

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Part 423**

[CMS-4130-P]

RIN 0938-A074

Medicare Program; Policy and Technical Changes to the Medicare Prescription Drug Benefit**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Proposed rule.

SUMMARY: This proposed rule would both codify prior clarifications of our policies associated with the Medicare Prescription Drug Benefit (also known as Medicare Part D) and propose certain clarifications of these policies. *These clarifications include the following:* Codifying our expectations of Part D sponsors regarding providing adequate access to home infusion pharmacies for infused covered Part D drugs and proposing standards with respect to timeliness of delivery of drugs; codifying our guidance that certain supplies associated with the inhalation of insulin are included in the definition of Part D drug; refining our definition of what may be included in the drug costs Part D sponsors use as the basis for calculating beneficiary cost sharing, reporting drug costs to CMS for the purposes of reinsurance reconciliation and risk sharing, as well submitting bids to CMS; reiterating our previous guidance explaining how we interpret the statutory exclusion from the definition of a Part D drug for any drug when used for the treatment of sexual or erectile dysfunction, unless that drug was used for an FDA-approved purpose other than sexual or erectile dysfunction; and codifying our guidance on plan-to-plan reconciliation and reconciliation to a payer other than the Part D of record. In addition, we are correcting the regulations to ensure that they reflect the appropriate subsidy for partial subsidy individuals subject to a late enrollment penalty. We also propose changes to the retiree drug subsidy regulations, including permitting non-calendar year plans to choose between the current year's or the subsequent year's Part D cost limits in certain circumstances and codifying our previous guidance on aggregating plan options for purposes of meeting the net test for actuarial equivalence.

DATES: To be assured consideration, comments must be received at one of

the addresses provided below, no later than 5 p.m. on July 24, 2007.

ADDRESSES: In commenting, please refer to file code CMS-4130-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Submit electronic comments on CMS regulations with an open comment period." (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4130-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 express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4130-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members. Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHS 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.)

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

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

FOR FURTHER INFORMATION CONTACT: For overall questions about this proposed rule, please contact Alissa DeBoy, (410) 786-6041. For other detailed questions on clarifications and/or proposed changes herein, please contact the following individuals for the applicable subpart.

Subpart B—James Slade, (410) 786-1073.

Subpart C—Vanessa Duran, (410) 786-8697 or Gregory Dill, (312) 353-1754.

Subparts F and G—Deondra Moseley, (410) 786-4577 or Meghan Elrington, (410) 786 8675.

Subpart I—James Slade, (410) 786-1073.

Subpart J—Deborah Larwood, (410) 786-9500 or Vanessa Duran, (410) 786-8697.

Subpart K—Mark Smith, (410) 786-8015.

Subpart P—Deondra Moseley, (410) 786-4577 or Christine Hinds, (410) 786-4578.

Subpart R—Adam Shaw, (410) 786-1091.

Subpart S—Christine Hinds, (410) 786-4578.

SUPPLEMENTARY INFORMATION:

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. You can assist us by referencing the file code CMS-4130-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. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Electronic Comments on CMS Regulations" on that Web site to view public comments.

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

I. Background

The Medicare Prescription Drug Benefit (also known as Part D) is a voluntary prescription drug benefit program enacted into law on December 8, 2003 in section 101 of title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). In the January 28, 2005 **Federal Register** (70 FR 4194), we published a final rule implementing the provisions of Part D, and these provisions became effective March 22, 2005.

Since publication of the January 28, 2005 final rule, we have issued several clarifications or interpretations of the final rule by way of interpretive guidance documents. In addition, we have issued guidance explaining how we will interpret a change to the Social Security Act (“Act”) that excludes drugs used in the treatment of erectile dysfunction from Part D, with a certain exception. In order to ensure public awareness of our policies, as well as to avoid potential confusion regarding them, in this preamble, we explain many of the respective clarifications or interpretations. Relatedly, we are proposing to codify some of these clarifications in regulation through this proposed rule, as well as making certain technical corrections to the January 28, 2005 final rule.

In addition, due to our experience to date in implementing Part D, we are proposing several new clarifications of our policy for Part D plans, to be implemented in contract year 2009, on which we specifically invite public comment.

II. Provisions of the Proposed Rule

A. Subpart B—Eligibility and Enrollment

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

In the preamble of the January 28, 2005 final rule, we discussed the approval of marketing materials and enrollment forms, to correspond with the regulations text at § 423.50. (70 FR 4223) In our response to public comments, we stated that it was “appropriate to allow providers and pharmacies to *market* to beneficiaries.” (emphasis added). (70 FR 4223) When we used the term “market” in the final rule, we used the term “market” in a more general sense, to mean assisting in enrollment or education directed at beneficiaries.

Subsequent to our publication of the final rule, we issued the *Medicare Marketing Guidelines* (“*The Guidelines*”). (See Centers for Medicare

& Medicaid Services, *Medicare Marketing Guidelines for: Medicare Advantage Plans (MAs); Medicare Advantage Prescription Drug Plans (MA-PDs); Prescription Drug Plans (PDPs); 1876 Cost Plans* <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FinalMarketingGuidelines.pdf> (last updated July 25, 2006).) *The Guidelines* contain a specific definition of the term, “marketing.” The Guidelines define “marketing” as “[s]teering, or attempting to steer, an undecided potential enrollee towards a plan, or limited number of plans, and for which the individual or entity performing marketing activities expects compensation directly or indirectly from the plan for such marketing activities.” (*The Guidelines*, page 8.) This definition further clarifies that neither “[a]ssisting in enrollment” nor “education” constitute “marketing.” (*The Guidelines*, page 8.) *The Guidelines* require Part D plan sponsors to ensure that their contracted providers agree to refrain from “marketing” to beneficiaries, as that term is defined by *The Guidelines* (that is, steering or attempting to steer an undecided beneficiary toward a plan based on the provider’s financial interest). Thus, our intent in the preamble was to acknowledge that providers and pharmacies are free to engage in either “assisting in enrollment” or “education” (as those terms are defined on page 6 of *The Guidelines*), including provider promotional activities as permitted under *The Guidelines*. We believe that the context of our discussion in the preamble demonstrates that we were discussing providers and pharmacies assisting in beneficiary enrollment, based on the beneficiary’s needs, and education. This is consistent with *The Guidelines*, which encourage providers to assist beneficiaries in objective assessments of the beneficiaries’ needs and potential plan options that may meet those needs. Given that the Guidelines’ definition of “market” was not issued until after publication of the final rule, we wish to emphasize our consistent policy: providers and pharmacies that are contracted with plan sponsors may not “market” to beneficiaries, as the term is defined in *The Guidelines*. However, providers and pharmacies may assist in enrollment, including participating in provider promotion activities within the parameters established in *The Guidelines*, and educate beneficiaries. We clarify this policy here in this proposed rule so as to avoid any confusion arising from our inaccurate

use of the term “market” in our discussion of the approval of marketing materials and enrollment forms in the January 28, 2005 final rule.

Section 423.50(f)(1)(v) states that in conducting marketing activities, a Part D plan may not “[u]se providers, provider groups, or pharmacies to distribute printed information comparing the benefits of different Part D plans unless the providers, provider groups or pharmacies accept and display materials from all Part D plan sponsors.” (70 FR 4532) One might infer from this language that when a Part D plan uses providers, provider groups, or pharmacies to distribute printed information comparing the benefits of different Part D plans, that the providers, provider groups, or pharmacies must not only accept and display printed information comparing the benefits of the Part D plans with whom they contract, but that they also must accept and display printed information comparing the benefits of different Part D plans with whom they do *not* contract. This interpretation would likely lead to beneficiary confusion because if a provider were required, per its contract with Part D plan sponsors, to display materials for plans with which the provider does not contract, beneficiaries, who may want to continue using the applicable provider because the provider has a history with the beneficiary, may mistakenly believe that he or she may continue to use the applicable non-contracted provider and receive the maximum amount of benefit. Even though we are requiring that plan sponsors only require their contracted providers to accept and display comparative materials from plans with which the provider contracts, *the Guidelines* require that providers in a health care setting inform prospective enrollees where they can obtain information on the full range of plan options, including referring beneficiaries to 1–800–MEDICARE, <http://www.medicare.gov>, State Health Insurance Assistance Programs. (*The Guidelines*, page 124.) We clarify here that a Part D plan can use providers, provider groups, or pharmacies to distribute printed information comparing the benefits of different Part D plans, so long as the providers, provider groups, or pharmacies accept and display printed information comparing the benefits of different Part D plans with whom they contract; the providers, provider groups, or pharmacies are not obliged to accept and display any comparative information regarding those Part D plans with whom they do *not* contract. This

clarification applies to comparative marketing materials and is in accord with *The Guidelines*. (*The Guidelines*, page 125.) We are codifying the policy in regulation by revising § 423.50(f)(1) to indicate a Part D plan may use providers, provider groups and pharmacies to distribute printed information comparing the benefits of different plans, so long as the providers, provider groups or pharmacies accept and display materials from all Part D plan sponsors with which the providers, provider groups or pharmacies contract.

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

In the regulation text of the January 28, 2005 final rule, we have identified a typographical error in § 423.56(b)(6). As published, § 423.56(b)(6) directs the reader to reference § 423.205 for a definition of the term “Medicare supplemental policy”. (70 FR 4532) However, the proper reference for the definition of the term “Medicare supplemental policy” is § 403.205. Therefore, we are revising the regulation text accordingly to state the correct reference; that is, § 403.205.

B. Subpart C—Benefits and Beneficiary Protections

1. Definitions

a. Part D Drug

(1) Erectile Dysfunction

In the preamble of the January 28, 2005 final rule (70 FR 4228 *et seq.*), we addressed the regulatory definition of the term “Part D drug” in § 423.100. (70 FR 4534) We stated that in accordance with section 1860D–2(e)(2) of the Act, the definition of a 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 under section 1927(d)(2) of the Act, with the exception of smoking cessation agents. On October 26, 2005, section 1860D–2(e)(2)(A) of the Act was amended to exclude from the statutory definition of a Part D drug “a drug when used for the treatment of sexual or erectile dysfunction, unless such drug were used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the Food and Drug Administration.” Consequently, beginning January 1, 2007, erectile dysfunction (ED) drugs will not be classified as Part D drugs under § 423.100 when they are used for the treatment of sexual or erectile dysfunction, unless they are used to treat a condition, other than sexual or

erectile dysfunction, for which the drug has been approved by the FDA. We note here that ED drugs will also not meet the definition of a Part D drug for off-label uses that by definition are not approved by the FDA. This includes non-FDA-approved uses contained in one of the compendia listed in section 1927(g)(1)(B)(i) of the Act: American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information (or its successor publications), and the DRUGDEX Information System.

This ED exclusion is cited in 1927(d)(2)(K), and because our definition of a Part D drug in § 423.100(2)(ii) excludes drugs which may be excluded under section 1927(d)(2) of the Act, no regulation text change is required. Similar to other excluded drugs contained in section 1927(d)(2) of the Act, those plans that wish to continue coverage of ED drugs may do so as a supplemental benefit through enhanced alternative coverage, consistent with existing policy. To ensure adequate notice of this new ED exclusion, we issued a question and answer (Q&A) notice to plans throughout our Healthcare Plan Management System (HPMS) on July 10, 2006 (Q&A 7682 http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_alp.php?p_sid=F*VR*Ygi). We believe that this Q&A, coupled with a considerable amount of media attention on the topic, has provided the industry a significant amount of notice regarding the implementation of this ED exclusion. Our provider and beneficiary outreach programs are also including the new ED exclusion in their broader education program to ensure all groups are prepared for the implementation of the ED exclusion on January 1, 2007.

(2) Morbid Obesity

Section 423.100 defines the term “Part D drug” and excludes from that definition “[d]rugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents.” (70 FR 4534) In the corresponding preamble of the January 28, 2005 final rule, we explained that this list of excluded drugs included agents when used for anorexia, weight loss, or weight gain and agents when used for cosmetic purposes or hair growth. (70 FR 4228) However, in the preamble we erroneously asserted that to the extent that a drug was dispensed for a “medically accepted indication” (70 FR 4230) as described in section 1860D–

2(e)(1) of the Act, weight loss agents could be covered for the treatment of morbid obesity. Therefore, we clarify here that agents, when used for anorexia, weight loss, or weight gain, are specifically excluded from the definition of Part D drugs. Thus, a weight loss agent, even when not used for cosmetic purposes, is still “an agent used for anorexia, weight loss, or weight gain,” for purposes of the exclusion from the definition of Part D drug. Similar to other excluded drugs contained in section 1927(d)(2) of the Act, those plans that wish to continue coverage of weight loss agents may do so as a supplemental benefit through enhanced alternative coverage, consistent with existing policy.

Since publication of the January 28, 2005 final rule, we have received requests for clarification about our preamble language regarding drugs used to treat morbid obesity. We clarified our policy in Q&A guidance to Part D plans released in Spring 2005. (Q&A 5279 http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_alp.php?p_sid=7KFqChi.) There, we stated that weight loss agents prescribed for the treatment of morbid obesity are not Part D drugs covered under 1860D–2(e)(2) of the Act, because even though they are not used for other excluded purposes such as cosmetic or hair growth, they nevertheless remain agents for anorexia, weight loss, or weight gain that are excluded from the definition of Part D drugs under section 1860D–2(e)(2) of the Act. We note that we are not expanding or changing current policy regarding the exclusion of agents used for weight loss from the definition of Part D drug. Rather, we are clarifying existing policy regarding the definition of a Part D drug that excludes agents used for weight loss, including in connection with morbid obesity.

(3) Insulin Inhalation Drugs and Supplies

[If you choose to comment on issues in this section, please include the caption “INSULIN INHALATION DRUGS AND SUPPLIES” at the beginning of your comments.]

With the passage of the MMA, Congress included within the definition of “Part D drug” found in section 1860D–2(e) of the Act “medical supplies associated with the injection of insulin (as defined in regulations of the Secretary)” as Part D drugs. We believe that Congress’ intent was to ensure that a beneficiary with diabetes had access to both the insulin and the supplies required to deliver insulin into the body. For example, in the conference report for the MMA, the conferees

specifically stated that: "It is the intent of conferees that the definition of insulin, and medical supplies associated with the administration of insulin, as a covered prescription drug shall include medical supplies that the Secretary determines to be reasonable and necessary, such as insulin, insulin syringes, and insulin delivery devices that are not otherwise covered under the durable medical equipment benefit." (H.R. Conf. Rep. 108-391, 108th Cong., 1st Sess. at 442 (2003))

Administration of insulin by injection, especially since it involves multiple injections daily, has fueled constant research into the delivery of insulin by another route. While there have been promising developments of an alternative delivery method over the past 8 years, no other insulin delivery method had obtained FDA approval as of the time we were undertaking rulemaking to implement the Part D program. Thus, in the final rule, we interpreted the term "medical supplies associated with the injection of insulin" as comprising syringes, needles, alcohol swabs, gauze, and insulin delivery devices not otherwise covered by Part B, such as insulin pens, pen supplies, and needle-free syringes. In doing this, we provided greater detail to Part D sponsors on what exactly met the definition of a Part D drug, but, like Congress, we derived our definition based upon the only approved administration method available to diabetics at the time.

On January 26, 2006, the FDA approved the first-ever inhaled insulin. This inhaled medication is a dry powder inhaler ("DPI") that requires a patient to place a small amount of powdered insulin into a hand-held chamber that permits inhalation of the insulin into the lungs.

Subsequent to the FDA approval, we began to receive questions regarding the reimbursement of this new product. For example, inquirers wanted to know whether the inhalation supplies associated with this new product would be included in the definition of a Part D drug, because while administration by inhalation offers the beneficiary an alternative method of receiving insulin for those appropriately qualified, the chamber and any associated accessories involved in inhalation are not specifically described in the definition of a Part D drug.

Upon review of these issues, we concluded it was not Congress' intention to prevent access to this novel insulin delivery method, as doing so would deny millions of Medicare beneficiaries an alternative way to manage diabetes. Thus, we have

determined that, consistent with Congressional intent, supplies associated with the inhalation of insulin meet the definition of a Part D drug. We propose to codify our existing guidance (Q&A 7940 http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_alp.php?p_sid=sXyWmkki) and revise the definition of Part D drug to include "[s]upplies that are directly associated with delivering insulin into the body through inhalation, such as the inhalation chamber used to deliver the insulin."

While this new definition would make these insulin inhalation supplies eligible for reimbursement as a Part D drug, unless our formulary guidelines required otherwise, it would be the Part D sponsor's decision (through its Pharmacy and Therapeutics Committee) whether to place these products on the formulary. Additionally, we would expect sponsors to apply drug utilization management tools to ensure the appropriate use of these supplies.

We note that our extension of insulin-related supplies extends only to those supplies that are directly associated with delivering the insulin into the body through inhalation, such as the inhalation chamber used to deliver the insulin. Where the relationship is more indirect, for example auxiliary supplies that might be used to hold the chamber, ease actuation or store the chamber, we would not consider such items to be an insulin delivery-related supply. We reiterate our statement in the final rule that our intention is to narrowly construe what constitutes these medical supplies in order to avoid an inappropriate expansion of the Part D benefit.

(4) Vaccine Administration Fee

We also propose to amend the definition of Part D drug to include a reference to vaccine administration on or after January 1, 2008, to conform to Section 1860D-2(e)(1)(B) of the Act, which was recently amended by Section 202(b) of the Tax Relief and Health Care Act of 2006. We intend to reflect the statutory change in the final rule.

b. Long-Term Care Facilities

In the January 28, 2005 final rule, § 423.100 defines the term "long term care facility" as a "skilled nursing facility as defined in section 1819(a) of the Act, or a medical institution or a nursing facility for which payment is made for an institutionalized individual under section 1902(q)(1)(B) of the Act." (70 FR 4534) However, in our corollary discussion of that term in the preamble, we inadvertently omitted institutions

for mental disease (IMDs) from the list of facilities that meet the definition of a long term care (LTC) facility. (70 FR 4236)

Since publication of the January 28, 2005 final rule, we have received numerous requests for clarification regarding the status of IMDs in terms of our definition of the term "long term care facility". Consequently, we have clarified, in Q&A guidance to Part D plans released on October 21, 2005 (<http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/IMDICFPharmacyGuidance.pdf>), the status of IMDs. The definition of an LTC facility would include an IMD that is a nursing facility or other medical institution (which is a term defined at 42 CFR 4435.1009) and receives Medicaid payment for its services to an institutionalized individual under section 1902(q)(1)(B) of the Act. In other words, to the extent that a nursing facility or medical institution that is an IMD has as an inpatient any institutionalized individual (which means any full benefit dual eligible individual for whom payment is made for IMD services under Medicaid throughout a month, as provided in section 1902(q)(1)(B) of the Act), that IMD will fall within the definition of an LTC facility in § 423.100. We are aware that there exists a statutory Federal financial participation exclusion under Medicaid affecting residents of IMDs between the ages of 22 and 64. However, the IMD exception to the definition of "medical assistance" under section 1902(q)(1)(B) of the Act does not apply to individuals who are age 65 and older. Thus, a State may elect to provide Medicaid coverage for services of an IMD to individuals over age 65. In these cases, all elderly full-benefit dual eligibles who are inpatients in an IMD for a full month are considered institutionalized individuals for that month. We note that we are not expanding or changing current policy regarding the definition of an LTC facility, but rather clarifying that IMDs are among the medical institutions that meet the definition of an LTC facility in § 423.100.

We also clarify that as medical institutions, hospitals, (including long-term care hospitals) that receive payments under section 1902(q)(1)(B) of the Act can meet the definition of an LTC facility. To the extent that inpatients in these hospitals exhaust their Part A inpatient days benefit, and payment is no longer available under Part A or Part B for drugs that would otherwise meet the definition of a Part D drug, such drugs are Part D drugs. Consequently, Part D sponsors must

ensure that they provide convenient access to network LTC pharmacies (which, in the case of a hospital, is typically the hospital's in-house pharmacy) for all of their enrollees who are inpatients in a hospital where the hospital is a "medical institution" under 1902(q)(1)(B) and therefore would meet the Part D definition of an LTC facility and whose Part A benefits have been exhausted.

c. Contracted Pharmacy Network

Section 423.100 defines the "contracted pharmacy network" as "pharmacies, including retail, mail-order, and institutional pharmacies, under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to Part D enrollees." (70 FR 4533) There, we made a technical error by inadvertently omitting clarifying language indicating that a pharmacy in a contracted pharmacy network must be licensed. We view this change as necessary in order to bring it in line with our term "retail pharmacy" which requires that a retail pharmacy be "licensed." (70 FR 4535) Further, we believe this is an important clarification to be made, given our commitment to safeguard beneficiaries' interests and health with respect to access to covered Part D drugs through network pharmacies, be they retail, home infusion, long-term care, I/T/U, or other types of pharmacies. Accordingly, we will revise the definition of "contracted pharmacy network" to state that a pharmacy participating in a contracted pharmacy network must be licensed.

d. Negotiated Prices

[If you choose to comment on issues in this section, please include the caption "NEGOTIATED PRICES" at the beginning of your comments.]

Under § 423.104(d)(2)(i), beneficiary cost sharing under the initial coverage limit is equal to 25 percent of "actual cost." (70 FR 4535) In addition, in accordance with § 423.104(g)(1), a Part D sponsor is required to provide beneficiaries with "access to negotiated prices for covered Part D drugs * * * even if no benefits are payable to the beneficiary * * * because of the application of any deductible or 100 percent coinsurance requirement." (70 FR 4536) In other words, even if a beneficiary is paying 100 percent of his or her costs, the beneficiary must be charged the same negotiated prices at a network pharmacy that would otherwise be used for calculating cost sharing.

Actual cost is defined in § 423.100 as "the negotiated price for a covered Part D drug when the drug is purchased at

a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of-network pharmacy consistent with § 423.124(a)." (70 FR 4533.) In § 423.100 "negotiated prices" means prices for covered Part D drugs that—

- Are available to beneficiaries at the point of sale at network pharmacies;
- Are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remunerations that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and
- Includes any dispensing fees. (70 FR 4534.)

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

In order to resolve the confusion caused by the Prescription Drug Benefit final rule, we are now proposing to amend the definition of "negotiated prices" to be effective for Part D contract year 2009 to require that beneficiary cost sharing must be based upon the price ultimately received by the pharmacy or other dispensing provider.

Therefore, we are proposing to revise § 423.100 so that the first part of the definition of "negotiated prices" would state that negotiated prices are prices that the Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount the network dispensing pharmacy or other network dispensing provider will receive, in total, for a particular drug. The term "intermediary contracting organization" refers to organizations such as pharmacy benefit managers that contract with plan sponsors to negotiate pharmacy contracts on their behalf.

We would also revise the definition of "negotiated prices" to include prices for covered Part D drugs negotiated between the Part D sponsor and other network dispensing providers. Part D sponsors can contract with providers other than a pharmacy to dispense covered Part D drugs, including them in their network. Therefore, we are amending the definition of negotiated prices to reflect the prices for covered

Part D drugs that Part D sponsors negotiate with all of their network dispensing providers.

In addition, although the definition of negotiated prices continues to state that these prices are reduced by discounts, rebates, and other direct and indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale, it is our understanding that in practice, Part D sponsors are unable to actually apply discounts, rebates, and other price concessions at the point of sale in order to reduce the price negotiated with the dispensing pharmacy or other dispensing provider. We recognize that negotiated prices would include only those price concessions actually passed through in order to result in a lower price to the beneficiary at the pharmacy (or other dispensing provider). To the extent no price concessions are passed through, of course, the negotiated prices would not be reduced.

2. Requirements Related to Qualified Prescription Drug Coverage (§ 423.104)—Waiver of Reduction of Part D Cost-Sharing by Pharmacies

In the January 28, 2005 final rule, we stated that we would allow waivers or reductions of cost-sharing by pharmacies to count as incurred costs. (70 FR 4240) Our statement, however, was limited only to pharmacies that are not also acting as other wrap-around coverage that generally would not count toward TrOOP. We did not intend to allow pharmacy waivers to count as incurred costs in cases where a pharmacy also met the definition of a group health plan, insurance or otherwise, or a third party payment arrangement, as those terms are defined in § 423.100. As provided in the definition of incurred costs in § 423.100 (70 FR 4534), wraparound assistance with covered Part D drug costs by group health plans, insurance or otherwise, or a third party payment arrangement does not count as costs incurred toward a Part D enrollee's annual out-of-pocket threshold.

In response to numerous requests for clarification of our policy with regard to waiver or reduction of Part D cost-sharing by network pharmacies, particularly by safety-net pharmacies, we have clarified, in question-and-answer guidance to Part D plans released on June 27, 2005 (Q & A number 5115 http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_alp.php?p_sid=gIVVcxhi), that although we will generally allow waivers or reductions of Part D cost-sharing by pharmacies to count toward

as incurred costs, this will not be the case for pharmacies affiliated with entities whose wraparound coverage does not count as an incurred cost. This includes pharmacies operated by entities that are group health plans, insurance, government-funded health programs, or third party payment arrangements with an obligation to pay for covered Part D drugs. As a result, many safety-net providers (who, because they are fully or partially funded through government grants are considered government-funded health programs as defined in § 423.100) will be unable to have any waiver or reduction of cost-sharing their pharmacies apply to Part D enrollees' Part D cost-sharing count as an incurred cost. This clarification does not represent a change or expansion to current policy given that, consistent with the section 1860D-2(b)(4)(C) of the Act, our regulations have made abundantly clear that cost-sharing paid for or reimbursed by group health plans, insurance or otherwise, or other third party payment arrangements cannot be counted toward a Part D enrollee's incurred cost total.

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

a. Applicability of Some Nonretail Pharmacies to Standards for Convenient Access (§ 423.120(a)(2))

In § 423.120(a)(2), we made a technical error by inadvertently referring to "rural health clinics" as "rural health centers." (70 FR 4537) In fact, there is no such entity as a "rural health center" for purposes of the Medicare statute or regulations. Our intent was to reference facilities described in section 1861(aa)(2) of the Act, as demonstrated by our reference in § 423.464(f)(1)(vii) to "Rural health centers as defined under section 1861(aa)(2) of the Act." The correct terminology for those facilities is "rural health clinics." Accordingly, we are revising the regulatory text to correctly reference these entities in § 423.120(a)(2) by removing the phrase "rural health centers" and adding in its place "rural health clinics."

b. Adequate Access to Home Infusion Pharmacies (§ 423.120(a)(4))

[If you choose to comment on issues in this section, please include the caption "ADEQUATE ACCESS TO HOME INFUSION PHARMACIES" at the beginning of your comments.]

We are proposing to codify in regulation, at § 423.120(a)(4) (70 FR 4537), guidance that we have already issued with regard to access to home

infusion pharmacies by Part D sponsors. This codification would ensure that the regulations provide specificity to our requirement that Part D enrollees receive adequate access to Part D-covered home infusion therapy. In addition, we propose one change to the regulations, on which we invite comments. This modification would require that Part D sponsors provide covered home infusion drugs within 24 hours of discharge from an acute setting.

In the January 28, 2005 final rule, we used our authority under section 1860D-4(b)(1)(C) of the Act to require Part D plans to provide adequate access to home infusion pharmacies. Given coverage of home infusion drugs under Part D, we did not believe it was an option for Part D plans not to include at least some home infusion pharmacies in their networks in order to provide enrollees with meaningful access to those drugs. As we stated in the preamble to the final rule (70 FR 4250), we were particularly concerned in regard to prescription drug plans which, unlike other Part D plans options, do not benefit from reduced medical costs associated with home infusion and may therefore have little incentive to contract with home infusion pharmacies. Therefore, we added a provision to our final regulations at § 423.120(a)(4) which requires Part D plans to demonstrate to us that they provide adequate access to home infusion pharmacies consistent with CMS operational guidance to Part D plans. In the preamble to our final rule, we also set forth our expectation that Part D plans would demonstrate adequate access based in part on the number of enrollees in their service areas and the geographic distribution and capacity of home infusion pharmacies in those service areas.

As we have gained experience with the Part D program, the need to clarify our expectations with regard to the provision of Part D-covered home infusion drugs became necessary. To this end, we issued a clarification of our expectations regarding adequate access to home infusion pharmacies to Part D plans on March 10, 2006. (http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/HomeInfusionReminder_03.10.06.pdf.) That policy memorandum clarified that, while we do not expect Part D plans to provide or pay for supplies, equipment, or the professional services needed for home infusion therapy, we do expect Part D sponsors' contracted pharmacy networks to deliver home infused drugs in a form that can be administered in a clinically appropriate fashion.

In addition, we clarified that home infusion networks must have contracted pharmacies capable of providing infusible Part D drugs for both short term acute care (for example, IV antibiotics) and long term chronic care (for example, alpha¹ protease inhibitor) therapies. While the same network pharmacy does not necessarily need to be capable of providing the full range of home infusion Part D drugs, the home infusion network, in the aggregate, must have a sufficient number of pharmacies capable of providing the full range of home infusion Part D drugs to ensure enrollees have adequate access to medically necessary home infusion therapies when needed.

In addition, we clarified that Part D plans must require their contracted network pharmacies that deliver home infusion drugs to ensure that the necessary professional services and ancillary supplies required for home infusion therapy are in place before dispensing home infusion drugs. In addition, we believe that plans must require the delivery of home infusion drugs within a reasonable time period based on these assurances. We note that, generally, facility discharge planners, in collaboration with a patient's physician, are responsible for ensuring that the components needed to safely administer a drug at home are present upon a patient's discharge. However, we expect the Part D plan's in-network contracted pharmacy vendors—particularly those that do not supply the necessary ancillary services (which are not a Medicare Part D benefit)—to receive assurances that another entity, such as a home health entity, can arrange for the provision of these services. We further clarified that we consider the action of obtaining assurances a minimum quality assurance requirement on Part D plans under § 423.153(c).

With respect to the timely delivery of home infusion drugs under Part D, we invite comments on the specification of a reasonable timeframe for delivery. In our ongoing discussions with home infusion providers we have learned that best practices involve the availability of infusion services upon discharge from a hospital either by the next required dose or within twenty-four hours of the discharge. Consequently, we are proposing a requirement that Part D plan sponsors provide covered home infusion drugs within 24 hours of discharge from an acute setting. We note that home infusion therapy may serve as a vehicle to promote early hospital discharge. Given that the need for home infusion therapy is often of an urgent nature, we believe that delivery of home infusion drugs should occur within 24

hours, provided that all necessary assurances have been received by the Part D plan sponsor that all ancillary services and professional services have been arranged.

Accordingly, in order to codify our previous guidance, we are proposing to revise § 423.120(a)(4) to expressly require that a Part D plan's contracted pharmacy network provide adequate access to home infusion pharmacies through a contracted pharmacy network that, at a minimum: (1) Is capable of delivering home infused drugs in a form that can be administered in a clinically appropriate fashion; (2) is capable of providing infusible Part D drugs for both short-term acute care and long-term chronic care therapies; and (3) ensures that the professional services and ancillary supplies necessary for home infusion therapy are in place before dispensing home infusion drugs. In addition, we propose to add a new requirement that a Part D plan's contracted pharmacy network also provide delivery of home infusion drugs within 24 hours. These proposed changes would codify our existing operational policies and impose a new requirement that Part D plans provide adequate access to home infusion therapy through their contracted pharmacy networks within 24 hours.

C. Subpart F—Submission of Bids and Monthly Beneficiary Premiums: Plan Approval—Timing of Payments
(§ 423.293(a))

We are making a technical correction to § 423.293(a) (70 FR 4546) to reflect the statutory requirement that all the provisions of section 1854(d) of the Act apply in the same manner as they apply under Part C of Title XVIII of the Act. Section 1860D–13(c)(1) of the Act states that, with two exceptions not particularly relevant to this discussion, the provisions of “section 1854(d) shall apply to PDP sponsors and premiums (and any late enrollment penalty) under this part in the same manner as they apply to MA organizations and beneficiary premiums under part C, except that any reference to a Trust Fund is deemed for this purpose a reference to the Medicare Prescription Drug Account.” Section 1854(d)(1) of the Act requires an organization to permit the payment of both basic and supplemental premiums on a monthly basis. This concept is reflected in the Part C regulations at § 422.262(e). In accordance with the statutory mandate, we have already required plans to permit beneficiaries to pay their premiums on a monthly basis. We are now making a technical correction to § 423.293(a) to cite both § 422.262(f) and

§ 422.262(e). This change reflects both our current policy as well as the statutory requirement.

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

1. Definitions and Terminology
(§ 423.308)

a. Administrative Costs (§ 423.308)

[If you choose to comment on issues in this section, please include the caption “ADMINISTRATIVE COSTS” at the beginning of your comments.]

The statute requires CMS to exclude administrative costs from the calculation of gross covered prescription drug costs and allowable risk corridor costs. However, administrative costs are not defined in either the statute or the January 28, 2005 final rule. Therefore, to explain this term and clarify which costs are included in administrative costs, we are adding a definition for the term “administrative costs”. In the definition, we define “administrative costs” as the Part D sponsor's costs other than those incurred to purchase or reimburse the purchase of Part D drugs under the Part D plan. Included in the definition of administrative costs are costs incurred by Part D plans that exceed the price charged by a dispensing entity for covered Part D drugs. For example, the profit retained by a PBM that negotiates prices with pharmacies on behalf of a Part D sponsor is considered an administrative cost and not a drug cost.

The policy refines our interpretation of the statutory and regulatory definitions of “allowable reinsurance costs” and “allowable risk corridor costs,” which in both cases exclude any administrative costs of the sponsor. By statute, “allowable reinsurance costs” are a subset of “gross covered prescription drug costs,” and Congress specifically defined these gross costs as “not including administrative costs.” (See sections 1860D–15(b)(2) and 1860D–15(b)(3) of the Act.) Similarly, Congress defined “allowable risk corridor costs” as “not including administrative costs.” (See section 1860D–15(e)(1)(B) of the Act.) In the January 28, 2005 final rule, we adopted these definitions. (70 FR 4547.) We interpret administrative costs to include any profit or loss incurred by an intermediary contracting organization (for example, a pharmacy benefit manager (PBM)) as a result of lock-in pricing. Therefore, this profit or loss must not be included in the reinsurance and risk corridor payments made by the government, as these payments exclude administrative fees. Thus, the Ingredient

Cost, Dispensing Fee, Sales Tax, Gross Drug Cost below the Out of Pocket Threshold, and Gross Drug Cost above the Out of Pocket Threshold fields would need to reflect the final amount ultimately received by the pharmacy at the point of sale.

b. Gross Covered Prescription Drug Costs (§ 423.308)

[If you choose to comment on issues in this section, please include the caption “GROSS COVERED PRESCRIPTION DRUG COSTS” at the beginning of your comments.]

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

There have been several questions regarding the appropriate drug costs to report, particularly when a Part D sponsor has contracted with a PBM. The January 28, 2005 final rule defines “gross covered prescription drug costs” as “those actually paid costs incurred under a Part D plan, excluding administrative costs * * * [equal to:] (1) All reimbursement paid by a Part D sponsor to a pharmacy (or other intermediary) * * * plus (2) All amounts paid under the Part D plan by or on behalf of an enrollee (such as the deductible, coinsurance, cost sharing, or amounts between the initial coverage limit and the out-of-pocket threshold) in order to obtain drugs covered under the Part D plan.” (70 FR 4547)

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

We propose rectifying these conflicting definitions to require the plan sponsor to include the profit or loss retained or incurred by a PBM as part of lock-in pricing to be part of the administrative costs of the plan sponsor.

This would require the amount ultimately received by the pharmacy (minus any point-of-sale price concessions) to be used in calculating cost-sharing for plan years 2009 and beyond. Specifically, we propose amending the definition of “gross covered prescription drug costs” to eliminate the parenthetical “or other intermediary” to require that all plan sponsors report the amount ultimately received by the pharmacy, other dispensing provider, or agent (as opposed to the amount paid to an intermediary contracting organization that does not serve as an agent, such as a PBM). We propose that the amount ultimately received by the pharmacy or other dispensing provider (whether directly or indirectly) for the particular drug will be the basis for— (1) calculating beneficiary cost sharing; (2) accumulating gross covered drug costs; (3) reporting drug costs on the Prescription Drug Event (PDE) records, and (4) developing bids submitted to CMS.

Similarly, we propose clarifying our definition of “allowable risk corridor costs” so that it is clear that these costs are only based upon the amounts received directly by the pharmacy or other dispensing provider. This is because we would consider any profit (or loss) earned by a PBM or other entity negotiating contracts with pharmacies to constitute an administrative cost, and therefore would be exempt from the definition of allowable risk corridor costs, as well as gross covered prescription drug costs. Thus, for example, if a Part D sponsor pays a PBM a certain amount for a particular drug, and then the PBM negotiates a different price with the pharmacy, any differential retained or lost by the PBM would be considered administrative, and could not be reported as part of drug costs.

We propose revising the definitions of “gross covered prescription drug costs” and “allowable risk corridor costs” to establish that the amount received by the dispensing pharmacy or other dispensing provider (whether directly or through an intermediary contracting organization) rather than just the amount paid by the Part D sponsor is the basis for drug cost that must be reported to CMS and used as the basis to calculate beneficiary cost sharing. Accordingly, we are revising § 423.308 to incorporate these changes.

We also propose amending the definition of “gross covered prescription drug costs” and “allowable risk corridor costs” to ensure that when entities other than pharmacies dispense Part D drugs and receive payment for Part D drugs,

these expenditures are also reflected in gross drug costs and allowable reinsurance costs, as well as allowable risk corridor costs. For instance, reimbursement for a vaccine that must be administered in a physician’s office, payments made to other Part D plans due to reconciliation, and reimbursement made to a third party payer for COB error are all legitimate drug costs that have been incurred through the payments indicated. In some cases, a Part D plan, other than the plan in which the beneficiary is correctly enrolled, may pay for a prescription drug on the beneficiary’s behalf (because of an erroneous belief that the beneficiary was actually enrolled in its plan). In these cases, when the enrollment error is corrected, the beneficiary’s true plan generally will reconcile payments with the original payer. The drug costs paid by Part D plans (as well as by the beneficiary) under these reconciliation processes reflect drug costs incurred by the plan’s enrollees that a payer other than the correct Part D plan of record paid as primary. As drug costs paid for Part D covered drugs under Part D plans, these costs are included in the calculations of reinsurance costs and risk corridor costs. Therefore, we have amended the definition of “gross covered prescription drug costs” and “allowable risk corridor costs” in § 423.308 to include all these drug costs.

We also propose amending the definition of “gross covered prescription drug costs” to ensure that when a beneficiary is paying 100 percent cost sharing (for example, in any applicable deductible or coverage gap) and the beneficiary obtains a covered Part D drug at a network pharmacy for a lower price than the plan’s negotiated price, the beneficiary’s out-of-pocket costs are counted toward both incurred costs (TrOOP) and total drug spending. This is consistent with guidance released via Q&A 7944 (issued May 9, 2006 http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_alp.php?p_sid=gIVVcxhi.) For example, if an enrollee in any applicable coverage gap or deductible phase of the Part D benefit is able to obtain a better cash price for a covered Part D drug at a network pharmacy than the plan offers via its negotiated price, and the enrollee takes advantage of the special cash price or discount being offered to all pharmacy customers or, alternatively, by using a discount card, the enrollee may purchase that covered Part D drug without using the Part D benefit or a supplemental card. If that purchase price is lower than the Part D

plan’s negotiated price, it will count toward TrOOP and total drug spend balances, provided the Part D plan finds out about the purchase. This means that the enrollee must take responsibility for submitting the appropriate documentation to the enrollee’s Part D plan, consistent with plan-established processes and instructions for submitting that information, in order to have that amount aggregated to the beneficiary’s TrOOP and total drug spend balances.

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

Although PAP payments made for covered Part D drugs outside the Part D benefit do not count toward enrollees’ TrOOP or total drug spend balances, nominal PAP copayment amounts paid by affected Part D enrollees can be aggregated to their TrOOP and total drug spend balances, provided the enrollees submit the appropriate documentation to their plan consistent with plan-established processes and instructions for submitting the information. The definition of “gross covered prescription drug costs” has been revised to include these drug costs and to reflect this sub-regulatory guidance.

2. Payment Appeals (§ 423.350(b))

In the January 28, 2005 final rule, we made a technical error in § 423.350(b). (70 FR 4550) In this paragraph, we inadvertently used the phrase “notice of

the adverse determination” when we said that the request for reconsideration for a payment determination must be filed within 15 days from the date of the notice of the adverse determination. The term “notice of the adverse determination” is a term that was inadvertently copied here from a fee-for-service policy, and is not relevant here. We are revising the regulation text to instead cite to the notice of final payment for risk adjustment, reinsurance, low-income cost sharing subsidies, or risk-sharing payments under §§ 423.343(b), 423.343(c), 423.343(d) or 423.336, respectively.

E. Subpart I—Organization Compliance With State Law and Preemption by Federal Law—Waiver of Certain Requirements To Expand Choice (§ 423.410)

In accordance with section 1860D–12(c)(2)(B) of the Act, which describes the special waivers available for the 2006 and 2007 plan years, we are revising section 423.410(d) of the January 28, 2005 final rule (70 FR 4551). We believe that the statute requires only a substantially complete (rather than a fully complete) application to have been submitted to the applicable state in order for an applicant to be granted the special waiver for 2006 and 2007. Therefore, we are correcting the regulatory language to require that an applicant submit a substantially completed application to the state, in order for the applicant to be eligible for the § 423.410(d) waiver.

F. Subpart J—Coordination of Part D Plans With Other Prescription Drug Coverage

1. Application of Part D Rules to Certain Part D Plans On and After January 1, 2006 (§ 423.458).

Application of Part D Rules to Certain Part D Plans On and After January 1, 2006 (§ 423.458).

We are revising the regulation text of § 423.458(d)(2)(ii), because we inadvertently omitted a reference to section 1894 of the Act in describing the statutory authorization for the benefits offered by a Program for All Inclusive Care For the Elderly (PACE) organization (70 FR 4552). Under § 423.458(d)(2)(ii), a PACE organization may request a waiver of a Part D requirement if the waiver would improve the coordination of benefits between Part D and the benefits offered by the PACE organization. As provided in section 1860D–21(f)(1) of the Act, Part D provisions will apply to PACE organizations electing to offer qualified prescription drug coverage in a manner

that is similar to the manner in which those provisions apply to an MA–PD local plan. In addition, section 1860D–21(f) provides that a PACE organization may be deemed to be an MA–PD local plan. Section 1860D–21(f) of the Act specifically refers to “a PACE program under section 1894.” As published in § 423.458(d)(2)(ii), we reference only section 1934 of the Act when describing benefits provided by PACE organizations. In fact, PACE operates under both the Medicare and Medicaid statutes, and all descriptions of PACE benefits should refer to both sections 1894 and 1934 of the Act. We are therefore revising § 423.458(d)(2)(ii) so that it refers to benefits offered by a PACE organization under both sections 1894 and 1934 of the Act.

2. Coordination of Benefits With Rural Health Clinics (§ 423.464)

a. Coordination of Benefits With Rural Health Clinics

In § 423.464(f)(1)(vii), we made a technical error by inadvertently referring to rural health clinics as rural health centers (70 FR 4553). In fact, our intent was to reference facilities described in section 1861(aa)(2) of the Act, and the correct terminology for those facilities is rural health clinics. Accordingly, we are correcting the reference to these entities in § 423.464(f)(1)(vii) by removing the phrase rural health centers and adding in its place rural health clinics.

b. Coordination of Benefits With Part D Plans and Other Payers

[If you choose to comment on issues in this section, please include the caption “COORDINATION OF BENEFITS WITH PART D PLANS AND OTHER PAYERS” at the beginning of your comments.]

We are codifying in § 423.464(f) guidance we have already issued to Part D sponsors addressing coordination of benefits requirements in cases that involve another Part D plan that is not the correct Part D plan of record or another payer that has incorrectly paid as primary for a covered Part D drug for an enrolled beneficiary. These revisions to § 423.464(f) reflect our historic policy that Part D plans must effectively coordinate benefits with other entities providing prescription drug coverage.

In accordance with sections 1860D–24(a)(1) and (b) of the Act, § 423.464(a) of the regulations extends the coordination of benefits requirements in section 1860D–23 of the Act applicable to Part D plans vis-à-vis State Pharmaceutical Assistance Programs (SPAPs) to other entities providing

prescription drug coverage. As provided in § 423.464(f)(1), these entities include Medicaid (including a plan operating under a waiver under section 1115 of the Act), group health plans, the Federal Employees Health Benefits Program (FEHBP), military coverage (including TRICARE), the Indian Health Service, Federally qualified health centers, rural health clinics, and other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of Part D drugs on behalf of Part D eligible individuals as CMS specifies. Consistent with section 1860D–23(a)(2) of the Act, § 423.464(a) specifies that the elements to be coordinated with entities providing prescription drug coverage include enrollment file sharing, the processing of claims (including electronic processing), claims payment, claims reconciliation reports, application of incurred costs, and other administrative processes and requirements we specify.

A number of issues associated with the implementation of Part D (including the presence of multiple payers, payer order, and retroactive eligibility) have created challenges for Part D plans in coordinating benefits with other entities providing prescription drug coverage. Since the publication of the January 28, 2005 Medicare Prescription Drug benefit final rule, we have developed, in cooperation with industry stakeholders, additional processes and requirements to address these challenges to Part D plan coordination of benefits.

Because of program start-up issues in 2006, lags in the information available to pharmacies at the point-of-sale regarding which Part D plan to bill may have resulted in the pharmacies’ having access to outdated or incomplete information. Because pharmacies generally relied in good faith on this information, in some cases the wrong payer paid for a prescription. Given the volume of drug claims that pharmacies would need to re-adjudicate as a result of incorrect Part D enrollment information available at the point-of-sale, re-adjudication would have imposed a significant administrative and financial burden on pharmacies. Therefore, payer-to-payer reconciliation procedures were developed by CMS and a workgroup of industry representatives, including industry trade groups, Part D plans, and pharmacies to mitigate the administrative and financial burden involved with re-adjudication of claims.

This payer-to-payer process was designed initially to be a temporary measure during Part D’s start-up phase. However, because many beneficiaries have the opportunity (through special election periods) to change their Part D

plan enrollment during the coverage year, there continues to be lag time associated with enrollment and information systems updates. Therefore, the Part D plan from which a beneficiary has transferred may make payment for covered prescription drug costs incurred after the effective date of the beneficiary's enrollment in the new Part D plan of record. As a result, while CMS continues to explore the plan-to-plan reconciliation and reimbursement procedures, we are requiring that plans continue to use the special prescription drug event submission and reimbursement processes established in 2006 as part of the plan-to-plan reconciliation process. In this proposed rule, we are merely codifying the already-existing procedures. (It is important to note that an essential element of the plan-to-plan reconciliation process as designed precludes plan use of claim denials or edits in the transition period. That is, the process's design reflects the consensus of Part D plans that it is necessary to prevent disclosure of proprietary pricing information by masking the NDC coding.)

In addition, unforeseeable future events may create further need for processes to reconcile payments when a payer other than the correct Part D plan of record pays as primary for a covered Part D drug for an enrolled beneficiary. These other reconciliation processes may be developed by CMS to accomplish payment reconciliation without involving pharmacy reversal and re-adjudication of claims or the public release of a payer's proprietary information, such as negotiated rates.

Therefore we are proposing to clarify § 423.464(f)(1) to state that included among the entities providing other prescription drug coverage with which Part D plans must coordinate are other Part D plans. Although Part D plans are already obligated to coordinate with group health plans, as provided in § 423.464(f)(1)(ii), we believe this revision formalizes our implicit recognition of other Part D plans as other entities providing prescription drug coverage with which a beneficiary's correct Part D plan of record must coordinate.

We also are clarifying § 423.464(f) to clearly specify additional elements of Part D plans' coordination of benefits requirements in order to address the reconciliation issues detailed in the preceding discussion. Section 1860D-23(a)(2)(F) of the Act gives the Secretary the discretion to identify other administrative processes that may be included in the required elements for coordination of benefits by Part D plans.

Consistent with this authority, we propose revising § 423.464(f) to add a fifth paragraph that clarifies that Part D plans coordinate benefits with other Part D plans through the reconciliation process we have developed for 2006, which involves making payments to other Part D plans on the basis of the covered plan-paid and low-income cost-sharing subsidy amounts reported to them by CMS with respect to transferred enrollees. Payments made by the Part D plans as part of this reconciliation process would be made without regard to the plan's formulary or drug utilization review edits.

In addition, we propose modifying § 423.464(f) by adding a sixth paragraph that would require Part D sponsors to coordinate benefits on a timely basis with other third parties and use CMS-developed reconciliation processes, when established, in situations in which a payer other than the correct Part D plan of record pays for covered Part D drug costs as a primary payer. This was the case in 2006 with respect to the State-to-Plan Reconciliation Project in which some States made drug payments for dual eligible beneficiaries and low-income subsidy entitled beneficiaries enrolled in Part D and were subsequently reimbursed by CMS through a special demonstration authority. Processes similar to those employed in 2006 may need to be developed by CMS in lieu of requesting pharmacy claims reversals and re-adjudications or the public release of a payer's proprietary information (such as negotiated prices).

The proposed changes described in this portion of this proposed rule would not change current coordination benefits policy. Rather, they would codify existing operational processes and reflect our historic policy that Part D plans must effectively coordinate benefits with entities providing other prescription drug coverage. We seek comment on our proposals regarding the plan-to-plan coordination process and CMS-developed reconciliation process.

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

1. General Provisions (§ 423.504)

a. Submission of Bids

In § 423.504, we inadvertently made reference to § 423.265(a)(1) rather than § 423.265 (70 FR 4555). Section 423.265(a) gives only the most narrow and rudimentary of information concerning the bidding process; that is, that an applicant may submit a bid to become a Part D plan sponsor. In fact, our intent was to cite in its entirety the

much broader list found under § 423.265 (Submission of bids and related information) that provides comprehensive and essential information for a Part D Plan sponsor to successfully contract with CMS (70 FR 4544). Accordingly, we are correcting the reference found under § 423.504(a) to cite all of § 423.265.

2. Contract Provisions (§ 423.505)

In § 423.505(h)(1), we are correcting the citation for the False Claims Act, from 32 U.S.C. 3729 *et seq.*, to 31 U.S.C. 3729 *et seq.* (70 FR 4556).

3. Failure To Comply With the Dissemination of Information Requirements Grounds for Contract Termination (§ 423.509(a)(9))

In § 423.509(a)(9), we indicate that CMS may terminate a plan's contract if the plan substantially fails to comply with the Part D marketing requirements (70 FR 4559). This provision cites the marketing requirements at § 423.128, which is an incorrect citation. Section 423.128 deals with the dissemination of Part D plan information, not with plans' marketing requirements, *per se*. Therefore, we are revising the regulation text, consistent with our original intent, to reflect that a plan contract may be terminated if a plan sponsor substantially fails to comply with the marketing requirements in § 423.50 or the dissemination of Part D plan information requirements in § 423.128.

H. Subpart M—Grievances, Coverage Determinations, and Appeals

1. Definitions (§ 423.560)

a. Appointed Representative

We are revising the regulation text of § 423.560 by making a technical change to the definition of "appointed representative." (70 FR 4562) In the Medicare Prescription Drug Benefit final rule, we inadvertently omitted language indicating that an enrollee's appointed representative may request a grievance on the enrollee's behalf. Current policy as reflected in Chapter 18 of the Prescription Drug Plan Manual permits an enrollee's appointed representative to request a grievance, obtain a coverage determination, or deal with any of the levels of the appeals process on the enrollee's behalf. We are codifying this already existing policy by amending the regulation text. The definition for appointed representative will state: "Appointed representative means an individual either appointed by an enrollee or authorized under State or other applicable law to act on behalf of the enrollee in filing a grievance, obtaining a coverage determination, or

in dealing with any of the levels of the appeals process. Unless otherwise stated in this subpart, the appointed representative has all of the rights and responsibilities of an enrollee in filing a grievance, 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.”

b. Projected Value

In addition, we are making a technical change to the definition of “projected value” in § 423.560 because it is not consistent with the definition of projected value provided on page 4360 of the preamble and in the regulation text at § 423.610(b). (70 FR 4568) The definition of “projected value” in § 423.560 includes “future charges that will be incurred within 12 months from the date the request for coverage determination or exception is received by the plan” as part of the projected value formula. However, the projected value formulas on page 4360 of the preamble to the final rule and § 423.610(b) of the regulations include “any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year.” Our policy regarding how to calculate projected value is consistent with the definition of projected value provided on page 4360 of the preamble to the final rule and in the regulation text at § 423.610(b). Therefore, we are revising the definition of projected value in § 423.560 to state: “Projected value of a Part D drug or drugs includes any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year. Projected value includes enrollee co-payments, all expenditures incurred after an enrollee’s expenditures exceed the initial coverage limit, and expenditures paid by other entities.”

2. Expediting Certain Coverage Determinations (§ 423.570)

We are amending the regulation text of § 423.570(d)(3) because we inadvertently omitted language indicating who is entitled to receive written notice of a plan sponsor’s denial of a request to expedite a coverage determination. (70 FR 4564) Our policy requires a plan sponsor to send written notice to the enrollee when it denies a request to expedite a coverage determination. We believe the regulation text of § 423.570(d)(3) must be revised to accurately reflect our policy. Accordingly, we propose to codify in the regulation text of § 423.570(d)(3) the requirement that

when a Part D sponsor denies a request to expedite a coverage determination, it must “subsequently deliver to the enrollee, within 3 calendar days, equivalent written notice.”

3. Expediting Certain Redeterminations (§ 423.584)

We are revising the regulation text of § 423.584(b) because we inadvertently omitted regulatory language regarding the procedures for filing and withdrawing a request for an expedited redetermination. (70 FR 4566) Sections 423.582(b), (c), and (d) explain the process for filing and withdrawing a request for a standard redetermination. These procedures also apply to requests for expedited redeterminations. We are revising the regulation text of § 423.584(b) to accurately reflect our policy that the provisions in § 423.582(b), (c), and (d) would also apply to § 423.584(b). We are revising § 423.584(b) by adding “(3) The provisions set forth in § 423.582(b), (c), and (d) also apply to expedited redeterminations.”

4. Right to an ALJ Hearing (§ 423.610)

We are revising the regulation text of § 423.610(c)(2) due to typographical errors. (70 FR 4568) The three requirements listed under § 423.610(c)(2) should have been numbered with (i), (ii), and (iii). We are revising § 423.610(c)(2) to reflect appropriate numeration. It will now read as follows: “Multiple enrollees. Two or more appeals may be aggregated by multiple enrollees to meet the amount in controversy for an ALJ hearing if—(1) the appeals have previously been reconsidered by an IRE; (2) the request for ALJ hearing lists all of the appeals to be aggregated and each aggregated appeal meets the filing requirement specified in § 423.612(b); and (3) the ALJ determines that the appeals the enrollees seek to aggregate involve the same prescription drug.”

I. Subpart P—Premiums and Cost-Sharing Subsidies for Low-Income Individuals

1. Premium Subsidy Amount (§ 423.780)

a. Low-Income Benchmark Premium Amount

Section 1860D–14 of the Act requires CMS to subsidize the monthly beneficiary premium and cost-sharing amounts incurred under Part D by Part D eligible individuals with income and resources below certain thresholds. Our rules mirror the statute’s structure, which divides low-income 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 premium assistance and reductions in cost sharing.

Since the Part D benefit has become operational, we have become aware that certain sections of part 423 subpart P need to be corrected to accurately reflect the statutory language. Specifically, there is an error in § 423.780(b). (70 FR 4574) As written, this section states that the premium subsidy amount is based upon the lesser of the plan’s premium or the low-income benchmark premium amount. The low-income benchmark premium amount, as defined in the statute at section 1860D–14 of the Act, specifically describes how to calculate the low-income subsidy for regions with only one PDP sponsor. At section 1860D–14(b)(2)(A)(i) of the Act, the statute indicates that “* * * the term * * * ‘low-income benchmark premium amount’ means, with respect to a PDP region in which all prescription drug plans are offered by the same PDP sponsor, the weighted average of the amounts described in subparagraph (B)(i) for such plans.” However, while the final regulation described the low-income benchmark premium amount calculation for regions with multiple drug plan sponsors, it did not describe the methodology for determining the low-income benchmark premium amount in a region with any number of MA–PD plans, but with only one PDP sponsor (although the preamble to the final rule did). We are correcting this error to comport with the statute and our intent as outlined in the preamble by adding a new subparagraph (A) to § 423.780(b)(2)(i). The new text will make clear that when there is only one PDP sponsor in the region, the low income benchmark weighted average includes only the premiums of basic PDPs in the area. The weighted average does not count the premium amounts of PDP plans offering supplemental coverage or MA–PD plans. This is in contrast to the weighted average calculated when there are multiple PDP sponsors. In that situation, the benchmark calculation includes not just the premiums of basic PDPs; it also includes the portion of a premium attributable to basic coverage, when a PDP offers both basic and supplemental coverage. In addition, for multiple-PDP regions, the benchmark would also include the amount charged for Part D coverage by MA–PD plans. We note that in 2006, all PDP regions included multiple PDP sponsors.

We also are revising § 423.780(b)(2)(ii). We want to make

clear that in multiple-PDP sponsor regions, the MA-PDs included in the weighted average are coordinated care plans.

b. Premiums Subsidy for Late Enrollment Penalty

We need to correct an omission related to the subsidy of the late enrollment penalty for other low-income subsidy individuals in the regulation text at § 423.780(e). In this paragraph, we inadvertently omitted a provision from the statute at section 1860D-14(a)(2)(A) of the Act, which requires a late enrollment penalty subsidy for other low-income subsidy eligible individuals. This subsidy is based on a linear sliding scale, with a higher subsidy available to individuals with incomes at or below 135 percent of the FPL (but who do not meet the asset requirements of a full subsidy eligible individual), and the lowest level subsidy available to individuals with incomes below 150 percent of the FPL. Specifically, section 1860D-14(a)(2)(A) of the Act reads, “(2) OTHER INDIVIDUALS WITH INCOME BELOW 150 PERCENT OF POVERTY LINE.—In the case of a subsidy eligible individual who is not described in paragraph (1), the individual is entitled under this section to the following: (A) SLIDING SCALE PREMIUM SUBSIDY.—An income-related premium subsidy determined on a linear sliding scale ranging from 100 percent of the amount described in paragraph (1)(A) for individuals with incomes at or below

135 percent of such level to 0 percent of such amount for individuals with incomes at 150 percent of such level.” (emphasis added). The “amount described in paragraph (1)(A)” encompasses the subsidy for the late enrollment penalty.

The current regulation does not include this sliding scale calculation. The regulation only cites the subsidy for the late enrollment penalty as something which is available only to full subsidy eligible individuals. Accordingly, we are proposing to revise § 423.780(e) to accurately reflect the statute. The sliding scale for the late enrollment penalty subsidy will be calculated based on the linear sliding scale for the premium subsidy, which is described in paragraph (d) of the regulation. Beneficiaries with incomes on the sliding scale will receive a late enrollment penalty subsidy that will be equal to a percentage of the late enrollment penalty subsidy for full subsidy individuals, based on the same 5 percent increment scale that applies for the premium subsidy in paragraph (d) (that is, 135, 140, 145 and 150 percent of FPL).

For the first 60 months the penalty is imposed, full subsidy individuals receive a late enrollment penalty subsidy equal to only 80 percent of the penalty amount. Therefore, the sliding scale premium subsidy percentages for each income level in paragraph (d) must be multiplied by 80 percent to arrive at the percentage of the late enrollment penalty that is subsidized for each

income level for the first 60 months. For example, for individuals with incomes greater than 135 percent, but at or below 140 percent of the FPL applicable to the family size, the late enrollment penalty subsidy will be equal to 60 percent of the late enrollment penalty for the first 60 months during which the penalty is imposed. Sixty percent is equal to 75 percent (the percentage of the premium subsidized for individuals with incomes greater than 135 percent, but at or below 140 percent of the FPL applicable to the family size in accordance with paragraph (d)(2)) multiplied by 80 percent (which, as stated, will be the amount of the late enrollment penalty that will be subsidized for full subsidy eligible individuals for the first 60 months during which the penalty is imposed on them, as described in paragraph (e)).

After the first 60 months the penalty is imposed, the sliding scale premium subsidy percentages for each income level in paragraph (d) will be multiplied by 100 percent, as 100 percent of the late enrollment penalty will be subsidized for full subsidy eligible individuals after the first 60 months. As stated, the resulting percentages will be the percent of the late enrollment penalty that will be subsidized and can therefore be multiplied by the individual’s late enrollment penalty to give the subsidy. The below table illustrates the penalty subsidy available to other low income subsidy individuals.

Income level	Percent of penalty subsidized during the first 60 months individual is subject to penalty	Percent of penalty subsidized after the first 60 months individual is subject to penalty
≤135% FPL	80	100
>135% and ≤140% FPL	60	75
>140% and ≤145% FPL	40	50
>145% and <150% FPL	20	25
≥150% FPL	0	0

J. Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

1. Requirements for Qualified Retiree Prescription Drug Plans (§ 423.884)

a. Application Timing

[If you choose to comment on issues in this section, please include the caption “APPLICATION TIMING” at the beginning of your comments.]

The enactment of Title I of the MMA provides sponsors of retiree prescription drug plans with multiple options for providing drug coverage to their retirees who are Medicare beneficiaries. One of

these is section 1860D-22(a) of the Act, which permits the sponsor of a qualified retiree prescription drug plan to receive a subsidy with respect to certain allowable prescription drug costs incurred by qualifying covered retirees, who must be eligible for, but not enrolled in, Part D. This is referred to in the regulations as the Retiree Drug Subsidy (RDS).

In implementing the statute, the regulations at § 423.884(c) outline the application requirements for the Retiree Drug Subsidy. (70 FR 4577) Section 423.884(c)(5)(i) requires a plan sponsor to file an application for the subsidy by

no later than 90 days before the beginning of its plan year, unless an extension is requested and granted (for example, the deadline for 2007 calendar year plans under the regulation would be October 2, 2006). Upon further review of this requirement, we believe that an end-of-month deadline would be administratively simpler for both plan sponsors and CMS to track. For example, for the 2006 calendar year, the initial deadline for the RDS applications, as established in the regulation, was September 30, 2005, which is actually 92 days before the

start of the plan year. In order to establish an appropriate application date for each contract year, we can announce the date in published guidance in advance to allow stakeholders sufficient time to do the necessary preparation and filing. Accordingly, we are proposing to replace the 90 day requirement with the phrase “by a date specified by CMS in published guidance” in this provision of the final rule to allow us the discretion to specify an end-of-month deadline in the future through guidance. This will also give CMS the flexibility to take into account operational systems changes in determining the Retiree Drug Subsidy application deadline, while providing adequate advance notice to plan sponsors and their advisers.

b. Data Match

[If you choose to comment on issues in this section, please include the caption “DATA MATCH” at the beginning of your comments.]

In order to properly administer the Retiree Drug Subsidy program, we must compare the retiree data that a plan sponsor submits to CMS records to ensure that sponsors are not claiming the subsidy for individuals that are enrolled in a Part D plan and are therefore not qualifying covered retirees. In § 423.884(c)(7)(i), we specifically referenced the Medicare Beneficiary Database (MBD) as the system of record for the data match. (70 FR 4578) While the MBD is currently the system by which the retirees’ status is verified, we also may use other systems of record for purposes of the data match.

Accordingly, we propose to modify our language to be more suitable by substituting a general reference to “CMS database(s)” for the “Medicare Beneficiary Database (MBD)” in the regulation text at § 423.884(c)(7)(i).

c. Actuarial Equivalence (§ 423.884)

(1) Medicare Supplemental Adjustment

Section 1860D–22(a)(2)(A) of the Act requires that a plan sponsor provide an attestation that its plan is actuarially equivalent to Medicare standard prescription drug coverage in order to claim RDS. Section 423.884(d)(5) sets forth a two-prong test for determining the actuarial value of the defined standard prescription drug coverage under Part D against which the actuarial value of the retiree coverage is measured. (70 FR 4578) The actuarial equivalence test includes a “gross test” and a “net test.” Section 423.884(d)(5)(iii)(B)(2) states that the net test includes a “Medicare supplemental adjustment” which allows a plan

sponsor that provides supplemental coverage for its retirees that elect Part D coverage to reflect the impact of the supplemental coverage on the net value of Part D coverage. Supplemental coverage for this purpose means drug coverage over and above Part D coverage for those retirees that enroll in Part D coverage. Our intent, which we clarified in operational guidance to plan sponsors, was that a sponsor must actually provide supplemental employer-provided retiree drug coverage in order to qualify for the Medicare supplemental adjustment. (See CMS Guidance on the Actuarial Equivalence Standard for the Retiree Drug Subsidy (April 7, 2005) available at <http://www.cms.hhs.gov/employerretireedrugsubsid>.) In accordance with our existing guidance, we are therefore revising § 423.884(d)(5)(iii)(B)(2) to indicate that plan sponsors must actually provide supplemental drug coverage for their retirees that elect Part D in order to do the adjustment to the net value of Part D in the actuarial equivalence test. We view this revision as merely incorporating previously issued guidance, and not as a new policy proposal.

(2) Non-Calendar Year Plans

[If you choose to comment on issues in this section, please include the caption “NON-CALENDAR YEAR PLANS” at the beginning of your comments.]

Sec. 1860D–22(a)(2)(A) of the Act requires a plan sponsor to provide an attestation that its plan is actuarially equivalent to the Medicare defined standard prescription drug coverage in order to claim RDS. As explained above, our regulation at § 423.884(d)(5) sets forth a two-prong test for actuarial equivalence. The actuarial equivalence test requires that the value of the plan sponsor’s retiree drug coverage be compared to the hypothetical value of the Medicare defined standard prescription drug coverage had the sponsor’s Part D eligible individuals taken that coverage.

Sections 423.884(d)(5)(iii)(C) and (D) state that the valuation of the Medicare defined standard prescription drug coverage for this purpose is based on the initial coverage limit, cost sharing amounts, and out-of-pocket threshold in effect at the start of the plan year. However, the attestation must be submitted to CMS no later than 60 days after the publication of the Part D coverage limits for the upcoming calendar year; otherwise, the valuation must be based on the initial coverage limit, cost sharing amounts, and out-of-

pocket threshold for the upcoming plan year. The intent of this 60 day provision is to prevent actuaries from having to redo calculations for non-calendar year plans that were based on the current calendar year initial coverage limit, cost sharing amounts, and out-of-pocket threshold when, after doing their calculations, but before the RDS application is submitted, we publish the Part D coverage limits for the upcoming calendar year.

Actuaries of plan sponsors have indicated to us that they believe they should have the flexibility for non-calendar year plans to use the Part D initial coverage limit, cost-sharing amounts, and out-of-pocket-threshold for the upcoming plan year, provided it does not impact their ability to meet the application deadline. We agree that actuaries should have this flexibility, and so we are proposing to amend the § 423.884(d)(5)(iii)(C) to permit a non-calendar year plan’s actuary to use either the current or subsequent year’s Part D cost limits when the attestation is submitted within 60 days of the publication of the following year’s cost limits. We also propose to make corresponding changes to § 423.884(d)(5)(iii)(C).

(3) Benefit Options

Employment-based retiree health coverage often has different plan design features or benefit options that apply to specific groups of retirees. Section 423.882 defines a benefit option as a particular benefit design, category of benefits, or cost sharing arrangement offered within a group health plan. Section 423.884(d)(5)(iv) states that a plan with more than one benefit option must pass the gross test separately on a disaggregated basis for each option, but that it may pass the net test on an aggregated or disaggregated basis. As we have indicated in subsequent guidance, our intent was that a plan sponsor should also have the option of aggregating a subset of the benefit options in a plan for the actuarial equivalence net test in addition to aggregating all of the options or evaluating each option individually. (See CMS Guidance on the Actuarial Equivalence Standard for the Retiree Drug Subsidy (April 7, 2005); available at www.cms.hhs.gov/employerretireedrugsubsid.) If the sponsor combines two or more benefit options, the sponsor may not claim the subsidy for those benefit options excluded from the net value calculation, even if those options meet the gross test. We are amending the final rule to reflect this clarification of our intent, which reflects policy that has been applied

consistently since the rule was published.

(4) Submission of Actuarial Attestation Upon Material Change

Section 1860D–22(a)(2)(A) of the Act requires that a plan sponsor submit an actuarial attestation annually or at another time as the Secretary may require. Section 423.884(d)(6)(ii) requires submission of an attestation no later than 90 days before the implementation of a material change to the coverage. While the term “material change” can be construed broadly to include any change to the value of a sponsor’s plan, we have issued guidance indicating that a resubmission is not necessary when a plan remains actuarially equivalent and no benefit options are being added. In this preamble we are also reiterating this interpretation: We would not require submission of an attestation under § 423.884(d)(6)(ii) where a plan sponsor still meets the actuarial equivalence test after the change, and there are no benefit options being added.

K. Subpart S—Special Rules for States—Eligibility

1. General Payment Provisions—Coordination With Medicare Prescription Drug Benefits (§ 423.906)

Section 1935(d) of the Act contains specific provisions regarding Medicaid coordination with Medicare prescription drug benefits. In the case of a full benefit dual eligible individual, Federal Financial Participation in State Medicaid expenditures is not available for Medicaid covered drugs that could be covered under Part D or for cost sharing related to these drugs. We are correcting § 423.906(b) and (c) to make clear that, in accordance with the statutory requirement in section 1935(d)(2) of the Act, only drugs specifically excluded from the definition of Part D drugs may be covered by medical assistance.

Currently, §§ 423.906(b) and (c) includes the word “covered.” (70 FR 4583) Since our regulatory definition of “Covered Part D drugs” excludes drugs that are not on a plan’s formulary, States may have interpreted the regulation to allow States to provide additional medical assistance for coverage of drugs not on a Part D plan’s formulary. The effect of these changes is to make clear that Federal financial participation is not available to States for coverage of drugs that would be Part D covered drugs except that they are not on a plan’s formulary. We are also adding a definition of “non-covered drugs” to the § 423.902.

2. States’ Contribution to Drug Benefit Costs Assumed by Medicare (§ 423.910)

Section 1935(b) of the Act, as amended by the MMA, requires States and the District of Columbia to be responsible for making monthly payments to the Federal government beginning in January 2006 to defray a portion of the Medicare drug expenditures for full benefit dual eligible individuals. The statute further defines full benefit dual eligible individuals to mean “for a State for a month an individual who has coverage for the month for covered part D drugs under a prescription drug plan under part D of title XVIII, or under an MA–PD plan under part C of such title. * * *”. In the January 28, 2005 final rule, we explained the calculation of the monthly State phased-down contributions. The calculation of the monthly state contribution is dependent upon the state’s reporting of the total number of full-benefit dual eligible individuals for the State in the applicable month. States are required, in accordance with the § 423.910(d), to submit an electronic file, in a manner specified by CMS, identifying each full benefit dual eligible individual enrolled in the State Medicaid program for each month. For States that do not submit an acceptable file by the end of the month, the phased down State contribution for that month is based on data deemed appropriate by CMS.

In § 423.910(b)(1) of the Medicare Prescription Drug Benefit final rule, we made a typographical error. (70 FR 4584) Section 423.910(b)(1) specified that “[f]or States that do not meet the *quarterly* reporting requirement for the monthly enrollment reporting, * * *”. The text should have read “For States that do not meet the *monthly* reporting requirement for the monthly enrollment reporting, * * *”, since there is no State quarterly reporting requirement referred to in either the statute or regulation when calculating the phased-down State contribution. Accordingly, we are revising the text consistent with the statute.

III. Collection of Information Requirements

This document does not impose additional information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132. With exception of the statutory change addressing the payment of vaccine administration under Part D beginning in 2008 for covered Part D vaccines, the impact of the policy supporting the clarifications in this proposed rule were addressed as part of a prior final rule and do not require further analysis. Specifically, a full regulatory impact analysis was performed for the January 28, 2005 final rule (70 FR 4454) implementing the Part D provisions of the MMA. As we explain below, many of the provisions in this proposed rule are simply clarifications of that final rule.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). Because of the addition of vaccine administration under Part D beginning in FY 2008, this rule meets the threshold to be economically significant; and is consequently a major rule. The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million or less to \$29 million in any 1 year. Individuals and States are not included in the definition of a small entity.

As stated previously the addition of vaccine administration under Part D is estimated to have a net impact to the fiscal year (FY) 2008 budget in the amount of \$100 million. Since the relevant monetary threshold has been exceeded, the RFA requires us to conduct a regulatory flexibility analysis

in regard to the implementation of vaccine administration under Part D. Given the nature of immunization in the U.S. market and its relation to the Part D benefit, we believe only two small business areas merit discussion, retail pharmacy and physicians in private practice.

The Small Business Administration (SBA) considers pharmacies with firm revenues of less than \$6 million to be small businesses. The 2002 Business Census (the latest available detailed data) indicates that there were about 19,488 firms operating about 40,152 retail pharmacies and drug store establishments (NAICS code 44611). Of these firms, 17,332 had revenues under \$5 million and operated a total of 19,488 establishments. Because more than 89 percent of retail pharmacy firms are small businesses (as defined by the SBA size standards), we expect that the inclusion of vaccine administration within the statutory definition of a covered Part D drug will have some effect on a substantial number of small retail pharmacies. However, we estimate that overall the revenue effect on the retail pharmacy industry, including small pharmacies, will be positive. In those states that permit pharmacists to administer vaccinations (currently 44 of 50 states), we anticipate Medicare beneficiaries will consider receiving immunization of Part D vaccines in a pharmacy setting, given the real-time nature of the Part D benefit and the pharmacy's ability to bill the Part D Sponsor without the beneficiary having to pay upfront for the vaccine and its administration, as he or she might in the physician's office. Over the past few years the number of beneficiaries seeking to obtain immunizations from pharmacies has continued to increase. We expect this trend to continue, when, beginning in 2008, in-network pharmacies will be able to seek compensation for the administration of Part D vaccines under the Part D program. While there may be some additional cost for pharmacist time in administering vaccines, these should be more than offset by the reimbursement of administration fees. Finally, a pharmacy could negotiate not to administer vaccine administration services and continue to participate in the Part D program, if it believed that the costs of providing vaccinations outweighed any potential benefits.

Almost all physicians in private practice (or the practices of which they are members) are small businesses, and, therefore, small entities because their annual revenues do not meet the Small Business Administration's threshold for "small" physician practices. We expect,

since a substantial number of vaccinations continue in the physician office setting, that physicians will benefit from the inclusion of vaccine administration in the statutory definition of a covered Part D drug because the administering physician will have a new source of reimbursement of Part D vaccine administration fees. We do not expect there will be any additional costs to the physicians practice.

With the respect to the other changes in the proposed rule, the definitions of negotiated prices, gross covered drug costs, and allowable risk corridor costs will not have a significant impact on small businesses, such as small pharmacies. Instead, they will primarily impact which drug costs are reported to CMS and how plans calculate beneficiary cost sharing. Moreover, they will require minimal if any changes in health plan, PBM and pharmacy operational systems. Even with these proposed changes in beneficiary cost sharing, health plans will still be required to ensure that pharmacies receive their contracted rate. If there were any additional costs due to the change in beneficiary costs, health plans would account for them in their bids.

The other technical corrections and substantive clarifications are not expected to affect small businesses in a significant manner, if at all. For example, although the substantive clarification relating to the delivery of home infusion medications may slightly increase the cost of delivering these medications for some plan sponsors because it may cost more for plan sponsors that do not currently have timeframe delivery provisions in their contracts with home infusion pharmacies, any increase will be accounted for in plan sponsors' bids. However, this increase is expected to be minimal, and is not expected to affect all plan sponsors. As for home infusion pharmacies themselves, the requirement to meet performance timeframes should also have no cost impact. Our ongoing communications with the home infusion industry revealed that these timeframes were already an industry standard. Thus, incorporation of these new requirements does not place any new burdens on the pharmacy cost structure, as home infusion pharmacies have already been meeting these performance standards in advance of our rulemaking.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the standards

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. Because prescription drugs including Part D vaccines, are dispensed in hospitals to Medicare outpatients, this final rule could have an effect on small rural hospitals who decide to offer Part D vaccines. Since a number of rural hospitals offer vaccine administration on an outpatient basis, they too will benefit by being able to collect a Part D vaccine administration fee. Rural hospitals should already have the systems in place to handle, store and administer vaccines and consequently small rural hospitals should only benefit from the availability of this new administration fee and should not incur new costs as a result of this proposed rule.

The additional clarification and proposed revisions related to the Medicare Part D drug benefit, which is the voluntary outpatient prescription drug benefit, not regulations relating to any drug benefit under Part A. Therefore these additional proposals do not affect small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$120 million. Many of the proposed changes are either corrections in the regulations to make the regulations comply with the statute, or the proposed changes are merely the formal proclamation of existing policies that are in line with the statute and do not cross the \$120 million dollar threshold. For example, one clarification, which brings the regulation in line with the statute, that will prohibit States from covering Part D drugs for recipients of Medicaid may save States the money they would have otherwise spent on these drugs, if they had chosen to cover the drugs at issue. Because the statute only allows States to cover excluded drugs, as opposed to noncovered drugs, and we expect that most States complied with the statute, as opposed to the Part D regulation, we do not believe that this clarification will significantly affect States. Therefore we do not expect that it will affect State, local, or tribal governments.

As stated previously, many of the proposed changes are either corrections in the regulations to make the regulations comply with the statute, or the proposed changes are merely the

formal proclamation of existing policies that are in line with the statute. Although there may be added costs to plan sponsors with the broadening of the definition of Part D drug to include “[s]upplies required to deliver insulin by inhalation[,]” plan sponsors are aware that new drugs and supplies become available on the market constantly and they account for these changes in their bids. Furthermore, only plan sponsors that choose to cover inhaled insulin will be affected. The expected costs to the private sector will be less than the \$120 million threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments,

preempts State law, or otherwise has Federalism implications. The proposed changes and technical clarifications will not have a substantial effect on State or local governments. For example, a clarification concerning timing of state reporting for the purposes of calculating State phase-down contributions is not expected to affect State governments, because monthly reporting is consistent with the statute. Although there is a provision in this proposal that relates to waivers of State plan licensure, there are no anticipated Federalism implications because the clarification to the applicable regulation makes the regulation comply with the existing statute.

B. Anticipated Effects

1. Effects on Health Plans, and Pharmacy Benefit Managers (PBM)

Part D plans will incur costs in implementing the reimbursement of Part D vaccine administration fees, this is a new benefit passed by Congress in the Tax Relief and Health Care Act of 2006. However, since Congress defined the Part D vaccine administration fee as a Part D drug cost, the impact will be no different than any other new drug entering the market. Part D Plans will consider Part D vaccine administration as part of their overall benefit and resulting bid. We estimate a net cost for FY 2008 which considers the offset associated with beneficiary cost sharing and the direct Federal subsidy and risk sharing, to be \$100 million.

ACCOUNTING STATEMENT.—CLASSIFICATION OF ESTIMATED EXPENDITURES, FY 2008

[In millions]

Category	Transfers
Annualized Monetized Transfers	\$100.
From Whom To Whom?	Federal Government To Part D Plans.

Our other revisions to the regulation, such as the proposed plan-to-plan reconciliation, we believe, merely reflect already existing policy. Nevertheless, even if this requirement were a new standard, we believe that all parties involved in the reconciliation would benefit, because the reconciliation process will involve fewer tasks than if pharmacies were required to reverse and re-adjudicate claims.

With respect to the proposed changes that will impact which drug costs are reported to CMS and how Part D plans calculate beneficiary cost sharing, we believe that the impact on pharmacies will be minimal, as the total compensation received by pharmacies should remain unaffected. The proposed changes may, however, require a small number of Part D sponsors to renegotiate their contracts with their PBMs to account for system changes to reflect the appropriate beneficiary cost sharing. We believe that most PBMs will be unaffected by the proposed changes in the drug costs reported and beneficiary cost sharing. Thus, the expected financial impact of these proposed changes on PBMs is minimal.

We do not believe the inclusion of inhaled insulin supplies or the substantive clarification relating to the delivery of home infusion medications will place any additional costs onto Part D plans. We estimate the gross costs of

inhaled insulin for FY 2008 will be \$10 million. The approval of inhaled insulin onto the U.S. market has been anticipated for years and should have been considered into the Part D Sponsor’s bid. As discussed earlier, the proposed home infusion delivery standard appears to be an existing standard that plans should be accustomed and consequently would not increase their costs in providing the benefit.

C. Alternatives Considered

We considered not proposing the regulation to address our policy clarifications and technical changes. However, we believed in order to ensure public awareness of our policies, as well as to avoid potential confusion regarding them, that we should codify our clarifications as well as make certain technical corrections to the January 28, 2005 final rule. In addition, we believe it is important to propose a few new clarifications for Part D plans as a result of our experience in implementing Part D. Finally, we believe it is important to acknowledge in this proposed rule changes made by the Congress to the statutory definition of a covered Part D drug.

D. Conclusion

Given that the cost of implementing vaccine administration under Part D is expected to exceed the \$100 million threshold in FY 2008, we have

performed an economic impact analysis on those entities potentially involved in providing Part D vaccine administration. Our analysis showed that entities such as physicians and pharmacies are situated to benefit from this change in 2008, whereas other entities such as Part D Sponsors will experience no or little difference in costs as a result of implementation.

As for other technical corrections and substantive clarifications contained in this proposed rule, as stated earlier, a full analysis was performed for the final regulations implementing the Part D provisions of Medicare Prescription Drug Improvement and Modernization Act of 2003, and for the reasons cited, we believe these additional proposals either do not require further analysis or are in practice today and, as such, are not economically significant.

V. Response to Comments

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

List of Subjects**42 CFR Part 423**

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

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

PART 423—MEDICARE PROGRAM; MEDICARE PRESCRIPTION DRUG PROGRAM

1. The authority citation for part 423 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

Subpart B—Eligibility and Enrollment

2. Section 423.50 is amended by revising paragraph (f)(1)(v) to read as follows:

§ 423.50 Approval of marketing materials and enrollment forms.

* * * * *

(f) * * *

(1) * * *

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

* * * * *

3. Section § 423.56 is amended by revising paragraph (b)(6) to read as follows:

§ 423.56 Procedures to determine and document creditable status of prescription drug coverage.

* * * * *

(b) * * *

(6) Coverage under a Medicare supplemental policy (Medigap policy) as defined at 42 CFR 403.205.

* * * * *

Subpart C—Benefits and Beneficiary Protections

4. Section 423.100 is amended by—

A. Revising the definition of “contracted pharmacy network.”

B. Revising the definition of “negotiated prices.”

C. Revising the definition of “part D drug.”

The revisions read as follows:

§ 423.100 Definitions.

* * * * *

Contracted pharmacy network means licensed pharmacies, including retail, mail-order, and institutional pharmacies, under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to Part D enrollees.

* * * * *

Negotiated prices means prices for covered Part D drugs that—

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

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

(3) Includes any dispensing fees.

* * * * *

Part D drug means—

(1) Unless excluded under paragraph (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) Medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze.

(v) A vaccine licensed under section 351 of the Public Health Service Act.

(vi) Supplies that are directly associated with delivering insulin into the body through inhalation, such as the inhalation chamber used to deliver the insulin.

(2) Does not include—

(i) Drugs for which payment as so prescribed and dispensed or administered to an individual is available for that individual under Part A or Part B (even though a deductible may apply, or even though the individual is eligible for coverage under Part A or Part B but has declined to enroll in Part A or Part B); and

(ii) Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under sections

1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents.

* * * * *

5. Section 423.120 is amended by revising paragraphs (a)(2) and (a)(4) to read as follows:

§ 423.120 Access to covered Part D drugs.

(a) * * *

(2) *Applicability of some non-retail pharmacies to standards for convenient access.* Part D plans may count I/T/U pharmacies and pharmacies operated by Federally Qualified Health Centers and Rural Health Clinics toward the standards for convenient access to network pharmacies in paragraph (a)(1) of this section.

* * * * *

(4) *Access to home infusion pharmacies.* A Part D plan’s contracted pharmacy network must provide adequate access to home infusion pharmacies consistent with CMS guidelines and instructions. A Part D plan must ensure that such network pharmacies, at a minimum—

(i) Are capable of delivering home infused drugs in a form that can be administered in a clinically appropriate fashion;

(ii) Are capable of providing infusible Part D drugs for both short-term acute care and long-term chronic care therapies;

(iii) Ensure that the professional services and ancillary supplies necessary for home infusion therapy are in place before dispensing Part D home infusion drugs; and

(iv) Provide delivery of home infusion drugs within at least 24 hours of discharge from an acute setting.

* * * * *

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

6. Section 423.293 is amended by revising paragraph (a) to read as follows:

§ 423.293 Collection of monthly beneficiary premium.

(a) *General rule.* Part D sponsors must charge enrollees a consolidated monthly Part D premium equal to the sum of the Part D monthly premium for basic prescription drug coverage (if any) and the premium for supplemental coverage (if any and if the beneficiary has enrolled in such supplemental coverage). Part D sponsors must permit payment of monthly Part D premiums (if any) under the timing of payments established in 422.262(e) of this chapter. Part D sponsors must also permit each enrollee, at the enrollee’s option, to make payment of premiums (if any)

under this part to the sponsor using any of the methods listed in § 422.262(f) of this chapter.

* * * * *

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

- 7. Section 423.308 is amended by—
 - A. Adding the definition of “administrative costs.”
 - B. Revising the definition of “allowable risk corridor costs.”
 - C. Revising the definition of “gross covered prescription drug costs.”

The addition and revisions read as follows:

§ 423.308 Definitions and terminology.

* * * * *

Administrative costs means costs incurred by a Part D sponsor in complying with the requirements of this Part for a coverage year and that are not drug costs incurred to purchase or reimburse the purchase of Part D drugs. Administrative costs include sponsor costs that exceed the amount paid by or on behalf of the Part D sponsor to a pharmacy or other entity that is the final dispenser of the drug for the provision of a covered Part D drug under the plan. When an intermediary acts on behalf of a Part D sponsor to negotiate prices with dispensing entities such as pharmacies, any profit retained by the intermediary contracting organization as a result of such negotiation (through discounts, manufacturer rebates, or other direct or indirect price concessions) is considered an administrative cost to the Part D sponsor and not a drug cost.

* * * * *

Allowable risk corridor costs means the subset of actually paid costs for Part D drugs (not including administrative costs, but including dispensing fees) that are attributable to basic prescription drug coverage only and that are incurred and actually paid by the Part D sponsor to—

- (1) A dispensing pharmacy or other dispensing provider (whether directly or through an intermediary contracting organization) under the Part D plan;
- (2) The parties listed in § 423.464(f)(1) with whom the Part D sponsor must coordinate benefits, including other Part D plans, as the result of any reconciliation process developed by CMS under § 423.464; or
- (3) An enrollee (or third party paying on behalf of the enrollee) to indemnify the enrollee when the reimbursement is associated with obtaining drugs under the Part D plan.

Costs must be based upon imposition of the maximum amount of copayments

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

* * * * *

Gross covered prescription drug costs mean those actually paid costs incurred under a Part D plan to purchase or reimburse the purchase of Part D drugs, excluding administrative costs, but including dispensing fees, during the coverage year. They equal—

- (1) The share of negotiated prices (as defined by § 423.100 of this chapter) actually paid by the Part D plan that is received as reimbursement by the pharmacy or other dispensing entity, reimbursement paid to indemnify an enrollee when the reimbursement is associated with an enrollee obtaining covered Part D drugs under the Part D plan, or payments made by the Part D sponsor to other parties listed in § 423.464(f)(1) with whom the Part D sponsor must coordinate benefits, including other Part D plans, as the result of any reconciliation process developed by CMS under § 423.464 of this chapter; plus

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

* * * * *

8. In § 423.350 paragraph (b)(1) is revised to read as follows:

§ 423.350 Payment appeals

(b) * * *

(1) *Time for filing a request.* The request for reconsideration must be filed within 15 days from the date of the final payment. For purposes of this paragraph, the date of final payment is: for risk adjustment, the date of the final reconciled payment under § 423.343(b); for reinsurance, the date of the final reconciled payment under § 423.343(c); for low-income cost sharing subsidies, the date of the final reconciled payment under § 423.343(d); or for risk-sharing payments, the date of the final payments under § 423.336.

Subpart I—Organizational Compliance With State Law and Preemption by Federal Law

9. Section 423.410 is amended by revising paragraph (d) to read as follows:

§ 423.410 Waiver of certain requirements to expand choice.

* * * * *

(d) 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 an applicant to become a PDP sponsor has submitted a substantially completed application for licensure to the State.

* * * * *

Subpart J—Coordination of Part D Plans With Other Prescription Drug Coverage

10. Section 423.458 is amended by revising paragraph (d)(2)(ii) to read as follows—

§ 423.458 Application of Part D rules to certain Part D plans on and after January 1, 2006.

* * * * *

(d) * * *

(2) * * *

(ii) A waiver of a requirement under this part otherwise applicable to cost plans or PACE organizations, if such waiver improves coordination of benefits provided by the cost plan under section 1876 of the Act, or by the PACE organization under section 1894 and 1934 of the Act, with the benefits under Part D.

11. Section 423.464 is amended by—
(A) Revising paragraph (f)(1)(vii), and (f)(1)(viii).

(B) Adding new paragraphs (f)(1)(ix) and (f)(5).

The revision and additions read as follows:

§ 423.464 Coordination of benefits with other providers of prescription drug coverage.

* * * * *

(f) * * *

(1) * * *

(vii) *Rural health clinics.* Rural health clinics as defined under section 1861(aa)(2) of the Act.

(viii) *Other Part D plans.*

(ix) *Other prescription drug coverage.* Other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of Part D drugs on behalf of Part D eligible individuals as CMS may specify.

* * * * *

(5) *Plan-to-plan liability.* In the process of coordinating benefits between Part D plans when a Part D plan from which a beneficiary has transferred has incorrectly made payment for covered prescription drug costs incurred after the effective date of the Part D enrollee's enrollment in the new Part D plan of record, the new Part D plan of record must make the reconciling payments based on amounts reported to it by CMS without regard to the Part D plan's own formulary or drug utilization review edits.

(6) *Use of other reconciliation processes.* In the process of coordinating benefits between the correct Part D plan of record and another entity providing prescription drug coverage when that entity has incorrectly paid as primary payer for a covered Part D drug on behalf of a Part D enrollee, the correct Part D plan of record must achieve timely reconciliation through working directly with the other entity that incorrectly paid as primary payer, unless CMS has established reconciliation processes for payment reconciliation, rather than requesting pharmacy claims reversal and re-adjudication.

Subpart K—Application Procedures and Contracts With Part D Sponsors

12. Section 423.504 is amended by revising paragraph (a) to read as follows:

§ 423.504 General provisions.

(a) *General rule.* Subject to the provisions at § 423.265 concerning submission of bids, to enroll beneficiaries in any Part D drug plan it offers and be paid on behalf of Part D eligible individuals enrolled in those plans, a Part D plan sponsor must enter into a contract with CMS. The contract may cover more than one Part D plan.

* * * * *

13. Section 423.505 is amended by revising paragraph (h)(1) to read as follows:

§ 423.505 Contract provisions.

* * * * *

(h) * * *

(1) Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. §§ 3729 et seq.), and the anti-kickback statute (section 1128B(b) of the Act).

* * * * *

14. Section 423.509 is amended by revising paragraph (a)(9) to read as follows:

§ 423.509 Termination of contract by CMS.

(a) * * *

(9) Substantially fails to comply with the marketing requirements in § 423.50, or the information dissemination requirements of § 423.128.

* * * * *

Subpart M—Grievances, Coverage Determinations, and Appeals

15. Section 423.560 is amended by

A. Revising the definition for "Appointed representative."

B. Revising the definition of "Projected Value."

§ 423.560 Definitions.

* * * * *

Appointed representative means an individual either appointed by an enrollee or authorized under State or other applicable law to act on behalf of the enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process. Unless otherwise stated in this subpart, the appointed representative has all of the rights and responsibilities of an enrollee in filing a grievance, 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.

* * * * *

Projected value of a Part D drug or drugs includes any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year. Projected value includes enrollee co-payments, all expenditures incurred after an enrollee's expenditures exceed the initial coverage limit, and expenditures paid by other entities.

* * * * *

16. Section 423.570 is amended by revising paragraph (d)(3) to read as follows:

§ 423.570 Expediting certain coverage determinations.

* * * * *

(d) * * *

(3) Subsequently deliver to the enrollee, within 3 calendar days, equivalent written notice.

* * * * *

17. Section § 423.584 is amended by adding a new paragraph (b)(3) as to read as follows:

§ 423.584 Expediting certain redeterminations.

* * * * *

(b) * * *

(3) The provisions set forth in § 423.582(b), (c), and (d) also apply to expedited redeterminations.

* * * * *

18. Section § 423.610 is amended by revising paragraph (c)(2) to read as follows:

§ 423.610 Right to an ALJ hearing.

* * * * *

(c) * * *

(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 each aggregated appeal meets the filing requirement specified in § 423.612(b); and

(iii) The ALJ determines that the appeals the enrollees seek to aggregate involve the same prescription drug.

Subpart P—Premiums and Cost Sharing Subsidies for Low-Income Individuals

19. Section 423.780 is amended by—

A. Revising paragraph (b)(1) introductory text, (b)(1)(i), (b)(1)(ii), and (b)(2)(i).

B. Revising paragraph (e).

The revisions read as follows:

§ 423.780 Premium subsidy.

* * * * *

(b) * * *

(1) The premium subsidy amount is equal to the lesser of—

(i) Under the Part D plan selected by the beneficiary, the portion of the monthly beneficiary premium attributable to basic coverage (for enrollees in PDPs) or the portion of the MA monthly prescription drug beneficiary premium attributable to basic prescription drug coverage (for enrollees in MA-PD plans) or

(ii) The greater of the low-income benchmark premium amount (determined under paragraph (b)(2) of

this section) for the region in which the subsidy eligible individual resides or the lowest monthly beneficiary premium for a PDP that offers basic prescription drug coverage in the region.

(2) * * *

(i) The low-income benchmark premium amount for a PDP region equals either—

(A) The weighted average of the monthly beneficiary premiums for all basic prescription drug plans (if all PDPs in the region are offered by the same PDP sponsor), with the weight for each basic PDP equal to a percentage, the numerator being equal to the number of Part D eligible individuals enrolled in the plan in the reference month (as defined in § 422.258(c)(1) of this chapter) and the denominator equal to the total number of Part D eligible individuals enrolled in all basic PDPs in the PDP region in the reference month.

(B) The weighted average of the premiums described in paragraph (b)(2)(i) of this section (if the PDPs in the region are offered by more than one PDP sponsor). The average is weighted using a percentage for each PDP, as well as for each MA–PD that is described in § 422.4(a)(1) of this chapter. Such percentage is calculated using a numerator equal to the number of Part D eligible individuals enrolled in each such plan in the reference month (as defined in § 422.258(c)(1) of this chapter) and the denominator equal to the total number of Part D eligible individuals enrolled in all such PDPs and MA–PD plans in the reference month.

* * * * *

(e) *Premium subsidy for late enrollment penalty.* (1) Amount of 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 enrollment penalty for the first 60 months during which the penalty is imposed and 100 percent of their late enrollment penalty thereafter.

(2) Other low-income subsidy eligible individuals— sliding scale premium subsidy for late enrollment penalty. Other low-income subsidy eligible individuals are entitled to a premium subsidy based on a linear sliding scale as follows:

(i) For individuals with income at or below 135 percent of the FPL applicable to the family size, a premium subsidy equal to 80 percent of the late enrollment for the first 60 months during which the penalty is imposed and 100 percent of their late enrollment penalty thereafter.

(ii) For individuals with income greater than 135 percent but at or below 140 percent of the FPL applicable to the family size, a premium subsidy equal to 60 percent of the late enrollment penalty for the first 60 months during which the penalty is imposed and 75 percent of their late enrollment penalty thereafter.

(iii) For individuals with income greater than 140 percent but at or below 145 percent of the FPL applicable to the family size, a premium subsidy equal to 40 percent of the late enrollment penalty for the first 60 months during which the penalty is imposed and 50 percent of their late enrollment penalty thereafter.

(iv) For individuals with income greater than 145 percent but below 150 percent of the FPL applicable to the family size, a premium subsidy equal to 20 percent of the late enrollment penalty for the first 60 months during which the penalty is imposed and 25 percent of their late enrollment penalty thereafter.

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

20. Section § 423.884 is amended by—

- A. Revising paragraph (c)(5)(i).
- B. Revising paragraph (c)(7)(i).
- C. Revising paragraph (d)(5)(iii)(B)(2).
- D. Revising paragraphs (d)(5)(iii)(C) and (D).

E. Revising the last sentence of paragraph (d)(5)(iv).

The affected paragraphs are revised to read as follows:

§ 423.884 Requirements for qualified retiree prescription drug plans.

* * * * *

(c) * * *

(5) Timing. (i) General rule. An application for a given plan year must be submitted prior to the beginning of the plan year by a date specified by CMS in published guidance, unless a request for an extension has been filed and approved under procedures set forth in such guidance.

* * * * *

(7) * * *

(i) Matches the names and identifying information for the individuals submitted as qualifying covered retirees with a CMS database(s) to determine which retirees are Part D eligible individuals who are not enrolled in a Part D plan.

* * * * *

(d) * * *

(5) * * *

(iii) * * *

(B) * * *

(2) An amount calculated to reflect the impact on the value of defined

standard prescription drug coverage of supplemental coverage actually provided by the sponsor. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified in this paragraph (d)(5)(iii)(B)(2).

(C) The valuation of defined standard prescription drug coverage for a given plan year is based on the initial coverage limit, cost-sharing amounts, and out-of-pocket threshold for defined standard prescription drug coverage under Part D in effect either at the start of the plan year or that is announced for the upcoming calendar year. In order to use the coverage limits in effect at the beginning of the plan year, the attestation must be submitted to CMS no later than 60 days after the publication of the Part D coverage limits for the upcoming calendar year; otherwise, the valuation is based on the upcoming year's initial coverage limit, cost-sharing amounts, and out-of-pocket threshold for defined standard prescription drug coverage under Part D.

(D) Example: If a sponsor's retiree prescription drug plan operates under a plan year that ends March 30, the sponsor has a choice of basing the attestation for the year April 1, 2007–March 30, 2008 on either: the initial coverage limit, cost-sharing amounts, and out-of-pocket threshold amounts that apply to defined standard prescription drug coverage under Part D in calendar year 2007, or the amounts announced for calendar year 2008. However, in order to use the amounts applicable in calendar year 2007, the sponsor must submit the attestation within 60 days after the publication of the Part D coverage limits for 2008. If the attestation is submitted more than 60 days after the 2008 coverage limits have been published, the 2008 coverage limits would apply.

(iv) * * * For the assurance required under paragraph (d)(1)(ii) of this section, the assurance may be provided either separately for each benefit option for which the sponsor provided assurances under paragraph (d)(1)(i) of this section, or in the aggregate for all benefit options (or for a subset of the benefit options).

* * * * *

Subpart S—Special Rules for States-Eligibility Determinations for Subsidies and General Payment Provisions

21. Section 423.902 is amended by adding the definition of “non-covered drugs” in alphabetical order to read as follows:

§ 423.902 Definitions.

* * * * *

Non-covered drugs are those drugs specifically excluded from the definition of Part D drug, which may be excluded from coverage or otherwise restricted under Medicaid under sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents.

* * * * *

- 22. Section 423.906 is amended by—
 - A. Revising paragraphs (b)(1) and (2).
 - B. Revising paragraph (c).
- The revisions read as follows:

§ 423.906 General payment provisions.

* * * * *

(b) * * *

- (1) Part D drugs; or
- (2) Any cost-sharing obligations under Part D relating to Part D drugs.

* * * * *

(c) Non-covered drugs. States may elect to provide coverage for outpatient drugs other than 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.

23. Section 423.910 is amended by revising paragraph (b)(1) introductory text to read as follows:

§ 423.910 Requirements.

(b) * * *

(1) Calculation of payment. The State contribution payment is calculated by CMS on a monthly basis, as indicated in the following chart. For States that do not meet the monthly reporting requirement for the monthly enrollment reporting, the State contribution

payment is calculated using a methodology determined by CMS.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 27, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: November 14, 2006.

Michael O. Leavitt,

Secretary.

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