are not held to the revenue requirements standard in paragraph (b)(1) of this section.

(2) *Requirements regarding negotiated prices.* These plans are not required to provide access to negotiated prices. However, if they do, they must meet the applicable requirements of § 423.104(h).

(3) *Modification of pharmacy access standard and disclosure requirement.* If the plan provides coverage for drugs purchased from all pharmacies, without charging additional cost sharing and without regard to whether they are participating providers, §§ 423.120(a) and 423.132 requiring certain network access standards and the disclosure of the availability of lower cost bioequivalent generic drugs does not apply to the plan.

§ 423.279 National average monthly bid amount.

(a) *Bids included.* For each year (beginning with 2006) CMS computes a national average monthly bid amount from approved bids in order to calculate the base beneficiary premium, as provided in § 423.286(c). The national average monthly bid amount is equal to a weighted average of the standardized bid amounts for each prescription drug plan and for each MA-PD plan described in section 1851(a)(2)(A)(i) of the Act. The calculation does not include bids submitted for MSA plans, MA private fee-for-service plans, specialized MA plans for special needs individuals, PACE programs under section 1894, and under reasonable cost reimbursement contracts under section 1876(h) of the Act.

(b) *Calculation of weighted average.* The national average monthly bid amount is a weighted average, with the weight for each plan equal to a percentage with the numerator equal to the number of Part D eligible individuals enrolled in the plan in the reference month (as defined in § 422.258(c)(1)) and the denominator equal to the total number of Part D eligible individuals enrolled in all the Part D plans included in the calculation of the national average bid amount in the reference month. For purposes of calculating the monthly national average monthly bid amount for 2006, CMS determines the weighted average for 2005.

(c) *Geographic adjustment.* (1) CMS establishes an appropriate methodology for adjusting the national average monthly bid amount to take into account differences in prices for covered Part D drugs among PDP regions.

(2) CMS does not apply any geographic adjustments if CMS determines that price variations among PDP regions are negligible.

(3) CMS applies any geographic adjustment in a budget neutral manner so as to not result in a change in the aggregate payments that may have been made if CMS had not applied an adjustment.

§ 423.286 Rules regarding premiums.

(a) *General rule.* Except as provided in paragraphs (d)(3) and (e) of this section, and in § 423.463(b) with regard to employer group waivers, the monthly beneficiary premium for a prescription drug plan or MA-PD plan in a PDP region is the same for all part D eligible individuals enrolled in the plan. The monthly beneficiary premium for a prescription drug plan or MA-PD plan is the base beneficiary premium, as determined in paragraph (c) of this section, adjusted as described in paragraph (d) of this section for the difference between the bid and the national average monthly bid amount, any supplemental benefits and for any late enrollment penalties.

(b) *Beneficiary premium percentage.* The beneficiary premium percentage for any year is a fraction, the—

(1) Numerator of which is 25.5 percent; and

(2) Denominator of which is as follows:

(i) 100 percent minus the percentage established in paragraph (b)(2)(ii) of this section.

(ii) The percentage established in this paragraph equals:

(A) The total reinsurance payments that CMS estimates will be paid under

§ 423.329(c) for the coverage year; divided by—

(B) The amount estimated under paragraph (b)(2)(ii)(A) of this section for the year plus total payments that CMS estimates will be paid to prescription drug plans and MA-PD plans that are attributable to the standardized bid amount during the year, taking into account amounts paid by both CMS and enrollees.

(c) *Base beneficiary premium.* The base beneficiary premium for a prescription drug plan for a month is equal to the product of the—

(1) Beneficiary premium percentage as specified in paragraph (b) of this section; and

(2) National average monthly bid amount (computed under § 423.279) for the month.

(d) *Adjustments to base beneficiary premium.* The base beneficiary premium may be adjusted to reflect any of the following scenarios, if applicable.

(1) *Adjustment to reflect difference between bid and national average bid.* If the amount of the standardized bid amount exceeds the amount of the adjusted national average monthly bid amount, the monthly base beneficiary premium is increased by the amount of the excess. If the amount of the adjusted national average monthly bid amount exceeds the standardized bid amount, the monthly base beneficiary premium is decreased by the amount of the excess.

(2) *Increase for supplemental prescription drug benefits.* The portion of the PDP or MA-PD plan approved bid that is attributable to supplemental prescription drug benefits increases the beneficiary premium. This supplemental portion of the bid may be adjusted to reflect the average risk score of the plan by multiplying by the plan average risk score provided in § 423.265(d)(5).

(3) *Increase for late enrollment penalty.* The base beneficiary premium is increased on a monthly basis by the amount of any late enrollment penalty.

(i) *Late Enrollment Penalty Amount.* The penalty amount for a Part D eligible individual for a continuous period of eligibility (as provided in § 423.46(a)) is the greater of—

(A) An amount that CMS determines is actuarially sound for each uncovered month in the same continuous period of eligibility; or

(B) 1 percent of the base beneficiary premium (computed under paragraph (c) of this section) for each uncovered month in the period.

(ii) *Special rule for 2006 and 2007.* In 2006 and 2007 the penalty amount discussed in paragraph (d)(3) will equal

the amount referenced in paragraph (d)(3)(i)(B) of this section unless another amount is specified in a separate issuance based on available analysis or other information as determined by the Secretary.

(e) *Decrease in monthly beneficiary premium for low-income assistance.* The monthly beneficiary premium may be eliminated or decreased in the case of a subsidy-eligible individual under § 423.780.

(f) *Special rules for fallback plans.* The monthly beneficiary premium charged under a fallback plan is calculated under § 423.867(a).

§ 423.293 Collection of monthly beneficiary premium.

(a) *General rule.* Subject to paragraphs (c) and (d) of this section, the provisions of section 1854(d) of the Act (as specified in § 422.262(b) on the consolidated monthly premium and paragraph (f) of this section on beneficiary payment options), 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 except that any reference to a Trust Fund is deemed for this purpose a reference to the Medicare Prescription Drug Account.

(b) *Crediting of late enrollment penalty.* CMS estimates and specifies the portion of the late enrollment penalty imposed under § 423.286(d)(3) attributable to increased actuarial costs assumed by the PDP sponsor or MA organization (and not taken into account through risk adjustment provided under § 423.329(b)(1) or through reinsurance payments under § 423.329(c)) as a result of the late enrollment.

(c) *Collection of late enrollment penalty.*

(1) *Collection through withholding.* In the case of a late enrollment penalty that is collected from a Part D eligible individual in the manner described in § 422.262(f)(1), CMS pays only the portion of the late enrollment penalty described in paragraph (b) of this section to the PDP sponsor or MA organization offering the Part D plan in which the individual is enrolled.

(2) *Collection by plan.* In the case of a late enrollment penalty collected from a Part D eligible individual in a manner other than the manner described in § 422.262(f)(1), CMS reduces payments otherwise made to the PDP sponsor or MA organization by an amount equal to this portion of the late enrollment penalty.

(d) *Special rule for fallback plans.* The collection requirements of this section do not apply to fallback

prescription drug plans. The fallback plans follow the requirements set forth in § 423.867(b).

Subpart G—Payments to PDP Sponsors and MA Organizations Offering MA–PD Plans For All Medicare Beneficiaries For Qualified Prescription Drug Coverage

§ 423.301 Scope.

This section sets forth rules for the calculation and payment of CMS direct and reinsurance subsidies for prescription drug plans and MA–PD plans; the application of risk corridors and risk-sharing adjustments to payments; and retroactive adjustments and reconciliations to actual enrollment and interim payments.

§ 423.308 Definitions and terminology.

For the purposes of this part, the following definitions apply—

Actually paid means that the costs must be actually incurred by the sponsor and must be net of any direct or indirect remuneration (including discounts, chargebacks or average percentage 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 by the sponsor for the drug.

Allowable reinsurance costs means the subset of gross covered prescription drug costs that are attributable to basic or standard benefits only and that are actually paid by the sponsor or organization or by (or on behalf of) an enrollee under the plan. The costs for any plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic coverage, but also to exclude any basic coverage costs determined to be attributable to increased utilization over the standard benefit as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

Allowable risk corridor costs means the subset of prescription drug costs (not including administrative costs, but including costs directly related to the dispensing of covered Part D drugs during the year) that are attributable to basic or standard benefits only and that are incurred and actually paid by the sponsor or organization under the plan. Costs may be based upon imposition of

the maximum amount of copayments permitted under § 423.782. The costs for any plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic coverage, but also to exclude any basic coverage costs determined to be attributable to increased utilization over the standard benefit as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

Coverage year means a calendar year in which covered Part D drugs are dispensed if the claim for those drugs (and payment on the claim) is made not later than 3 months after the end of the year.

Gross covered prescription drug costs means those costs incurred under a Part D plan, excluding administrative costs, but including costs related to the dispensing of covered Part D drugs during the year and costs relating to the deductible. They equal—

(1) All reimbursement paid by a PDP sponsor or an MA organization offering an MA–PD plan to a pharmacy (or other intermediary) or to indemnify an enrollee when the reimbursement is associated with an enrollee obtaining drugs under the plan; plus

(2) All amounts paid under the 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 plan. These costs are determined regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

Target amount for any prescription drug plan or MA–PD plan equals the total amount of payments (from CMS and enrollees) to that plan for the 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.

§ 423.315 General payment provisions.

(a) *Source of payments.* CMS payments under this section are made from the Medicare Prescription Drug Account.

(b) *Monthly payments.* CMS provides a direct subsidy in the form of advance monthly payments equal to the plan's standardized bid, risk adjusted for health status as provided in § 423.329(b), minus the beneficiary monthly premium as determined in § 423.286.

(c) *Reinsurance subsidies.* CMS provides reinsurance subsidy payments described in § 423.329(c) through

payments of amounts on an as-incurred basis as provided under § 423.329(c)(2)(i) and final reconciliation to actual allowable reinsurance costs as provided in § 423.343(c).

(d) *Low-income subsidies.* CMS makes payments for premium and cost sharing subsidies, including additional coverage above the initial coverage limit, on behalf of certain subsidy-eligible enrollees as provided in § 423.780 and § 423.782. CMS provides low-income cost-sharing subsidy payments described in § 423.782 through interim payments of amounts as provided under § 423.329(d)(2)(i) and reconciliation to actual allowable reinsurance costs as provided in § 423.343(d).

(e) *Risk-sharing arrangements.* CMS may issue lump-sum payments or adjust monthly payments in the following payment year based on the relationship of the plan's adjusted allowable risk corridor costs to predetermined risk corridor thresholds in the coverage year as provided in § 423.336.

(f) *Retroactive adjustments and reconciliations.* CMS reconciles payment year disbursements with updated enrollment and health status data, actual low-income cost-sharing costs and actual allowable reinsurance costs as provided in § 423.343.

(g) *Special rules for private fee-for-service plans.*

(1) *Application of reinsurance.* For private fee-for-service plans, CMS determines the amount of reinsurance payments as provided under § 423.329(c)(3).

(2) *Exemption from risk corridor provisions.* The provisions of § 423.336 regarding risk sharing do not apply.

(h) *Special rules for fallback plans.* In lieu of the amounts otherwise payable under § 423.329, the amount payable to a PDP sponsor offering a fallback prescription drug plan is the amount determined under the contract for the plan in accordance with § 423.871(e).

§ 423.322 Requirement for disclosure of information.

(a) *Payment conditional upon provision of information.* Payments to a PDP sponsor or MA organization are conditioned upon provision of information to CMS that is necessary to carry out this subpart, or as required by law.

(b) *Restriction on use of information.* Officers, employees and contractors of the Department of Health and Human Services may use the information disclosed or obtained in accordance with the provisions of this subpart only for the purposes of, and to the extent necessary in, carrying out this subpart

including, but not limited to, determination of payments and payment-related oversight and program integrity activities. This restriction does not limit OIG authority to conduct audits and evaluations necessary for carrying out these regulations.

§ 423.329 Determination of payment.

(a) *Subsidy payments.* (1) *Direct subsidy.* CMS makes a direct subsidy payment for each eligible beneficiary enrolled in a prescription drug plan or MA-PD plan for a month equal to the amount of the plan's approved standardized bid, adjusted for health status (as determined under § 423.329(b)(1)), and reduced by the base beneficiary premium for the plan (as determined under § 423.286(c) and adjusted in § 423.286(d)(1)).

(2) *Subsidy through reinsurance.* CMS makes reinsurance subsidy payments as provided under paragraph (c) of this section.

(3) *Low-income cost-sharing subsidy.* CMS makes low-income cost-sharing subsidy payments as provided under paragraph (d) of this section.

(b) *Health status risk adjustment.* (1) *Establishment of risk factors.* CMS establishes an appropriate methodology for adjusting the standardized bid amount under paragraph (a)(1) of this section, to take into account variation in costs for basic prescription drug coverage among prescription drug plans and MA-PD plans based on the differences in actuarial risk of different enrollees being served. Any risk adjustment is designed in a manner so as to be budget neutral in the aggregate to the risk of the Part D eligible individuals who enroll in Part D plans.

(2) *Considerations.* In establishing the methodology under paragraph (b)(1) of this section, CMS takes into account the similar methodologies used under § 422.308(c)(1) to adjust payments to MA organizations for benefits under the original Medicare fee-for-service program option.

(3) *Data collection.* In order to carry out this paragraph, CMS requires—

(i) PDP sponsors to submit data regarding drug claims that can be linked at the individual level to Part A and Part B data in a form and manner similar to the process provided under § 422.310 and other information as CMS determines necessary; and

(ii) MA organizations that offer MA-PD plans to submit data regarding drug claims that can be linked at the individual level to other data that the organizations are required to submit to CMS in a form and manner similar to the process provided under § 422.310

and other information as CMS determines necessary.

(4) *Publication.* At the time of publication of risk adjustment factors under § 422.312(a)(1)(ii), CMS publishes the risk adjusters established under this paragraph of this section for the upcoming calendar year.

(c) *Reinsurance payment amount.* (1) *General rule.* The reinsurance payment amount for a Part D eligible individual enrolled in a prescription drug plan or MA-PD plan for a coverage year is an amount equal to 80 percent of the allowable reinsurance costs attributable to that portion of gross covered prescription drug costs incurred in the coverage year after the individual has truly incurred out-of-pocket costs that exceed the annual out-of-pocket threshold specified in § 423.108(b)(4)(iii).

(2) *Payment method.* Payments under this section are based on a method as CMS determines.

(i) *Payments during the coverage year.* CMS establishes a payment method by which monthly payments of amounts under this section are made during a year based on allowable reinsurance costs incurred in each month of the coverage year.

(ii) *Final payments.* CMS reconciles the payments made during the coverage year to final actual allowable reinsurance costs as provided in § 423.343(c).

(3) *Special rules for private fee-for-service Plans offering prescription drug coverage.* CMS determines the amount of reinsurance payments for private fee-for-service plans offering prescription drug coverage using a methodology that—

(i) Bases the amount on CMS' estimate of the amount of the payments that are payable if the plan were an MA-PD plan described in section 1851(a)(2)(A)(i); and

(ii) Takes into account the average reinsurance payments made under § 423.329(c) for populations of similar risk under MA-PD plans described in the section.

(d) *Low-income cost sharing subsidy payment amount.*

(1) *General rule.* The low-income cost sharing subsidy payment amount on behalf of a low-income subsidy eligible individual enrolled in a prescription drug plan or MA-PD plan for a coverage year is the amount described in § 423.782.

(2) *Payment method.* Payments under this section are based on a method that CMS determines.

(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.

(ii) *Final payments.* CMS reconciles the interim payments to actual incurred low-income cost-sharing costs as provided in § 423.343(d).

§ 423.336 Risk-sharing arrangements.

(a) *Portion of total payments to a sponsor or organization subject to risk.*

(1) *Adjusted allowable risk corridor costs.* For purposes of this paragraph, the term adjusted allowable risk corridor costs means—

(i) The allowable risk corridor costs for the plan for the coverage year, reduced by—

(ii) The sum of—

(A) The total reinsurance payments made under § 423.329(c) to the sponsor of the plan for the year; and

(B) The total non-premium subsidy payments made under § 423.782 to the sponsor of the plan for the coverage year.

(2) *Establishment of risk corridors.* (i)

Risk corridors. For each year, CMS establishes a risk corridor for each prescription drug plan and each MA-PD plan. The risk corridor for a plan for a year is equal to a range as follows:

(A) *First threshold lower limit.* The first threshold lower limit of the corridor is equal to—

(1) The target amount for the plan; minus

(2) An amount equal to the first threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(A) of this section) of the target amount.

(B) *Second threshold lower limit.* The second threshold lower limit of the corridor is equal to—

(1) The target amount for the plan; minus

(2) An amount equal to the second threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(B) of this section) of the target amount.

(C) *First threshold upper limit.* The first threshold upper limit of the corridor is equal to the sum of—

(1) The target amount; and

(2) An amount equal to the first threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(A) of this section) of the target amount.

(D) *Second threshold upper limit.* The second threshold upper limit of the corridor is equal to the sum of—

(1) The target amount; and

(2) An amount equal to the second threshold risk percentage for the plan

(as determined under paragraph (a)(2)(ii)(B) of this section) of the target amount.

(ii) *First and second threshold risk percentage defined.* (A) *First threshold risk percentage.* Subject to paragraph (a)(2)(iii) of this section, the first threshold risk percentage is for—

- (1) 2006 and 2007, and 2.5 percent;
- (2) 2008 through 2011, 5 percent; and
- (3) 2012 and subsequent years, a percentage CMS establishes, but in no case less than 5 percent.

(B) *Second threshold risk percentage.* Subject to paragraph (a)(2)(iii) of this section, the second threshold risk percentage is for—

- (1) 2006 and 2007, 5.0 percent;
- (2) 2008 through 2011, 10 percent
- (3) 2012 and subsequent years, a percentage CMS establishes that is greater than the percent established for the year under paragraph (a)(2)(ii)(A)(3) of this section, but in no case less than 10 percent.

(iii) *Reduction of risk percentage to ensure two Plans in an area.* In accordance with § 423.265(e), a PDP sponsor may submit a bid that requests a decrease in the applicable first or second threshold risk percentages or an increase in the percents applied under paragraph (b) of this section.

(3) *Plans at risk for entire amount of supplemental prescription drug coverage.* A PDP sponsor and MA organization that offer a plan that provides supplemental prescription drug benefits are at full financial risk for the provision of the supplemental benefits.

(b) *Payment adjustments.* (1) *No adjustment if adjusted allowable risk corridor costs within risk corridor.* If the adjusted allowable risk corridor costs for the plan for the year are at least equal to the first threshold lower limit of the risk corridor (specified in paragraph (a)(2)(i)(A) of this section) but not greater than the first threshold upper limit of the risk corridor (specified in paragraph (a)(2)(i)(C) of this section) for the plan for the year, CMS makes no payment adjustment.

(2) *Increase in payment if adjusted allowable risk corridor costs above upper limit of risk corridor.*

(i) *Costs between first and second threshold upper limits.* If the adjusted allowable risk corridor costs for the plan for the year are greater than the first threshold upper limit, but not greater than the second threshold upper limit, of the risk corridor for the plan for the year, CMS increases the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount equal to 50 percent (or, for 2006 and

2007, 75 percent or 90 percent if the conditions described in paragraph (b)(2)(iii) of this section are met for the year) of the difference between the adjusted allowable risk corridor costs and the first threshold upper limit of the risk corridor.

(ii) *Costs above second threshold upper limits.* If the adjusted allowable risk corridor costs for the plan for the year are greater than the second threshold upper limit of the risk corridor for the plan for the year, CMS increases the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount equal to the sum of—

(A) 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions specified in paragraph (b)(2)(iii) of this section are met for the year) of the difference between the second threshold upper limit and the first threshold upper limit; and

(B) 80 percent of the difference between the adjusted allowable risk corridor costs and the second threshold upper limit of the risk corridor.

(iii) *Conditions for application of higher percentage for 2006 and 2007.* The conditions specified in this paragraph are met for 2006 or 2007 if CMS determines for the year that—

(A) At least 60 percent of prescription drug plans and MA-PD plans to which this paragraph applies have adjusted allowable risk corridor costs for the plan for the year that are more than the first threshold upper limit of the risk corridor for the plan for the year; and

(B) The plans represent at least 60 percent of Part D eligible individuals enrolled in any prescription drug plan or MA-PD plan.

(3) *Reduction in payment if adjusted allowable risk corridor costs below lower limit of risk corridor.*

(i) *Costs between first and second threshold lower limits.* If the adjusted allowable risk corridor costs for the plan for the year are less than the first threshold lower limit, but not less than the second threshold lower limit, of the risk corridor for the plan for the year, CMS reduces the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount (or otherwise recovers from the sponsor or organization an amount) equal to 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit of the risk corridor and the adjusted allowable risk corridor costs.

(ii) *Costs below second threshold lower limit.* If the adjusted allowable risk corridor costs for the plan for the year are less than the second threshold lower

limit of the risk corridor for the plan for the year, CMS reduces the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount (or otherwise recovers from the sponsor or organization an amount) equal to the sum of—

(A) 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit and the second threshold lower limit; and

(B) 80 percent of the difference between the second threshold upper limit of the risk corridor and the adjusted allowable risk corridor costs.

(c) *Payment methods.* CMS makes payments after a coverage year after obtaining all of the cost data information in paragraph (c)(1) of this section necessary to determine the amount of payment. CMS will not make payments under this section if the PDP sponsor or MA organization fails to provide the cost data information in paragraph (c)(1) of this section.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the PDP sponsor or MA organization offering a MA-PD plan sponsor must provide to CMS the following information:

(i) The gross covered prescription drug costs segregated by enrollee and date of service.

(ii) The allowable risk corridor costs (defined in § 423.308) for the coverage year.

(iii) The adjusted allowable risk corridor costs for the coverage year.

(iv) Costs incurred for supplemental benefits distinguished from those for basic coverage.

(v) Other information stipulated by CMS.

(2) *Lump sum and adjusted monthly payments.* CMS at its discretion makes either lump-sum payments or adjusts monthly payments in the following payment year based on the relationship of the plan's adjusted allowable risk corridor costs to the predetermined risk corridor thresholds in the coverage year, as determined under paragraph (a) of this section.

(d) *No effect on monthly premium.* No adjustment in payments made by reason of this section may affect the monthly beneficiary premium or the MA monthly prescription drug beneficiary premium.

§ 423.343 Retroactive adjustments and reconciliations.

(a) *Application of enrollee adjustment.* The provisions of § 422.308 apply to payments to PDP sponsors under this section in the same manner as they apply to payments to MA

organizations under section 1853(a) of the Act.

(b) *Health status.* CMS makes adjustments to payments made under § 423.329(a)(1) to account for updated health status risk adjustment data as provided under § 422.310(g)(2). CMS may recover payments associated with health status adjustments if the MA organization or PDP sponsor fails to provide the information described in § 423.329(b)(3).

(c) *Reinsurance.* CMS makes final payment for reinsurance after a coverage year after obtaining all of the information necessary to determine the amount of payment.

(1) *Submission of cost data.* Within 6 months after the end of a coverage year, the PDP sponsor or MA organization offering a MA-PD plan must provide CMS the following information:

(i) The gross covered prescription drug costs segregated by enrollee and date of service.

(ii) The allowable reinsurance costs segregated by enrollee and date of service.

(iii) The costs incurred by the plan delineated separately from those incurred by or on behalf of the enrollee for purposes of determining out-of-pocket expenditures.

(iv) Costs incurred for supplemental benefits distinguished from those for basic coverage.

(v) Other information stipulated by CMS.

(2) *Payments.* CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between monthly reinsurance payments made during the coverage year and the amount payable in § 423.329(c) for the coverage year. CMS may recover payments made through a lump sum recovery or by adjusting monthly payments throughout the remainder of the coverage year if the monthly reinsurance payments made during the coverage year exceed the amount payable under § 423.329(c) or if the PDP sponsor or MA organization does not provide the data in paragraph (c)(1) of this section.

(d) *Low-income cost-sharing subsidy.* CMS makes final payment for low-income cost-sharing subsidies after a coverage year after obtaining all of the information necessary to determine the amount of payment.

(1) *Submission of cost data.* Within 6 months after the end of a coverage year, the PDP sponsor or MA organization offering a MA-PD plan must provide CMS the following information:

(i) The gross covered prescription drug costs segregated by enrollee and date of service.

(ii) The costs incurred by the plan delineated separately than those incurred by or on behalf of the enrollee for purposes of determining out-of-pocket expenditures.

(iii) Other information stipulated by CMS.

(2) *Payments.* CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between interim low-income cost-sharing subsidy payments and total low-income cost-sharing subsidy costs eligible for subsidy under § 423.782 submitted by the plan for the coverage year. CMS may recover payments made through a lump sum recovery or by adjusting monthly payments throughout the remainder of the coverage year if interim low-income cost-sharing subsidy payments exceed the amount payable under § 423.782 or if the PDP sponsor or MA organization does not provide the data in paragraph (d)(1) of this section.

§ 423.346 Reopening

(a) CMS may reopen and revise a final payment determination (including a determination on the final amount of direct subsidy described in § 423.329(a)(1), final reinsurance payments described in § 423.329(c), the final amount of the low income subsidy described in § 423.329(d), or final risk corridor payments as described in § 423.336)—

(1) For any reason, within 12 months from the date of the notice of the final determination to the PDP sponsor or MA organization;

(2) After that 12-month period, but within 4 years after the date of the notice of the initial determination to the individual, upon establishment of good cause for reopening; or

(3) At any time when the determination or decision was procured by fraud or similar fault of the PDP sponsor, MA organization, or any subcontractor of such sponsor or organization.

(b) For purposes of this section, CMS will find good cause if—

(1) New and material evidence that was not readily available at the time the final determination was made is furnished;

(2) A clerical error in the computation of payments was made; or

(3) The evidence that was considered in making the determination clearly shows on its face that an error was made.

(c) For purposes of this section, CMS will not find good cause if the only reason for reopening is a change of legal interpretation or administrative ruling upon which the final determination was made.

Subpart I—Organization Compliance With State Law and Preemption by Federal Law

§ 423.401 General requirements for PDP sponsors.

(a) *General requirements.* Each PDP sponsor of a prescription drug plan must meet the following requirements:

(1) *Licensure.* Except in cases where there is a waiver as specified at § 423.410, the sponsor is organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan. If not commercially licensed, the sponsor obtains certification from the State that the organization meets a level of financial solvency and other standards as the State may require for it to operate as a PDP sponsor.

(2) *Assumption of financial risk for unsubsidized coverage.* The entity assumes financial risk on a prospective basis for benefits that it offers under a prescription drug plan and that is not covered under 1860D-15(b) of the Act.

(b) *Reinsurance permitted.* The plan sponsor may obtain insurance or make other arrangements for the cost of coverage provided to any enrollee to the extent that the sponsor is at risk for providing the coverage.

(c) *Solvency for unlicensed sponsors.* In the case of a PDP sponsor that is not described in § 423.401(a)(1) and for which a waiver is approved under § 423.410, the sponsor must meet § 423.420.

§ 423.410 Waiver of certain requirements to expand choice.

(a) *Authorizing waiver.* In the case of an entity that seeks to offer a prescription drug plan in a State, CMS waives the licensure requirement at § 423.401(a)(1), which requires that the entity be licensed in that State if CMS determines, based on the application and other evidence presented, that any of the grounds for approval of the application described in paragraphs (c), (d), or (e) of this section are met.

(b) *Application of regional plan waiver rule.* In addition to the waiver available under paragraphs (c), (d) and (e) of this section, the following waiver may be requested—

(1) *In general.* Subject to paragraphs (b)(2) and (b)(3) of this section, if an

applicant seeking to become a PDP sponsor operates in more than one State in a region, and is licensed as a risk bearing entity in at least one State in such region, then the applicant may receive a regional plan waiver for the States in which it is not licensed.

(2) *Filing of application.* The applicant must demonstrate to the satisfaction of CMS that it filed the necessary licensure applications with each State in the region for which it does not already have State licensure, except that no such application is necessary if CMS determines that the State does not have a licensing process for potential PDP sponsors.

(3) *Time limit.* The waiver will expire at the end of the time period that the Secretary determines is appropriate for timely processing of the application, but in no case will a waiver extend beyond the end of the calendar year.

(c) *Grounds for approval of waivers.* Subject to the waiver requirements specified in § 423.410(f), waivers may be granted under any of the following conditions:

(1) *Failure to act on licensure application on a timely basis.* The State failed to complete action on the licensure application within 90 days of the date that the State received a substantially complete application.

(2) *Denial of application based on discriminatory treatment.* The State has—

(i) Denied the license application on the basis of material requirements, procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or

(ii) Required, as a condition of licensure that the organization offer any product or plan other than a prescription drug plan.

(3) *Denial of application based on application of solvency requirements.*

(i) The State has denied the licensure application, in whole or in part, on the basis of the PDP sponsor's failure to meet solvency requirements that are different from the solvency standards CMS established under 423.420; or

(ii) CMS determines that the State has imposed, as a condition of licensing, any documentation or information requirements relating to solvency that are different from the standards CMS establishes pursuant to § 423.420.

(4) *Grounds other than those required by federal law.* The application by a State of any grounds other than those required under Federal law.

(d) *Waiver when licensing process not in effect.* The grounds for approval specified in paragraph(c)(1) of this

section are deemed met if the State does not have a licensing process in effect with respect to PDP sponsors.

(e) *Special waiver for plan years beginning before January 1, 2008.* For plan years beginning before January 1, 2008, if the State has a prescription drug plan or PDP sponsor licensing process in effect, CMS grants a waiver upon a demonstration that a PDP sponsor has submitted a substantially complete licensure application to the State.

(f) *Waiver requirements.* Except for the waivers described in paragraph (b) of this section, the following rules apply to waiver applications or waivers granted under this section.

(1) *Treatment of waiver.* The waiver applies only to that State, is effective only for 36 months and cannot be renewed.

(2) *Prompt action on application.* CMS grants or denies a waiver application under this section within 60 days after CMS determines that a substantially complete waiver application is received by CMS.

(3) In the case of a State that does not have a PDP sponsor licensing process, the 36 month deadline on the waiver discussed in paragraph (f)(1) of this section does not apply, and the waiver may continue in effect for a given State as long as the State does not have a PDP sponsor licensing process in effect.

§ 423.420 Solvency standards for non-licensed entities.

(a) *Establishment and publication.* CMS establishes and publishes reasonable financial solvency and capital adequacy standards for entities specified in paragraph (b) of this section.

(b) *Compliance with standards.* A PDP sponsor that is not licensed by a State and for which a waiver application is approved by CMS under § 423.410 (b), (c), (d), or (e) must maintain reasonable financial solvency and capital adequacy in accordance with the standards established by CMS under paragraph(a) of this section.

§ 423.425 Licensure does not substitute for or constitute certification.

The fact that a PDP sponsor is State licensed or has a waiver application approved under § 423.410 does not deem the sponsor to meet other requirements imposed under this part for a PDP sponsor.

§ 423.440 Prohibition of State imposition of premium taxes; relation to State laws.

(a) *Federal preemption of State law.* The standards established under this part supersede any State law or regulation (other than State licensing laws or State laws relating to plan

solvency) with respect to prescription drug plans offered by PDP sponsors and MA-PD plans offered by MA organizations.

(b) *State premium taxes prohibited.*

(1) *Basic rule.* No premium tax, fee, or other similar assessment may be imposed by any State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa, the Mariana Islands or any of their political subdivisions or other governmental authorities with respect to any payment CMS makes on behalf of MA-PD plan or prescription drug plan enrollees under subpart G of this part; or with respect to any payment made to prescription drug plans or MA-PD plans by a beneficiary or by a third party on behalf of a beneficiary.

(2) *Construction.* Nothing in this section shall be construed to exempt any PDP sponsor from taxes, fees, or other monetary assessments related to the net income or profit that accrues to, or is realized by, the organization from business conducted under this part, if that tax, fee, or payment is applicable to a broad range of business activity.

Subpart J—Coordination Under Part D With Other Prescription Drug Coverage

§ 423.452 Scope.

This section sets forth the application of Part D rules to Part C plans, establishes waivers for employer-sponsored group prescription drug plans, and establishes requirements for coordination of benefits with State Pharmaceutical Assistance Programs and other providers of prescription drug coverage.

§ 423.454 Definitions and Terminology.

For purposes of this subpart, the following definitions apply—

Part D plan or Medicare Part D plan is a prescription drug plan or an MA-PD plan.

Employer-sponsored group prescription drug plan means a prescription drug plan under a contract between a PDP sponsor or an MA organization offering an MA-PD plan and employers, labor organizations, or the trustees of funds established by one or more employers or labor organizations to furnish prescription drug benefits under employment-based retiree health coverage (as defined in § 423.822). (Published elsewhere in this Federal Register.)

State Pharmaceutical Assistance Program (SPAP) means a State program (operated by or under contract with a State) that meets the requirements described under § 423.464(c).

§ 423.458 Application of Part D rules to MA–PD plans on and after January 1, 2006.

(a) *Relationship to Part C.* Except as otherwise provided in this Part, the requirements of this Part apply to prescription drug coverage provided by Medicare Advantage prescription drug plans offered by Medicare Advantage organizations.

(b) *MA Waiver.* CMS waives any provision of this Part as applied to MA–PD plans to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to the MA organization or MA–PD plan under Part C of Medicare or as may be necessary in order to improve coordination of this part with the benefits under Part C.

(1) *Application of Waiver.* Any waiver or modification granted by CMS under this section will apply to any other similarly situated organization offering or seeking to offer a MA–PD plan that meets the conditions of the waiver.

(2) *Request for waivers.* Organizations offering or seeking to offer a Medicare Advantage–Prescription Drug plan may request from CMS in writing—

(i) A waiver of those requirements under Part D of Medicare that are duplicative of, or that are in conflict with provisions otherwise applicable to the MA–PD plan, or proposed MA–PD plan, under Part C of Medicare.

(ii) A waiver of a requirement under Medicare Part D, if such waiver would improve coordination of benefits provided under Part C of Medicare with the benefits under Part D.

(c) *Employer Group Waiver.* (1) *General rule.* Prescription drug plans may request, in writing, a waiver or modification of those requirements under Part D of Medicare that hinder the design of, the offering of, or the enrollment in, an employer-sponsored group prescription drug plan. This provision applies to prescription drug plans in the same manner that the provisions of section 1857(i) of the Act apply to an MA plan or MA–PD plan in relation to employer-sponsored group MA plans or MA–PD plans, including authorizing the establishment of separate premium amounts for enrollees of the employer-sponsored group prescription drug plan and limitations on enrollment in such plan to Part D eligible individuals participating in the employment-based retiree health coverage sponsored by the employer, labor organization, or the trustees of a fund established by one or more employers or labor organizations.

(2) *Use of waiver.* Waivers or modifications approved by CMS under this section apply to any similarly situated prescription drug plan meeting

the conditions of the waiver or modification.

(d) *Other Waivers.* CMS waives any provision of this Part as applied to a section 1876 cost HMO/CMP (as defined in § 417.401) or PACE organization (as defined in § 460.6) that offers qualified prescription drug coverage under Part D to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to the 1876 cost HMO/CMP under section 1876 of the Act or provisions applicable to PACE organizations under sections 1894 and 1934 of the Act or as may be necessary in order to improve coordination of this Part with the benefits offered by 1876 cost HMOs/CMPs or PACE organizations.

(1) *Application of Waiver.* Any waiver or modification granted by CMS under this section will apply to any other similarly situated organization offering or seeking to offer qualified prescription drug coverage as an 1876 cost HMO/CMP or as a PACE organization that meets the conditions of the waiver.

(2) *Request for waivers.* Section 1876 cost HMOs/CMPs or PACE organizations seeking to offer qualified prescription drug coverage may request from CMS in writing—

(i) A waiver of those requirements under Part D of Medicare that are duplicative of, or that are in conflict with provisions otherwise applicable to 1876 cost HMOs/CMPs or PACE organizations.

(ii) A waiver of a requirement under Medicare Part D, if such waiver would improve coordination of benefits provided by the section 1876 cost HMO/CMP or PACE organization with the benefits under Part D.

§ 423.462 Medicare secondary payer procedures.

The provisions of § 422.108 of this chapter regarding Medicare secondary payer procedures apply to PDP sponsors in the same way as they apply to MA organizations under Part C of Title XVIII of the Act, except all references to MA organizations are considered references to PDP sponsors.

§ 423.464 Coordination of Benefits With Other Providers of Prescription Drug Coverage.

(a) *General rule.* A PDP sponsor and Medicare Advantage organization offering a MA–PD plan must permit State Pharmaceutical Assistance Programs described in paragraph (e) of this section and the plans described in paragraph (f) of this section to coordinate benefits with the prescription drug plan or MA–PD plan and must comply with all

administrative processes and requirements established by CMS to ensure effective exchange of information and coordination between a Part D plan and a State pharmaceutical assistance program and other plans providing prescription drug coverage for—

(1) Payment of premiums and coverage; and

(2) Payment for supplemental prescription drug benefits as described in § 423.104(g)(1)(ii) (including payment to a Medicare Part D plan on a lump sum per capita basis) for Part D eligible individuals enrolled in the Part D plan and the SPAP or other plan.

(b) *Medicare as primary payer.* The requirements of this subpart do not change or affect the primary or secondary payor status of a Medicare Part D plan and a SPAP or other plan. A Medicare Part D plan is always the primary payor relative to a State Pharmaceutical Assistance Program.

(c) *User fees.* CMS may impose user fees for the transmittal of information necessary for benefit coordination in accordance with administrative processes and requirements established by CMS to ensure effective exchange of information and coordination between a Part D plan and a State Pharmaceutical Assistance Program and other plans providing prescription drug coverage in a manner similar to the manner in which user fees are imposed under section 1842(h)(3)(B), except that CMS may retain a portion of user fees to defray costs in carrying out such procedures. CMS will not impose user fees under this subpart for a State pharmaceutical assistance program.

(d) *Cost management tools.* The requirements of this subpart do not prevent an organization sponsoring a Medicare Part D plan from using cost management tools (including differential payments) under all methods of operation.

(e) *Coordination with State Pharmaceutical Assistance Programs.*

(1) *Requirements to be a State Pharmaceutical Assistance Program (SPAP).* A program operated by or under contract with a State will be considered to be a State Pharmaceutical Assistance Program for purposes of this part if it—

(i) Provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals;

(ii) Provides assistance to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls;

(iii) Meets the benefit coordination requirements specified in this part; and

(iv) Does not follow or adopt rules that change or affect the primary payor status of a Part D plan. The definition of SPAP excludes State Medicaid programs, section 1115 demonstration programs, and any other program where the majority of the funding is from Federal grants, awards, contracts, entitlement programs, or other Federal sources of funding.

(2) *Special treatment under out-of-pocket rule.* A PDP sponsor and Medicare Advantage organization offering a MA-PD plan shall collect information on and apply expenditures made by SPAPs for costs of covered Part D drugs meeting the definition of incurred costs (as described in § 423.100) for purposes of reaching the out-of-pocket threshold provided under § 423.104(e)(5)(iii).

(3) *Use of a single card.* A card that is issued under § 423.120(c) for use under a Medicare Part D plan may also be used in connection with coverage of benefits provided under a State pharmaceutical assistance program and, in such a case, may contain an emblem or symbol indicating such connection.

(4) *Construction.* Nothing in this subpart requires a State Pharmaceutical Assistance Program to coordinate with, or provide financial assistance to enrollees in, any Medicare Part D plan.

(f) *Coordination with other plans.* (1) *Definition of other plans.* Other plans that provide prescription drug coverage include any of the following:

(i) *Medicaid programs.* A State plan under title XIX of the Act, including such a plan operating under a waiver under section 1115 of the Act, if it meets the requirements of paragraph (e)(1)(ii) of this section.

(ii) *Group health plans.* An employer group health plan as defined in § 411.101.

(iii) *FEHBP.* The Federal employees' health benefits plan under chapter 89 of title 5, United States Code.

(iv) *Military coverage (including TRICARE).* Coverage under chapter 55 of title 10, United States Code.

(v) *Other health benefit plans or programs.* Other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of Medicare Part D eligible individuals as CMS may specify.

(2) *Treatment under out-of-pocket rule.* A PDP sponsor and Medicare Advantage organization offering a MA-PD plan shall exclude expenditures made by other plans for costs of covered Part D drugs for purposes of reaching the out-of-pocket threshold provided under § 423.104(e)(5)(iii).

(3) *Imposition of fees.* A prescription drug plan sponsor or an organization offering an MA-PD plan may not impose fees on other plans that are unrelated to the cost of the coordination of benefits.

Subpart K—Application Procedures and Contracts With PDP Sponsors

§ 423.501 Definitions.

For purposes of this subpart, the following definitions apply:

Business transaction means any of the following kinds of transactions:

(1) Sale, exchange, or lease of property.

(2) Loan of money or extension of credit.

(3) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(i) Salaries paid to employees for services performed in the normal course of their employment; or

(ii) Health services furnished to the PDP sponsor's enrollees by pharmacies and other providers, by PDP sponsor staff, medical groups, or independent practice associations, or by any combination of those entities.

Significant business transaction means any business transaction or series of transactions of the kind specified in the above definition of business transaction that, during any fiscal year of the PDP sponsor, have a total value that exceeds \$25,000 or 5 percent of the PDP sponsor's total operating expenses, whichever is less.

Downstream entity means any party that enters into an acceptable written arrangement below the level of the arrangement between a PDP sponsor (or contract applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

First tier entity means any party that enters into an acceptable written arrangement with a PDP sponsor or contract applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.

Party in interest means the following:

(1) Any director, officer, partner, or employee responsible for management or administration of a PDP sponsor.

(2) Any person who is directly or indirectly the beneficial owner of more than 5 percent of the organization's equity; or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization.

(3) In the case of a PDP sponsor organized as a nonprofit corporation, an

incorporator or member of the corporation under applicable State corporation law.

(4) Any entity in which a person specified in paragraphs (1), (2), or (3) of this definition—

- (i) Is an officer, director, or partner; or
- (ii) Has the kind of interest described in paragraphs (1), (2), or (3) of this definition.

(5) Any person that directly or indirectly controls, is controlled by, or is under common control with the PDP sponsor.

(6) Any spouse, child, or parent of an individual specified in paragraphs (1), (2), or (3) of this definition.

Related entity means any entity that is related to the PDP sponsor by common ownership or control and—

(1) Performs some of the PDP sponsor's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the PDP sponsor at a cost of more than \$2,500 during a contract period.

§ 423.502 Application requirements.

(a) *Scope.* This section sets forth application requirements for an entity that seeks a contract with CMS as a PDP sponsor.

(b) *Completion of an application.* (1)

In order to obtain a determination on whether it meets the requirements to become a PDP sponsor, an entity, or an individual authorized to act for the entity (the applicant), must complete a certified application in the form and manner required by CMS, including the following:

(i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards as specified in subpart I of this part; or

(ii) A Federal waiver as specified in subpart I of this part.

(2) The authorized individual must describe thoroughly how the entity meets, or plans to meet, the requirements described in this part.

(c) *Responsibility for making determinations.* CMS is responsible for determining whether an entity qualifies as a PDP sponsor and meets the requirements of this part.

(d) *Disclosure of application information under the Freedom of Information Act.* An applicant submitting material that he or she believes is protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act, or because of

exceptions provided in 45 CFR part 5 (the Department's regulations providing exceptions to disclosure), must label the material "privileged" and include an explanation of the applicability of an exception specified in 45 CFR part 5.

§ 423.503 Evaluation and determination procedures for applications to be a sponsor.

(a) *Basis for evaluation and determination.* (1) CMS evaluates an entity's application for a contract as a PDP sponsor on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits, publicly available information, and any other appropriate procedures.

(2) If the application is incomplete, CMS notifies the contract applicant and allows 10 days from the date of the notice for the contract applicant to furnish the missing information.

(3) After evaluating all relevant information, CMS determines whether the contract applicant's application meets the applicable requirements specified in § 423.504.

(b) *Use of information from a prior contracting period.* If a PDP sponsor, Medicare Advantage Organization, or Medicare cost plan fails to comply with the terms of a previous year's contract with CMS under title XVIII of the Act, or fails to complete a corrective action plan during the term of the contract, CMS may deny an application from a contract applicant based on the contract applicant's failure to comply with that prior contract with CMS even if the contract applicant meets all of the current requirements.

(c) *Notice of determination.* CMS notifies each applicant that applies for a contract as a PDP sponsor, under this part, of its determination on the application and the basis for the determination. The determination may be one of the following:

(1) *Approval of application.* If CMS approves the application, it gives written notice to the contract applicant, indicating that it meets the requirements for a contract as a PDP sponsor.

(2) *Intent to deny.* (i) If CMS finds that the contract applicant does not appear to meet the requirements for a PDP sponsor contract, it gives the contract applicant notice of intent to deny the application for a PDP contract and a summary of the basis for this preliminary finding.

(ii) Within 10 days from the date of the notice, the contract applicant may respond in writing to the issues or other matters that were the basis for CMS's preliminary finding and may revise its

application to remedy any defects CMS identified.

(d) *Denial of application.* If CMS denies the application, it gives written notice to the contract applicant indicating—

(1) That the contract applicant does not meet the contract requirements under Part D of title XVIII of the Act;

(2) The reasons why the contract applicant does not meet the contract requirements; and

(3) The contract applicant's right to request reconsideration in accordance with the procedures specified in § 423.644.

(e) *Oversight of continuing compliance.* (1) CMS oversees a PDP sponsor's continued compliance with the requirements for a PDP sponsor.

(2) If a PDP sponsor no longer meets those requirements, CMS terminates the contract in accordance with § 423.509.

§ 423.504 General provisions.

(a) *General rule.* Subject to the provisions at § 423.265(a)(1) concerning submission of bids, to enroll beneficiaries in any prescription drug plan it offers and be paid on behalf of Medicare beneficiaries enrolled in those plans, a PDP sponsor must enter into a contract with CMS. The contract may cover more than one prescription drug plan.

(b) *Conditions necessary to contract as a PDP sponsor.* Any entity seeking to contract as a PDP sponsor must—

(1) Complete an application as described in § 423.502.

(2) Be organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan, or have secured a Federal waiver, as described in subpart I of this part.

(3) Meet the minimum enrollment requirements of § 423.512(a) unless waived under § 423.512(b) or (c).

(4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following:

(i) A policy making body that exercises oversight and control over the PDP sponsor's policies and personnel to ensure that management actions are in the best interest of the organization and its enrollees.

(ii) Personnel and systems sufficient for the PDP sponsor to organize, implement, control, and evaluate financial and marketing activities, the furnishing of prescription drug services, the quality assurance, medical therapy management, and drug and or utilization management programs, and the administrative and management aspects of the organization.

(iii) At a minimum, an executive manager whose appointment and removal are under the control of the policy making body.

(iv) A fidelity bond or bonds, procured and maintained by the PDP sponsor, in an amount fixed by its policymaking body but not less than \$100,000 per individual, covering each officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the PDP sponsor.

(v) Insurance policies or other arrangements, secured and maintained by the PDP sponsor and approved by CMS to insure the PDP sponsor against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.

(vi) A compliance plan that consists of the following—

(A) Written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State standards.

(B) The designation of a compliance officer and compliance committee accountable to senior management.

(C) Effective training and education between the compliance officer and organization employees.

(D) Effective lines of communication between the compliance officer and the organization's employees.

(E) Enforcement of standards through well-publicized disciplinary guidelines.

(F) Procedures for internal monitoring and auditing.

(G) Procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract as a PDP sponsor.

(1) If the PDP sponsor discovers from any source evidence of misconduct related to payment or delivery of prescription drug items or services under the contract, it must conduct a timely, reasonable inquiry into that misconduct;

(2) If, after reasonable inquiry, the PDP sponsor has determined that the misconduct may violate criminal, civil or administrative law, the sponsor must report the existence of the misconduct to the appropriate Government authority within a reasonable period, but not more than 60 days after the determination that a violation may have occurred. If the potential violation relates to Federal criminal law, the civil False Claims Act, Federal Anti-Kickback provisions, the civil monetary penalties authorities (primarily under section 1128A and 1857 of the Act), or related statutes enforced by the HHS Office of

Inspector General, the report must be made to that Office.

(3) The PDP sponsor must conduct appropriate corrective actions (for example, repayment of overpayments and disciplinary actions against responsible employees) in response to the potential violation referenced above.

(4) The PDP sponsor's contract must not have been non-renewed under § 422.507 within the past 2 years unless—

(i) During the 6-month period, beginning on the date the organization notified CMS of the intention to non-renew the most recent previous contract, there was a change in the statute or regulations that had the effect of increasing PDP sponsor payments in the payment area or areas at issue; or

(ii) CMS has otherwise determined that circumstances warrant special consideration.

(c) *Contracting authority.* Under section 1860D-12 (b)(3)(B) of the Act, CMS may enter into contracts under this part, or in order to carry out this part, without regard to Federal and Departmental acquisition regulations set forth in Title 48 of the CFR and provisions of law or other regulations relating to the making, performance, amendment, or modification of contracts of the United States if CMS determines that those provisions are inconsistent with the efficient and effective administration of the Medicare program. Some of the FAR provisions may apply to fallback plans. See subparts F and Q of this part for any contracting provisions unique to fallback plans.

(d) *Protection against fraud and beneficiary protections.* (1) CMS annually audits the financial records (including, but not limited to, data relating to Medicare utilization and costs, including allowable reinsurance and risk corridor costs as well as low income subsidies and other costs) under this part of at least one-third of the PDP sponsors (including fallback plans) offering prescription drug plans.

(2) Each contract under this section must provide that CMS, or any person or organization designated by CMS, has the right to—

(i) Inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the PDP sponsor's contract;

(ii) Inspect or otherwise evaluate the facilities of the organization when there is reasonable evidence of some need for the inspection; and

(iii) Audit and inspect any books, contracts, and records of the PDP sponsor that pertain to—

(A) The ability of the organization or its first tier or downstream providers to bear the risk of potential financial losses; or

(B) Services performed or determinations of amounts payable under the contract.

(e) *Severability of contracts.* The contract must provide that, upon CMS' request—

(1) The contract could be amended to exclude any State-licensed entity, or a PDP plan specified by CMS; and

(2) A separate contract for any excluded plan or entity must be deemed to be in place when a request is made.

§ 423.505 Contract provisions.

(a) *General rule.* The contract between the PDP sponsor and CMS must contain the provisions specified in paragraph (b) of this section.

(b) *Specific provisions.* The PDP sponsor agrees to comply with the following:

(1) All the applicable requirements and conditions set forth in this part and in general instructions.

(2) To accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments, as provided in subpart B of this part.

(3) To comply with the prohibition in § 423.34(a) on discrimination in beneficiary enrollment.

(4) To provide the basic benefits as required under § 423.108 and, to the extent applicable, supplemental benefits under § 423.112.

(5) To disclose information to beneficiaries in the manner and the form specified by CMS under § 423.128.

(6) To operate quality assurance, cost and utilization management, medication therapy management, and fraud, abuse and waste programs as required under subpart D of this part.

(7) To comply with all requirements in subpart M of this part governing coverage determinations, grievances, and appeals.

(8) To comply with the reporting requirements in § 423.514 and the requirements in § 423.329(b)(3) for submitting drug claims and related information to CMS for its use in risk adjustment calculations.

(9) Each contract under this part provides that—(i) The PDP sponsor offering a prescription drug plan must provide CMS with the information CMS determines is necessary to carry out payment provisions in subpart G of this part.

(ii) CMS has the right, as applied under section 1860D-12(b)(3)(C) of the Act and in accordance with section 1857(d)(2)(B) of the Act, to inspect and

audit any books and records of a PDP sponsor that pertain to the information regarding costs provided to CMS under paragraph(9)(i) of this section.

(10) To be paid under the contract in accordance with the payment rules in subpart G of this part.

(11) To submit its bid, including all required information on premiums, benefits, and cost-sharing, by the due date, as provided in subpart F of this part.

(12) That its contract may not be renewed or may be terminated in accordance with this subpart and subpart N of this part.

(13) To comply with the confidentiality and enrollee record accuracy specified in § 423.136.

(14) To comply with State law and preemption by Federal law requirements described in subpart I of this part.

(15) To comply with the coordination requirements with plans and programs that provide prescription drug coverage as described in subpart J of this part.

(16) To provide benefits by means of point of service systems to adjudicate drug claims, except when necessary to provide access in underserved areas, I/T/U pharmacies (as defined in § 423.100), and long-term care pharmacies.

(c) *Communication with CMS.* The PDP sponsor must have the capacity to communicate with CMS electronically in accordance with CMS requirements.

(d) *Maintenance of records.* The PDP sponsor agrees to maintain, for 6 years, books, records, documents, and other evidence of accounting procedures and practices that—

(1) Are sufficient to do the following:

(i) Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computation of the bid of PDP sponsors).

(ii) Enable CMS to inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the contract and the facilities of the organization.

(iii) Enable CMS to audit and inspect any books and records of the PDP sponsor that pertain to the ability of the organization to bear the risk of potential financial losses, or to services performed or determinations of amounts payable under the contract.

(iv) Properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the PDP sponsor's bid and necessary for the calculation of gross covered prescription drug costs, allowable reinsurance costs, and allowable risk corridor costs (as defined in § 423.308).

(v) Establish the basis for the components, assumptions, and analysis used by the PDP in determining the actuarial valuation of standard, basic alternative, or enhanced alternative coverage offered in accordance with the CMS guidelines specified in § 423.265(b)(3).

(2) Include records of the following:

(i) Ownership and operation of the PDP sponsor's financial, medical, and other record keeping systems.

(ii) Financial statements for the current contract period and 6 prior periods.

(iii) Federal income tax or informational returns for the current contract period and 6 prior periods.

(iv) Asset acquisition, lease, sale, or other action.

(v) Agreements, contracts, and subcontracts.

(vi) Franchise, marketing, and management agreements.

(vii) Matters pertaining to costs of operations.

(viii) Amounts of income received by source and payment.

(ix) Cash flow statements.

(x) Any financial reports filed with other Federal programs or State authorities.

(xi) All prescription drug claims for the current contract period and 6 prior periods.

(xii) All price concessions (including concessions offered by manufacturers) for the current contract period and 6 prior periods accounted for separately from other administrative fees.

(e) *Access to facilities and records.*

The PDP sponsor agrees to the following:

(1) HHS, the Comptroller General, or their designee may evaluate, through inspection or other means—

(i) The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;

(ii) The facilities of the PDP sponsor; and

(iii) The enrollment and disenrollment records for the current contract period and 6 prior periods.

(2) HHS, the Comptroller General, or their designees may audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of the PDP sponsor, related entity(s), contractor(s), subcontractor(s), or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the contract.

(3) The PDP sponsor agrees to make available, for the purposes specified in

paragraph (d) of this section, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require.

(4) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 6 years from the end of the final contract period or completion of audit, whichever is later unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the PDP sponsor at least 30 days before the normal disposition date;

(ii) There is a termination, dispute, or allegation of fraud or similar fault by the PDP sponsor, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, or fraud or similar fault; or

(iii) CMS determines that there is a reasonable possibility of fraud or similar fault, in which case CMS may inspect, evaluate, and audit the PDP sponsor at any time.

(f) *Disclosure of information.* The PDP sponsor agrees to submit to CMS—

(1) Certified financial information that must include the following:

(i) Information as CMS may require demonstrating that the organization has a fiscally sound operation.

(ii) Information as CMS may require pertaining to the disclosure of ownership and control of the PDP sponsor.

(2) All information to CMS that is necessary for CMS to administer and evaluate the program and to simultaneously establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining prescription drug coverage. This information includes, but is not limited to:

(i) The benefits covered under a prescription drug plan.

(ii) The PDP monthly basic beneficiary premium and PDP monthly supplemental beneficiary premium, if any, for the plan.

(iii) The service area of each plan.

(iv) Plan quality and performance indicators for the benefits under the plan including—

(A) Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years;

(B) Information on Medicare enrollee satisfaction;

(C) The recent records regarding compliance of the plan with requirements of this part, as determined by CMS; and

(D) Other information determined by CMS to be necessary to assist beneficiaries in making an informed choice regarding PDP plans.

(v) Information about beneficiary appeals and their disposition.

(vi) Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization.

(vii) Any other information deemed necessary to CMS for the administration or evaluation of the Medicare program.

(3) To its enrollees, all informational requirements under § 423.128(b) and, upon an enrollee's request, the financial disclosure information required under § 423.128(c)(4).

(g) *Beneficiary financial protections.* The PDP sponsor agrees to comply with the following requirements:

(1) Each PDP sponsor must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the PDP sponsor. To meet this requirement, the PDP sponsor must—

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

(ii) Indemnify the beneficiary enrollee for payment of any fees that are the legal obligation of the PDP sponsor for covered prescription drugs furnished by non-contracting pharmacists, or that have not otherwise entered into an agreement with the PDP sponsor, to provide services to the organization's beneficiary enrollees.

(2) In meeting the requirements of this paragraph, other than the provider contract requirements specified in paragraph (g)(1)(i) of this section, the PDP sponsor may use—

(i) Contractual arrangements;

(ii) Insurance acceptable to CMS;

(iii) Financial reserves acceptable to CMS; or

(iv) Any other arrangement acceptable to CMS.

(h) *Requirements of other laws and regulations.* The PDP sponsor agrees to comply with—

(1) Title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR part 84.

(2) The Age Discrimination Act of 1975 as implemented by regulations at 45 CFR part 91.

(3) The Rehabilitation Act of 1973.

(4) The Americans with Disabilities Act.

(5) HIPAA Administrative Simplification rules at 45 CFR Parts 160, 162, and 164.

(6) Other laws applicable to recipients of Federal funds.

(7) All other applicable laws and rules.

(8) PDP sponsors receiving Federal payments under PDP sponsor contracts, and related entities, contractors, and subcontractors paid by a PDP sponsor to fulfill its obligations under its contract with CMS, are subject to certain laws that are applicable to individuals and entities receiving Federal funds. PDP sponsors must inform all related entities, contractors and subcontractors that payments they receive are, in whole or in part, from Federal funds.

(i) *PDP sponsor relationship with related entities, contractors, and subcontractors.* (1) Notwithstanding any relationship(s) that the PDP sponsor may have with related entities, contractors, or subcontractors, the PDP sponsor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.

(2) The PDP sponsor agrees to require all related entities, contractors, or subcontractors to agree that—

(i) HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent contracts, books, documents, papers, and records of the related entity(s), contractor(s), or subcontractor(s) involving transactions related to CMS' contract with the PDP sponsor; and

(ii) HHS', the Comptroller General's, or their designee's right to inspect, evaluate, and audit any pertinent information for any particular contract period exists through 6 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(3) All contracts or written arrangements between PDP sponsors and providers, related entities, contractors, subcontractors, first tier and downstream entities must contain the following:

(i) Enrollee protection provisions that provide, consistent with paragraph (g)(1) of this section, arrangements that prohibit pharmacies from holding an enrollee liable for payment of any fees that are the obligation of the PDP sponsor.

(ii) Accountability provisions that indicate that the PDP sponsor may only delegate activities or functions to a pharmacy, related entity, contractor, or subcontractor in a manner consistent with requirements set forth at paragraph (i)(4) of this section.

(iii) A provision requiring that any services or other activity performed by a related entity, contractor,

subcontractor, or first-tier or downstream entity in accordance with a contract or written agreement are consistent and comply with the PDP sponsor's contractual obligations.

(4) If any of the PDP sponsors' activities or responsibilities under its contract with CMS is delegated to other parties, the following requirements apply to any related entity, contractor, subcontractor, or pharmacy:

(i) Written arrangements must specify delegated activities and reporting responsibilities.

(ii) Written arrangements must either provide for revocation of the delegation activities and reporting requirements or specify other remedies in instances when CMS or the PDP sponsor determine that the parties have not performed satisfactorily.

(iii) Written arrangements must specify that the PDP sponsor on an ongoing basis monitors the performance of the parties.

(iv) All contracts or written arrangements must specify that the related entity, contractor, or subcontractor must comply with all applicable Federal laws, regulations, and CMS instructions.

(5) If the PDP sponsor delegates selection of its prescription drug providers to another organization, the PDP sponsor's written arrangements with that organization must state that the CMS-contracting PDP sponsor retains the right to approve, suspend, or terminate any such arrangement.

(j) *Additional contract terms.* The PDP sponsor agrees to include in the contract other terms and conditions as CMS may find necessary and appropriate in order to implement requirements in this part.

(k) *Severability of contracts.* The contract must provide that, upon CMS's request—

(1) The contract is amended to exclude any State-licensed entity, or PDP sponsor specified by CMS; and

(2) A separate contract for any excluded plan or entity is deemed to be in place when the request is made.

(l) *Certification of data that determine payment.* (1) *General rule.* As a condition for receiving a monthly payment under subpart G of this part, the PDP sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment

information, claims data, bid submission data, and other data that CMS specifies.

(2) *Certification of enrollment and payment information.* The CEO, CFO, 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 each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

(3) *Certification of claims data.* The CEO, CFO, or an individual delegated with 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 claims data it submits under § 423.329(b)(3) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. If the claims data are generated by a related entity, contractor, or subcontractor of a PDP sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement.

(4) *Certification of bid submission information.* The CEO, CFO, 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 in its bid submission and assumptions related to projected reinsurance and low income cost sharing subsidies is accurate, complete, and truthful and fully conforms to the requirements in § 423.265.

(5) *Certification of allowable costs for risk corridor and reinsurance information.* The CEO, CFO, 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, is accurate, complete, and truthful and fully conforms to the requirements in § 423.336(c) and § 423.343(c) and acknowledge that this information will be used for the

purposes of obtaining Federal reimbursement.

(6) *Certification of Accuracy of Data for Price Comparison.* The CEO, CFO, 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 price comparison is accurate, complete, and truthful.

§ 423.506 Effective date and term of contract.

(a) *Effective date.* The contract is effective on the date specified in the contract between the PDP sponsor and CMS.

(b) *Term of contract.* Each contract is for a period of 12 months. The contract period for a fallback plan is specified in § 423.871(b).

(c) *Renewal of contract.* In accordance with § 423.507 of this subpart, contracts are renewed annually only if—

- (1) CMS informs the PDP sponsor that it authorizes a renewal; and
- (2) The PDP sponsor has not provided CMS with a notice of intention not to renew.

§ 423.507 Nonrenewal of Contract.

(a) *Nonrenewal by a PDP sponsor.* (1) A PDP sponsor may elect not to renew its contract with CMS as of the end of the term of the contract for any reason provided it meets the timeframes for doing so set forth in paragraphs (a)(2) and (a)(3) of this section.

(2) If a PDP sponsor does not intend to renew its contract, it must notify—

(i) CMS in writing by the first Monday of June in the year in which the contract ends;

(ii) Each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective. This notice must include a written description of alternatives available for obtaining Medicare prescription drug services within the PDP region, including MA-PDs, and other PDPs, and must receive CMS approval prior to issuance; and

(iii) The general public, at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the PDP sponsor's service area.

(3) If a PDP sponsor does not renew a contract under paragraph (a) of this section, CMS cannot enter into a contract with the organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS.

(b) *CMS decision not to renew.* (1) CMS may elect not to authorize renewal

of a contract for any of the following reasons:

(i) For any of the reasons listed in § 423.509(a) that also permits CMS to terminate the contract.

(ii) The PDP sponsor has committed any of the acts in § 423.752 that supports the imposition of intermediate sanctions or civil money penalties under § 423.750.

(2) *Notice of decision.* CMS provides notice of its decision whether to authorize renewal of the contract as follows:

(i) To the PDP sponsor by May 1 of the contract year.

(ii) If CMS decides not to authorize a renewal of the contract, to the PDP sponsor's Medicare enrollees by mail at least 90 days before the end of the current calendar year.

(iii) If CMS decides not to authorize a renewal of the contract, to the general public at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the PDP sponsor's service area.

(3) *Notice of appeal rights.* CMS gives the PDP sponsor written notice of its right to appeal the decision not to renew in accordance with § 423.642(b).

§ 423.508 Modification or termination of contract by mutual consent.

(a) *General rule.* A contract may be modified or terminated at any time by written mutual consent.

(b) *Notification of termination.* If the contract is terminated by mutual consent, the PDP sponsor must provide notice to its Medicare enrollees and the general public as provided in paragraph (c) of this section.

(c) *Notification of modification.* If the contract is modified by mutual consent, the PDP sponsor must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification within timeframes specified by CMS.

§ 423.509 Termination of contract by CMS.

(a) *Termination by CMS.* CMS may terminate a contract for any of the following reasons if the PDP sponsor—

(1) Failed substantially to carry out the terms of its contract with CMS;

(2) Is carrying out its contract with CMS in a manner that is inconsistent with the effective and efficient implementation of this part;

(3) No longer meets the requirements of this part for being a contracting organization;

(4) There is credible evidence that the PDP sponsor committed or participated in false, fraudulent, or abusive activities

affecting the Medicare program, including submission of false or fraudulent data;

(5) Experiences financial difficulties so severe that its ability to provide necessary prescription drug coverage is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that a risk to health exists;

(6) Substantially fails to comply with the requirements in subpart M of this part relating to grievances and appeals;

(7) Fails to provide CMS with valid risk adjustment, reinsurance and risk corridor related data as required under § 423.329;

(8) Substantially fails to comply with the service access requirements in § 423.120;

(9) Substantially fails to comply with the marketing requirements in § 423.128;

(10) Substantially fails to comply with the coordination with plans and programs that provide prescription drug coverage as described in subpart J of this part; or

(11) Substantially fails to comply with the cost and utilization management, quality improvement, medication therapy management and fraud, abuse and waste program requirements as specified in subpart D of this part.

(b) *Notice of termination.* If CMS decides to terminate a contract for reasons other than the grounds specified in § 423.509(a)(4) or (a)(5) of this section, it gives notice of the termination as follows:

(1) *Termination of contract by CMS.*

(i) CMS notifies the PDP sponsor in writing 90 days before the intended date of the termination.

(ii) The PDP sponsor notifies its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination.

(iii) The PDP sponsor notifies the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the PDP sponsor's service area.

(2) *Immediate termination of contract by CMS.* (i) For terminations based on violations specified in § 423.509(a)(4) or § 423.509(a)(5) of this section, CMS notifies the PDP sponsor in writing that its contract is terminated effective the date of the termination decision by CMS. If termination is effective in the middle of a month, CMS has the right to recover the prorated share of the prospective monthly payments made to the PDP sponsor covering the period of

the month following the contract termination.

(ii) CMS notifies the PDP sponsor's Medicare enrollees in writing of CMS's decision to terminate the PDP sponsor's contract. This notice occurs no later than 30 days after CMS notifies the plan of its decision to terminate the PDP sponsor's contract. CMS simultaneously informs the Medicare enrollees of alternative options for obtaining prescription drug coverage, including alternative PDP sponsors and MA-PDs in a similar geographic area.

(iii) CMS notifies the general public of the termination no later than 30 days after notifying the plan of CMS's decision to terminate the PDP sponsor's contract. This notice is published in one or more newspapers of general circulation in each community or county located in the PDP sponsor's service area.

(c) *Corrective action plan.* (1) *General rule.* Before terminating a contract for reasons other than the grounds specified in paragraph (a)(4) or (a)(5) of this section, CMS provides the PDP sponsor with reasonable opportunity to develop and receive CMS approval of a corrective action plan to correct the deficiencies that are the basis of the proposed termination.

(2) *Exception.* If a contract is terminated under § 423.509(a)(4) or § 423.509(a)(5) of this section, the PDP sponsor does not have the opportunity to submit a corrective action plan.

(d) *Appeal rights.* If CMS decides to terminate a contract, it sends written notice to the PDP sponsor informing it of its termination appeal rights in accordance with § 423.642.

§ 423.510 Termination of contract by the PDP sponsor.

(a) *Cause for termination.* The PDP sponsor may terminate its contract if CMS fails to substantially carry out the terms of the contract.

(b) *Notice of termination.* The PDP sponsor must give advance notice as follows:

(1) To CMS, at least 90 days before the intended date of termination. This notice must specify the reasons why the PDP sponsor is requesting contract termination.

(2) To its Medicare enrollees, at least 60 days before the termination effective date. This notice must include a written description of alternatives available for obtaining Medicare drug services within the services area, including alternative PDPs, MA-PDPs, and original Medicare and must receive CMS approval.

(3) To the general public, at least 60 days before the termination effective date by publishing a CMS-approved

notice in one or more newspapers of general circulation in each community or county located in the PDP sponsor's geographic area.

(c) *Effective date of termination.* The effective date of the termination is determined by CMS and is at least 90 days after the date CMS receives the PDP sponsor's notice of intent to terminate.

(d) *CMS's liability.* CMS's liability for payment to the PDP sponsor ends as of the first day of the month after the last month for which the contract is in effect.

(e) *Effect of termination by the organization.* CMS will not enter into an agreement with an organization that has terminated its contract within the preceding 2 years unless there are circumstances that warrant special consideration, as determined by CMS.

§ 423.512 Minimum enrollment requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, CMS will not enter into a contract under this subpart unless the organization meets the following minimum enrollment requirement:

(1) At least 5,000 individuals are enrolled for the purpose of receiving prescription drug benefits from the organization; or

(2) At least 1,500 individuals are enrolled for purposes of receiving prescription drug benefits from the organization and the organization primarily serves individuals residing outside of urbanized areas as defined in § 412.62(f) of this chapter;

(3) Except as provided for in paragraph (b) of this section, a PDP sponsor must maintain a minimum enrollment as defined in paragraphs (a)(1) and (a)(2) of this section for the duration of its contract.

(b) *Minimum enrollment waiver.* CMS waives the requirement of paragraphs (a)(1) and (a)(2) of this section during the first contract year for an organization in a region.

§ 423.514 Reporting requirements.

(a) *Required information.* Each PDP sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires statistics indicating the following—

(1) The cost of its operations.

(2) The patterns of utilization of its services.

(3) The availability, accessibility, and acceptability of its services.

(4) Information demonstrating that the PDP sponsor has a fiscally sound operation.

(5) Other matters that CMS may require.

(b) *Significant business transactions.* Each PDP sponsor must report to CMS annually, within 120 days of the end of its fiscal year (unless, for good cause shown, CMS authorizes an extension of time), the following:

(1) A description of significant business transactions, as defined in § 423.501, between the PDP sponsor and a party in interest, includes the following:

(i) Indication that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that are incurred if these transactions were with someone who is not a party in interest; or

(ii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.

(2) A combined financial statement for the PDP sponsor and a party in interest if either of the following conditions is met:

(i) Thirty five percent or more of the costs of operation of the PDP sponsor go to a party in interest.

(ii) Thirty five percent or more of the revenue of a party in interest is from the PDP sponsor.

(c) Requirements for combined financial statements.

(1) The combined financial statements required by paragraph (b)(2) of this section must display in separate columns the financial information for the PDP sponsor and each of the parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) The statements must be examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.

(4) Upon written request from a PDP sponsor showing good cause, CMS may waive the requirement that the organization's combined financial statement include the financial information required in this paragraph (c) of this section for a particular entity.

(d) *Reporting and disclosure under Employee Retirement Income Security Act of 1974 (ERISA).* (1) For any employees' health benefits plan that includes a PDP sponsor in its offerings, the PDP sponsor must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (for the particular PDP sponsor) under the Employee

Retirement Income Security Act of 1974 (ERISA).

(2) The PDP sponsor must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term "administrator" is defined in ERISA.

(e) *Loan information.* Each organization must notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

(f) *Enrollee access to information.* Each PDP sponsor must make the information reported to CMS under this section available to its enrollees upon reasonable request.

§ 423.516 Prohibition of midyear implementation of significant new regulatory requirements.

CMS may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan.

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

§ 423.551 General provisions.

(a) *Change of ownership.* The following constitute a change of ownership:

(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law, constitutes a change of ownership.

(2) *Asset sale.* Transfer of substantially all the assets of the sponsor to another party constitutes a change of ownership.

(3) *Corporation.* The merger of the PDP sponsor's corporation into another corporation or the consolidation of the PDP sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership, exception.* Transfer of corporate stock or the merger of another corporation into the PDP sponsor's corporation, with the PDP sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement.* (1) A PDP sponsor that has a Medicare contract in effect under § 423.502 and is considering or is negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. The PDP sponsor must also provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) If the PDP sponsor fails to give CMS the required notice in a timely manner, it continues to be liable for payments that CMS makes to it on behalf of Medicare enrollees after the date of change of ownership.

(d) *Novation agreement defined.* A novation agreement is an agreement among the current owner of the PDP sponsor, the prospective new owner, and CMS—

(1) That is embodied in a document executed and signed by all 3 parties;

(2) That meets the requirements of § 423.552; and

(3) Under which CMS recognizes the new owner as the successor in interest to the current owner's Medicare contract.

(e) *Effect of change of ownership without novation agreement.* Except to the extent provided in paragraph (c)(2) of this section, the effect of a change of ownership without a novation agreement is that—

(1) The existing contract becomes invalid; and

(2) If the new owner wishes to participate in the Medicare program, it must apply for, and enter into, a contract in accordance with subpart K of this part.

(f) *Effect of change of ownership with novation agreement.* If the PDP sponsor submits a novation agreement that meets the requirements of § 423.552 and CMS signs it, the new owner becomes the successor in interest to the current owner's Medicare contract under § 423.502.

§ 423.552 Novation agreement requirements.

(a) *Conditions for CMS approval of a novation agreement.* CMS approves a novation agreement if the following conditions are met:

(1) *Advance notification.* The PDP sponsor notifies CMS at least 60 days before the date of the proposed change of ownership. The PDP sponsor also provides CMS with updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) *Advance submittal of agreement.* The PDP sponsor submits to CMS, at least 30 days before the proposed change of ownership date, three signed copies of the novation agreement containing the provisions specified in paragraph (b) of this section, and one copy of other relevant documents required by CMS.

(3) *CMS's determination.* When reviewing a novation agreement, CMS makes a determination concerning the following—

(i) The proposed new owner is in fact a successor in interest to the contract.

(ii) Recognition of the new owner as a successor in interest to the contract is in the best interest of the Medicare program.

(iii) The successor organization meets the requirements to qualify as a PDP sponsor under subpart K of this part.

(b) *Provisions of a novation agreement.* A valid novation agreement requires the following:

(1) *Assumption of contract obligations.* The new owner must assume all obligations under the contract.

(2) *Waiver of right to reimbursement.* The previous owner must waive its rights to reimbursement for covered services furnished during the rest of the current contract period.

(3) *Guarantee of performance.* The previous owner must—

(i) Guarantee performance of the contract by the new owner during the contract period; or

(ii) Post a performance bond that is satisfactory to CMS.

(4) *Records access.* The previous owner must agree to make its books and records and other necessary information available to the new owner and to CMS to permit an accurate determination of costs for the final settlement of the contract period.

§ 423.553 Effect of leasing of a PDP sponsor's facilities.

(a) *General effect of leasing.* If a PDP sponsor leases all or part of its facilities to another entity, the other entity does not acquire PDP sponsor status under section 1860D-12(b) of the Act.

(b) *Effect of lease of all facilities.* (1) If a PDP sponsor leases all of its facilities to another entity, the contract terminates.

(2) If the other entity wishes to participate in Medicare as a PDP sponsor, it must apply for and enter into a contract in accordance with § 423.502.

(c) *Effect of partial lease of facilities.* If the PDP sponsor leases part of its facilities to another entity, its contract with CMS remains in effect while CMS surveys the PDP sponsor to determine whether it continues to be in compliance with the applicable requirements and qualifying conditions specified in subpart K of this part.

Subpart M—Grievances, Coverage Determinations, and Appeals

§ 423.560 Definitions.

As used in this subpart, unless the context indicates otherwise—

Appeal means any of the procedures that deal with the review of adverse

coverage determinations made by the PDP sponsor on the benefits under a prescription drug plan the enrollee believes he or she is entitled to receive, including delay in providing or approving the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage, as defined in § 423.566(b). These procedures include redeterminations by the PDP sponsor, and if necessary, appeals to an independent review entity, hearings before ALJs, review by the Medicare Appeals Council (MAC), and judicial review. An appeal does not include a grievance or a request for an exception to a tiered cost-sharing structure or formulary.

Authorized representative means an individual authorized by an enrollee, or under State law, to act on his or her behalf in obtaining a coverage determination or in dealing with any of the levels of the appeals process, subject to the rules described in part 422, subpart M of this chapter, to the extent they are appropriate, unless otherwise stated in this subpart.

Drug Use means an enrollee is receiving the drug in the course of treatment, including time off if it is part of the treatment.

Enrollee means a Part D eligible individual, or his or her authorized representative, who has elected a prescription drug plan offered by a PDP sponsor.

Grievance means any complaint or dispute, other than one that involves a coverage determination, expressing dissatisfaction with any aspect of a PDP sponsor's operations, activities, or behavior, regardless of whether remedial action is requested.

Physician has the meaning given the term in section 1861(r) of the Act.

Reconsideration means a review of an adverse coverage determination by an independent review entity (IRE), the evidence and findings upon which it was based, and any other evidence the enrollee submits or the IRE obtains.

Redetermination means a review of an adverse coverage determination by a PDP sponsor, the evidence and findings upon which it is based, and any other evidence the enrollee submits or the PDP sponsor obtains.

§ 423.562 General provisions.

(a) *Responsibilities of the PDP sponsor.* A PDP sponsor must meet all of the following requirements.

(1) A PDP sponsor, for each prescription drug plan that it offers, must establish and maintain—

(i) A grievance procedure as described in § 423.564 for addressing issues that do not involve coverage determinations;

(ii) A procedure for making timely coverage determinations;

(iii) A procedure for handling exceptions to a tiered cost-sharing structure;

(iv) A procedure for handling exceptions to a formulary; and

(v) Redetermination and appeal procedures that meet the requirements of this subpart for issues that involve coverage determinations.

(2) A PDP sponsor must ensure that all enrollees receive written information about the—

(i) Grievance and appeal procedures that are available to them through the PDP sponsor; and

(ii) Complaint process available to the enrollee under the QIO process as set forth under section 1154(a)(14) of the Act.

(3) In accordance with subpart K of this part, if the PDP sponsor delegates any of its responsibilities under this subpart to another entity or individual through which the sponsor provides covered benefits, the PDP sponsor is ultimately responsible for ensuring that the entity or individual satisfies the relevant requirements of this subpart.

(b) *Rights of PDP enrollees.* In accordance with the provisions of this subpart, enrollees have all of the following rights in relation to PDP sponsors:

(1) The right to have grievances between the enrollee and the PDP sponsor heard and resolved by the sponsor, as described in § 423.564.

(2) The right to a timely coverage determination by the sponsor, as specified in § 423.566.

(3) The right to request from the sponsor an expedited coverage determination, as specified in § 423.570.

(4) The right to request from the sponsor an exception to a PDP's tiered cost-sharing structure or formulary, as specified in § 423.578.

(5) If dissatisfied with any part of a coverage determination, all of the following appeal rights:

(i) The right to a redetermination of the adverse coverage determination by the PDP sponsor, as specified in § 423.580.

(ii) The right to request an expedited redetermination, as provided under § 423.584.

(iii) If, as a result of a redetermination, a PDP sponsor affirms, in whole or in part, its adverse coverage determination, the right to a reconsideration by an independent review entity (IRE) contracted by CMS, as specified in § 423.600.

(iv) The right to an ALJ hearing if the amount in controversy meets the requirements in § 423.610 and part 422, subpart M of this chapter.

(v) The right to request MAC review of the ALJ hearing decision, as specified in § 423.620.

(vi) The right to judicial review of the hearing decision if the amount in controversy meets the requirements in § 423.630 and part 422, subpart M of this chapter.

(c) *Limits on when this subpart applies.* (1) If an enrollee has no further liability to pay for prescription drugs furnished through a PDP, a determination regarding these items or services is not subject to appeal.

(2) If an enrollee seeks coverage of prescription drugs received from a non-network provider (that is, a non-network pharmacy), except in those situations in which, under subpart C of this part, the PDP is obligated to cover such drugs, a determination regarding the prescription drugs is not subject to appeal.

(d) *When other regulations apply.* Unless this subpart provides otherwise, the regulations in part 422, subpart M of this chapter (concerning the administrative review and hearing processes under titles II and XVIII, and representation of parties under title XVIII of the Act) and any interpretive rules or CMS rulings issued under these regulations, apply under this subpart to the extent they are appropriate.

§ 423.564 Grievance procedures.

(a) *General rule.* Each PDP sponsor must provide meaningful procedures for timely hearing and resolving grievances between enrollees and the sponsor or any other entity or individual through whom the sponsor provides covered benefits under any PDP it offers.

(b) *Distinguished from appeals.* Grievance procedures are separate and distinct from appeal procedures, which address coverage determinations as defined in § 423.566(b). Upon receiving a complaint, a PDP sponsor must promptly determine and inform the enrollee whether the complaint is subject to its grievance procedures or its appeal procedures.

(c) *Distinguished from the quality improvement organization complaint process.* Under section 1154(a)(14) of the Act, the quality improvement organization (QIO) must review enrollees' written complaints about the quality of services they have received under the Medicare program. This process is separate and distinct from the grievance procedures of the PDP sponsor. For quality of care issues, an enrollee may file a grievance with the

PDP sponsor, file a written complaint with the QIO, or both. For any complaint submitted to a QIO, the PDP sponsor must cooperate with the QIO in resolving the complaint.

(d) *Expedited grievances.* A PDP sponsor must respond to an enrollee's grievance within 24 hours if—

(1) The complaint involves a PDP sponsor's decision to invoke an extension relating to a coverage determination or redetermination.

(2) The complaint involves a PDP sponsor's refusal to grant an enrollee's request for an expedited coverage determination under § 423.570 or expedited redetermination under § 423.584, and the enrollee has not yet purchased or received the drug that is in dispute.

(e) *Record keeping.* The PDP sponsor must have an established process to track and maintain records on all grievances received both orally and in writing, including, at a minimum, the date of receipt, final disposition of the grievance, and the date that the PDP sponsor notified the enrollee of the disposition.

§ 423.566 Coverage determinations.

(a) *Responsibilities of the PDP sponsor.* Each PDP sponsor must have a procedure for making timely coverage determinations in accordance with the requirements of this subpart regarding the prescription drug benefits an enrollee is entitled to receive under a PDP, including basic coverage as specified in § 423.108 and supplemental coverage as specified in § 423.112, and the amount, if any, that the enrollee is required to pay for a drug. The PDP sponsor must have a standard procedure for making determinations, in accordance with § 423.568, and an expedited procedure for situations in which applying the standard procedure may seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with § 423.570.

(b) *Actions that are coverage determinations.* The following actions by a PDP sponsor are coverage determinations:

(1) Failure to provide or pay for a covered Part D drug (including failure to pay because the drug is not on the plan's formulary, because the drug is determined not to be medically necessary, because the drug is furnished by an out-of-network pharmacy, or because the sponsor determines that the drug is otherwise excluded under section 1862(a) of the Act) that the enrollee believes may be furnished by the PDP.

(2) Failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee.

(3) A decision on the amount of cost sharing for a drug.

(4) A decision on whether a drug is a preferred drug for an enrollee.

(c) *Who can request a coverage determination.* Individuals who can request a standard or expedited coverage determination are—

(1) The enrollee, including his or her authorized representative; or
(2) The prescribing physician, on behalf of the enrollee.

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

(a) *Timeframe for requests for drug benefits.*

(1) When a party makes a request for a drug benefit, the PDP sponsor must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after receipt of the request.

(2) The PDP sponsor may extend the timeframe by up to 14 calendar days under the following circumstances:

(i) If the enrollee requests the extension.

(ii) If the sponsor justifies a need for additional information and explains how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence may change a sponsor's decision to deny).

(3) If the PDP sponsor extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the sponsor's decision to invoke an extension.

(4) For extensions, the PDP sponsor must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(b) *Timeframe for requests for payment.* When a party makes a request for payment, the PDP sponsor must notify the enrollee of its determination no later than 30 calendar days after receipt of the request.

(c) *Written notice for PDP sponsor denials.* If a PDP sponsor decides to deny a drug benefit, in whole or in part, it must give the enrollee written notice of the determination.

(d) *Form and content of the denial notice.* The notice of any denial under paragraph (c) of this section must—

(1) Use approved notice language in a readable and understandable form;

(2) State the specific reasons for the denial;

(3) Inform the enrollee of his or her right to a redetermination;

(i) For drug coverage denials, describe both the standard and expedited redetermination processes, including the enrollee's right to, and conditions for, obtaining an expedited redetermination and the rest of the appeal process;

(ii) For payment denials, describe the standard redetermination process and the rest of the appeal process; and

(4) Comply with any other notice requirements specified by CMS.

(e) *Effect of failure to provide timely notice.* If the PDP sponsor fails to provide the enrollee with timely notice of a coverage determination as specified in subparagraph (a) of this section, this failure itself constitutes an adverse determination and may be appealed.

§ 423.570 Expediting certain coverage determinations.

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

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

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

(c) *How the PDP sponsor must process requests.* The PDP sponsor must establish and maintain the following procedures for processing requests for expedited determinations:

(1) An efficient and convenient means for individuals to submit oral or written requests.

(2) Documentation of all oral requests in writing and maintain the documentation in the case file.

(3) Prompt decisions on expediting a determination, based on the following requirements:

(i) For a request made by an enrollee, provide an expedited determination if it determines 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.

(ii) For a request made or supported by an enrollee's prescribing physician, provide an expedited determination if

the physician 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 PDP sponsor denies a request for expedited determination, it must take the following actions:

(1) Automatically transfer the request to the standard timeframe and make the determination within the 14-calendar day timeframe established in § 423.568(a) for a standard determination. The 14-calendar day period begins with the day the PDP sponsor receives the request for expedited determination.

(2) Give the enrollee prompt oral notice of the denial and subsequently deliver, within 3 calendar days, a written letter that—

(i) Explains that the PDP sponsor must process the request using the 14-calendar day timeframe for standard determinations;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the PDP sponsor's decision not to expedite;

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

(iv) Provides instructions about the grievance process and its timeframes.

(e) *Actions on accepted requests for expedited determination.* If a PDP sponsor grants a request for expedited determination, it must make the determination and give notice in accordance with § 423.572.

§ 423.572 Timeframes and notice requirements for expedited coverage determinations.

(a) *Timeframe for determinations and notification.* Except as provided in paragraph (b) of this section, a PDP sponsor that approves a request for expedited determination must make its determination and notify the enrollee (and the prescribing physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.

(b) *Extensions of timeframe.* (1) *General rule.* The PDP sponsor may extend the 72-hour timeframe by up to 14 calendar days if the enrollee requests the extension or if the sponsor justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence may

change a PDP sponsor's decision to deny).

(2) *Notification of extension.* When the PDP sponsor extends the deadline, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the sponsor's decision to invoke an extension.

(3) *Timeline for notification of extension.* The PDP sponsor must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(c) *Confirmation of oral notice.* If the PDP sponsor first notifies an enrollee of an adverse expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(d) *Content of the notice of expedited determination.*

(1) The notice of any expedited determination must state the specific reasons for the determination in understandable language.

(2) If the determination is not completely favorable to the enrollee, the notice must—

(i) Inform the enrollee of his or her right to a redetermination;

(ii) Describe both the standard and expedited redetermination processes, including the enrollee's right to request, and conditions for obtaining, an expedited redetermination, and the rest of the appeal process; and

(iii) Comply with any other requirements specified by CMS.

(e) *Effect of failure to provide a timely notice.* If the PDP sponsor fails to provide the enrollee with timely notice of an expedited coverage determination as specified in this section, this failure constitutes an adverse coverage determination and may be appealed.

§ 423.576 Effect of a coverage determination.

The coverage determination is binding on the PDP sponsor and the enrollee unless it is reconsidered under § 423.580 through § 423.630 or is reopened and revised under § 423.634.

§ 423.578 Exceptions process.

(a) *Requests for exceptions to a PDP's tiered cost-sharing structure.* Each PDP 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 an exceptions process.

(1) The sponsor's exceptions process must address each of the following circumstances:

(i) The enrollee is using a drug and the applicable tiered cost-sharing structure changes mid-year;

(ii) The enrollee is using a drug and the applicable tiered cost-sharing structure changes at the beginning of a new plan year; or

(iii) There is no pre-existing use of the drug by the enrollee.

(2) A PDP sponsor's exception criteria must include, but are not limited to—

(i) A description of the criteria a PDP sponsor uses to evaluate a determination made by the enrollee's prescribing physician under paragraph (a)(3) of this section.

(ii) Consideration of the cost difference between the *preferred drug* and the requested prescription drug that is the subject of the exceptions request.

(iii) Consideration of whether the requested prescription drug that is the subject of the exceptions request is the therapeutic equivalent of any other drug on the sponsor's formulary. For purposes of this subpart, drug products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference when substituted for the requested drug.

(iv) Consideration of the number of drugs on the sponsor's formulary that are in the same class and category as the requested prescription drug that is the subject of the exceptions request.

(3) An enrollee, the enrollee's authorized representative, or the enrollee's prescribing physician may file a request for an exception.

(4) A PDP sponsor may require a written certification from the enrollee's prescribing physician that the preferred drug on the sponsor's formulary is not as effective for the enrollee as the requested drug that is the subject of the requested exception, or that the preferred drug on the sponsor's formulary may have adverse effects for the enrollee, or both.

(5) The PDP sponsor may require the written certification to include only the following information:

(i) The enrollee's name, group or contract number, subscriber number or other information necessary to identify the enrollee.

(ii) The enrollee's patient history.

(iii) The primary diagnosis related to the requested prescription drug that is the subject of the exceptions request.

(iv) Why the "preferred drug" is not acceptable for the enrollee.

(v) Why the prescription drug that is the subject of the exceptions request is needed for the enrollee.

(vi) Any other information reasonably necessary to evaluate the medical necessity of the exceptions request.

(b) *Request for exceptions involving a nonformulary drug.* Each PDP sponsor

that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a formulary must establish and maintain an exceptions process. Formulary use includes the application of a dose restriction that causes a particular drug not to be covered for the number of doses prescribed or a step therapy requirement that causes a particular drug not to be covered until the requirements of the sponsor's coverage policy are met.

(1) The sponsor's exceptions process must address each of the following circumstances:

(i) Coverage of a prescription drug that is not covered based on the PDP sponsor's formulary.

(ii) Continued coverage of a particular prescription drug that the sponsor is discontinuing coverage on the formulary for reasons other than safety or because the prescription drug cannot be supplied by or was withdrawn from the market by the drug's manufacturer.

(iii) An exception to a sponsor's coverage policy that causes a prescription drug not to be covered until the step therapy requirement is satisfied or not to be covered at the prescribed number of doses.

(2) A PDP sponsor's exception procedures must include, but are not limited to—

(i) A description of the criteria a PDP sponsor uses to evaluate a prescribing physician's determination made under paragraph (b)(3) of this section;

(ii) A process for comparing applicable medical and scientific evidence on the safety and effectiveness of the requested nonformulary drug with the formulary drug for the enrollee; and

(iii) A description of the cost-sharing scheme that will be applied when coverage is provided for a non-formulary drug.

(iv) If the sponsor covers a non-formulary drug, the cost(s) incurred by the enrollee for that drug are treated as being included for purposes of calculating and meeting the annual out-of-pocket threshold.

(3) An enrollee, the enrollee's authorized representative, or the prescribing physician (on behalf of the enrollee) may file a request for an exception request.

(4) A PDP sponsor may require a written certification from the enrollee's prescribing physician that the requested prescription drug is medically necessary to treat the enrollee's disease or medical condition because—

(i) There is not a prescription drug listed on the formulary to treat the

enrollee's disease or medical condition that is an acceptable clinical alternative;

(ii) The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements—

(A) Has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

(B) Has caused or based on sound clinical evidence and medical and scientific evidence is likely to cause an adverse reaction or other harm to the enrollee; or

(iii) The number of doses that is available under a dose restriction for the prescription drug has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.

(5) The PDP sponsor may require the written certification to include only the following information:

(i) The enrollee's name, group or contract number, subscriber number or other information necessary to identify the enrollee.

(ii) Patient history.

(iii) The primary diagnosis related to the requested prescription drug that is the subject of the exceptions request.

(iv) Based on paragraph (b)(4) of this section, the reason—

(A) Why the formulary drug is not acceptable for the enrollee;

(B) If the medical exceptions request involves a step therapy requirement, why the prescription drug required to be used is not acceptable for the enrollee; or

(C) If the medical exceptions request involves a dose restriction, why the available number of doses for the prescription drug is not acceptable for the enrollee;

(D) The reason why the prescription drug that is the subject of the exceptions request is needed for the enrollee; and

(E) Any other information reasonably necessary to evaluate the medical necessity of the medical exceptions request.

(c) *PDP sponsor requirements for exceptions determinations.* (1) General

rule. A PDP sponsor's decision concerning an exceptions request under this section constitutes a PDP coverage determination as specified at § 423.566.

(2) *When a sponsor does not make a timely decision.* If the PDP sponsor fails to make a decision on an exceptions request for continued coverage of a drug the sponsor is removing from its formulary (for reasons other than safety or because the drug cannot be supplied or is withdrawn from the market by the manufacturer) and to provide notice of the decision within the timeframe required under § 423.568(a)—

(i) The enrollee is entitled to have coverage for up to 1 month's supply of the prescription drug that is the subject of the request; and

(ii) The PDP sponsor must make a decision on the exceptions request before the enrollee's completion of the supply in paragraph (c)(2)(i) of this section.

(iii) If the PDP sponsor fails to make a decision on the exceptions request and provide notice of the decision before to the enrollee's completion of the supply provided in paragraph (c)(2)(i) of this section, the sponsor must maintain coverage, as specified in paragraph (c)(2)(i) of this section, unless—

(A) There is a material change in the enrollee's terms of coverage or the applicable benefit limits have been exhausted;

(B) The drug is no longer prescribed for the enrollee or is not considered safe for the treatment of the enrollee's disease or medical condition; or

(C) A decision is made on the exceptions request and notice of that decision is provided.

(3) *When an exceptions request is approved.* Whenever an exceptions request made under § 423.578 is approved, the PDP sponsor must provide coverage for the approved prescription drug and must not—

(i) Require the enrollee to request approval for a refill or a new prescription to continue using the prescription drug after the refills for the initial prescription are exhausted, as long as—

(A) The enrollee's prescribing physician continues to prescribe the drug; and

(B) The drug continues to be considered safe for treating the enrollee's disease or medical condition.

(ii) Establish a special formulary tier or copayment or other cost-sharing requirement that is applicable only to prescription drugs approved for coverage under this section.

(d) Nothing in this section will be construed to allow an enrollee to use the exceptions processes set out in this

section to request coverage for a prescription drug that is not a covered Part D drug.

§ 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. An enrollee or an enrollee's prescribing physician (acting on behalf of an enrollee) may request an expedited redetermination specified in § 423.584.

§ 423.582 Request for a standard redetermination.

(a) *Method and place for filing a request.* An enrollee must ask for a redetermination by making an oral or written request with the PDP sponsor that made the coverage determination.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, an enrollee must file a request for a redetermination 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 shows good cause, the PDP 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 may file a request for redetermination and extension of time frame with the PDP 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 for withdrawal at one of the places listed in paragraph (a) of this section.

§ 423.584 Expediting certain redeterminations.

(a) *Who may request an expedited redetermination.* An enrollee or an enrollee's prescribing physician may request that a PDP sponsor expedite a redetermination that involves the issues specified in § 423.566(b)(1) and (b)(2). (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 acting on behalf of an enrollee must submit an oral or

written request directly to the PDP sponsor or, if applicable, to the entity responsible for making the redetermination, as directed by the PDP sponsor.

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

(c) *How the PDP sponsor must process requests.* The PDP sponsor must establish and maintain the following procedures for processing requests for expedited redetermination:

(1) *Handling of requests.* The PDP sponsor must establish an efficient and convenient means for individuals to submit oral or written requests, document all oral requests in writing, and maintain the documentation in the case file.

(2) *Prompt decision.* The PDP sponsor must promptly decide on whether to expedite the redetermination or follow the timeframe for standard redetermination based on the following requirements:

(i) For a request made by an enrollee, the PDP sponsor must provide an expedited redetermination if it determines that applying the standard timeframe for making a redetermination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a prescribing physician, the PDP sponsor must provide an expedited redetermination if the physician 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) *Actions following denial of a request.* If a PDP sponsor denies a request for expedited redetermination, it must take the following actions:

(1) Automatically transfer a request to the standard timeframe and make the determination within the 30-day timeframe established in § 423.590(a). The 30-day period begins the day the PDP sponsor receives the request for expedited redetermination.

(2) Give the enrollee prompt oral notice, and subsequently deliver, within 3 calendar days, a written letter that—

(i) Explains that the PDP sponsor processes the enrollee's request using the 30-day timeframe for standard redetermination;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the sponsor's decision not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited

redetermination with the prescribing physician's support; and

(iv) Provides instructions about the grievance process and its timeframes.

(e) *Action following acceptance of a request.* If a PDP sponsor grants a request for expedited redetermination, it must conduct the redetermination and give notice in accordance with § 423.590(d).

§ 423.586 Opportunity to submit evidence.

The PDP sponsor must provide the enrollee or the prescribing physician, 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 PDP sponsor must inform the enrollee or the prescribing physician of the conditions for submitting the evidence.

§ 423.590 Timeframes and responsibility for making redeterminations.

a. *Standard redetermination—request for covered drug benefits.* (1) If the PDP sponsor makes a redetermination that is completely favorable to the enrollee, the PDP sponsor must issue the redetermination (and effectuate it in accordance with § 423.636(a)(1)) as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard redetermination.

(2) If the PDP sponsor makes a redetermination that affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard redetermination.

(3) The PDP sponsor may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the sponsor justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence may change a PDP sponsor's decision to deny).

(4) When the PDP sponsor extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the PDP sponsor's decision to invoke an extension.

(5) For extensions, the PDP sponsor must issue its determination as

expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(b) *Standard redetermination—request for payment.* (1) If the PDP sponsor makes a redetermination that is completely favorable to the enrollee, the PDP sponsor must issue its redetermination to the enrollee (and effectuate it in accordance with § 423.636(a)(2)) no later than 60 calendar days from the date it receives the request for redetermination.

(2) If the PDP sponsor affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination no later than 60 calendar days from the date it receives the request for redetermination.

(c) *Effect of failure to meet timeframe for standard redetermination.* If the PDP sponsor fails to provide the enrollee with a redetermination within the timeframes specified in paragraphs (a) or (b) of this section, this failure constitutes an affirmation of its adverse coverage determination and is subject to appeal to the IRE.

(d) *Expedited redetermination.* (1) *Timeframe.* Except as provided in paragraph (d)(2) of this section, a PDP sponsor that approves a request for expedited redetermination must complete its redetermination and give the enrollee (and the prescribing physician 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.

(2) *Extensions.* The PDP sponsor may extend the 72-hour deadline by up to 14 calendar days if the enrollee requests the extension or if the sponsor justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence may change a PDP sponsor's decision to deny).

(3) *Notification of extension.* (i) *Timeframe.* The PDP sponsor must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension.

(ii) *Content of notification.* When the PDP sponsor extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the PDP sponsor's decision to invoke an extension.

(4) *How the PDP sponsor must request additional information.* If the PDP sponsor must receive medical information, the PDP sponsor must

request the necessary information within 24 hours of the initial request for an expedited redetermination. Regardless of whether the PDP sponsor must request additional information, the PDP sponsor is responsible for meeting the timeframe and notice requirements.

(5) *Affirmation of an adverse expedited coverage determination.* If, as a result of its redetermination, the PDP sponsor affirms, in whole or in part, its adverse expedited coverage determination, the PDP sponsor must give the enrollee (and the prescribing physician 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 (or no later than the expiration of an extension specified in paragraph (d)(2) of this section).

(e) *Failure to meet timeframe for expedited redetermination.* If the PDP sponsor fails to provide the enrollee or the prescribing physician, as appropriate, with the results of its expedited redetermination within the timeframe described in paragraph (d) of this section, this failure constitutes an affirmation of its adverse expedited coverage determination and is subject to appeal to the IRE.

(f) *Who must reconsider an adverse coverage determination.* (1) A person or persons who were not involved in making the coverage determination must conduct the redetermination.

(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.

§ 423.600 Reconsideration by an independent review entity (IRE).

(a) An enrollee who is dissatisfied with the redetermination of a PDP sponsor has a right to a reconsideration by an independent review entity that contracts with CMS. An enrollee must file a written request for reconsideration at one of the places listed in § 423.582(a) or with the IRE within 60 days of the date of the sponsor's redetermination.

(b) When an enrollee files an appeal, the IRE is required to solicit the views of the prescribing physician.

(c) In order for an enrollee to request an IRE reconsideration of a PDP sponsor's determination not to provide for a covered Part D drug that is not on

the PDP formulary, the prescribing physician must determine that all covered Part D drugs on any tier of the formulary for treatment of the same condition is not as effective for the individual as the nonformulary drug, has adverse effects for the individual, or both.

(d) The independent review entity must conduct the reconsideration as expeditiously as the enrollee's health condition requires but must not exceed the deadlines specified in its contract.

§ 423.602 Notice of reconsideration determination by the independent review entity.

(a) *Responsibility for the notice.* When the IRE makes its reconsideration determination, it is responsible for mailing a notice of its determination to the enrollee and PDP sponsor, and for sending a copy to CMS.

(b) *Content of the notice.* The notice must—

(1) State the specific reasons for the IRE's decision in understandable language;

(2) If the reconsideration determination is adverse (that is, does not completely reverse the PDP sponsor's adverse coverage determination), inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement under § 423.610;

(3) Describe the procedures that must be followed to obtain an ALJ hearing; and

(4) Comply with any other requirements specified by CMS.

§ 423.604 Effect of a reconsideration determination.

A reconsideration determination is final and binding on the enrollee and the PDP sponsor, unless the enrollee files a request for a hearing under the provisions of § 423.612.

§ 423.610 Right to an ALJ hearing.

(a) If the amount remaining in controversy after the IRE reconsideration meets the threshold requirement established annually by the Secretary, an enrollee who is dissatisfied with the IRE reconsideration determination has a right to a hearing before an ALJ.

(b) If the basis for the appeal is the PDP sponsor's refusal to provide drug benefits, CMS uses the projected value of those benefits to compute the amount remaining in controversy.

(c) *Aggregating appeals to meet the amount in controversy.* (1) *Enrollee.* Two or more appeals may be aggregated by an enrollee to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(ii) The request for ALJ hearing lists all of the appeals to be aggregated and is filed within 60 days after all of the IRE reconsideration determinations being appealed have been received; and

(iii) The ALJ determines that the appeals the enrollee seeks to aggregate involve the delivery of prescription drugs to a single enrollee.

(2) *Multiple enrollees.* Two or more appeals may be aggregated by multiple enrollees to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(ii) The request for ALJ hearing lists all of the appeals to be aggregated and is filed within 60 days after all of the IRE reconsideration determinations being appealed have been received; and

(iii) The ALJ determines that the appeals the enrollees seek to aggregate involve the same prescription drug.

§ 423.612 Request for an ALJ hearing.

(a) *How and where to file a request.* The enrollee must file a written request for a hearing at one of the places specified in § 423.582(a) or with the IRE. The organizations specified in § 423.582(a) forward the request to the independent review entity, which is responsible for transferring the case to the appropriate ALJ office.

(b) *When to file a request.* Except when an ALJ extends the timeframe as provided in part 422, subpart M of this chapter, the enrollee must file a request for a hearing within 60 days of the date of the notice of an IRE reconsideration determination.

(c) *Insufficient amount in controversy.* (1) If a request for a hearing clearly shows that the amount in controversy is less than that required under § 423.610, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than the amount required under § 423.610, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal.

§ 423.620 Medicare Appeals Council (MAC) review.

An enrollee who is dissatisfied with an ALJ hearing decision may request that the MAC review the ALJ's decision or dismissal. The regulations under part 422, subpart M of this chapter regarding MAC review apply to matters addressed by this subpart.

§ 423.630 Judicial review.

(a) *Review of ALJ's Decision.* The enrollee may request judicial review of an ALJ's decision if—

(1) The MAC denied the enrollee's request for review; and

(2) The amount in controversy meets the threshold requirement established annually by the Secretary.

(b) *Review of MAC decision.* The enrollee may request judicial review of the MAC decision if it is the final decision of CMS and the amount in controversy meets the threshold established in paragraph (a)(2) of this section.

(c) *How to request judicial review.* In order to request judicial review, an enrollee must file a civil action in a district court of the United States in accordance with section 205(g) of the Act. (See part 422, subpart M of this chapter, for a description of the procedures to follow in requesting judicial review.)

§ 423.634 Reopening and revising determinations and decisions.

(a) A coverage determination or reconsideration made by a PDP sponsor, a reconsideration made by the independent review entity specified in § 423.600, or the decision of an ALJ or the MAC that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, under the rules in part 422, subpart M of this chapter.

(b) The filing of a request for reopening does not relieve the PDP sponsor of its obligation to make payment or provide benefits as specified in § 423.636 or § 423.638.

(c) Once an entity issues a revised determination or decision, the revisions made by the decision may be appealed.

(d) A decision of a PDP sponsor or any other entity not to reopen is not subject to review.

§ 423.636 How a PDP sponsor must effectuate standard predeterminations, reconsideration determinations, or decisions.

(a) *Reversals by the PDP sponsor.* (1) *Requests for benefits.* If, on redetermination of a request for benefit, the PDP sponsor completely reverses its coverage determination, the sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days after the date the PDP sponsor receives the request for redetermination (or no later than upon expiration of an extension described in § 423.590(a)(3)).

(2) *Requests for payment.* If, on redetermination of a request for payment, the PDP sponsor completely reverses its coverage determination, the sponsor must pay for the benefit no later than 60 calendar days after the date the

PDP sponsor receives the request for redetermination.

(b) *Reversals by the independent review entity.* (1) *Requests for benefits.* If, on reconsideration of a request for benefit, the PDP sponsor's determination is reversed in whole or in part by the independent review entity, the PDP sponsor must authorize the benefit under dispute within 72 hours from the date it receives notice reversing the determination, or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days from that date. The PDP sponsor must inform the independent review entity that the sponsor has effectuated the decision.

(2) *Requests for payment.* If, on reconsideration of a request for payment, the PDP sponsor's determination is reversed in whole or in part by the independent review entity, the PDP sponsor must pay for the benefit no later than 30 calendar days from the date it receives notice reversing the coverage determination. The PDP sponsor must inform the independent review entity that the sponsor has effectuated the decision.

(c) *Reversals other than by the PDP sponsor or the independent review entity.* If the IRE's determination is reversed in whole or in part by the ALJ, or at a higher level of appeal, the PDP sponsor must pay for, authorize, or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days from the date it receives notice reversing the determination. The PDP sponsor must inform the independent review entity that the sponsor has effectuated the decision.

§ 423.638 How a PDP sponsor must effectuate expedited redeterminations or reconsidered determinations.

(a) *Reversals by the PDP sponsor.* If, on redetermination of an expedited request for benefits, the PDP sponsor completely reverses its coverage determination, the PDP sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the PDP sponsor receives the request for redetermination (or no later than upon expiration of an extension specified in § 423.590(d)(2)).

(b) *Reversals by the independent review entity.* If the PDP sponsor's determination is reversed in whole or in part by the independent review entity, the PDP sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health

condition requires but no later than 72 hours from the date it receives notice reversing the determination. The PDP sponsor must inform the independent review entity that the sponsor has effectuated the decision.

(c) *Reversals other than by the PDP sponsor or the independent review entity.* If the IRE's expedited determination is reversed in whole or in part by the ALJ, or at a higher level of appeal, the PDP sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 days from the date it receives notice reversing the determination. The PDP sponsor must inform the independent review entity that the sponsor has effectuated the decision.

Subpart N—Medicare Contract Determinations and Appeals

§ 423.641 Contract determinations.

This subpart establishes the procedures for making and reviewing the following contract determinations:

- (a) A determination that an entity is not qualified to enter into a contract with CMS under Part D of Title XVIII of the Act.
- (b) A determination to terminate a contract with a PDP sponsor in accordance with § 423.509.
- (c) A determination not to authorize a renewal of a contract with a PDP sponsor in accordance with § 423.507(b).

§ 423.642 Notice of contract determination.

(a) When CMS makes a contract determination, it gives the PDP sponsor written notice.

(b) The notice specifies the—
 (1) Reasons for the determination; and
 (2) PDP sponsor's right to request reconsideration.
 (c) For CMS-initiated terminations, CMS mails notice 90 days before the anticipated effective date of the termination. For terminations based on initial determinations described at § 423.509(a)(4) or (a)(5), CMS immediately notifies the PDP sponsor of its decision to terminate the organization's PDP contract.

(d) When CMS determines that it is not going to authorize a contract renewal, CMS mails the notice to the PDP sponsor by May 1 of the current contract year.

§ 423.643 Effect of contract determination.

The contract determination is final and binding unless—

(a) The determination is reconsidered in accordance with § 423.644 through § 423.649;

(b) A timely request for a hearing is filed under § 423.651; or
 (c) The reconsideration decision is revised as a result of a reopening under § 423.668.

§ 423.644 Reconsideration: Applicability.

(a) Reconsideration is the first step for appealing a contract determination specified in § 423.641.

(b) CMS reconsiders the specified determinations if the contract applicant or the PDP sponsor files a written request in accordance with § 423.645.

§ 423.645 Request for reconsideration.

(a) *Method and place for filing a request.* A request for reconsideration must be made in writing and filed with any CMS office.

(b) *Time for filing a request.* The request for reconsideration must be filed within 15 days from the date of the notice of the initial determination.

(c) *Proper party to file a request.* Only an authorized official of the contract applicant or PDP sponsor that was the subject of a contract determination may file the request for reconsideration.

(d) *Withdrawal of a request.* The PDP sponsor or contract applicant who filed the request for a reconsideration may withdraw it at any time before the notice of the reconsidered determination is mailed. The request for withdrawal must be in writing and filed with CMS.

§ 423.646 Opportunity to submit evidence.

CMS provides the PDP sponsor or contract applicant and the CMS official or officials who made the contract determination reasonable opportunity, not to exceed the timeframe in which a PDP sponsor chooses to request a hearing as described at § 423.651, to present as evidence any documents or written statements that are relevant and material to the matters at issue.

§ 423.647 Reconsidered determination.

A reconsidered determination is a new determination that—

(a) Is based on a review of the contract determination, the evidence and findings upon which that was based, and any other written evidence submitted before notice of the reconsidered determination is mailed, including facts relating to the status of the PDP sponsor subsequent to the contract determination; and

(b) Affirms, reverses, or modifies the initial determination.

§ 423.648 Notice of reconsidered determination.

(a) CMS gives the PDP sponsor or contract applicant written notice of the reconsidered determination.

(b) The notice—

(1) Contains findings for the contract applicant's qualifications to enter into, or the PDP sponsor's qualifications to remain under, a contract with CMS under Part D of the Act;

(2) States the specific reasons for the reconsidered determination; and

(3) Informs the PDP sponsor or contract applicant of its right to a hearing if it is dissatisfied with the determination.

§ 423.649 Effect of reconsidered determination.

A reconsidered determination is final and binding unless a request for a hearing is filed in accordance with § 423.651 or it is revised in accordance with § 423.668.

§ 423.650 Right to a hearing.

The following parties are entitled to a hearing:

(a) A contract applicant that is determined in a reconsidered determination to be unqualified to enter into a contract with CMS under Part D of title XVIII of the Act.

(b) A PDP sponsor whose contract with CMS is terminated or is not renewed as a result of a contract determination as provided in § 423.641.

§ 423.651 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or PDP sponsor that was the party to the determination under appeal. The request for a hearing must be filed with any CMS office.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 days after the date of the reconsidered determination.

(c) *Parties to a hearing.* The parties to a hearing must be—

(1) The parties described in § 423.650;
 (2) At the discretion of the hearing officer, any interested parties who make a showing that their rights may be prejudiced by the decision to be rendered at the hearing; and
 (3) CMS.

§ 423.652 Postponement of effective date of a contract determination when a request for a hearing for a contract determination is filed timely.

(a) CMS postpones the proposed effective date of the contract determination to terminate a contract with a PDP sponsor until a hearing decision is reached and affirmed by the Administrator following review under § 423.666 in instances where a PDP sponsor requests review by the Administrator; and

(b) CMS extends the current contract at the end of the contract period (in the case of a determination not to renew) only—

(1) If CMS finds that an extension of the contract is consistent with the purpose of this part; and

(2) For the period as CMS and the PDP sponsor agree.

(c) *Exception:* A contract terminated in accordance with § 423.509(a)(4) or (a)(5) is immediately terminated and is to be postponed if a hearing is requested.

§ 423.653 Designation of hearing officer.

CMS designates a hearing officer to conduct the hearing. The hearing officer need not be an ALJ.

§ 423.654 Disqualification of hearing officer.

(a) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(c) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(1) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(2) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to CMS.

§ 423.655 Time and place of hearing.

(a) The hearing officer fixes a time and place for the hearing, which is not to exceed 30 days from the receipt of the request for the hearing, and sends written notice to the parties. The notice also informs the parties of the general and specific issues to be resolved and information about the hearing procedure.

(b) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing. The hearing officer may adjourn or postpone the hearing.

(c) The hearing officer gives the parties reasonable notice of any change in time or place of hearing, or of adjournment or postponement.

§ 423.656 Appointment of representatives.

A party may appoint as its representative at the hearing anyone not disqualified or suspended from acting as

a representative before the Secretary or otherwise prohibited by law.

§ 423.657 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 423.656, on behalf of the represented party—

(1) Gives or accepts any notice or request pertinent to the proceedings set forth in this subpart;

(2) Presents evidence and allegations as to facts and law in any proceedings affecting that party; and

(3) Obtains information to the same extent as the party.

(b) A notice or request sent to the representative has the same force and effect as if it is sent to the party.

§ 423.658 Conduct of hearing.

(a) The hearing is open to the parties and to the public.

(b) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(c) The hearing officer provides the parties an opportunity to enter any objection to the inclusion of any document.

(d) The hearing officer decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

§ 423.659 Evidence.

The hearing officer rules on the admissibility of evidence and may admit evidence that is inadmissible under rules applicable to court procedures.

§ 423.660 Witnesses.

(a) The hearing officer may examine the witnesses.

(b) The parties or their representatives are permitted to examine their witnesses and cross-examine witnesses of other parties.

§ 423.661 Discovery.

(a) Prehearing discovery is permitted upon timely request of a party.

(b) A request is timely if it is made before the beginning of the hearing.

(c) A reasonable time for inspection and reproduction of documents is provided by order of the hearing officer.

(d) The hearing officer's order on all discovery matters is final.

§ 423.662 Prehearing.

The hearing officer may schedule a prehearing conference if he or she believes that a conference may more clearly define the issues.

§ 423.663 Record of hearing.

(a) A complete record of the proceedings at the hearing is made and

transcribed and made available to all parties upon request.

(b) The record may not be closed until a hearing decision is issued.

§ 423.664 Authority of hearing officer.

In exercising his or her authority, the hearing officer must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act.

§ 423.665 Notice and effect of hearing decision.

(a) As soon as practical after the close of the hearing, the hearing officer issues a written decision that—

(1) Is based upon the evidence of record; and

(2) Contains separately numbered findings of fact and conclusions of law.

(b) The hearing officer provides a copy of the hearing decision to each party.

(c) The hearing decision is final and binding unless it is reversed or modified by the Administrator following review under § 423.666, or reopened and revised in accordance with § 423.668.

§ 423.666 Review by the Administrator.

(a) *Request for review by Administrator.* A PDP sponsor that receives a hearing decision upholding a contract termination determination may request review by the Administrator within 15 days of receiving the hearing decision as provided under § 423.665(b).

(b) *Review by the Administrator.* The Administrator must review the hearing officer's decision, and determine, based upon this decision, the hearing record, and any written arguments submitted by the PDP sponsor, whether the termination decision must be upheld, reversed, or modified.

(c) *Decision by the Administrator.* The Administrator issues a written decision, and furnishes the decision to the PDP sponsor requesting review.

§ 423.667 Effect of Administrator's decision.

A decision by the Administrator under section § 423.666(c) is final and binding unless it is reopened and revised in accordance with § 423.668.

§ 423.668 Reopening of contract or reconsidered determination or decision of a hearing officer or the Administrator.

(a) *Initial or reconsidered determination.* CMS may reopen and revise an initial or reconsidered determination upon its own motion within 1 year of the date of the notice of determination.

(b) *Decision of hearing officer.* A decision of a hearing officer that is

unfavorable to any party and is otherwise final may be reopened and revised by the hearing officer upon the officer's own motion within 1 year of the notice of the hearing decision.

Another hearing officer designated by CMS may reopen and revise the decision if the hearing officer who issued the decision is unavailable.

(c) *Decision of Administrator.* A decision by the Administrator that is otherwise final may be reopened and revised by the Administrator upon the Administrator's own motion within 1 year of the notice of the Administrator's decision.

(d) *Notices.* (1) The notice of reopening and of any revisions following the reopening is mailed to the parties.

(2) The notice of revision specifies the reasons for revisions.

§ 423.669 Effect of revised determination.

The revision of a contract or reconsidered determination is binding unless a party files a written request for hearing of the revised determination in accordance with § 423.651.

§ 423.650 Right to a hearing.

The following parties are entitled to a hearing:

(a) A contract applicant that is determined in a reconsidered determination to be unqualified to enter into a contract with CMS under Part D of title XVIII of the Act.

(b) A PDP sponsor whose contract with CMS is terminated or is not renewed as a result of a contract determination as provided in § 423.641.

§ 423.651 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or PDP sponsor that was the party to the determination under appeal. The request for a hearing must be filed with any CMS office.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 days after the date of the reconsidered determination.

(c) *Parties to a hearing.* The parties to a hearing must be—

(1) The parties described in § 423.650;

(2) At the discretion of the hearing officer, any interested parties who make a showing that their rights may be prejudiced by the decision to be rendered at the hearing; and

(3) CMS.

§ 423.652 Postponement of effective date of a contract determination when a request for a hearing for a contract determination is filed timely.

(a) CMS postpones the proposed effective date of the contract determination to terminate a contract with a PDP sponsor until a hearing decision is reached and affirmed by the Administrator following review under § 423.666 in instances where a PDP sponsor requests review by the Administrator; and

(b) CMS extends the current contract at the end of the contract period (in the case of a determination not to renew) only—

(1) If CMS finds that an extension of the contract is consistent with the purpose of this part; and

(2) For the period as CMS and the PDP sponsor agree.

(c) *Exception:* A contract terminated in accordance with § 423.509 (a)(4) or (a)(5) is immediately terminated and is not be postponed if a hearing is requested.

§ 423.653 Designation of hearing officer.

CMS designates a hearing officer to conduct the hearing. The hearing officer need not be an ALJ.

§ 423.654 Disqualification of hearing officer.

(a) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(c) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(1) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(2) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to CMS.

§ 423.655 Time and place of hearing.

(a) The hearing officer fixes a time and place for the hearing, which is not to exceed 30 days from the receipt of the request for the hearing, and sends written notice to the parties. The notice also informs the parties of the general and specific issues to be resolved and information about the hearing procedure.

(b) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing. The hearing officer may adjourn or postpone the hearing.

(c) The hearing officer gives the parties reasonable notice of any change in time or place of hearing, or of adjournment or postponement.

§ 423.656 Appointment of representatives.

A party may appoint as its representative at the hearing anyone not disqualified or suspended from acting as a representative before the Secretary or otherwise prohibited by law.

§ 423.657 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 423.656, on behalf of the represented party—

(1) Gives or accepts any notice or request pertinent to the proceedings set forth in this subpart;

(2) Presents evidence and allegations as to facts and law in any proceedings affecting that party; and

(3) Obtains information to the same extent as the party.

(b) A notice or request sent to the representative has the same force and effect as if it is sent to the party.

§ 423.658 Conduct of hearing.

(a) The hearing is open to the parties and to the public.

(b) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(c) The hearing officer provides the parties an opportunity to enter any objection to the inclusion of any document.

(d) The hearing officer decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

§ 423.659 Evidence.

The hearing officer rules on the admissibility of evidence and may admit evidence that is inadmissible under rules applicable to court procedures.

§ 423.660 Witnesses.

(a) The hearing officer may examine the witnesses.

(b) The parties or their representatives are permitted to examine their witnesses and cross-examine witnesses of other parties.

§ 423.661 Discovery.

(a) Prehearing discovery is permitted upon timely request of a party.

(b) A request is timely if it is made before the beginning of the hearing.

(c) A reasonable time for inspection and reproduction of documents is provided by order of the hearing officer.

(d) The hearing officer's order on all discovery matters is final.

§ 423.662 Prehearing.

The hearing officer may schedule a prehearing conference if he or she believes that a conference may more clearly define the issues.

§ 423.663 Record of hearing.

(a) A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request.

(b) The record may not be closed until a hearing decision is issued.

§ 423.664 Authority of hearing officer.

In exercising his or her authority, the hearing officer must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act.

§ 423.665 Notice and effect of hearing decision.

(a) As soon as practical after the close of the hearing, the hearing officer issues a written decision that—

(1) Is based upon the evidence of record; and

(2) Contains separately numbered findings of fact and conclusions of law.

(b) The hearing officer provides a copy of the hearing decision to each party.

(c) The hearing decision is final and binding unless it is reversed or modified by the Administrator following review under § 423.666, or reopened and revised in accordance with § 423.668.

§ 423.666 Review by the Administrator.

(a) *Request for review by Administrator.* A PDP sponsor that receives a hearing decision upholding a contract termination determination may request review by the Administrator within 15 days of receiving the hearing decision as provided under § 423.665(b).

(b) *Review by the Administrator.* The Administrator must review the hearing officer's decision, and determine, based upon this decision, the hearing record, and any written arguments submitted by the PDP sponsor, whether the termination decision must be upheld, reversed, or modified.

(c) *Decision by the Administrator.* The Administrator issues a written decision, and furnishes the decision to the PDP sponsor requesting review.

§ 423.667 Effect of Administrator's decision.

A decision by the Administrator under section § 423.666(c) is final and binding unless it is reopened and revised in accordance with § 423.668.

§ 423.668 Reopening of contract or reconsidered determination or decision of a hearing officer or the Administrator.

(a) *Initial or reconsidered determination.* CMS may reopen and revise an initial or reconsidered determination upon its own motion within 1 year of the date of the notice of determination.

(b) *Decision of hearing officer.* A decision of a hearing officer that is unfavorable to any party and is otherwise final may be reopened and revised by the hearing officer upon the officer's own motion within 1 year of the notice of the hearing decision. Another hearing officer designated by CMS may reopen and revise the decision if the hearing officer who issued the decision is unavailable.

(c) *Decision of Administrator.* A decision by the Administrator that is otherwise final may be reopened and revised by the Administrator upon the Administrator's own motion within 1 year of the notice of the Administrator's decision.

(d) *Notices.* (1) The notice of reopening and of any revisions following the reopening is mailed to the parties.

(2) The notice of revision specifies the reasons for revisions.

§ 423.669 Effect of revised determination.

The revision of a contract or reconsidered determination is binding unless a party files a written request for hearing of the revised determination in accordance with § 423.651.

§ 423.650 Right to a hearing.

The following parties are entitled to a hearing:

(a) A contract applicant that is determined in a reconsidered determination to be unqualified to enter into a contract with CMS under Part D of title XVIII of the Act.

(b) A PDP sponsor whose contract with CMS is terminated or is not renewed as a result of a contract determination as provided in § 423.641.

§ 423.651 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or PDP sponsor that was the party to the determination under appeal. The request for a hearing must be filed with any CMS office.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 days after the date of the reconsidered determination.

(c) *Parties to a hearing.* The parties to a hearing must be—

(1) The parties described in § 423.650;

(2) At the discretion of the hearing officer, any interested parties who make a showing that their rights may be prejudiced by the decision to be rendered at the hearing; and

(3) CMS.

§ 423.652 Postponement of effective date of a contract determination when a request for a hearing for a contract determination is filed timely.

(a) CMS postpones the proposed effective date of the contract determination to terminate a contract with a PDP sponsor until a hearing decision is reached and affirmed by the Administrator following review under § 423.666 in instances where a PDP sponsor requests review by the Administrator; and

(b) CMS extends the current contract at the end of the contract period (in the case of a determination not to renew) only—

(1) If CMS finds that an extension of the contract is consistent with the purpose of this part; and

(2) For the period as CMS and the PDP sponsor agree.

(c) *Exception:* A contract terminated in accordance with § 423.509(a)(4) or (a)(5) is immediately terminated and is not be postponed if a hearing is requested.

§ 423.653 Designation of hearing officer.

CMS designates a hearing officer to conduct the hearing. The hearing officer need not be an ALJ.

§ 423.654 Disqualification of hearing officer.

(a) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(c) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(1) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(2) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before

another hearing officer. The objections must be submitted in writing to CMS.

§ 423.655 Time and place of hearing.

(a) The hearing officer fixes a time and place for the hearing, which is not to exceed 30 days from the receipt of the request for the hearing, and sends written notice to the parties. The notice also informs the parties of the general and specific issues to be resolved and information about the hearing procedure.

(b) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing. The hearing officer may adjourn or postpone the hearing.

(c) The hearing officer gives the parties reasonable notice of any change in time or place of hearing, or of adjournment or postponement.

§ 423.656 Appointment of representatives.

A party may appoint as its representative at the hearing anyone not disqualified or suspended from acting as a representative before the Secretary or otherwise prohibited by law.

§ 423.657 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 423.656, on behalf of the represented party—

(1) Gives or accepts any notice or request pertinent to the proceedings set forth in this subpart;

(2) Presents evidence and allegations as to facts and law in any proceedings affecting that party; and

(3) Obtains information to the same extent as the party.

(b) A notice or request sent to the representative has the same force and effect as if it is sent to the party.

§ 423.658 Conduct of hearing.

(a) The hearing is open to the parties and to the public.

(b) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(c) The hearing officer provides the parties an opportunity to enter any objection to the inclusion of any document.

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§ 423.659 Evidence.

The hearing officer rules on the admissibility of evidence and may admit evidence that is inadmissible under rules applicable to court procedures.

§ 423.660 Witnesses.

(a) The hearing officer may examine the witnesses.

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§ 423.661 Discovery.

(a) Prehearing discovery is permitted upon timely request of a party.

(b) A request is timely if it is made before the beginning of the hearing.

(c) A reasonable time for inspection and reproduction of documents is provided by order of the hearing officer.

(d) The hearing officer's order on all discovery matters is final.

§ 423.662 Prehearing.

The hearing officer may schedule a prehearing conference if he or she believes that a conference may more clearly define the issues.

§ 423.663 Record of hearing.

(a) A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request.

(b) The record may not be closed until a hearing decision is issued.

§ 423.664 Authority of hearing officer.

In exercising his or her authority, the hearing officer must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act.

§ 423.665 Notice and effect of hearing decision.

(a) As soon as practical after the close of the hearing, the hearing officer issues a written decision that—

(1) Is based upon the evidence of record; and

(2) Contains separately numbered findings of fact and conclusions of law.

(b) The hearing officer provides a copy of the hearing decision to each party.

(c) The hearing decision is final and binding unless it is reversed or modified by the Administrator following review under § 423.666, or reopened and revised in accordance with § 423.668.

§ 423.666 Review by the Administrator.

(a) *Request for review by Administrator.* A PDP sponsor that receives a hearing decision upholding a contract termination determination may request review by the Administrator within 15 days of receiving the hearing decision as provided under § 423.665(b).

(b) *Review by the Administrator.* The Administrator must review the hearing

officer's decision, and determine, based upon this decision, the hearing record, and any written arguments submitted by the PDP sponsor, whether the termination decision must be upheld, reversed, or modified.

(c) *Decision by the Administrator.* The Administrator issues a written decision, and furnishes the decision to the PDP sponsor requesting review.

§ 423.667 Effect of Administrator's decision.

A decision by the Administrator under section § 423.666(c) is final and binding unless it is reopened and revised in accordance with § 423.668.

§ 423.668 Reopening of contract or reconsidered determination or decision of a hearing officer or the Administrator.

(a) *Initial or reconsidered determination.* CMS may reopen and revise an initial or reconsidered determination upon its own motion within 1 year of the date of the notice of determination.

(b) *Decision of hearing officer.* A decision of a hearing officer that is unfavorable to any party and is otherwise final may be reopened and revised by the hearing officer upon the officer's own motion within 1 year of the notice of the hearing decision. Another hearing officer designated by CMS may reopen and revise the decision if the hearing officer who issued the decision is unavailable.

(c) *Decision of Administrator.* A decision by the Administrator that is otherwise final may be reopened and revised by the Administrator upon the Administrator's own motion within 1 year of the notice of the Administrator's decision.

(d) *Notices.* (1) The notice of reopening and of any revisions following the reopening is mailed to the parties.

(2) The notice of revision specifies the reasons for revisions.

§ 423.669 Effect of revised determination.

The revision of a contract or reconsidered determination is binding unless a party files a written request for hearing of the revised determination in accordance with § 423.651.

Subpart O—Intermediate Sanctions

§ 423.750 Kinds of sanctions.

(a) The following intermediate sanctions and civil money penalties may be imposed:

(1) Civil money penalties ranging from \$10,000 to \$100,000 depending upon the violation.

(2) Suspension of enrollment of Medicare beneficiaries.

(3) Suspension of payment to the PDP sponsor for Medicare beneficiaries who enroll.

(4) Suspension of all PDP marketing activities to Medicare beneficiaries for the MA plan subject to the intermediate sanctions.

(b) The enrollment, payment, and marketing sanctions continue in effect until CMS is satisfied that the deficiency on which the determination was based is corrected and is not likely to recur.

§ 423.752 Basis for imposing sanctions.

(a) *All intermediate sanctions.* For the violations listed below, CMS may impose any of the sanctions specified in § 423.750 on any PDP sponsor that has a contract in effect. The PDP sponsor may also be subject to other applicable remedies available under law.

(1) Fails substantially to provide, to a PDP enrollee, medically necessary services that the organization is required to provide (under law or under the contract) to a PDP enrollee, and that failure adversely affects (or is substantially likely to adversely affect) the enrollee.

(2) Imposes on PDP enrollees premiums in excess of the monthly basic and supplemental beneficiary premiums permitted under section 1860D of the Act and subpart F of this part.

(3) Acts to expel or refuses to reenroll a beneficiary in violation of the provisions of this part.

(4) Engages in any practice that may reasonably be expected to have the effect of denying or discouraging enrollment of individuals whose medical condition or history indicates a need for substantial future medical services.

(5) Misrepresents or falsifies information that it furnishes—

(i) To CMS; or

(ii) To an individual or to any other entity under the Part D drug benefit program.

(6) Employs or contracts with an individual or entity who is excluded from participation in Medicare under section 1128 or 1128A of the Act (or with an entity that employs or contracts with an individual or entity) for the provision of any of the following:

(i) Health care.

(ii) Utilization review.

(iii) Medical social work.

(iv) Administrative services.

(b) *Suspension of enrollment and marketing.* If CMS makes a determination that could lead to a contract termination under § 423.509(a), CMS may instead impose the intermediate sanctions in § 423.756(c)(1) and (c)(3).

§ 423.756 Procedures for imposing sanctions.

(a) *Notice of sanction and opportunity to respond.*

(1) *Notice of sanction.* Before imposing the intermediate sanctions specified in paragraph (c) of this section CMS—

(i) Sends a written notice to the PDP sponsor stating the nature and basis of the proposed sanction; and

(ii) Sends the Office of the Inspector General a copy of the notice.

(2) *Opportunity to respond.* CMS allows the PDP sponsor 15 days from receipt of the notice to provide evidence that it has not committed an act or failed to comply with the requirements described in § 423.752, as applicable. CMS may allow a 15-day addition to the original 15 days upon receipt of a written request from the PDP sponsor. To be approved, the request must provide a credible explanation of why additional time is necessary and be received by CMS before the end of the 15-day period following the date of receipt of the sanction notice. CMS does not grant an extension if it determines that the PDP sponsor's conduct poses a threat to an enrollee's health and safety.

(b) *Informal reconsideration.* If, consistent with paragraph (a)(2) of this section, the PDP sponsor submits a timely response to CMS' notice of sanction, CMS conducts an informal reconsideration that—

(1) Consists of a review of the evidence by an CMS official who did not participate in the initial decision to impose a sanction; and

(2) Gives the PDP sponsor a concise written decision setting forth the factual and legal basis for the decision that affirms or rescinds the original determination.

(c) *Specific sanctions.* If CMS determines that a PDP sponsor has acted or failed to act as specified in § 423.752 and affirms this determination in accordance with paragraph (b) of this section, CMS may—

(1) Require the PDP sponsor to suspend acceptance of applications made by Medicare beneficiaries for enrollment in the sanctioned plan during the sanction period;

(2) In the case of a violation under § 423.752(a), suspend payments to the PDP sponsor for Medicare beneficiaries enrolled in the sanctioned plan during the sanction period; and

(3) Require the PDP sponsor to suspend all marketing activities for the sanctioned plan to Medicare enrollees.

(d) *Effective date and duration of sanctions.* (1) *Effective date.* Except as provided in paragraph (d)(2) of this section, a sanction is effective 15 days

after the date that the organization is notified of the decision to impose the sanction or, if the PDP sponsor seeks reconsideration in a timely manner under paragraph (b) of this section, on the date specified in the notice of CMS' reconsidered determination.

(2) *Exception.* If CMS determines that the PDP sponsor's conduct poses a serious threat to an enrollee's health and safety, CMS may make the sanction effective on a date before issuance of CMS' reconsidered determination.

(3) *Duration of sanction.* The sanction remains in effect until CMS notifies the PDP sponsor that CMS is satisfied that the basis for imposing the sanction is corrected and is not likely to recur.

(e) *Termination by CMS.* In addition to or as an alternative to the sanctions described in paragraph (c) of this section, CMS may decline to authorize the renewal of an organization's contract in accordance with § 423.507(b)(2) and (b)(3), or terminate the contract in accordance with § 423.509.

(f) *Civil money penalties.* (1) If CMS determines that a PDP sponsor has committed an act or failed to comply with a requirement described in § 423.752, CMS notifies the OIG of this determination, and also notifies OIG when CMS reverses or terminates a sanction imposed under this part.

(2) In the case of a violation described in § 423.752(a), or a determination under § 423.752(b) based upon a violation under § 423.509(a)(4) (involving fraudulent or abusive activities), in accordance with the provisions of part 1005 of this chapter, the OIG may impose civil money penalties on the PDP sponsor in accordance with part 1005 of this chapter in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

(3) In the case of a determination under § 423.752(b) other than a determination based upon a violation under § 423.509(a)(4), in accordance with the provisions of part 1005 of this chapter, CMS may impose civil money penalties on the PDP sponsor in the amounts specified in § 423.758 in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

§ 423.758 Maximum amount of civil money penalties imposed by CMS.

If CMS makes a determination under § 423.752(b), based on any determination under § 423.509(a) except a determination under § 423.509(a)(4), CMS may impose civil money penalties in the following amounts:

(a) If the deficiency on which the determination is based has directly

adversely affected (or has the substantial likelihood of adversely affecting) one or more PDP enrollees—up to \$25,000 for each determination.

(b) For each week that a deficiency remains uncorrected after the week in which the PDP sponsor receives CMS' notice of the determination—up to \$10,000 per week.

(c) If CMS makes a determination under § 423.752(b) and § 423.756(f)(3), based on a determination under § 423.509(a)(1) that a PDP sponsor has terminated its contract with CMS in a manner other than described under § 423.510—\$250 per Medicare enrollee from the terminated PDP plan or plans at the time the PDP sponsor terminated its contract, or \$100,000, whichever is greater.

§ 423.760 Other applicable provisions.

The provisions of section 1128A of the Act (except paragraphs (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a civil money penalty or procedure under section 1128A of the Act.

Subpart P—Premiums and Cost-Sharing Subsidies for Low-Income Individuals

Note: Regulations concerning the low-income premium and cost-sharing subsidy under Medicaid can be found at Subpart S, Special Rules for States—Eligibility Determinations for Subsidies and General Payment Provisions.

§ 423.771 Basis and scope.

(a) *Basis.* This subpart is based on section 1860D–14 of the Act.

(b) *Scope.* This subpart sets forth the requirements and limitations for payments by and on behalf of low-income Medicare beneficiaries who enroll in a prescription drug plan or MA-PD plan.

§ 423.772 Definitions.

For purposes of this subpart, the following definitions apply:

Family size means the applicant, the spouse who is living in the same household, if any, and the number of individuals who are related to the applicant or applicants, who are living in the same household and who are dependent on the applicant or the applicant's spouse for at least one-half of their financial support.

Federal poverty line (FPL) has the meaning given that term in section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2)), including any revision required by that section.

Full benefit dual eligible individual means an individual who, for any month—

(1) Has coverage for the month under a prescription drug plan under Part D of title XVIII, or under an MA-PD plan under Part C of title XVIII; and

(2) Is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. (This does not include individuals under Pharmacy Plus program demonstrations.) It also includes any individual who is determined by the State to be eligible for medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) for any month if the individual was eligible for medical assistance in any part of the month.

Full subsidy eligible individuals means individuals meeting the eligibility requirements under § 423.773(b).

Income means income as described under section 1905(p)(1) of the Act without use of any more liberal disregards under section 1902(r)(2) of the Act (that is, as defined by section 1612 of the Act). This definition includes the income of the applicant and spouse who is living in the same household, if any, regardless of whether the spouse is also an applicant.

Institutionalized individual means a full-benefit dual eligible individual who is an inpatient in a medical institution or nursing facility for which payment is made under Medicaid throughout a month, as defined under section 1902(q)(1)(B) of the Act.

Other subsidy eligible individuals means those individuals meeting the eligibility requirements under § 423.773(d).

Personal representatives means—

(1) Individuals who are authorized to act on behalf of the applicant;

(2) If the applicant is incapacitated; or incompetent, someone acting responsibly on their behalf, or

(3) An individual of the applicant's choice who is requested by the applicant to act as his or her representative in the application process.

Resources means liquid resources of the individual (and his or her spouse if the individual is married, who is living in the same household), such as checking and savings accounts, stocks, bonds, and other resources that can be readily converted to cash within 20

days, that are not excluded from resources in section 1613 of the Act, and real estate that is not the applicant's primary residence or the land on which the primary residence is located.

State means for purposes of this subpart each of the 50 States and the District of Columbia.

Subsidy eligible individuals means those individuals meeting the eligibility requirements under § 423.773.

§ 423.773 Requirements for eligibility

(a) *Subsidy eligible individual.* A subsidy eligible individual is a Part D eligible individual residing in a State who is enrolled in a prescription drug plan or MA-PD plan and meets the following requirements:

(1) Has income below 150 percent of the FPL applicable to the individual's family size.

(2) Has resources at or below the resource thresholds set forth in § 423.773(b)(2) or (d)(2).

(b) *Full subsidy eligible individual.* A full subsidy eligible individual is a subsidy eligible individual who—

(1) Has income below 135 percent of the FPL applicable to the individual's family size; and

(2) Has resources that do not exceed—
(i) For 2006, 3 times the amount of resources an individual may have and still be eligible for benefits under the SSI program (including the assets or resources of the individual's spouse).

(ii) For subsequent years, the amount of resources allowable for the previous year under this paragraph (b)(2) increased by the annual percentage increase in the consumer price index (all items, U.S. city average) as of September of that previous year, rounded to the nearest multiple of \$10.

(c) *Individuals treated as full subsidy eligible.* An individual must be treated as meeting the eligibility requirements for full subsidy eligible individuals under paragraph (b) of this section if the individual is a—

(1) Full benefit dual eligible individual;

(2) Recipient of SSI benefits under title XVI of the Act; or

(3) Eligible for Medicaid as a Qualified Medicare Beneficiary (QMB), Specified Low Income Medicare Beneficiary (SLMB), or a Qualifying Individual (QI) under a State's plan. The State agency must notify an individual treated as a full benefit dual eligible that the individual is eligible for a full subsidy of Part D premiums and deductibles and must either enroll with a PDP or MA-PD or be randomly assigned to a PDP or MA-PD.

(d) *Other low-income subsidy individuals.* Other low-income subsidy

individuals are subsidy eligible individuals who—

(1) Have income less than 150 percent of the FPL applicable to the individual's family size; and

(2) Have resources that do not exceed—

(i) For 2006, \$10,000 if single or \$20,000 if married (including the assets or resources of the individual's spouse).

(ii) For subsequent years, the resource amount allowable for the previous year under this paragraph (d)(2), increased by the annual percentage increase in the consumer price index (all items, U.S. city average) as of September of the previous year, rounded to the nearest multiple of \$10.

§ 423.774 Eligibility determinations, redeterminations, and applications.

(a) *Determinations of whether an individual is a subsidy eligible individual.* Determinations of eligibility for subsidies under this section are made by the State under its State plan under title XIX if the individual applies with the Medicaid agency, or if the individual applies with SSA, the Commissioner of Social Security in accordance with the requirements of section 1860D-14(a)(3) of the Act.

(b) *Effective date of initial eligibility determinations.* Eligibility determinations are effective beginning with the first day of the month in which the individual applies, or January 1, 2006 if the application was taken in advance of that date, and remain in effect for a period not to exceed 1 year.

(c) *Redeterminations and appeals of low-income subsidy eligibility.* (1) *Redeterminations and appeals of low-income subsidy eligibility determinations—eligibility determinations made by States.* Redeterminations and appeals of low-income subsidy eligibility determinations by States must be made in the same manner and frequency as the redeterminations and appeals are made under the State's plan.

(2) *Redeterminations and appeals of low-income subsidy eligibility—eligibility determinations made by Commissioner.* Redeterminations and appeals of eligibility determinations made by the Commissioner must be made in the manner specified by the Commissioner.

(d) *Application requirements.* (1) In order for low-income subsidy applications to be considered complete, individuals applying for the low-income subsidy, or personal representatives applying on the individual's behalf, must—

(i) Complete all required elements of the application;

(ii) Provide any statements from financial institutions, as requested, to support information in the application; and

(iii) Certify, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the application form.

(d)(2) [Reserved]

§ 423.780 Premium subsidy.

(a) *Full subsidy eligible individuals.* Full subsidy individuals are entitled to a premium subsidy equal to 100 percent of the "premium subsidy amount," not to exceed the basic premium for coverage under the prescription drug plan selected by the beneficiary, and the greater of the low-income benchmark premium or the lowest monthly beneficiary premium for a prescription drug plan that offers basic prescription drug coverage in the PDP region. (The premium subsidy determined in this way applies regardless of whether the individual enrolls in a PDP or MA-PD.) In the event the low-income benchmark premium is less than the lowest monthly beneficiary premium for basic prescription drug coverage offered by a PDP sponsor in a PDP region, in accordance with section 1860D-14(b)(3) of the Act, the premium subsidy will be equal to the lowest monthly beneficiary premium for basic prescription drug coverage offered by a PDP sponsor in the PDP region. The low-income benchmark premium amount for a region equals either—

(1) If all PDPs in the PDP region are offered by the same PDP sponsor, the weighted average of the monthly beneficiary premiums for basic prescription drug coverage; or

(2) If the PDPs in the region are offered by more than one PDP sponsor, the weighted average of the monthly beneficiary premiums for basic prescription drug coverage for all PDP and MA-PD plans in the region (excluding section 1876 cost plans, PACE plans, specialized MA plans for special needs individuals, and private fee-for-service plans) and the portion of the monthly beneficiary premium for alternative prescription drug coverage attributable to basic prescription drug coverage for all PDPs and MA-PD plans in the region. Fallback plans will be treated the same as risk-bid plans for the calculation of the low-income benchmark premium. The weighted average is determined based on enrollment in PDPs and MA-PDs in the region.

(b) *Other low-income subsidy eligible individuals—sliding scale premium.* Other low-income subsidy eligible individuals are entitled to a premium

subsidy based on a linear sliding scale ranging from 100 percent of the amount described in paragraph (a) of this section, for individuals with incomes at or below 135 percent of the FPL applicable to their family size, to 0 percent for individuals with incomes at 150 percent of the FPL applicable to their family size.

(c) *Premium subsidy for late enrollment penalty.* Full subsidy eligible individuals who are subject to late enrollment penalties under § 423.46 are entitled to an additional premium subsidy equal to 80 percent of the late penalty for the first 60 months during which the penalty is imposed and 100 percent of the penalty thereafter.

§ 423.782 Cost-sharing subsidy.

(a) *Full subsidy eligible individuals.* Full subsidy eligible individuals are entitled to the following:

(1) Elimination of the annual deductible under § 423.104(e)(1).

(2) Reduction in cost-sharing for all covered Part D drugs covered under the PDP or MA-PD plan below the out-of-pocket limit (under § 423.104), including Part D drugs covered under the PDP or MA-PD plan obtained after the initial coverage limit (under § 423.104(e)(4)), as follows:

(i) Except as provided under paragraphs (a)(2)(ii) and (a)(2)(iii) of this section, copayment amounts not to exceed the copayment amounts specified in § 423.104. This applies to those full benefit dual eligible individuals who are not institutionalized and who have income above 100 percent of the Federal poverty line applicable to the individual's family size.

(ii) Institutionalized individuals have no cost-sharing for covered Part D drugs covered under their PDP or MA-PD plans.

(iii) Non-institutionalized full benefit dual eligible individuals with incomes that do not exceed 100 percent of the Federal poverty line applicable to the individual's family size are subject to cost-sharing for covered drugs equal to the lesser of a copayment amount of \$1 for a generic drug or preferred multiple source drug of \$3 for any other drug, or the amount charged to other individuals with income below 135 percent of the FPL and resources not greater than 3 times the amount an individual may have and still be eligible for benefits under the SSI program. These amounts are increased each year beginning in 2007 by the percentage increase in CPI, rounded to the nearest multiple of 5 cents or 10 cents, respectively.

(iv) Non-institutionalized full benefit dual eligible individuals with incomes

that exceed 100 percent of the Federal poverty line applicable to the individual's family size are subject to cost-sharing for covered drugs equal to the lesser of a copayment amount of \$2 for a generic drug or preferred multiple source drug or \$5 for any other drug, or the amount charged to other individuals with income below 135 percent of the FPL and resources not greater than 3 times the amount an individual may have and still be eligible for benefits under the SSI program.

(3) Elimination of all cost-sharing for covered Part D drugs covered under the PDP or MA-PD plan above the out-of-pocket limit (under § 423.104(e)(5)).

(b) *Other low-income subsidy eligible individuals.* Other low-income subsidy eligible individuals are entitled to the following:

(1) Reduction in the annual deductible under § 423.104 to \$50. This amount is increased each year beginning in 2007 by the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of \$1.

(2) 15 percent coinsurance for all covered drugs covered under the individual's PDP or MA-PD plan obtained after the initial coverage limit (under § 423.104), up to the out-of-pocket limit (under § 423.104).

(3) For covered drugs above the out-of-pocket limit (under § 423.104), copayments not to exceed \$2 for a generic drug or preferred multiple source and \$5 for any other drug. These amounts are increased each year beginning in 2007 by the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of 5 cents.

§ 423.800 Administration of subsidy program.

(a) *Notification of eligibility for low-income subsidy.* CMS notifies the PDP sponsor offering the PDP or the MA organization offering the MA-PD plan, in which a subsidy eligible individual is enrolled, of the individual's eligibility for a subsidy and the amount of the subsidy.

(b) *Reduction of premium or cost-sharing by PDP sponsor or organization.* The PDP sponsor offering the PDP, or the MA organization offering the MA-PD 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 PDP sponsor and MA-PD organization must track the application of the low-income cost-sharing

subsidies to be applied to the out-of-pocket threshold.

(c) *Reimbursement to sponsor or organization for the amount of the reductions.* CMS reimburses sponsors and MA organizations for reductions under paragraph (b) of this section, or, if a PDP sponsor or MA organization elects to be paid on a capitated basis under paragraph (e) of this section, the capitated amounts under paragraph (e) of this section, in the manner determined by CMS.

(d) *Reimbursement for cost-sharing on a capitated basis.* Reimbursement for cost-sharing subsidies may be computed on a capitated basis, taking into account the actuarial value of the subsidies and making appropriate adjustments to reflect differences in the risks actually involved.

(e) *Reimbursement for cost-sharing paid before notification of eligibility for low-income subsidy.* The PDP sponsor offering the PDP plan, or MA-PD organization offering the MA-PD plan, must reimburse low-income subsidy eligible individuals any out-of-pocket costs relating to excess premiums and cost-sharing paid before the date the individual is notified of subsidy eligibility and after the date subsidy eligibility is effective.

Subpart Q—Guaranteeing Access to a Choice of Coverage (Fallback Plans)

§ 423.851 Scope.

This section sets forth—the rights of beneficiaries to a choice of at least two sources of prescription drug coverage; requirements and limitations on the bid submission, review and approval of fallback prescription drug plans, and the determination of enrollee premium and plan payments for these plans.

§ 423.855 Definitions.

As used in this subpart, unless specified otherwise—

Eligible Fallback Entity or Fallback Entity means an entity that, with respect to a particular contract period—

(1) meets all the requirements to be a PDP sponsor except that it does not have to be a risk-bearing entity; and

(2) does not submit a bid under § 423.265 for any prescription drug plan for any PDP region for the first year of that contract period. An entity is treated as submitting a bid if the entity is acting as a subcontractor for an integral part of the drug benefit management activities of a PDP sponsor. An entity is not treated as submitting a bid if it is a subcontractor of an MA organization, unless that organization is acting as a PDP sponsor for a prescription drug plan.

Fallback Prescription Drug Plan means a plan offered by a fallback entity that—

(1) Offers only actuarially equivalent standard prescription drug coverage as defined in § 423.100;

(2) Provides access to negotiated prices, including discounts from manufacturers; and

(3) Meets other requirements as specified by CMS.

Qualifying Plan means a full-risk or limited-risk prescription drug plan, as defined in § 423.258, or an MA plan described in section 1851(a)(2)(A)(i) of the Act, that either provides basic prescription drug coverage, as defined in § 423.100, or provides alternative prescription drug coverage for no additional premium because it applies a premium rebate under Part C of Medicare as a credit against the supplemental coverage premium, as described under § 422.266(b)(1). An MA—

PD plan must be open for enrollment and not operating under a capacity waiver to be counted as a qualifying plan.

§ 423.859 Assuring access to a choice of coverage.

(a) *Choice of at least 2 qualifying plans in each area.* Each Part D eligible individual must have available a choice of enrollment in at least 2 qualifying plans (as defined in § 423.855) in the area in which the individual resides. This requirement is not satisfied if only one entity offers all the qualifying plans in the area. At least 1 of the 2 qualifying plans must be a prescription drug plan.

(b) *Fallback service area.* (1) *For coverage year.* Before the start of each coverage year CMS determines if Part D eligible individuals residing in a PDP region have access to a choice of enrollment in a minimum of 2 qualifying plans, as described in paragraph (a) of this section. If CMS determines that Part D eligible individuals in a PDP region, or some portion of the region, do not have available a choice of enrollment in a minimum of two qualified plans, CMS designates the region or portion of a region as a fallback service area. Each Part D eligible individual in a fallback service area is given the opportunity to enroll in a fallback prescription drug plan.

(2) *For mid-year changes.* If a contract with a qualifying plan is terminated in the middle of a contract year (as provided for in §§ 423.508, 423.509, or 423.510), CMS determines if Part D eligible individuals residing in the affected PDP region still have access to

a choice of enrollment in a minimum of 2 qualifying plans. If CMS determines that Part D eligible individuals in a PDP region, or some portion of the region, no longer have available a choice of enrollment in a minimum of two qualifying plans, CMS designates the region or portion of a region as a fallback service area.

(c) *Access to coverage in the territories.* CMS may waive or modify the requirements of this part if—

(1) CMS determines that waiver or modification is necessary to secure access to qualified prescription drug coverage for Part D eligible individuals residing in a State other than the 50 States or the District of Columbia; or

(2) An entity seeking to become a prescription drug plan in a State other than the 50 States or the District of Columbia requests waiver or modification of any Part D requirement in order to provide qualified prescription drug coverage in a State other than the 50 States or the District of Columbia.

§ 423.863 Submission and approval of bids.

(a) *Submission of Bids.* (1) *Solicitation of bids.* Separate from the bidding process under § 423.265, CMS solicits bids from eligible fallback entities for the offering in all fallback service areas in one or more PDP regions of a fallback prescription drug plan during the contract period specified in § 423.871(c).

(2) *Timing of bids.* CMS will determine when to solicit bids for 2006 so that potential fallback plans will have enough time to prepare a bid. After that, bids will be solicited on three-year cycles, or annually thereafter as needed to replace contractors between contracting cycles.

(3) *Format of bid.* CMS specifies the form and manner in which fallback bids are submitted in separate guidance to bidders.

(b) *Negotiation and acceptance of bids.*

(1) *General rule.* Except as provided in this section, the provisions of § 423.272 apply for the approval or disapproval of fallback prescription drug plans. CMS enters into contracts under this paragraph with eligible fallback entities for the offering of approved fallback prescription drug plans in potential fallback service areas.

(2) *Flexibility in risk assumed and application of fallback plan.* In order to ensure access in an area pursuant to § 423.859(a), CMS may approve limited risk plans under § 423.272(c) for that area. If the access requirement is still not met after applying § 423.272(c),

CMS provides for the offering of a fallback prescription drug plan in that area.

(3) *Limitation of 1 Plan for all fallback service areas in a PDP region.* All fallback service areas in any PDP region for a contract period must be served by the same fallback prescription drug plan.

(4) *Competitive procedures.* CMS uses competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5)) to enter into a contract under this paragraph. The provisions of section 1874A(d) of the Act apply to a contract under this section in the same manner as they apply to a contract under that section.

(5) *Timing of contracts.* CMS approves a fallback prescription drug plan for a PDP region in a manner so that, if there are any fallback service areas in the region for a year, the fallback prescription drug plan is offered at the same time as prescription drug plans are otherwise offered. In the event of mid-year changes and as required by § 423.859(b)(2), CMS approves a fallback prescription drug plan for a PDP region in a manner so that the fallback plan is offered within 90 days of notice.

(6) *No national fallback plan.* CMS may not enter into a contract with a single fallback entity for the offering of fallback plans throughout the United States.

§ 423.867 Rules regarding premiums.

(a) *Monthly beneficiary premium.* Except as provided in § 423.286(d)(3) (relating to late enrollment penalty) and subject to Subpart P (relating to low-income assistance), the monthly beneficiary premium under a fallback prescription drug plan must be uniform for all fallback service areas in a PDP region. It must equal 25.5 percent of CMS's estimate of the average monthly per capita actuarial cost, including administrative expenses, of providing coverage in the region based on similar expenses of prescription drug plans that are not fallback prescription drug plans.

(b) *Special rule for collection of premiums in fallback plans.* In the case of a fallback prescription drug plan, the provisions of § 423.293 (b) concerning payments of the late enrollment penalty do not apply and the monthly beneficiary premium is collected in the manner specified in § 422.262(f)(1) (or other manner as may be provided under section 1840 of the Act in the case of monthly premiums under section 1839 of the Act).

§ 423.871 Contract terms and conditions.

(a) *General.* Except as may be appropriate to carry out the requirements of this section, the terms and conditions of contracts with eligible fallback entities offering fallback prescription drug plans are the same as the terms and conditions of contracts at § 423.504 for prescription drug plans.

(b) *Period of contract.* Except as may be renewed after a subsequent bidding process, a contract with a fallback entity for fallback service areas for a PDP region is in effect for a period of 3 years. However, a fallback prescription drug plan may be offered for any year within the contract period for a particular area only if the area is a fallback service area for that year.

(c) *Entity not permitted to market or brand fallback prescription drug plans.* An eligible fallback entity with a contract under this part may not engage in any marketing or branding of a fallback prescription drug plan.

(d) *Performance measures.* CMS issues guidance establishing performance measures for fallback prescription drug plans based on the following:

(1) *Types of Performance Measures.* Performance measures include at least measures for each of the following:

(i) *Costs.* The entity contains costs to the Medicare Prescription Drug Account and to Part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity through mechanisms such as generic substitution and price discounts, including discounts from manufacturers.

(ii) *Quality programs.* The entity provides the enrollees with quality programs that avoid adverse drug reactions and over utilization and reduce medical errors.

(iii) *Customer service.* The entity provides timely and accurate delivery of services and pharmacy and beneficiary support services.

(iv) *Benefit administration and claims adjudication.* The entity provides efficient and effective benefit administration and claims adjudication.

(2) *Development of performance measures.* CMS establishes detailed performance measures for use in evaluating fallback entity performance and determination of certain management fees based on criteria from historical performance, application of acceptable statistical measures of variation to fallback entity and PDP sponsor experience nationwide during a base period, or changing program emphases or requirements.

(e) *Payment terms.* A contract approved with a fallback entity includes terms for payment for—

(1) The actual costs (taking into account negotiated price concessions described in § 423.108(d) of covered Part D drugs provided to Part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity); and

(2) Management fees that are tied to the performance measures established by CMS for the management, administration, and delivery of the benefits under the contract as provided under paragraph (d) of this section.

(f) *Requirement for the submission of information.* Each contract for a fallback prescription drug plan requires an eligible fallback entity offering a fallback prescription drug plan to provide CMS with the information CMS determines is necessary to carry out this section, or as required by law. Officers, employees and contractors of the Department of Health and Human Services may use any information disclosed or obtained in accordance with the provisions of this part only for the purposes of, and to the extent necessary in, carrying out this part. This restriction does not limit OIG authority to conduct audits and evaluations necessary for carrying out these regulations.

(g) *Amendment to reflect changes in service area.* The contract may be amended by CMS at any time as needed to reflect the exact regions or counties to be included in the fallback service area(s).

§ 423.875 Payments to fallback plans.

The amount payable for a fallback prescription drug plan is the amount determined under the contract for the plan in accordance with § 423.871(e).

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

§ 423.880 Basis and scope.

(a) *Basis.* This subpart is based on section 1860D–22 of the Act, as amended by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

(b) *Scope.* This section implements the statutory requirement that a subsidy payment be made to sponsors of qualified retiree prescription drug plans.

§ 423.882 Definitions.

For the purposes of this subpart, the following definitions apply:

Allowable retiree costs in accordance with section 1860D–22(a)(3)(C)(i) of the Act, means gross covered retiree plan-related prescription drug costs between

the cost threshold and cost limit, as defined under § 423.886(b), that are actually paid by either the qualified retiree prescription drug plan or the qualifying covered retiree (or on the retiree's behalf), net of any manufacturer or pharmacy discounts, chargebacks, rebates, and similar price concessions.

Covered Part D drug has the same meaning as defined in § 423.100.

Retiree drug subsidy amount means the subsidy amount paid to sponsors of qualified retiree prescription drug coverage under § 423.886(a).

Employment-based retiree health coverage means coverage of health care costs under a group health plan based on an individual's status as a retired participant in the plan, or as the spouse or dependent of a retired participant. The term includes coverage provided by voluntary insurance coverage, or coverage as a result of statutory or contractual obligation.

Gross covered retiree plan-related prescription drug costs, or gross retiree costs means, for a qualifying covered retiree who is enrolled in a qualified retiree prescription drug plan during a plan year, non-administrative costs incurred under the plan for covered Part D drugs during the year, whether paid for by the plan or the retiree, including costs directly related to the dispensing of covered Part D drugs.

Group health plan has the same meaning as defined in section 607(1) of ERISA, 29 U.S.C. 1167(1). This definition also includes the following plans:

(1) *Federal and State governmental plan* means a plan established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision of a State, or by any agency or instrumentality or any of the foregoing, including a health benefits plan offered under chapter 89 of title 5, United States Code (the Federal Employee Health Benefit Plan (FEHBP)).

(2) *Collectively bargained plan* means a plan established or maintained under or by one or more collective bargaining agreements.

(3) *Church plan* means a plan established and maintained for its employees or their beneficiaries by a church or by a convention or association of churches that is exempt from tax under section 501 of the Internal Revenue Code of 1986 (26 U.S.C. 501).

Part D eligible individual is defined in § 423.4 of our proposed rule.

Qualified retiree prescription drug plan means employment-based retiree health coverage that meets the requirements set forth in § 423.884(a) through (d) of this chapter for a Part D

eligible individual who is a participant or beneficiary under the coverage.

Qualifying covered retiree means a Part D eligible individual who is a participant under the qualified retiree prescription drug plan or the spouse or dependent of a participant under the qualified prescription drug plan, who is not enrolled in a Part D prescription drug plan or a Medicare Advantage-Prescription Drug (MA–PD) plan.

Standard Prescription Drug Coverage has the same meaning as defined in § 423.100.

Sponsor is a plan sponsor as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974 (ERISA), except that, in the case of a plan maintained jointly by one employer and an employee organization and for which the employer is the primary source of financing, the term means the employer.

§ 423.884 Requirements for qualified retiree prescription drug plans.

A qualified retiree prescription drug plan must meet the requirements of this section.

(a) *Actuarial Attestation.* The sponsor of the plan (or a plan administrator designated by the sponsor) provides to CMS an attestation that the actuarial value of the retiree prescription drug coverage under the plan is at least equal to the actuarial value of the standard prescription drug coverage under Part D. The attestation must—

(1) Be provided annually, no later than 90 days prior to the start of the calendar year, except that for 2006, the attestation must be provided by September 30, 2005;

(2) Be provided no later than 90 days before the implementation of a material change to the drug coverage of the plan that impacts the actuarial value of the coverage;

(3) Certify that the values have been calculated according to established CMS actuarial guidelines based on generally accepted actuarial principles;

(4) Be certified by a qualified actuary who is a member of the American Academy of Actuaries. Applicants may use qualified outside actuaries.

(5) Be signed under the penalty of perjury;

(6) State that the information contained in the attestation is true and accurate to the best of the attester's knowledge;

(7) Contain an acknowledgement that the information being provided in the attestation is being used to obtain Federal funds.

(b) *Sponsor application for the subsidy payment.*

(1) *Deadlines.* The sponsor must submit an application for the subsidy,

signed by an authorized representative of the sponsor, to CMS by no later than for:

- (i) The year 2006, September 30, 2005.
- (ii) All other years, 90 days prior to the start of the year.

(iii) Plans that begin coverage in the middle of a year, 90 days prior to the date the coverage begins.

(iv) New plans that institute coverage after September 30, 2005, 150 days prior to the start of the new plan.

(2) *Required information.* The following information must be submitted with the application:

- (i) Employer Tax ID Number (if applicable).
- (ii) Sponsor name and address.
- (iii) Contact name and email address.
- (iv) Actuarial attestation and supporting documentation for each qualified retiree prescription drug plan for which the sponsor seeks subsidy payments.
- (v) Full names of each qualifying covered retiree enrolled in each prescription drug plan (including spouses and dependents, if Medicare-eligible), and the following information:

(A) Health Insurance Claim (HIC) number (when available).

(B) Date of birth.

(C) Sex.

(D) Social Security number.

(E) Relationship to the retired employee.

(3) *Terms and conditions.* The application must specify acceptance of the terms and conditions of eligibility to receive a subsidy payment. The sponsor must—

(i) Agree to comply with all Federal laws and regulations, and the terms and conditions of eligibility for a subsidy payment, including those concerning auditing of claims for subsidy payments and combating fraud and abuse;

(ii) Acknowledge that the information is being provided to obtain Federal funds;

(iii) Require that all subcontractors, including administrators, acknowledge that information provided in connection with the subcontract is used for purposes of obtaining Federal funds;

(iv) Sign any further certification that CMS may require.

(4) *Signature by sponsor.* An authorized representative of the requesting sponsor must sign the completed application. The signed application constitutes an agreement between CMS and the sponsor.

(5) *Updates.* The sponsor (or the plan administrator designated by the sponsor) must provide updates to CMS of the information required in paragraph (b)(2) of this section in the manner and frequency specified by CMS.

(6) *Data match.* Once the full application for the subsidy payment is submitted, CMS—

- (i) Matches the names of the qualifying covered retirees and the identifying information of each retiree with the Medicare Data Base (MBD) to determine which retirees are qualifying covered retirees.
- (ii) Provides to the sponsor (or to a plan administrator designated by a sponsor) the names, and other identifying information if necessary, of the sponsor's qualifying covered retirees.

(c) *Disclosure of creditable coverage status.* The sponsor must disclose to all of its retirees and their spouses and dependents eligible to participate in its plan who are Part D eligible individuals whether the coverage is creditable coverage under § 423.4 in accordance with the notification requirements under § 423.56.

(d) *Audits, CMS access to records.*

The sponsor must meet the requirements of § 423.888 (d).

§ 423.886 Retiree drug subsidy amounts.

(a) *Amount of subsidy payment.* For each qualifying covered retiree enrolled with the sponsor of a qualified retiree prescription drug plan in a plan year in which the retiree's gross covered retiree plan-related prescription drug costs (as defined in § 423.882) exceeds the cost threshold defined in paragraph (b)(1) of this section, the sponsor receives a subsidy payment in the amount of 28 percent of the allowable retiree costs (as defined in § 423.882) attributable to the gross covered prescription drug costs between the cost threshold and the cost limit defined in paragraph (b)(2) of this section.

(b) *Cost threshold and cost limit.* The following cost threshold and cost limits apply—

(1) Subject to paragraph (b)(3) of this section, the cost threshold under this section is equal to \$250 for calendar year 2006.

(2) Subject to paragraph (b)(3) of this section, the cost limit under this section is equal to \$5,000 for calendar year 2006.

(3) The cost threshold and cost limit specified in paragraphs (b)(1) and (b)(2) of this section, for years after 2006, is adjusted in the same manner as the annual Part D deductible and the annual Part D out-of-pocket threshold are adjusted annually under §§ 423.104(e)(1)(ii) and (e)(4)(iii)(B), respectively.

§ 423.888 Payment methods, including provision of necessary information.

(a) *Basis.* The provisions of § 423.301 through § 423.343, including

requirement to provide information necessary to ensure accurate subsidy payments, govern payment under § 423.886.

(b) *Payment.* Payment under § 423.886 is conditioned on provision of accurate and truthful information in a form and manner specified by CMS. When directed by the sponsor of a qualified retiree prescription drug plan applying for payment under this section, the qualified retiree prescription drug plan (or an administrator or insurer of the qualified retiree prescription drug plan, if applicable) must submit in the form and manner CMS specifies, the information required to CMS.

(c) *Use of information provided.*

Officers, employees and contractors of the Department of Health and Human Services, including the Office of Inspector General (OIG), may use information collected under paragraphs (a) and (d) of this section only for the purposes of, and to the extent necessary in, carrying out this subpart including, but not limited to, determination of payments and payment-related oversight and program integrity activities, or as otherwise required by law. This restriction does not limit OIG authority to conduct audits and evaluations necessary for carrying out these regulations.

(d) *Maintenance of records.* (1) The sponsor of the qualified retiree prescription drug plan and the qualified retiree prescription drug plan (or an administrator or insurer of the qualified retiree prescription drug plan), as applicable, must maintain, and furnish to CMS or the Office of Inspector General (OIG) upon request, the records enumerated in paragraph (d)(3) of this section. The records must be maintained for 6 years after the expiration of the plan year in which the costs were incurred for the purposes of audits and other oversight activities conducted by CMS to assure the accuracy of the actuarial attestation and the accuracy of payments.

(2) CMS or the OIG may extend the 6-year retention requirement in the event of an ongoing investigation, litigation or negotiation.

(3) The records that must be retained are:

(i) Reports and working documents of the actuaries who wrote the attestation submitted in accordance with § 423.884(a).

(ii) All documentation of costs incurred and other relevant information utilized for calculating the amount of the subsidy payment made in accordance with § 423.886, including the underlying claims data.

§ 423.890 Appeals.(a) *Informal written reconsideration.*

(1) *Initial determinations.* A sponsor is entitled to an informal written reconsideration of an adverse initial determination. An initial determination is a determination regarding the following:

(i) The amount of the subsidy payment.

(ii) The actuarial equivalence of the sponsor's retiree prescription drug plan.

(iii) If an enrollee in a retiree prescription drug plan is a qualifying covered retiree; or

(iv) Any other similar determination (as determined by CMS) that affects eligibility for, or the amount of, a subsidy payment.

(2) *Effect of an initial determination regarding the retiree drug subsidy.* An initial determination is final and binding unless reconsidered in accordance with this paragraph (a).

(3) *Manner and timing for request.* A request for reconsideration must be made in writing and filed with CMS within 15 days of the date on the notice of adverse determination.

(4) *Content of request.* The request for reconsideration must specify the findings or issues with which the sponsor disagrees and the reasons for the disagreements. The request for reconsideration may include additional documentary evidence the sponsor wishes CMS to consider.

(5) *Conduct of informal written reconsideration.* In conducting the reconsideration, CMS reviews the subsidy determination, the evidence and findings upon which it was based, and any other written evidence submitted by the sponsor or by CMS before notice of the reconsidered determination is made.

(6) *Decision of the informal written reconsideration.* CMS informs the sponsor of the decision orally or through electronic mail. CMS sends a written decision to the sponsor on the sponsor's request.

(7) *Effect of CMS informal written reconsideration.* A reconsideration decision, whether delivered orally or in writing, is final and binding unless a request for hearing is filed in accordance with paragraph (b) of this section, or it is revised in accordance with paragraph (d) of this section.

(b) *Right to informal hearing.* A sponsor dissatisfied with the CMS reconsideration decision is entitled to an informal hearing as provided in this section.

(1) *Manner and timing for request.* A request for a hearing must be made in writing and filed with CMS within 15

days of the date the sponsor receives the CMS reconsideration decision.

(2) *Content of request.* The request for informal hearing must include a copy of the CMS reconsideration decision (if any) and must specify the findings or issues in the decision with which the sponsor disagrees and the reasons for the disagreements.

(3) *Informal hearing procedures.* (i) CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The hearings are conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made both its initial and reconsideration determinations.

(iii) If CMS did not issue a written reconsideration decision, the hearing officer may request, but not require, a written statement from CMS or its contractors explaining CMS' determination, or CMS or its contractors may, on their own, submit the written statement to the hearing officer. Failure of CMS to submit a written statement does not result in any adverse findings against CMS and may not in any way be taken into account by the hearing officer in reaching a decision.

(4) *Decision of the CMS Hearing Officer.* The CMS hearing officer decides the case and sends a written decision to the sponsor, explaining the basis for the decision.

(5) *Effecting of hearing officer decision.* The hearing officer decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (c) of this section.

(c) *Review by the Administrator.* (1) A sponsor that has received a hearing officer decision upholding a CMS initial or reconsidered determination may request review by the Administrator within 15 days of receipt of the hearing officer's decision.

(2) The Administrator may review the hearing officer's decision, any written documents submitted to CMS or to the hearing officer, as well as any other information included in the record of the hearing officer's decision and determine whether to uphold, reverse or modify the hearing officer's decision.

(3) The Administrator's determination is final and binding.

(d) *Reopening.* (1) *Ability to reopen.* CMS may reopen and revise an initial or reconsidered determination upon its own motion or upon the request of a sponsor:

(i) Within 1 year of the date of the notice of determination for any reason.

(ii) Within 4 years for good cause.

(iii) At any time when the underlying decision was obtained through fraud or similar fault.

(2) *Notice of reopening.* (i) Notice of reopening and any revisions following the reopening are mailed to the sponsor.

(ii) Notice of reopening specifies the reasons for revision.

(3) *Effect of reopening.* The revision of an initial or reconsidered determination is final and binding unless—

(i) The sponsor requests reconsideration in accordance with paragraph (a) of this section;

(ii) A timely request for a hearing is filed under paragraph (b) of this section;

(iii) The determination is reviewed by the Administrator in accordance with paragraph (c) of this section; or

(iv) The determination is reopened and revised in accordance with paragraph (d) of this section.

(4) *Good cause.* For purposes of this section, CMS finds good cause if—

(i) New and material evidence that was not readily available at the time the initial determination was made is furnished;

(ii) A clerical error in the computation of payments was made; or

(iii) The evidence that was considered in making the determination clearly shows on its face that an error was made.

(5) For purposes of this section, CMS does not find good cause if the only reason for reopening is a change of legal interpretation or administrative ruling upon which the initial determination was made.

§ 423.892 Change in ownership.

(a) *Change of ownership.* Any of the following constitutes a change of ownership:

(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law, constitutes a change of ownership.

(2) *Asset sale.* Transfer of substantially all of the assets of the sponsor to another party constitutes a change of ownership.

(3) *Corporation.* The merger of the sponsor's corporation into another corporation or the consolidation of the sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership, exception.* Transfer of corporate stock or the merger of another corporation into the sponsor's corporation, with the sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement.* A sponsor that has a retiree drug subsidy agreement in effect under this part and is considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change.

(d) *Assignment of agreement.* When there is a change of ownership as specified in paragraph (a) of this section, and this results in a transfer of the liability for prescription drug costs the existing sponsor agreement is automatically assigned to the new owner.

(e) *Conditions that apply to assignment agreements.* The new owner to whom a sponsor agreement is assigned is subject to all applicable statutes and regulations and to the terms and conditions of the sponsor agreement.

§ 423.894 Construction.

Nothing in this part must be interpreted as prohibiting or restricting—

(a) A Part D eligible individual who is covered under employment-based retiree health coverage, including a qualified retiree prescription drug plan, from enrolling in a prescription drug plan or in a MA-PD plan;

(b) A sponsor or other person from paying all or any part of the monthly beneficiary premium (as defined in § 423.286) for a prescription drug plan or MA-PD plan on behalf of a retiree (or his or her spouse or dependents);

(c) A sponsor from providing coverage to Part D eligible individuals under employment-based retiree health coverage that is—

(1) Supplemental to the benefits provided under a prescription drug plan or a MA-PD plan.

(2) Of higher actuarial value than the actuarial value of standard prescription drug coverage (as defined in § 423.104(e)); or

(d) Sponsors from providing for flexibility in the benefit design and pharmacy network for their qualified retiree prescription drug coverage, without regard to the requirements applicable to PDPs and MA-PD plans under § 423.104, as long as the requirements under § 423.884 are met.

Subpart S—Special Rules for States—Eligibility Determinations for Subsidies and General Payment Provisions

§ 423.900 Basis and scope.

(a) *Basis.* This subpart is based on sections 1935(a) through (d) of the Act as amended by section 103 of the MMA.

(b) *Scope.* This subpart specifies State agency obligations for the Part D prescription drug benefit.

§ 423.902 Definitions.

The following definitions apply to this subpart:

Actuarial value of capitated prescription drug benefits is the estimated actuarial value of prescription drug benefits provided under a capitated Medicaid managed care plan per full-benefit dual eligible individual for 2003, as determined using data as the Secretary determines appropriate.

Applicable growth factor for each of 2004, 2005, and 2006, is the average annual percent change (to that year from the previous year) of the per capita amount of prescription drug expenditures (as determined based on the most recent National Health Expenditure projections for the years involved). The growth factor for 2007 and succeeding years will equal the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals for the 12-month period ending in July of the previous year.

Base year Medicaid per capita expenditures is equal to the weighted average of:

(1) The gross base year (calendar year 2003) per capita Medicaid expenditures for prescription drugs, reduced by the rebate adjustment factor; and

(2) The estimated actuarial value of prescription drug benefits provided under a capitated Medicaid managed care plan per full-benefit dual eligible for 2003. The per capita payments for full benefit dual eligibles with managed care and non-managed care are weighted by the respective average monthly full dual eligible enrollment populations.

Full-benefit dual eligible individual means an individual who, for any month—

(1) Has coverage for the month under a prescription drug plan under Part D of title XVIII, or under an MA-PD plan under Part C of title XVIII; and

(2) Is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. (This does not include individuals under Pharmacy Plus demonstrations.) It also includes any individual who is determined by the State to be eligible for medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) of the Act for any month if the individual was eligible for medical assistance in any part of the

month. For the 2003 baseline calculations, the full-benefit dual eligibles are those individuals having Medicaid drug benefit coverage and Medicare Part A or Part B coverage.

Gross base year Medicaid per capita expenditures are equal to the expenditures, including dispensing fees, made by the State during calendar year 2003 for covered outpatient drugs, excluding drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1860D-2 of the Act, other than smoking cessation agents determined per full-benefit-dual-eligible-individual for the individuals not receiving medical assistance for the drugs through a Medicaid managed care plan. This amount is determined based on MSIS drug claims paid during the four quarters of calendar year 2003 and the associated dual eligibility enrollment status of the beneficiary.

Phased-down State contribution factor for a month in 2006 is 90 percent; in 2007 is 88 1/3 percent; in 2008 is 86 2/3 percent; in 2009 is 85 percent; in 2010 is 83 1/3 percent; in 2011 is 81 2/3 percent; in 2012 is 80 percent; in 2013 is 78 1/3 percent; in 2014 is 76 2/3 percent; or after December 2014, is 75 percent.

Phased-down State contribution payment refers to the States' monthly payment made to the Federal government beginning in 2006 to defray a portion of the Medicare drug expenditures for full benefit dual eligible individuals whose Medicaid drug coverage is assumed by Medicare Part D. The contribution is calculated by 1/12th of the product of the base year (2003) Medicaid per capita expenditures for prescription drugs (that is, covered Part D drugs) for full-benefit dual eligible individuals, and multiplied by the—

(1) State medical assistance percentage;

(2) Applicable growth factor;

(3) Number of the State's full-benefit dual eligibles for the given month; and

(4) Phased-down State contribution factor.

Rebate adjustment factor takes into account drug rebates and, for a State, is equal to the ratio for the State for the four quarters of calendar year 2003 of aggregate rebate payments received by the State under section 1927 of the Act to the gross expenditures for covered outpatient drugs.

State Medical Assistance Percentage means the proportion equal to 100 percent minus the State's Federal medical assistance percentage, applicable to the State for the fiscal year in which the month occurs.

§ 423.904 Eligibility determinations for low-income subsidies.

(a) *General rule.* The State agency must make eligibility determinations and redeterminations for low-income premium and cost-sharing subsidies in accordance with § 423.774.

(b) *Notification to CMS.* The State agency must inform CMS of cases where eligibility is established or redetermined, in a manner determined by CMS.

(c) *Screening for eligibility for Medicare cost-sharing and enrollment under the State plan.* States must—

(1) Screen individuals who apply for subsidies under this part for eligibility for Medicaid programs that provide assistance with Medicare cost-sharing specified in section 1905(p)(3) of the Act.

(2) Offer enrollment for the programs under the State plan (or under a waiver of the plan) for those meeting the eligibility requirements.

(3) Notify deemed subsidy eligibles of their subsidy eligibility in accordance with the requirements of § 423.34(d).

(d) *Application form and process.*

(1) *Assistance with application.* No later than July 1, 2005, States must make available—

(i) Low-income subsidy application forms;

(ii) Information on the nature of, and eligibility requirements for, the subsidies under this section; and

(iii) Assistance with completion of low-income subsidy application forms.

(2) *Completion of application.* The State must require an individual or personal representative applying for the low-income subsidy to—

(i) Complete all required elements of the application and provide documents, as necessary, consistent with paragraph (3) of this section; and

(ii) Certify, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the application form.

(3) *The application process and States.*

(i) States may require submission of statements from financial institutions for an application for low-income subsidies to be considered complete; and

(ii) May require that information submitted on the application be subject to verification in a manner the State

determines to be most cost-effective and efficient.

(4) *Other information.* States must provide CMS with other information as specified by CMS that may be needed to carry out the requirements of the Part D prescription drug benefit.

§ 423.906. General payment provisions.

(a) *Regular Federal matching.* Regular Federal matching applies to the eligibility determination and notification activities specified in § 423.904(a) and (b).

(b) *Medicare as primary payer.* Medicare is the primary payer for covered drugs for Part D eligible individuals. Medicaid assistance is not available to full benefit dual eligible individuals, including those not enrolled in a PDP or MA-PD, for—

(1) Covered Part D drugs; or
(2) Any cost-sharing obligations under Part D relating to covered Part D drugs.

(3) The effective date of paragraphs (b)(1) and (b)(2) of this section is January 1, 2006.

(c) *Non-covered drugs.* States may elect to provide coverage for outpatient drugs other than covered Part D drugs in the same manner as provided for non-full benefit dual eligible individuals or through an arrangement with a prescription drug plan or a MA-PD plan.

§ 423.907 Treatment of territories.

(a) *General rules.* (1) Low-income Part D eligible individuals who reside in the territories are not eligible to receive premium and cost-sharing subsidies under subpart P of this part.

(2) A territory may submit a plan to the Secretary under which medical assistance is to be provided to low-income individuals for the provision of covered Part D drugs.

(3) Territories with plans approved by the Secretary will receive increased grants under sections 1108 (h) and (g) of the Act as described in (c) of this section.

(b) *Plan requirements.* Plans submitted to the Secretary must include the following:

(1) A description of the medical assistance to be provided.

(2) The low-income population (income less than 150 percent of the Federal poverty level) to receive medical assistance.

(3) An assurance that no more than 10 percent of the amount of the increased grant will be used for administrative expenses.

(c) *Increased grant amounts.* The amount of the grant provided under sections 1108 (h) and (k) of the Act for each territory with an approved plan for a year shall be the amount in paragraph (d) of this section multiplied by the ratio of—

(1) The number of individuals who are entitled to benefits under Part A or enrolled under Part B and who reside in the territory (as determined by the Secretary based on the most recent available data for the beginning of the year); and

(2) The sum of the number of individuals in all territories in paragraph (c)(1) of this section with approved plans.

(d) *Total grant amount.* The total grant amount is—

(1) For the last three quarters of fiscal year 2006, \$28,125,000;

(2) For fiscal year 2007, \$37,500,000; and

(3) For each subsequent year, the amount for the prior fiscal year increased by the annual percentage increase described in § 423.104.

§ 423.908. Phased-down State contribution to drug benefit costs assumed by Medicare.

This subpart sets forth the requirements for State contributions for Part D drug benefits based on dual eligible drug expenditures.

§ 423.910 Requirements.

(a) *General rule.* Each of the 50 States and the District of Columbia is required to provide for payment to the Secretary a phased-down contribution to defray a portion of the Medicare drug expenditures for individuals whose projected Medicaid drug coverage is assumed by Medicare Part D.

(b) *State contribution payment.* (1) *Calculation of payment.* The State contribution payment is calculated by the Secretary on a monthly basis, as indicated in the chart below. For States that do not meet the quarterly reporting requirement for the monthly enrollment reporting, the state contribution payment is calculated using a methodology determined by the Secretary.

ILLUSTRATIVE CALCULATION OF STATE PHASED-DOWN MONTHLY CONTRIBUTION FOR 2006

Item	Illustrative value	Source
(i) Gross per capita Medicaid expenditures for prescription drugs for 2003 for full-benefit dual eligibles not receiving drug coverage through a Medicaid managed care plan, excluding drugs not covered by Part D.	\$2,000	CY MSIS data.

ILLUSTRATIVE CALCULATION OF STATE PHASED-DOWN MONTHLY CONTRIBUTION FOR 2006—Continued

Item	Illustrative value	Source
(ii) Aggregate State rebate receipts in calendar year 2003	\$100,000,000	CMS–64.
(iii) Gross State Medicaid expenditures for prescription drugs in calendar year 2003.	\$500,000,000	CMS–64.
(iv) Rebate adjustment factor	0.2000	$(2) \div (3)$.
(v) Adjusted 2003 gross per capita Medicaid expenditures for prescription drugs for full-benefit dual eligibles not in managed care plans.	\$1,600	$(1) \times [1-(4)]$.
(vi) Estimated actuarial value of prescription drug benefits under capitated managed care plans for full-benefit dual eligibles for 2003.	\$1,500	To Be Determined.
(vii) Average number of full-benefit dual eligibles in 2003 who did not receive covered outpatient drugs through Medicaid managed care plans.	90,000	CY MSIS data.
(viii) Average number of full-benefit dual eligibles in 2003 who received covered outpatient drugs through Medicaid managed care plans.	10,000	CY MSIS data.
(ix) Base year State Medicaid per capita expenditures for covered Part D drugs for full-benefit dual eligible individuals (weighted average of (5) and (6)).	\$1,590	$[(7) \times (5) + (8) \times (6)] \div [(7) + (8)]$.
(x) 100 minus Federal Medical Assistance Percentage (FMAP) applicable to month of state contribution (as a proportion).	0.4000	FEDERAL REGISTER.
(xi) Applicable growth factor (cumulative increase from 2003 through 2006)	50.0%	NHE projections.
(xii) Number of full-benefit dual eligibles for the month	120,000	State submitted data.
(xiii) Phased-down State reduction factor for the month	0.9000	Specified in statute.
(xiv) Phased-down State contribution for the month	\$8,586,000	$1/12 \times (9) \times (10) \times [1+(11)] \times (12) \times (13)$.

(2) *Method of payment.* State payment must be made in a manner specified by the Secretary that is similar to the manner in which State payments are made under an agreement entered into under section 1843 of the Act, except that all payments must be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

(3) *Failure to pay.* If a State fails to pay to the Secretary the required amount, interest accrues on the amount at the rate provided under section 1903(d)(5) of the Act. The amount so owed and applicable interest must be immediately offset against amounts otherwise payable to the State under section 1903(a) of the Act, in accordance with the Federal Claims Collection Act of 1996 and applicable regulations.

(c) *State Medicaid Statistical Information System (MSIS) Reporting.* Effective with calendar year (CY) 2003 and all subsequent MSIS data submittals, States are required to provide accurate and complete coding to identify the numbers and types of

Medicaid and Medicare dual eligibles. Calendar year 2003 submittals must be complete and must be accepted, based on CMS' data quality review, by December 31, 2004.

(d) *State monthly enrollment reporting.* Effective January 2006, and each subsequent month, States must submit an electronic file, in a manner specified by the Secretary, identifying each full benefit dual eligible enrolled in the State for each month with Part D drug coverage who is also determined to be full benefit eligible by the State for full Medicaid benefits. The State will submit this file to CMS no later than 30 days after the end of each month.

(e) *Data match.* The Secretary performs those periodic data matches as may be necessary to identify and compute the number of full-benefit dual eligible individuals needed to establish the State contribution payment.

(f) *Rebate adjustment factor.* The Secretary establishes the rebate adjustment factor using total drug expenditures made and drug rebates received during calendar year 2003 as

reported on CMS 64 Medicaid expenditure reports for the four quarters of calendar year 2003 that were received by CMS on or before March 31, 2004. Rebates include rebates received under the national rebate agreement and under a State supplemental rebate program, as reported on CMS–64 expenditure reports for the four quarters of calendar year 2003.

(g) *Annual per capita drug expenditures.* The Secretary notifies each State no later than October 15 before each calendar year, beginning October 15, 2005, of their annual per capita drug payment expenditure amount for the next year.

Mark B. McClellan,
Administrator, Centers for Medicare & Medicaid Services.

Approved: July 23, 2004.

Tommy G. Thompson,
Secretary.

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