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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

#### **42 CFR Part 423**

**[CMS-4130-F]**

**RIN 0938-A074**

### **Medicare Program; Policy and Technical Changes to the Medicare Prescription**

#### **Drug Benefit**

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

**ACTION:** Final rule.

**SUMMARY:** This final rule codifies clarifications of existing policies associated with the Medicare Prescription Drug Benefit (also known as Medicare Part D), including the following: guidance that certain supplies associated with the administration of insulin are included in the definition of a Part D drug; guidance regarding the statutory exclusion from the definition of a Part D drug of any drug when used for the treatment of sexual or erectile dysfunction, unless that drug is used for an FDA-approved purpose other than sexual or erectile dysfunction; a recent statutory change that allows for the payment of vaccine administration under Part D for Part D covered vaccines; and guidance on plan-to-plan reconciliation and reconciliation with a payer other than the Part D plan of record.

This final rule also codifies clarifications of existing policies associated with the Retiree Drug Subsidy (RDS) program, including guidance on aggregating plan options for purposes of meeting the net test for actuarial equivalence and guidance on applying the Medicare supplemental adjustment when calculating actuarial equivalence.

In addition, new clarifications and modifications in this final rule include establishing standards with respect to the timely delivery of infusible drugs covered under Part D and modifications to the retiree drug subsidy regulations. This final rule also codifies certain technical corrections to our regulations and clarifies our intent with respect to certain preamble discussions in a prior final rule implementing the Medicare prescription drug benefit.

**EFFECTIVE DATES:** These regulations are effective on June 9, 2008.

**FOR FURTHER INFORMATION CONTACT:**

Alissa DeBoy (410) 786-6041	General questions regarding the final rule.
Vanessa Duran, (410) 786-8697	Subpart B- approval of marketing and materials and enrollment forms; procedures to determine and document creditable status of prescription drug coverage; Subpart C- the definition of a long-term care facility; the definition of a contracted pharmacy network; the waiver or reduction of Part D cost-sharing by pharmacies; access to covered Part D drugs, including adequate access to home infusion pharmacies; Subpart E-organization

compliance with State law and preemption by Federal law; and Subpart K-application procedures and contracts with Part D plan sponsors.

Gregory Dill (312) 353-1754 Subpart C-definition of a Part D drug, including the exclusion of drugs used to treat erectile dysfunction, the exclusion of drugs related to morbid obesity, supplies associated with the delivery of insulin into the body, and vaccine administration fees.

Meghan Elrington (410) 786- 8675 Subpart F-timing of payments.

Deondra Moseley (410) 786-4577 Subpart G-payment appeals; and Subpart P-low-income benchmark premium amount, and premium subsidy for late enrollment penalty.

Deborah Larwood (410) 786-9500 Subpart J-coordination of Part D plans with other prescription drug coverage.

John Scott (410) 786-3636 Subpart M-grievances, coverage determinations, and appeals.

Christine Hinds (410) 786-4578 Subpart P-premiums and cost-sharing subsidies for low-income individuals.

David Mlawsky (410) 786-6851 Subpart R-payments to sponsors of retiree prescription drug plans.

Christine Hinds (410) 786-4578 Subpart S-special rules for States.

**SUPPLEMENTARY INFORMATION:**

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**I. Background**

A. Requirements for Issuance of Regulations

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) amended section 1871(a)(3) of the Social Security Act (the Act) and requires the Secretary, in consultation with the Director of the Office of

Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 1871(a)(3)(B) of the Act also states that the timelines for these regulations may vary, but shall not exceed 3 years after publication of the preceding proposed or interim final regulation, except under exceptional circumstances. This final rule finalizes provisions set forth in the May 25, 2007 proposed rule (72 FR 29403), hereinafter referred to as the May 2007 proposed rule. In addition, this final rule has been published within the 3-year time limit imposed by section 1871(a)(3)(B) of the Act. Therefore, we believe our final rule is in accordance with the Congress' intent to ensure timely publication of final regulations.

#### B. General Overview

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 MMA. The Retiree Drug Subsidy (RDS) program, which provides payments to employer and union sponsors of qualified retiree prescription drug plans for Part D drug costs within certain limits, was also enacted as part of MMA. The final rule implementing the provisions of Part D appeared in the **Federal Register** on January 28, 2005, and these provisions became effective March 22, 2005. We hereinafter refer to this rule as the January 2005 final rule. Since publication of the January 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 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, we explained many of the respective clarifications or interpretations in the May 2007 proposed rule. We also proposed to codify some of these clarifications in regulation, as well as to make certain technical corrections. Finally, due to our experience to date in implementing the Part D program, we proposed several new clarifications of our policy for Part D plans on which we specifically invited public comment.

## **II. Provisions of the Proposed Rule with an Analysis of and Response to Public Comments**

We received approximately 60 items of timely correspondence containing comments on the May 2007 proposed rule. Commenters included health plans and health plan associations, pharmacies and pharmacist associations, prescription benefit managers (PBMs), physicians and other health care professionals, beneficiary advocacy groups, representatives of hospitals, Part D beneficiaries, and others.

In this final rule, we address all relevant comments we received regarding the provisions of our proposed rule with the exception of the provisions on what may be included in the drug costs Part D sponsors use as the basis for calculating beneficiary cost sharing and reporting drug costs to CMS for the purposes of reinsurance reconciliation and risk sharing, as well as submitting bids to CMS. We are not finalizing these provisions at this time. We intend to revisit this issue in future rulemaking and will address the comments at that time. We appreciate the comments and will take them

under consideration as we continue to assess the underlying policy and its associated impact.

Most of the comments addressed multiple issues. The areas of our proposed rule that we are finalizing that received the most comment include the provisions on ensuring adequate access to home infusion pharmacies and the provisions addressing the coordination of Part D plans with other prescription drug coverage. Generally, the vast majority of commenters expressed strong support for the provisions of our proposed rule, declaring them essential to the success and continued operation of the Medicare Part D program. This was especially true with regard to our proposal to establish a standard for the timely delivery of home infusion drugs. A significant subset of the comments regarding home infusion access suggested even more rigorous standards for ensuring the timely delivery of Part D infusible drugs.

We also received a significant number of comments that addressed our proposed clarifications on permissible activities vis-à-vis provider marketing and the coverage of drugs when used to treat morbid obesity. In general, commenters supported our clarifications or technical corrections. However, on some issues, commenters asked for reinterpretations of the statute.

In this final rule, we address comments received on the May 2007 proposed rule largely in the numerical order of the related regulation sections.

A. Subpart B—Eligibility and Enrollment

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

In our May 2007 proposed rule (70 FR 4223), we clarified that when we used the term “market” in the preamble to the January 2005 final rule in the context of our discussion of the approval process for marketing materials and enrollment forms, we used it in a more general sense to mean assisting in enrollment or education directed at beneficiaries, and not marketing per se as the term is understood to mean in the commercial context. This clarification was necessary to distinguish our preamble discussion and our narrower definition of the term “marketing” in the Medicare Marketing Guidelines, which were issued subsequent to our publication of that final rule. (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 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.” (Medicare Marketing Guidelines, page 8.) This definition further clarifies that neither “[a]ssisting in enrollment” nor “education” constitute “marketing” as those terms are defined in The Guidelines (Medicare Marketing Guidelines, page 8.) The Medicare Marketing Guidelines specify that “assisting in enrollment” consists of assisting a potential enrollee with the completion of an application and objectively discussing characteristics of different plans to assist a potential enrollee with appraising the relative

merits of all available individual plans, based solely on the potential enrollee's needs; further, the individual or entity performing these activities may not receive compensation directly or indirectly from a plan for such assistance in enrollment (Medicare Marketing Guidelines, page 6.) "Education" is defined in the Medicare Marketing Guidelines as informing a potential enrollee about Medicare Advantage or other Medicare programs, generally or specifically, but not steering, or attempting to steer, a potential enrollee towards a specific plan or limited number of plans (Medicare Marketing Guidelines, page 6.) Thus, our intent in the preamble of the January 2005 final rule was to acknowledge that providers and pharmacies are free to engage in either "assisting in enrollment" or "education," including provider promotional activities as permitted under the Medicare Marketing Guidelines, but not to "market" to beneficiaries, as the term is defined in the Medicare Marketing Guidelines. We maintain this clarification in the final rule, as noted in our response to comment.

Additionally, we proposed to clarify the provision that currently 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)." We believed it was necessary to clarify this provision because it was possible to infer from it that when a Part D plan used providers, provider groups, or pharmacies to distribute printed information comparing the benefits of the Part D plans with which they contracted, they would also have to accept and display printed information comparing the benefits of different plans with which they did

not contract. Our concern was that this interpretation could lead to situations in which a beneficiary made a plan selection and realized too late that the provider or pharmacist from whom they obtained printed information about a particular plan was not in fact contracted with that plan. Therefore, in the proposed rule, we clarified that a Part D plan could use providers, provider groups, or pharmacies to distribute printed information comparing the benefits of different Part D plans, provided those providers, provider groups, or pharmacies accepted and displayed printed information comparing the benefits of all the different Part D plans with which they contract. However, the providers, provider groups, or pharmacies were not obliged to accept and display any comparative information regarding those Part D plans with which they did not contract. We stipulated that this clarification would apply to comparative marketing materials and was in accord with the Medicare Marketing Guidelines (Medicare Marketing Guidelines, page 125.) In this final rule, we codify this policy by revising §423.50(f)(1)(v).

Comment: A large number of commenters supported our clarification that providers and pharmacies that are contracted with plan sponsors may not market to beneficiaries but may assist in enrollment, including participating in provider promotion activities within the parameters established in the Marketing Guidelines, and educate enrollees. However, two commenters believed that CMS should withdraw this clarification given that it is based on a term we use in the Medicare Marketing Guidelines, which is not a regulatory document. Further, these commenters questioned the validity and utility of the Medicare Marketing Guidelines in the long-term care setting.

Response: The two commenters who asked us to withdraw this clarification did so based on arguments about the validity of the Medicare Marketing Guidelines, which we believe are outside the scope of this regulation. In the proposed rule and in this final rule, we are merely clarifying our policy so as to avoid any confusion arising from the broader use of the term “market” in a response to comment in the January 2005 final rule.

Comment: Several commenters supported our proposed revision to §423.50(f)(1) allowing Part D plans to use providers, provider groups and pharmacies to distribute printed information comparing the benefits of different plans only if those providers, provider groups or pharmacies accept and display materials from all Part D plan sponsors with which they contract. Two of these commenters were especially pleased with our clarification that providers, provider groups, or pharmacies are not obliged to accept and display any comparative information regarding those Part D plans with which they do not contract. However, another commenter believed that instead of requiring providers to accept and display information for every plan with which they have contracted, we should allow them to accept and display materials from a reasonable cross-section of contracted plans, as long as the provider posts a notice informing beneficiaries that the displayed material describes the benefits of only a subset of contracted plans and explains where beneficiaries may obtain information on the full array of benefits available to them.

Response: Our goal is to ensure that beneficiaries receive the information they need to make a plan selection that is based on their particular needs. We disagree with the commenter who believes that we should allow Part D plan contracted providers,

provider groups, and pharmacies to accept and display materials from only a subset of plans with which they contract – even if they direct beneficiaries to resources for obtaining information on all plans. We believe the proposed requirement strikes a balance between allowing providers and pharmacies contracted with Part D plans to provide enrollment assistance and education, while ensuring that beneficiaries are provided with information about the full array of plans with which that provider or pharmacy contracts – not on a limited subset that may reflect the provider’s financial interest – and can make a plan selection that best meets their needs. Accordingly, we have adopted the revision to §423.50(f)(1) as set forth in the proposed rule. However, we note that plans must provide contracted pharmacies with materials in order for pharmacies to display their plan information along with any other materials received from other contracted plans.

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

The regulation text of the January 2005 final rule (70 FR 4532) contained a typographical error in §423.56(b)(6) that referenced §423.205 for a definition of the term “Medicare supplemental policy.” However, the proper reference for the definition of the term “Medicare supplemental policy” is §403.205. Therefore, we proposed revising the regulation text accordingly to state the correct reference – that is, §403.205. We received no comments with regard to our proposed revision. Therefore, this final rule adopts this revision without change.

### B. Subpart C — Benefits and Beneficiary Protections

1. Definitions (§423.100)

a. Part D Drug

(1) Erectile Dysfunction (ED)

On October 20, 2005, Congress amended section 1860D-2(e)(2)(A) of the Act to exclude erectile dysfunction (ED) drugs from the statutory definition of a Part D drug. Section 1860D(2)(e)(2)(A) of the Act excludes from the definition of Part D drugs those drugs or classes of drugs, or their medical uses, set forth under section 1927(d)(2) of the Act (other than subparagraph (E)). The ED drug exclusion is cited in section 1927(d)(2)(K) of the Act.

In the May 2007 proposed rule, we reiterated that beginning January 1, 2007, ED drugs would 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 Food and Drug Administration (FDA). We noted that ED drugs would 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 -- including the treatment of a condition other than sexual or erectile dysfunction 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. 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, we also noted that no regulation text change is required to



implement this new statutory exclusion.

Comment: One commenter asked that we share our interpretation of the statutory ED drug exclusion with our independent review entity (IRE).

Response: Since October 20, 2005, we have provided information about the ED drug exclusion in our outreach efforts to beneficiaries, advocates, and our own contractors. Our guidance to Part D sponsors on the ED drug exclusion was included in Chapter 6 (“Part D Drugs and Formulary Requirements”) of our Prescription Drug Benefit Manual, which is posted on the CMS Web site at [http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBMChap6FormularyReqrmts\\_03.09.07.pdf](http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBMChap6FormularyReqrmts_03.09.07.pdf). As a result of our efforts, we believe stakeholders are now well aware of this statutory change.

## (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 2005 final rule (70 FR 4228), 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. However, in response to comment, we had erroneously asserted that to the extent that a drug was dispensed for a “medically accepted indication” as described in section 1860D-2(e)(1) of the Act, the drug could be covered for the treatment of morbid obesity (70 FR 4230). Both in the May 2007

proposed rule and in this final rule, we clarify that agents, when used for anorexia, weight loss, or weight gain, are specifically excluded from the definition of Part D drugs. 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.

Comment: We received several comments asserting that the clarification we made in the proposed rule regarding Part D coverage of drugs used to treat a medically accepted indication of obesity was a reversal of current Part D coverage policy.

Response: We disagree with these commenters. The clarification in our proposed rule did not expand or change our current policy regarding the exclusion from the definition of Part D drugs or agents used for anorexia, weight loss, or weight gain. Our policy with regard to coverage of these drugs has remained consistent since well before the Part D benefit was implemented on January 1, 2006 and is in accord with the statutory exclusion of such drugs from the definition of Part D drug as provided in section 1860D-2(e)(2) of the Act. In the May 2007 proposed rule, we simply clarified that we had made an error in the preamble of the January 2005 final rule by asserting that weight loss drugs could be potentially covered under the Part D program as part of a Part D basic prescription drug benefit. As discussed in the May 2007 proposed rule, we corrected this error via guidance to Part D sponsors and other stakeholders in July 2005.

Comment: A number of commenters asserted that our interpretation of the statutory exclusion of weight loss drugs was too narrow and that CMS was not appropriately distinguishing “cosmetic” weight loss from those clinical circumstances in

which drugs are being specifically prescribed for an indication of obesity or significant weight management. Other commenters maintained that Congress intended for reimbursement of weight loss drugs when they were used in the treatment of defined disease states; that given the potential impact of obesity on American health care, as well as Medicare Part A coverage of obesity treatments, drugs when used to treat obesity should also be covered under Part D; and that Part D coverage of drugs used to treat obesity would be consistent with guidance and decision-making about these drugs by other DHHS agencies (for example, the National Institute of Health's (NIH) treatment guidelines regarding obesity drugs and the Food and Drug Administration's (FDA) approval of drugs indicated for the treatment of obesity).

Response: Section 1860D-2(e)(2) of the Act specifically excludes from the definition of a Part D drug agents when used to treat anorexia, weight loss, or weight gain. Therefore, drugs when used to treat a medical indication of morbid obesity are not considered Part D drugs. While this statutory exclusion may create an inconsistency with regard to treatment approaches for morbid obesity under different parts of the Medicare program, Part D coverage policy is based on completely distinct statutory authority than Parts A and B. We note that similar to other drugs contained in section 1927(d)(2) of the Act that are excluded from the definition of Part D drugs (other than over-the-counter drugs), those Part D plans wishing to provide coverage of weight loss agents may do so as a supplemental benefit under enhanced alternative coverage, consistent with §423.104(f).

Comment: A number of commenters asked that CMS clearly state that the Part D

exclusion of weight loss drugs will not affect Part D coverage of drugs that may cause weight loss, but whose primary indication is not for obesity. A few other commenters noted that our exclusion of obesity drugs is inconsistent with CMS policy regarding Part D coverage of weight loss drugs under certain clinical situations (for example, Part D and Medicaid coverage for drugs when used to treat cachexia or AIDS wasting).

Response: Drugs that are excluded from coverage under Part D when used as agents for certain conditions may be considered covered when used to treat other conditions not specifically excluded by section 1927(d)(2) of the Act, provided they otherwise meet the requirements of section 1860D-2(e)(1) of the Act and are not otherwise excluded under section 1860D-2(e)(2)(B) of the Act. A Part D drug's clinical side effect of weight loss would not permit its exclusion via section 1927(d)(2) of the Act since the drug's use was not prescribed for that purpose.

We have previously stated that we do not consider prescription drug products being used to treat AIDS wasting and cachexia as either agents used for weight gain or agents used for cosmetic purposes. Given the clinical complexities associated with AIDS wasting and cachexia, and the documented therapeutic action of these drugs to work beyond weight gain and prevent associated morbidity and mortality, the use of these products cannot be excluded from Part D by reference to section 1927(d)(2) of the Act. A summary of similar potential exclusions and their associated explanations can be found in Appendix B of Chapter 6 (Part D Drugs and Formulary Requirements of our Prescription Drug Benefit Manual), which is posted on the CMS Web Site at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBMChap6Formular>

[yReqrmts\\_03.09.07.pdf](#).

(3) Insulin Inhalation Drugs and Supplies

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).” In the January 2005 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. On January 27, 2006, the FDA approved the first-ever inhaled insulin product. 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 reviewed the issues surrounding inhaled insulin and concluded it would be appropriate to revise the definition of Part D drug to include certain supplies associated with the delivery of inhaled insulin. We proposed revising the definition of a Part D drug under §423.100 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.” We also indicated that our proposed change to the definition of a Part D drug was crafted consistent with our intention to narrowly construe what constitutes medical supplies associated with the delivery of insulin into the body in order to avoid an inappropriate expansion of the Part D benefit. Thus, we stated in the preamble to our proposed rule that we would expect Part D sponsors to apply drug utilization management tools to

ensure the appropriate use of these supplies.

While we have learned since the publication of our May 2007 proposed rule that marketing of the first inhaled insulin product may be discontinued, the fact remains that this product is still approved for the U.S. market. Additionally, we received comments indicating that there are insulin products administered through routes other than injection in various stages of research and FDA approval. As a result, we believe our policy on inhaled insulin is still necessary and sound.

Comment: Most commenters on this issue supported our proposal to expand the definition of a Part D drug to cover those supplies directly associated with inhaled insulin. However, other commenters opined that the proposed definition was too narrow and CMS should broaden the definition of a Part D drug to encompass other potential mechanisms or supplies used for delivery of insulin into the body, such as novel insulin dosage forms and delivery systems that are currently under review by the FDA. Some commenters noted developments in diabetes treatment including new transdermal, intranasal and aerosolized insulin delivery methods. These commenters held that by not broadening the Part D drug definition to include insulin delivery supplies that are currently in the research and development pipeline, but which might someday be FDA-approved, CMS would be burdened with future rulemaking to modify the definition of a Part D drug when new FDA-approved products came to market. As a result, CMS might provide a competitive advantage to manufacturers whose insulin-related supplies are currently encompassed within the definition of a Part D drug over other manufacturers whose insulin supplies are also related to the direct delivery of insulin into

the body but would not be covered under Part D in the absence of a further broadening of the definition of a Part D drug under §423.100.

Response: We agree that our proposed rule too narrowly construed what constitutes medical supplies associated with delivery of insulin into the body for purposes of the definition of a Part D drug under §423.100. Moreover, we believe that Congress intended to ensure diabetics' access to insulin by providing for coverage of the medical supplies directly associated with delivering insulin into the body. In light of continuing medical research and development of alternative mechanisms for insulin delivery, we believe it is consistent with Congressional intent that our definition of these supplies encompass all products that are directly associated with the delivery of insulin into the body, including future potential delivery mechanisms, and not limit coverage to supplies associated with the only two mechanisms of insulin delivery (injection and inhalation) available to diabetics today. Consequently, we have removed our reference to the specific route of administration, "through inhalation," in the definition of a Part D drug at §423.100(i)(iv). Instead, our definition of a Part D drug will encompass supplies that are directly associated with delivering insulin into the body, such as the inhalation chamber used to deliver the insulin. We believe this modification will obviate the need for continued future rulemaking to ensure coverage of supplies that are directly associated with delivery of insulin into the body. In addition, we believe that our revised definition of the term Part D drug will level the playing field for the manufacturers of novel administration insulin supplies while avoiding an inappropriate expansion of the Part D benefit to insulin-related supplies in which the relationship to delivery into the body is

more indirect. We have retained the example of the inhalation chamber in the definition of a Part D drug under §423.100 only as an example of a product that is directly associated with the delivery of insulin into the body.

Comment: A few commenters suggested that we clarify that our proposed modification of the definition of a Part D drug excludes any insulin delivery device covered under the Part B durable medical equipment benefit.

Response: Paragraph (2)(i) of our existing definition of a Part D drug already excludes from Part D coverage those 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. We believe that further clarification of this exclusion is unnecessary.

Comment: We received comments asking that CMS issue separate guidance indicating whether any novel insulin-related product will be covered under Part D.

Response: We disagree that we should issue product-specific Part D coverage guidance for all new FDA approvals. Part D sponsors and their Pharmacy and Therapeutics (P&T) Committees are required to evaluate new FDA-approved products and make timely coverage determinations that are consistent with the definition of a Part D drug under §423.100. While we provide Part D sponsors with tools to assist sponsors with their reviews of new products, coverage determinations are ultimately a Part D sponsor's responsibility.

Comment: A number of commenters asked that we retract the statement we made in our proposed rule that we would expect Part D sponsors to apply drug utilization management tools to inhaled insulin supplies. These commenters stated that the



application of such pharmacy based edits would impede access to these inhaled insulin supplies for beneficiaries who are appropriately qualified for this insulin delivery mechanism. Many of these same commenters stated that inhaled insulin supplies should be provided free of any utilization management tools to maximize use of this new therapy.

Response: We remind these commenters that all Part D sponsors, with the exception of Medicare Advantage private fee-for-service (PFFS) plans, are required under §423.153(b) to establish reasonable and appropriate drug utilization management programs. As we stated in the May 2007 proposed rule, sponsors should ensure the appropriate and prudent use of all Part D drugs, including supplies associated with the direct delivery of insulin into the body and the use of drug utilization management tools, is appropriate to prevent inappropriate coverage and utilization of insulin-related supplies. In general, inhaled insulin supplies have either a specific life span based on the number of doses or actuations they deliver or, for more durable items, a manufacturer's recommended life span ranging from a few months to a year or more with proper cleaning and maintenance. It is therefore appropriate for a sponsor to evaluate claims for inhaled insulin supplies that are submitted for a period less than their recommended life span or period of use.

#### (4) Vaccine Administration Fee

On December 20, 2006, the Tax Relief and Health Care Act of 2006 was signed into law. Section 202(b) of that legislation amended the definition of a Part D drug at section 1860D-2(e)(1)(B) of the Act to include a reference to vaccine administration on

or after January 1, 2008. In the May 2007 proposed rule (72 FR 29406) we indicated that we would amend the definition of Part D drug to conform to the statutory change. Accordingly, in this final rule, we have amended the definition of a Part D drug to include a reference to vaccine administration on or after January 1, 2008, consistent with the statute.

Comment: One commenter suggested we increase our outreach efforts regarding the availability of vaccine administration under Part D.

Response: We agree with this comment and have employed a number of methods to ensure that beneficiaries and providers are aware of this statutory change. We have updated our beneficiary outreach materials with specific information on Part D vaccine administration reimbursement, including the addition of a section to the annual evidence of coverage (EOC) notice that was mailed to all currently enrolled beneficiaries in advance of the 2008 Part D contract year. We have also incorporated information regarding Part D vaccine administration into our provider programs and have conducted a number of national level outreach programs addressing the availability of reimbursement under Part D for this new benefit in 2008. We have generated MedLearn Matters Articles on Part D vaccines and vaccine administration for display on the CMS Web site (<http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0727.pdf>). We have also issued guidance to Part D sponsors on vaccine administration so they can prepare for covering these services and address beneficiary questions. We plan on continuing various tiers of communication on Part D vaccine administration into 2008 and subsequent years.

Comment: One commenter asked that we monitor billing and payment for Part D vaccine administration over the next several months to identify and resolve issues that may arise with implementation of this new benefit under Part D.

Response: We agree with this comment. We intend to work very closely with our Part D sponsors on resolving any issues that arise with covering Part D vaccine administration in 2008 and subsequent years. We have developed a number of communication channels to solicit feedback from various stakeholders regarding the ongoing implementation of this new benefit, and we will take appropriate actions to address any issues with our Part D sponsors as they occur.

Comment: One commenter specifically suggested that we amend §423.100 to add the following language to the definition of a Part D drug under paragraph (1)(v) of that definition: “and for vaccine administration on or after January 1, 2008, its administration.”

Response: We agree with this comment. We are changing the definition of a Part D drug at §423.100 to conform to the statutory change made by the Tax Relief and Health Care Act of 2006 to section 1860D-2(e)(1)(b) of the Act. Accordingly, we are modifying §423.100 to include vaccine administration for Part D-covered vaccines on or after January 1, 2008.

#### b. Long-Term Care Facilities

In the January 2005 final rule (70 FR 4534), the term “long-term care facility” is defined in §423.100 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.” However, in our corollary discussion of that term in the preamble of the January 2005 final rule (70 FR 4236), we inadvertently omitted institutions for mental disease (IMDs) from the list of facilities that meet the definition of a long term care (LTC) facility.

In the May 2007 proposed rule, we clarified that 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 a LTC facility in §423.100.

We also clarified 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, we indicated that 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: (1) need drugs for which payment is no longer available under Part A or Part B and otherwise meet the

definition of a Part D drug; and (2) are inpatients in a hospital where the hospital is a “medical institution” under section 1902(q)(1)(B) of the Act and therefore would meet the Part D definition of an LTC facility.

Comment: Several commenters supported our clarification that an IMD may meet our definition of a long-term care facility and that, consequently, Part D plans must provide convenient access to a network long-term care pharmacy to the residents of such facilities. One commenter supported our proposed policy clarification but noted that there were significant practical implications. For example, plans might not receive notice that their members are IMD patients until after prescriptions have been filled and claims are submitted. Both this and the fact that most of these facilities use only in-house, State-run pharmacies to fill prescriptions often prevent plans from anticipating the need for contracts with these institutional LTC pharmacies. Another commenter echoed this statement, noting that Part D sponsors have experienced difficulty contracting with certain LTC pharmacies. One commenter asked us to clarify that we would determine a Part D plan to be in compliance with our convenient access requirements if it limited itself to pursuing contracts only with institutional LTC pharmacies that proactively sought inclusion in a plan’s pharmacy network, consistent with the “any willing pharmacy” requirement. Another commenter asked us to clarify that plans would be considered compliant with the convenient access requirements even if they did not come to terms with an institutional LTC pharmacy, provided they made a good faith effort to contract.

Response: The fact that a Part D plan has met our LTC pharmacy network

submission requirements as part of the application approval process does not preclude it from continuing its contracting efforts with LTC pharmacies as needed. In fact, continued contracting likely will be necessary in order for plans to meet the convenient access standard articulated at §423.120(a)(5). This is particularly true as plans continue to identify LTC facilities and LTC pharmacies, and as they examine their auto-enrollment assignments and incoming enrollments. To the extent that a beneficiary is enrolled in a plan that does not have a contract with a LTC pharmacy that can serve the LTC facility in which he or she resides, the appropriate action for a plan to take is to contract with the facility's contracted LTC pharmacy or – if that pharmacy will not sign a contract – with another LTC pharmacy that can serve that facility. In some cases, a retroactive contract may be necessary to ensure coverage for enrollees in a particular facility. For example, if a Part D sponsor becomes aware that one or more of its enrollees resides in a LTC facility that is not serviced by one of its network LTC pharmacies and cannot immediately either identify a network LTC pharmacy that can serve this particular facility or negotiate a contract with the facility's contracted LTC pharmacy, a retroactive contract might be necessary to ensure convenient access for the enrollees in question. This would particularly be the case if the facility's contracted pharmacy makes a good faith effort to negotiate but the sponsor does not quickly finalize a contract. We emphasize that plans will not be compliant with our LTC convenient access standard if they do not provide access to covered Part D drugs via a LTC pharmacy in their network for all of their enrollees who reside in LTC facilities.

We understand that there sometimes may be issues associated with contracting with the in-house, and often State-run and operated, pharmacies that many ICFs/MR, IMDs, and LTC hospitals use to provide drugs and pharmacy services to their patients – for example, multiple claim formats, post-consumption billing, and potential delays in billing due to systems and other start-up issues – that could delay or complicate contracting negotiations. In some States, licensing laws preclude facilities from obtaining prescription drugs and LTC services for their residents from anywhere but the facility’s in-house pharmacy. Further, States may not be able to agree to certain standard clauses in some LTC standard contracts because of constitutional and legal restraints on States. For example, contractual provisions that require arbitration may be problematic for States that are legally precluded from going to arbitration. In these situations, Part D plans should be prepared to readily negotiate with States to address these issues. To the extent that plan contracting efforts involve communication with State-run and operated pharmacies, we have consistently encouraged sponsors to coordinate their efforts through a single point of contact at the State level. We provide lists of State contacts for IMDs and ICFs/MR on the CMS Web site at

[http://www.cms.hhs.gov/PrescriptionDrugCovContra/11\\_PartDContacts.asp#TopOfPage](http://www.cms.hhs.gov/PrescriptionDrugCovContra/11_PartDContacts.asp#TopOfPage).

Comment: Several commenters supported our clarification that plans must provide convenient access to a LTC pharmacy to inpatients in hospitals who have exhausted their Part A inpatient days benefit and whose drugs qualify as Part D drugs given that coverage is not available under Part A or Part B. One commenter expressed concern that our policy clarification was confusing and could create an unintended

expansion of the Part D benefit. This commenter urged CMS to provide more specific guidance, consistent with the Part D statutory and regulatory framework, regarding the circumstances under which Part D coverage would be available to patients who have exhausted their Part A inpatient days and for whom Part B coverage is not available.

Response: Section 1860D-2(e)(2)(B) of the Act requires the exclusion of coverage under Part D of any drug for which, as prescribed and dispensed or administered to an individual, payment would be available under Parts A or B of Medicare for that individual. In the preamble to January 2005 final rule, we clarified that this requirement meant that if payment could be available under Part A or Part B to that individual for such drug, then it would not be covered under Part D. This means that if an individual could sign up for Parts A or B, payment could be available under Part A or Part B, regardless of whether they actually enrolled. All individuals who are entitled to premium-free Part A are eligible to enroll in Part B. All individuals who are entitled to Part B only are almost never eligible for premium-free Part A but are eligible to buy into Part A for a premium. Consequently, for all Part D eligible individuals, drugs covered under Parts A and B are available if they choose to pay the appropriate premiums.

However, drugs provided in an inpatient setting to an individual who has exhausted his or her lifetime inpatient hospital benefit under Part A are not drugs that could be covered under Part A for that individual. Unlike a beneficiary who, for example, chooses not to buy into Part B, there is no way for an individual who has exhausted his or her Part A inpatient stay benefit to obtain coverage under Part A for his or her drugs. Thus, once a Part D enrollee exhausts his or her Part A inpatient days benefit, any drugs that cannot be



covered under Part B are Part D drugs provided they otherwise meet the definition of a Part D drug at §423.100. The LTC convenient access standard is implicated when these individuals reside in hospitals that meet our definition of a LTC facility. However, because we envision it will be rare (and typically unforeseen) that an individual exhausts his or her inpatient Part A hospital benefit and remains hospitalized – and that the hospital meets the definition of a LTC facility – we expect that the need to contract with hospital pharmacies to provide Part D drugs to these individuals will be quite rare, and that contracting will be undertaken only on an as-needed basis. As discussed elsewhere in this preamble, to the extent that a beneficiary is enrolled in a plan that does not have a contract with a LTC pharmacy that can serve the LTC facility in which he or she resides, the appropriate action for a plan to take is to contract with the facility’s contracted pharmacy or – if that pharmacy will not sign a contract – with another network LTC pharmacy that can serve that facility. In some cases, a retroactive contract may be necessary to ensure coverage for enrollees in a particular facility. Part D plans will not be compliant with our LTC convenient access standard if they do not provide access to covered Part D drugs via a LTC pharmacy in their network for all of their enrollees who reside in LTC facilities. We will take appropriate compliance action if LTC enrollees’ access to covered Part D drugs is compromised due to the unavailability of a network LTC pharmacy.

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. In the January 2005 final rule (70 FR 4535), 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.” We proposed revising the definition of “contracted pharmacy network” to state that a pharmacy participating in a contracted pharmacy network must be licensed.

We received only one comment on this clarification, which supported our proposed revision. Accordingly, we are adopting the revised definition of “contracted pharmacy network” as set forth in the proposed rule without change.

## 2. Requirements Related to Qualified Prescription Drug coverage (§423.104) – Waiver or Reduction of Part D Cost-sharing by Pharmacies

In the January 2005 final rule (70 FR 4240), we stated that we would allow waivers or reductions of cost-sharing by pharmacies to count as incurred costs. However, our statement was limited to pharmacies that are not also acting as other wrap-around coverage that generally would not count toward incurred costs (or true-out-of-pocket, (TrOOP) costs). We did not intend to allow pharmacy waivers to count as incurred costs in cases where a pharmacy also meets the definition of a group health plan, insurance or otherwise, or a third party payment arrangement, as those terms are defined in §423.100.

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 clarified in the proposed rule that although we will generally

allow waivers or reductions of Part D cost-sharing by pharmacies to count as incurred costs, this will not be the case for pharmacies affiliated with entities whose wrap-around 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 noted in our response to comments below, we maintain our position in this final rule.

Comment: One commenter disagreed with our proposed clarification regarding the applicability to TrOOP of pharmacy waivers or reductions of Part D cost-sharing made by certain entities. This commenter believes that our clarification penalizes Part D sponsors that, as non-profit organizations, have historically and responsibly provided financial assistance (and now pharmacy waivers) to financially needy members as part of their mission. The commenter recommended that CMS either allow all or no pharmacy waived cost-sharing to count toward TrOOP, since every pharmacy is affiliated with one or more Part D sponsors and any pharmacy waiver can serve the economic interests of both the pharmacy and the sponsor. The commenter believes it is preferable for CMS to develop standards under which Part D sponsors could – through cost-sharing waivers granted by affiliated network pharmacies – assist non-LIS eligible enrollees with a demonstrated financial need and have that waived cost-sharing count toward TrOOP.

Response: We disagree with this commenter's recommendation. While we appreciate the fact that some Part D sponsors are non-profit entities with charitable missions, we note that a pharmacy owned and operated by an insurer is acting on behalf of an insurer. Because a Part D drug costs paid or reimbursed by an insurer, as that term

is defined in §423.100, cannot count as an incurred cost, per the definition of the term “incurred cost” in §423.100, allowing pharmacy waivers funded by an insurer to count toward an enrollee’s TrOOP balance would essentially be an end run around our rules regarding incurred costs.

Comment: Two commenters did not support our policy clarification regarding the applicability to TrOOP of pharmacy waivers or reductions of Part D cost-sharing made by safety-net pharmacies, including Federally-qualified health centers (FQHCs). Given that many safety-net providers are fully or partially funded through government grants, their waivers or reductions of cost-sharing may leave many low-income individuals unable to reach the catastrophic coverage portion of their Part D benefits. These commenters assert that although safety-net providers rely on a variety of revenue sources – both public and private – to provide health care services, unlike other programs identified as “government-funded health programs” in the preamble to the January 2005 final rule, FQHCs do not necessarily use government funds to pay the cost of Part D drugs and should not necessarily be categorized as government-funded health programs. One of these commenters believes that recent operational guidance released by CMS indicating that DSH funds could count toward TrOOP further supports its position that health center-subsidized cost-sharing should count toward TrOOP. The commenter asserts that the receipt of any source of Federal funding should not automatically result in excluding health center cost-sharing from TrOOP expenditures.

Response: Payments made for Part D enrollees’ Part D cost-sharing by any entity – including an FQHC or other safety-net pharmacy – that has an obligation to pay for

covered Part D drugs on behalf of Part D enrollees, or which voluntarily elects to use public funds, in whole or in part, for that purpose, will not count toward that beneficiary's TrOOP expenditures. We understand that safety-net providers use a mix of private and public revenue sources to provide health care services and prescription drugs. As we stated in the January 2005 final rule, to the extent that an entity pays for the cost of drugs using a mix of private and public funds, the entity is considered a government-funded health program, and all of its Part D drug spending is excluded from TrOOP. However, if an entity can demonstrate to a Part D sponsor that it uses only non-public funds to pay for the cost of Part D drugs, that sponsor may allow for cost-sharing waivers or reductions in cost-sharing paid for by that entity's pharmacies to count toward TrOOP. Part D sponsors remain ultimately accountable for correctly tracking their enrollees' TrOOP expenditures.

We view Medicare and Medicaid DSH funds essentially as adjustments to the Medicare and Medicaid reimbursements these facilities already receive for covered services. In other words, receipt of Medicaid or Medicare DSH payments by a hospital does not, in and of itself, render a DSH facility (and any Part D network pharmacy it owns or operates) a "government-funded health program." Even though DSH funds are not considered government funding streams that would render an entity a government-funded health program, DSH hospitals may be government-funded health programs given other government funding streams they receive. An entity that receives DSH funds but uses non-DSH government funding streams to provide to or pay on behalf of an individual the costs of Part D drugs will still meet our definition of a

government-funded health program, and any reduction or waiver of Part D cost-sharing that it offers will not count toward a Part D enrollee's TrOOP balance. The same logic applies to FQHC pharmacies, meaning that cost-sharing waivers or reductions applied by an FQHC or other safety-net provider pharmacy that uses government funding streams to provide or pay on behalf of an individual the costs of Part D drugs, the costs of these drugs will not count toward a beneficiary's TrOOP balance.

Comment: One commenter asked us to clarify that only cost-sharing reductions that are in fact paid for by group health plans, government-funded health programs, or other third party payment arrangements will not count toward "incurred costs" and that cost-sharing waivers by a pharmacy, even if the pharmacy is affiliated with a payer, will count toward incurred costs. This commenter is particularly concerned that this language could be misconstrued to disallow waivers by pharmacies that are affiliated with Part D sponsors providing supplemental benefits under enhanced alternative coverage. The commenter also stated that this prohibition should apply only if the reduction or waiver is part of the coverage provided by a health plan or other third party payment arrangement, and not a waiver funded by the affiliated pharmacy itself.

Response: As we have previously stated, pharmacy waivers or reductions of Part D cost-sharing will count toward TrOOP when the pharmacy waiving or reducing the Part D cost-sharing does not meet the definition of a group health plan, insurance, government-funded health program, or party to a third party payment. A pharmacy is not subject to this prohibition simply because it is contracted with a Part D sponsor as a network pharmacy. We note that any cost-sharing associated with non-Part D drugs

covered under a supplemental benefit does not meet the definition of an incurred cost per the definition of that term in §423.100 and, therefore, any pharmacy waiver or reduction of such cost-sharing would have no impact on a beneficiary's TrOOP balance in any case.

### 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 the January 2005 final rule (70 FR 4537), we made a technical error in §423.120(a)(2) by inadvertently referring to “rural health clinics” as “rural health centers.” The correct terminology for those facilities is “rural health clinics.” Accordingly, we proposed to revise 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.” We received no comments with regard to this proposed revision. Therefore, this final rule adopts the proposed revision to §423.120(a)(2) without change.

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

We proposed to codify in regulation, at §423.120(a)(4) (70 FR 4537), guidance that we issued with regard to access to home infusion pharmacies by Part D sponsors subsequent to our publication of the January 2005 final rule. This codification would ensure that our regulations provide specificity to the requirement that Part D enrollees receive adequate access to Part D-covered home infusion therapy. We specifically proposed 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 invited comments on the specification of a reasonable timeframe for the timely delivery of home infusion drugs under Part D. We proposed a new requirement, at §423.120(a)(4)(iv) of the proposed rule, that Part D plan sponsors provide covered home infusion drugs within 24 hours of discharge from an acute care setting. Except as otherwise noted below, this final rule adopts the requirements related to ensuring adequate home infusion access set forth in our proposed rule. Although the requirement for the timely delivery of home infusion drugs covered under Part D will be effective within 60 days of this final rule's appearance in the **Federal Register**, Part D sponsors will not be expected to implement this provision until January 1, 2009.

Comment: A number of commenters supported our proposal to codify in regulation how Part D sponsors were to ensure that enrollees have adequate access to home infusion pharmacies. Commenters specifically expressed support for our proposals to codify requirements that Part D plans ensure that their network pharmacies are capable of delivering home infused drugs in a manner than can be administered in a clinically appropriate fashion; provide infusible Part D drugs for both short-term and long-term



chronic care therapies; and ensure that the professional services and ancillary supplies necessary for home infusion therapy are in place before dispensing Part D home infusion drugs. However, several other commenters requested clarification regarding our proposed language at §423.120(a)(4)(iii), which would require Part D plans to ensure that their network pharmacies receive assurances that the professional services and ancillary supplies necessary for home infusion therapy be in place prior to delivery of a Part D home infusion drug. Some of these commenters recommended that we clarify that Part D plans – and not their network pharmacies – are ultimately responsible for ensuring this requirement is met. One commenter believed it was incumbent upon us to clarify that contracted pharmacies providing Part D enrollees with home infusion drugs need not make arrangements for the ancillary supplies and professional services themselves and that, instead, could meet the requirement by seeking and relying upon assurances from the discharging entity that infusion therapy supplies and services had been arranged. Another commenter believed that this proposed requirement fell outside the scope of the responsibilities of both Part D sponsors and their contracted pharmacies. This commenter pointed to the definition of dispensing fees at §423.100, which does not encompass professional services, supplies, or equipment related to the administration of home infusion drugs, to bolster its argument that the professional services and ancillary supplies are not Part D-covered and, as such, outside the scope of benefits Part D sponsors are responsible for providing or even coordinating. Instead, this coordination should be the clinical responsibility of those health care providers – including hospitals, home health agencies, outpatient facilities, and physician offices – that are responsible for

the implementation of continued care following a patient's discharge from an acute care setting.

Response: Although the Part D benefit does not cover equipment, supplies, and professional services associated with home infusion therapy, it does cover the ingredient costs and dispensing fees associated with infused Part D drugs. We disagree with the position that, because coverage under the Part D benefit is limited to the ingredient cost and dispensing fees associated with a Part D infusible drug, it is not within the scope of a Part D sponsor's responsibilities (or its home infusion network pharmacies' responsibilities) to ensure that the items and services that are necessary for providing home infusion therapy are in place prior to delivery of a home infusion drug. It is poor clinical practice to simply deliver a drug to an enrollee without assurances that these items and services – regardless of their source of coverage – have been arranged for prior to dispensing a Part D home infusion drug. We clarify that neither Part D plans nor their network pharmacies must directly make arrangements for the provision of the components needed to safely administer home infusion drugs (save for delivery of the drug itself) prior to an enrollee's discharge from an acute care setting; generally, facility discharge planners, in collaboration with a patient's physician, are responsible for ensuring that those components have been arranged for upon a patient's discharge. However, when plans' home infusion network pharmacies do not themselves supply the necessary supplies and services (which, again, are not covered under the Medicare Part D benefit), the Part D sponsor through its home infusion network pharmacy delivering the infusible Part D drug must, at a minimum, ensure that another entity, such as a home

health agency, DME supplier, or the discharging hospital, has arranged for the provision of these supplies and services. In order for sponsors to comply with this requirement, their home infusion network pharmacies may seek and rely upon assurances from another entity (such as a home health agency, DME supplier, or discharging hospital) that the supplies and services in question have been arranged. Under our regulations at §423.153(c), a Part D sponsor must have established quality assurance measures and systems to reduce medication errors and adverse drug interactions, and to improve medication use. We consider the follow-up to ensure that home infusion supplies and services are in place essential to ensuring that home infused drugs are administered in a clinically appropriate manner. Because this follow-up improves the use of home infusion medications and facilitates home infusion therapy more generally, we believe it is a minimum quality assurance standard under §423.153(c).

As specified in §423.120(a)(4), we expect that Part D sponsors will meet the requirements for ensuring adequate home infusion access through their contracted home infusion pharmacies. However, we clarify that, as provided in §423.505(i), Part D sponsors remain ultimately responsible for compliance with all Part D requirements, even when they delegate services or activities to a contractor such as a network pharmacy, and that delegation of any of their Part D responsibilities must be consistent with the requirements of §423.505(i)(4).

Coverage under the Part D benefit is limited to the ingredient cost and dispensing fees associated with a Part D infusible drug. Although the Part D benefit does not cover equipment, supplies, and professional services associated with home infusion therapy,

there are instances in which some of the supplies and professional services can be covered under Part A or Part B. If a Medicare beneficiary is under an active home health plan of care and is receiving Medicare home health services, the cost of some of the infusion supplies (if the infusion is provided via gravity feed method) and the professional services are included in the Medicare home health 60-day episode payment. A list of supplies consolidated under the home health prospective payment system (HH PPS) is available on the CMS home health Web site at [http://www.cms.hhs.gov/HomeHealthPPS/03\\_coding&billing.asp#TopOfPage](http://www.cms.hhs.gov/HomeHealthPPS/03_coding&billing.asp#TopOfPage).

Comment: We received a significant number of comments regarding our proposed requirement in §423.120(a)(4)(iv) of the proposed rule that Part D plans provide covered home infusion drugs within 24 hours of discharge from an acute care setting. Many commenters supported this proposed new requirement. Two commenters expressed concern that the proposed requirement is unfair and burdensome to the extent that it applies directly to the Part D plan itself. Because these commenters contend that our proposed requirement would result in plans having to build costly reporting processes and protocols to ensure compliance by contracted pharmacies, they recommend that we clarify that Part D sponsors will be in compliance with this provision if they include a requirement in their network pharmacy contracts that pharmacies provide covered home infusion drugs within the timeframes established by CMS.

A number of other commenters recommended that CMS strengthen its proposed requirement such that plans must provide covered home infusion drugs by the next required dose because patients that are discharged on home infusion therapy that is

administered more frequently than at 24 hour intervals may not receive their drugs in a clinically acceptable timeframe. These commenters believe that modification of this requirement would bring it in line with industry best practices to make infusion drugs available by either the next required dose or within 24 hours. Another commenter expressed concern that the establishment of a 24-hour requirement is arbitrary and could create situations in which a contracted pharmacy is required to deliver products well in advance of the next scheduled dose. This commenter recommended that we modify our proposed requirement such that plans must ensure that the prescribed infusion drugs are delivered at the later of 24 hours after discharge or the time the product is required for the first post-discharge dose. Finally, several commenters asked us to clarify that the provision of home infusion drugs within 24 hours of discharge from an acute care setting should be contingent on the pharmacy being notified of the discharge by the enrollee or acute care provider prior to the discharge.

Response: We recognize that home infusion therapy may serve as a vehicle to promote early hospital discharge. Although we have learned – in our discussions with home infusion providers – that best practices involve the availability of infusion services upon discharge from an acute care setting either by the next required dose or within 24 hours of the discharge, we deliberately chose to phrase our proposed requirement at §423.120(a)(4)(iv) such that home infusion drugs were to be provided within 24 hours of discharge from an acute care setting, and not by either the next required dose or within 24 hours of discharge. We believe our proposed timely delivery requirement struck a reasonable balance between ensuring the timely delivery of drugs needed for home

infusion therapy and ensuring plan compliance with our standard. Because the timing of the next required dose post-discharge will vary by beneficiary and by drug, monitoring compliance with a “next available dose” requirement would be very difficult. For this reason, we are maintaining our proposed requirement that plans provide delivery of home infusion drugs within 24 hours of discharge. However, we did find some merit to the point raised by one commenter that the next required dose could be later than within 24 hours after discharge from an acute care setting and that it would be unfair to penalize a plan that did not deliver the necessary home infusion drug until sometime after the 24 hours post-discharge have elapsed, even if such delivery is consistent with the prescription as written. For this reason, our final rule modifies our proposed requirement by requiring delivery within 24 hours after discharge, unless the next required dose, as prescribed, is required to be administered later than 24 hours after discharge. Plans may contractually delegate the responsibility for ensuring timely delivery of home infusion drugs to their network pharmacies provided they meet the requirements of §423.505(i) regarding relationships with pharmacies or other providers, related entities, contractors, subcontractors, and first tier and downstream entities. We also clarify that in order to comply with §423.120(a)(4)(iv), a Part D plan or one of its home infusion network pharmacies must receive notification from a facility discharge planner or a similar entity of an acute care discharge and the need for home infusion therapy. However, we do not believe that Part D sponsors must build “costly reporting processes and protocols” to comply with our requirement at §423.120(a)(4)(iv).

Comment: Two commenters urged us to ensure that Part D sponsors do not implement policies that could potentially delay or restrict beneficiary access to home infusion therapies, such as imposing prior authorization or utilization management edits on home infusion therapies, in order to facilitate a timely and efficient hospital discharge. Another commenter asked us to instruct plans to make available through their network pharmacies home infusion drugs in manufacturer-prepared, ready-to-use premixed formats or pharmacy filled single-use infusion devices, as these formats promote enhanced patient safety.

Response: We agree that Part D sponsors should not implement coverage restrictions that unduly limit access to infusible Part D drugs. CMS, in conjunction with industry partners, has identified a list of acute care drugs that are most commonly utilized in the home infusion setting. This list is available as part of our formulary guidance to Part D sponsors in Chapter 6 of our Prescription Drug Benefit Manual (see [http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBMChap6FormularyReqrmts\\_03.09.07.pdf](http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBMChap6FormularyReqrmts_03.09.07.pdf)). The use of these drugs or drug classes often results in an earlier hospital discharge and reduced health care costs, and rapid access to these agents is imperative to these health care transitions. It is our expectation that Part D sponsors will not implement policies that could potentially delay or restrict beneficiary access to these important agents. In general, should prior authorization or other utilization management edits apply to any of these agents, we expect Part D sponsors to handle these edits in an expedited manner in order to facilitate hospital discharge within appropriate timeframes. To the extent that we receive complaints from plan enrollees or providers indicating that

this is not the case, we will investigate and follow-up with plans to ensure they are complying with our requirements. We note, as well, that we expect Part D plans to include multiple strengths and dosage forms, when available, for each drug included in each drug category or class on their formularies. This includes those dosage forms commonly used in long term care and home infusion settings.

Comment: One commenter encouraged CMS to conduct a study on Part D enrollees' access to home infusion drugs and their out-of-pocket expenditures.

Response: Access to home infusion drugs is important. We plan to continue to assess the adequacy of home infusion pharmacy access based on an evaluation of plans' home infusion pharmacy networks. We also plan to aggressively respond to beneficiary and provider complaints alleging compromised access. As we continue to implement the Part D benefit, we will consider other ways of monitoring access to home infusion drugs to ensure it is adequate.

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

We proposed 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 proposed to make a technical correction to §423.293(a) to cite both §422.262(f) and §422.262(e). We did not receive any comments on the proposed changes to §423.293(a) and therefore adopt the changes as final without modification.

D. Subpart G – Payments to Part D Plan Sponsors For Qualified Prescription Drug Coverage: Payment Appeals (§423.350(b))

In the January 2005 final rule (70 FR 4550), we made a technical error in §423.350(b). 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 not relevant here. We proposed to revise 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. We did not receive any comments on the proposed changes to §423.350(b), and therefore, adopt the changes as final without modification.

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 proposed to revise §423.410(d) to correct an error. 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 proposed to correct 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. We received no comments regarding our proposed change. Therefore, this final rule adopts the proposed revision to §423.410(d) without change.

#### 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)

We proposed to revise §423.458(d)(2)(ii) because we inadvertently omitted a reference to section 1894 of the Act in describing the statutory authority for the benefits offered by a Program of All Inclusive Care For the Elderly (PACE) organization. As published in January 2005 final rule (70 FR 4552), §423.458(d)(2)(ii) referenced 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 to PACE benefits should refer to both sections 1894 and 1934 of the Act. We therefore proposed to revise §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. We received no comments

on our proposed revision to §423.458(d)(2)(ii) and are therefore adopting it as proposed.

2. Coordination of Benefits with Other Providers of Prescription Drug Coverage  
(§423.464)

a. Coordination of Benefits with Rural Health Clinics

In the January 2005 final rule (70 FR 4553), we made a technical error in §423.464(f)(1)(vii) by inadvertently referring to rural health clinics as rural health centers. 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 proposed to correct 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.

We did not receive any public comments on our proposed correction to §423.464(f)(1)(vii) and are therefore adopting the correction as proposed.

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

We proposed to codify 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. 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. We proposed 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 believed 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 proposed to amend §423.464(f) by adding 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 proposed 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. Except as otherwise provided below, the final rule adopts the revisions to §423.464(f) set forth in our proposed rule.

Comment: Many commenters supported our proposed clarification and codification of previously issued guidance on Part D plan sponsor coordination of benefits with other payers. Several commenters, in expressing their support, noted the importance of the reconciliation processes in avoiding pharmacy reversal and claims re-

adjudication. One commenter agreed with the proposed codification, but requested that the provision specifically address the reconciliation of inaccurate cost sharing amounts withheld from pharmacy payments by Part D plan sponsors.

Response: We are pleased with the extent of the support expressed for the proposed changes. However, we believe the coordination of benefits (COB) provisions at section 1860D-24 of the Act do not permit expanding §423.464 to address the reconciliation of inaccurate cost sharing withheld from pharmacy payments. The reconciliation process provision is specific to other entities providing prescription drug coverage and the inclusion of pharmacies would be inconsistent with section 1860D-24(b) of the Act. Paragraph (5) of this section of the Act extends the COB requirements to “other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision” of drugs; it does not apply to providers holding accounts receivables resulting from incorrect cost sharing or otherwise.

Further, the requested extension of the reconciliation process to include pharmacies cannot be construed as a logical extension of the proposed rule and therefore its inclusion would violate the requirements of the Administrative Procedures Act concerning adequate public notice. Although we are not extending the provision as requested, existing CMS policy requires Part D plan sponsors to pay for covered Part D drugs provided during the retroactive enrollment periods. We have clarified in our policy issuances that this requirement includes both out-of-network pharmacies holding receivable balances for covered Part D drug costs, and network pharmacies holding receivable balances for covered Part D drug claims incurred during a beneficiary’s period

of retroactive Part D enrollment.

Comment: Another commenter agreed with our proposed clarification, but recommended that CMS require that reconciliation processes with non-Part D sponsors include the submission of claims-level data to the Part D plan sponsors. The commenter notes that claims-level data is required for the accurate calculation of beneficiary true out-of-pocket costs, prescription drug event data reporting, and payment reconciliation with CMS.

Response: While we appreciate the importance of claims-level data to reconciliation with non-Part D payers, we do not have the authority to regulate the activities of non-Part D payers. Also, we do not believe it would be appropriate to include the detail recommended by the commenter when it concerns as-yet-to-be developed CMS reconciliation processes.

Comment: Two commenters expressed concern that the proposed provision does not address the payment reconciliation process or adjustments for claims Part D plans receive after the coverage year. The commenters noted that this non-point-of-sale claims volume is not insignificant and therefore recommended that CMS extend the periods of time for submission of claims and data reporting so that these claims may be included in the payment reconciliation process.

Response: The established deadlines for submission of claims and data reporting are necessary in order to ensure a timely payment reconciliation process. However, we understand and appreciate the concern that some claims will not be available for submission until after these deadlines, and therefore, will not be included in the payment

reconciliation process. Per §423.346, we have discretion to reopen and revise initial or reconsidered final Part D payment determinations. One of the grounds for finding good cause to reopen a final payment determination is the furnishing of new and material evidence that was not readily available at the time the final determination was made..

Thus, in cases where claims data becomes available after the submission deadlines which would have a material impact on the final Part D payments, we will determine whether a reopening of the final Part D payments is appropriate.

G. Subpart K - Application Procedures and Contracts with Part D Plan Sponsors

1. General Provisions (§423.504)--Submission of Bids

In §423.504, we inadvertently made reference to §423.265(a)(1) rather than §423.265. Section 423.265(a) gives only the most narrow and rudimentary of information concerning the bidding process, our intent was to cite in its entirety the much broader list found under §423.265 (Submission of bids and related information).

Accordingly, we proposed to correct the reference in §423.504(a) to cite all of §423.265 (72 FR 29412). We received no comments regarding our proposed correction.

Therefore, the final rule adopts the revision to §423.504 set forth in our proposed rule.

2. Contract Provisions (§423.505)

We proposed to correct the citation for the False Claims Act in §423.505. The correct reference to the False Claims Act is 31 U.S.C. 3729 et. seq. Accordingly, we proposed to correct the reference found under §423.505 (h)(1) by replacing 32 U.S.C. 3729 et. seq with 31 U.S.C. 3729 et. seq. (72 FR 29412). We received no comments regarding our proposed correction. Therefore, the final rule adopts the revision to

§423.505 (h)(1) set forth in our proposed rule.

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 proposed to revise 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. (72 FR 29412). We received no comments regarding our proposed correction. Therefore, the final rule adopts the revision to §423.509(a)(9) as proposed without change.

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

1. Definitions (§ 423.560)

We proposed to make technical changes to the definitions of "appointed representative" and "projected value," and to add language to the definition of appointed representative indicating that an enrollee's appointed representative may request a grievance on the enrollee's behalf. We also proposed to revise the definition of projected value in §423.560 to be consistent with the definition of projected value provided in the preamble of the January 2005 final rule (70 FR 4360) and in the regulation text at §423.610(b).



Comment: We received a comment suggesting that we grant appointed representative status to long-term care (LTC) facility staff.

Response: We agree with the commenter that LTC caregivers should be able to represent resident enrollees in the Part D appeals process. However, the decision to have a representative is left with the enrollee, and we neither encourage nor discourage representation. If a Part D enrollee chooses to appoint an LTC caregiver as his or her representative in the Part D appeals process, the current regulations allow the enrollee to do so.

Comment: Another commenter asked that the appointed representative policy operate consistent with State family and surrogate laws.

Response: We agree with the commenter's recommendation and believe that the regulations already address the commenter's suggestion. Section 423.560 defines appointed representative as any person properly appointed by an enrollee, or any person authorized to act as an enrollee's representative under a State or other applicable law. Thus, both individuals appointed by enrollees and individuals authorized under State or other applicable law may act on behalf of Part D enrollees in obtaining coverage determinations or in dealing with any of the levels of the appeals process, subject to the rules described in part 423, subpart M.

Comment: We received one comment recommending that we modify the definition of projected value in §423.610(b) to comply with the definition in §423.560 instead of revising the definition of projected value in §423.560 to comply with the definition in §423.610(b).

Response: We disagree with the commenter. As noted in the May 2007 proposed rule, the definition of projected value in §423.560 is not consistent with the definitions of projected value in the January 2005 final rule (70 FR 4360) and in §423.610(b) of the regulations. Both of those definitions limit projected value to benefits incurred within a plan year. Limiting projected value to benefits incurred within a plan year is consistent with sections of the regulation that limit exception approvals to a plan year and permit enrollees to switch plans at the beginning of each plan year. (See §423.38 and §423.578(c).)

## 2. Expediting Certain Coverage Determinations (§423.570)

We proposed to amend the regulation text of §423.570(d)(3) by requiring a Part D sponsor to deliver written notice to an enrollee within 3 calendar days after it denies a request to expedite a coverage determination.

Comment: We received one comment suggesting that we require plans to deliver notice of a decision not to expedite a coverage determination to a dispensing pharmacy when an enrollee is a resident of a LTC facility.

Response: We disagree with the commenter. Section 423.570(d)(2) of the regulations requires plan sponsors to deliver oral notice of a decision not to expedite a coverage determination to the enrollee (or the enrollee's appointed representative) and the enrollee's prescribing physician. Section 423.570(d)(3) requires the plan sponsor to send an equivalent written notice, but it does not indicate if the notice must be sent to the enrollee (or the enrollee's appointed representative), the prescribing physician, or both. Our proposal simply corrects this omission. The commenter's recommendation to add a

new party to the list of recipients would create a new regulatory requirement that is not directly related to our proposed clarification. However, it is worth noting that an employee of a pharmacy could receive this and other notices if he or she were an enrollee's appointed representative.

Comment: Another commenter recommended requiring plans to deliver notice of a decision not to expedite a coverage determination both to the enrollee and to his or her appointed representative, if one is on record.

Response: We do not agree with the commenter's suggestion. We require notices to be delivered to an enrollee or an enrollee's appointed representative, but not to both. If a representative is acting on behalf of an enrollee in the Part D appeals process, he or she is standing in the shoes of the enrollee and must inform the enrollee of the status of a coverage determination or appeal and the results of any actions taken on behalf of the enrollee. It could be confusing for an enrollee to receive a notice that is also sent to his or her appointed representative since the enrollee is relying on that person to resolve any issues related to his or her Part D appeal.

### 3. Expediting Certain Redeterminations (§423.584)

We proposed to revise the regulation text of §423.584(b) to include the procedures for filing and withdrawing a request for an expedited redetermination. We did not receive any comments on the proposed change to §423.584(b) and therefore adopt this change as final without modification.

### 4. Right to an ALJ Hearing (§423.610)

We proposed revising the regulation text of §423.610(c)(2) by numbering the

three requirements listed under §423.610(c)(2) with (i), (ii), and (iii). We did not receive any comments on the proposed change to §423.610(c)(2) and therefore adopt this change as final without modification.

#### I. Subpart P - Premium 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 us 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 (as defined at §423.772); and (2) other low-income subsidy eligible individuals (as defined at §423.772). The different groups are entitled to different amounts of premium assistance and reductions in cost sharing.

As stated in the May 2007 proposed rule, we became aware that certain sections of part 423 subpart P need to be corrected to accurately reflect the statutory language in section 1860D-14 of the Act. Specifically, in the January 2005 final rule (70 FR 4574) there is an error in §423.780(b), which sets forth the methodology for determining the premium subsidy amount. In accordance with section 1860D-14(b)(1) of the Act, §423.780(b)(1) of the regulation provides that the premium subsidy amount for a full low-income subsidy eligible individual is equal to the lesser of-- (1) the portion of his or her plan's monthly beneficiary premium attributable to basic coverage; or (2) the greater

of the low-income benchmark premium amount or the lowest monthly beneficiary premium for a PDP offering basic prescription drug coverage in the PDP region where the individual resides. 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 §423.780(b)(2)(i) accurately describes the low-income benchmark premium amount calculation for PDP regions with multiple PDP sponsors, it omits the methodology for determining the low-income benchmark premium amount in a PDP region with any number of MA-PD plans but only one PDP sponsor (although the preamble of the January 2005 final rule correctly describes this methodology). We proposed to correct this error in the current rule to comport with the statute and our intent as outlined in the preamble of the January 2005 final rule by adding a new subparagraph (A) to §423.780(b)(2)(i) to correctly reflect the methodology for situations where there is only one PDP sponsor. We note that in 2006, all PDP regions included multiple PDP sponsors.

We also proposed revisions to §423.780(b)(2)(i)(B). Our proposed change would make clear that in multiple-PDP sponsor regions, the MA-PD plans included in the calculation of the low income benchmark weighted average are coordinated care plans, as

defined at §422.4(a)(1)(iii). We did not receive any comments on the proposed changes §423.780(b)(1) and (2)(i). Therefore, we are adopting the changes to §423.780(b)(1) as final without modification. However, we are not finalizing the changes to §423.780(b)(2)(i) in this final rule; rather, we have revised this provision in the Modification to the Weighting Methodology Used to Calculate the Low-income Benchmark Amount final rule that published in the April 3, 2008 **Federal Register** (73 FR 18176).

b. Premium Subsidy for Late Enrollment Penalty

We indicated in the May 2007 proposed rule that we needed to correct an omission in the regulation text at §423.780(e) related to the subsidy of any late enrollment penalty imposed on other low-income subsidy individuals. In this paragraph, we omitted a provision from the statute at section 1860D-14(a)(2)(A) of the Act, which provides for a subsidy or any late enrollment penalty imposed on other low-income subsidy eligible individuals. Accordingly, we proposed to revise §423.780(e) to accurately reflect the statute. We proposed that this subsidy would be based on a linear sliding scale, with a higher subsidy available to other low income subsidy eligible individuals with incomes at or below 135 percent of the Federal poverty line (FPL), and the lowest level subsidy available to other low income subsidy eligible individuals with incomes below 150 percent of the FPL.

The table below illustrates the penalty subsidy available to other low income subsidy individuals.

<b>Income Level</b>	<b>Percent of Penalty Subsidized During the First 60 Months Individual is Subject to Penalty</b>	<b>Percent of Penalty Subsidized After the First 60 Months Individual is Subject to Penalty</b>
≤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%

Comment: Commenters supported the proposed changes to calculation of the low-income premium subsidies for other low income subsidy eligible individuals. However, they also indicated that other low-income subsidy beneficiaries subject to the late enrollment penalty are still burdened with paying 20 percent of such penalty for the first 60 months during which the penalty is imposed, and that this burden serves as a disincentive for low-income beneficiaries to enroll in Medicare Part D.

Response: While we recognize the concern of the commenters for the needs of low-income beneficiaries, section 1860D-14(a)(1)(A) of the Act requires late enrollment penalties for the low-income subsidy population. Therefore, we are adopting these proposed revisions in the final rule. Please note, however, that we have used the Secretary’s authority under section 402(a)(1)(A) of the Social Security Amendments of 1967, 42 U.S.C. 1395b-1(a)(1)(A) (expressly made applicable to Part D in section 1860D-42(b) of the Act) to implement the Medicare payment demonstration entitled “Elimination of 2006 Late Enrollment Penalty.” Under this demonstration, as amended in 2007, we will not collect the late enrollment penalty from individuals who receive a low-income subsidy and enroll in the Medicare Prescription Drug Program in

2006, 2007, or 2008. As long as these individuals remain continuously enrolled in Medicare Part D, they will not be assessed a late enrollment penalty. This demonstration is of limited duration and is only applicable to low-income subsidy eligible individuals who enroll in Medicare Part D in 2006, 2007, or 2008. Following an evaluation of this Medicare payment demonstration, we will review the results of the evaluation and may consider recommending that Congress eliminate the late enrollment penalty for individuals who receive the low-income subsidy.

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

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

###### a. Application Timing

Section 423.884(c) sets forth the application requirements for the retiree drug subsidy (RDS). 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 we grant the sponsor's request for an extension (for example, the deadline for 2007 calendar year plans under the regulation was October 2, 2006). As we stated in the proposed rule, we believe that an end-of-month deadline would be administratively simpler for both plan sponsors and CMS to track. Accordingly, we proposed to replace the 90-day requirement with the phrase "by a date specified by CMS in published guidance" to allow us the discretion to specify an end-of-month deadline in the future through guidance. We noted that this would give us the flexibility to take into account operational systems changes in determining the RDS application deadline, while providing adequate advance notice to plan sponsors and their advisers. We did not receive any comments on the proposed



change to §423.884(c)(5)(i) and therefore adopt this change as final without modification.

b. Data Match

In accordance with section 1860D-22(a)(1), employer and union sponsors of qualified retiree prescription drug plans may receive the RDS only for their enrollees who are eligible for, but not enrolled in, a Part D plan. In order to properly administer this requirement, we compare the retiree enrollment data that a plan sponsor submits to us with CMS enrollment records to ensure that sponsors are only receiving retiree drug subsidies for qualifying covered retirees, as defined in §423.882. In §423.884(c)(7)(i), we specifically referenced the Medicare Beneficiary Database (MBD) as the system of record for this data match (70 FR 4578). While the MBD is currently the system we use to verify retirees' Part D eligibility and enrollment status, we also may use other systems of record for purposes of the data match. Accordingly, we proposed to modify §423.884(c)(7)(i) by substituting a general reference to "CMS database(s)" for the "Medicare Beneficiary Database (MBD)." We did not receive any comments on the proposed change to §423.884(c)(7)(i) and therefore are finalizing this change without modification.

c. Actuarial Equivalence

(1) Medicare Supplemental Adjustment

Section 1860D-22(a)(2)(A) of the Act requires that a plan sponsor claiming the RDS provide an attestation that its qualified retiree prescription drug plan is actuarially equivalent to Medicare standard prescription drug coverage. 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 prescription coverage under the qualified retiree prescription drug plans 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 defined standard prescription drug coverage under Part D. Supplemental coverage for this purpose means drug coverage over and above defined standard prescription drug coverage under Part D for those retirees that enroll in Part D coverage. As stated in the preamble to the May 2007 proposed rule, our intent, which we clarified in operational guidance to plan sponsors, was that a sponsor must actually provide employer or union-sponsored supplemental retiree drug coverage to its retirees who enroll in Part D in order to qualify for the Medicare supplemental adjustment. Therefore, we proposed to revise §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 take advantage of the Medicare supplemental adjustment provided for in §423.884(d)(5)(iii)(B)(2). We view this revision as merely incorporating previously issued guidance, and not as a new policy proposal. We did not receive any comments on the proposed change to §423.884(d)(5)(iii)(B)(2) and therefore adopt this change as final without modification.

## (2) Noncalendar Year Plans

Section 1860D-22(a)(2)(A) of the Act requires a plan sponsor claiming the RDS

to provide an attestation that its qualified retiree prescription drug plan is actuarially equivalent to the Medicare defined standard prescription drug coverage. The actuarial equivalence test requires that the actuarial value of the plan sponsor's retiree drug coverage under its qualified retiree prescription drug plan be compared to the actuarial 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 for purposes of comparing the actuarial value of the retiree coverage under the sponsor's plan and the Medicare defined standard prescription drug coverage, the actuarial valuation of the latter is based on the initial coverage limit, cost sharing amounts, and annual out-of-pocket threshold in effect at the start of the plan year. However, the attestation must be submitted to us no later than 60 days after the publication of these coverage limits for the upcoming calendar year; otherwise, the valuation must be based on the initial coverage limit, cost sharing amounts, and annual out-of-pocket threshold for the upcoming plan year. The intent of this 60-day provision is to prevent actuaries from having to redo valuations for noncalendar year plans that were based on the current calendar year initial coverage limit, cost sharing amounts, and annual out-of-pocket threshold when, after doing their calculations but prior to submission of the RDS application, we publish the coverage limits for defined standard drug coverage for the upcoming calendar year.

As we stated in the proposed rule, plan sponsors' actuaries have indicated to us that they believe they should have the flexibility for non-calendar year plans to use the initial coverage limit, cost-sharing amounts, and annual out-of-pocket-threshold for

defined standard drug coverage for the upcoming plan year, provided it does not impact their ability to meet the application deadline. We agreed that actuaries should have this flexibility, and proposed to amend §423.884(d)(5)(iii)(C) to permit a noncalendar year plan's actuary to use either the current or subsequent year's coverage limits for defined standard prescription drug coverage when the attestation is submitted within 60 days of the publication of the following year's cost limits. We also proposed to make corresponding changes to §423.884(d)(5)(iii)(D). We did not receive any comments on the proposed change to §§423.884(d)(5)(iii)(C) and (D), and therefore are finalizing this change without modification.

### (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 stated in the proposed rule and in guidance published previous to that rule, our intent was that a plan sponsor should also have the option of aggregating a subset of the benefit options in a group health plan for the actuarial equivalence net test in addition to aggregating all of the options or evaluating each option individually. 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 (unless the excluded benefit options each individually meet the net test). We proposed to amend the final rule to reflect this clarification of our intent, which reflects policy that has been applied consistently since the rule was published. We did not receive any comments on the proposed change to §423.884(d)(5)(iv) and therefore are finalizing this change without modification.

#### (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 indicated in the proposed rule that “[w]e 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” (72 FR 29416). We did not receive any comments on this clarification of our policy. However, as has always been the intent of the regulations, an attestation must be submitted only when coverage satisfies the actuarial equivalence standards in the regulations, and should not and must not be submitted when coverage fails to satisfy those standards. Therefore, in the text of the final regulation, we are articulating the clarification in the proposed regulation in a way that makes this distinction. Specifically, §423.884(d)(6)(ii) in the final regulation states that an attestation must be provided no later than 90 days before the implementation of a material change to the sponsor’s drug coverage, and that the term

“material change” means the addition of a benefit option that does not have the impact of causing the actuarial value of the retiree prescription drug coverage to fail the actuarial equivalence standards set forth in the regulations. (Regardless of whether there has been such an impact, a plan sponsor, upon deleting a benefit option for RDS purposes, must provide an update to CMS of its list of individuals for whom it is claiming RDS. (See §423.884(c)(6)). The final regulation also adds §423.884(d)(7), which states that a sponsor must notify CMS, in a form and manner specified by CMS, no later than 90 days before the implementation of a change to the drug coverage that does have the impact of causing the actuarial value of the retiree prescription drug coverage to fail the actuarial equivalence standards set forth in the regulations.

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 (FFP) 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 proposed 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. The effect of these changes is to make clear that FFP 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 also proposed adding a definition of "noncovered drugs" to §423.902. We did not receive comments regarding our proposed changes. Therefore, the final rule adopts the revisions to §423.906(b) and (c) and §423.902 set forth in the proposed rule.

## 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 and is determined eligible by the State for medical assistance for full benefits under this title..." In the January 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, 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 proposed to revise the text to be consistent with the statute. We did not receive comments regarding our proposed changes. Therefore, the final rule adopts the proposed revisions to §423.910(b)(1) without modification.

#### L. Out-of-Scope Comments

We received a number of comments that were beyond the scope of the clarifications in the proposed rule but, rather, addressed other policy areas or sought new clarifications that we did not propose to clarify in this final rule. Specifically, we received public comments recommending that we- -

- Implement rules providing for consistency in utilization management requirements across Part D sponsors;
- Establish rules requiring a universal prescription drug card;
- Eliminate proposed rules removing the e-prescribing facsimile exemption;
- Address beneficiary related concerns with the coverage gap or Part D drug coverage in general;
- Codify the six classes of clinical concern;
- Add cancer treatments to the six classes of clinical concern;
- Change the cut-off date for the six classes of clinical concern to January 1, 2008;



- Limit expansion of the parameters for Agency Record Searches;
- Allow tiering exceptions for specialty tier drugs;
- Address lags in the transfer of information, particularly regarding beneficiary Medicaid eligibility, and Part D plan sponsor unwillingness to accept documentation of Medicaid as proof of a beneficiary's dual status;
- Address cases of retroactive Medicaid eligibility and Part D enrollment and direct Part D plan sponsors to not deny claims incurred during the period of retroactive eligibility;
- Direct Part D sponsors to provide disclosure instructions for the filing of claims incurred during periods of retroactive Part D enrollment;
- Act on MedPAC recommendations on vaccine reimbursement;
- Withdraw the Medicare Marketing Guidelines or, at a minimum, eliminate or loosen current restrictions contained in the Medicare Marketing Guidelines on provider marketing activities – particularly when providers are acting independently of Part D plans or when there is no direct financial conflict of interest under the Federal anti-kickback statute.
- Expand the definition of a long-term care facility under §423.100 to include assisted living facilities;
- Revise our policies to require Part D coverage of the professional services, supplies, and equipment associated with home infusion of Part D drugs;
- Direct that appeals overturned by an administrative law judge are effective for a period of 12 months, not just the remainder of the plan year.

Because these comments are beyond the scope of the proposed rule, we are not responding to them in this final rule.

### **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 examined the impacts of our May 2007 proposed 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. We received only one comment with regard to our impact analysis concerning the definition of negotiated prices, which is not addressed in this final rule. As a result, we restate that impact analysis below.

With the 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 clarifications in this final rule were addressed as part of a prior final rule and do not require further analysis. Specifically, we performed a full regulatory impact analysis (RIA) for the January 2005 final rule (70 FR 4454) implementing the Part D provisions of the Medicare Prescription Drug Improvement and Modernization Act of 2003. Many of the provisions in this final rule are simply clarifications of provisions in

the January 2005 final rule.

Executive Order 12866 (as amended by Executive Order 13258) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). The RFA requires agencies to analyze options for regulatory relief of small 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.

We estimate that the coverage of vaccine administration under Part D to have a net impact to the FY 2008 budget in the amount of \$100 million and an impact for FY 2008 through 2017 in the amount of \$340 million. Given this estimated net impact of vaccine administration coverage under Part D beginning in FY 2008, the final rule meets the threshold of being “economically significant” and is consequently a major rule. Therefore, the RFA requires us to conduct a regulatory flexibility analysis with regard to the implementation of vaccine administration coverage under Part D. Table I provides the costs associated with vaccine administration for FYs 2008 through 2017.

**Table 1: Vaccine Administration Costs for FY 2008 - FY 2017**

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FYs 2008-2017
Vaccine Administration Costs (in millions)	\$100	\$80	\$40	\$20	\$20	\$20	\$10	\$10	\$20	\$20	\$340

In the proposed rule we made a technical error when we listed the Small Business Administration’s consideration of small business at \$6 million and used an inappropriate census table. We have corrected these errors in this final rule. The corrected calculations did not have an impact on our analysis. The Small Business Administration (SBA) considers pharmacies with firm revenues of less than \$6.5 million to be small businesses. The 2004 Business Census (the latest available detailed data) indicates that there were about 19,443 firms operating about 40,115 retail pharmacies and drug store establishments (NAICS code 44611). Of these firms, 17,835 had revenues under \$6.5 million and operated a total of 17,835 establishments. Because more than 90 percent of retail pharmacy firms are small businesses (as defined by the SBA size standards), we estimate that the inclusion of vaccine administration within the statutory definition of a 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. Given the nature of immunization in the U.S. market and the nature of Part D coverage of vaccines, only two small business areas – retail pharmacy and physicians in private practice – merit analysis.

Given the real-time nature of the Part D benefit and the fact that – unlike physician offices – pharmacies are network providers that can bill Part D sponsors for

vaccines and vaccine administration costs at the point of sale, we anticipate that Medicare beneficiaries will consider receiving Part D vaccine immunization in a pharmacy setting in those States that permit pharmacists to administer vaccinations (currently 46 of 50 States – two more States since the publication of our May 2007 proposed rule). We expect this trend to continue, when, beginning in 2008, Part D plans' network pharmacies are able to seek reimbursement for the administration of Part D vaccines. While there may be some additional cost associated with pharmacists' time in administering vaccines, these costs should be more than offset by the reimbursement of vaccine administration costs. We note that network pharmacies can negotiate with Part D sponsors so that they do not administer vaccines if they believe that the costs of administering vaccines outweigh any potential benefits.

Almost all physicians in private practice (or the practices of which they are members) are small businesses because their annual revenues do not meet the Small Business Administration's threshold for "small" physician practices; therefore, they are small entities. Since we expect that a substantial number of Part D vaccines will continue to be administered in the physician office setting, we believe physicians will benefit from the inclusion of vaccine administration in the statutory definition of a Part D drug. Beginning in calendar year 2008, administering physicians will have a new source of reimbursement for Part D vaccine administration fees. As physicians will likely bill beneficiaries directly for Part D vaccines and its administration, we do not expect there will be any additional costs to the physicians in private practice as a result of this statutory change.

The other technical corrections and substantive clarifications in this final rule are not expected to affect small businesses in a significant manner, if at all. For example, although the clarification relating to the delivery of home infusion medications may result in a slight increase to the cost of delivering these medications for some Part D sponsors given potential increased costs for sponsors that do not currently have timely delivery provisions in their contracts with home infusion pharmacies, any such increase will be accounted for in plan sponsors' bids. However, we expect any such increase to be minimal and to affect only some sponsors. The final rule's requirements regarding timely delivery of home infusion pharmacies should have no cost impact on network home infusion pharmacies. In our ongoing communications with the home infusion industry, we have learned that these delivery timeframes are 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 should already be meeting these performance standards.

Section 1102(b) of the Act requires us to prepare a RIA 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 to Medicare outpatients in hospitals, the final rule's change to the definition of a Part D drug to include vaccine administration could have an effect on small rural hospitals that administer Part D

vaccines. Since a number of rural hospitals administer vaccines on an outpatient basis, they too would likely benefit from the ability to collect a Part D vaccine administration fee. Rural hospitals should already have the systems in place to handle, store, and administer vaccines. While some rural hospital pharmacies may become Part D network pharmacies, we do not expect the majority will do so. Consequently, small rural hospitals should only benefit from Part D sponsors' coverage of Part D vaccine administration fees and should not incur new costs as a result of our final rule. Additionally, the other policy clarifications in our final rule are related to the Medicare Part D drug benefit and not to prescription drug coverage under Medicare 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 \$127 million. Many of the final rule's provisions are either corrections to bring our regulations in line with statute or merely the formal proclamation of existing policies that are consistent with the statute and do not exceed the \$127 million dollar threshold. For example, one clarification we made in our final rule to bring our regulations in line with statute prohibits States from covering Part D drugs for Medicaid recipients. This provision 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 Part D 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, local, or tribal governments.

As stated above, many of the final rule's provisions are either corrections to bring our regulations in line with statute or merely the formal proclamation of existing policies that are consistent with the statute. Although there may be added costs for Part D sponsors associated with the broadening of the definition of Part D drug to include "[s]upplies required to deliver insulin by inhalation[,]" sponsors are aware that new drugs and supplies come to market constantly and account for these potential formulary changes in their bids. Furthermore, only those sponsors that choose to cover inhaled insulin will be affected by the change to our final rule to broaden the definition of supplies associated with the delivery of insulin into the body encompassed within the definition of a Part D drug. We expect the costs to the private sector resulting from this change will be less than the \$130 million threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. The changes and technical clarifications in this final rule will not have a substantial effect on State or local governments. For example, our clarification in the final rule concerning timing of State reporting for the purposes of calculating State phase-down contributions is not expected to affect State governments, since monthly reporting is consistent with the statute. In addition, although there is a provision in this final rule clarification that relates to waivers of State plan licensure, there are no anticipated Federalism implications



because the clarification simply brings our regulations in line with existing statute.

B. Anticipated 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, since this is a new Part D benefit established 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 of this statutory change will be no different than for any other new drug entering the market. Part D plans will need to factor Part D vaccine administration into their benefit designs and resulting bids. We estimate the net cost of vaccine administration coverage for FY 2008 to be \$100 million. This estimate takes into account the offset associated with beneficiary cost sharing and the Federal direct subsidy and risk-sharing.

We believe that our other provisions of our final rule merely reflect existing policy and have no cost impact on health plans and PBMs. For example, the final rule's changes associated with plan-to-plan reconciliation reflect current plan requirements. Even if this requirement were a new standard, we believe that all parties involved in the reconciliation will benefit, since the reconciliation process will be simpler than if pharmacies were required to reverse and re-adjudicate claims.

We also do not believe our broadening of the definition of medical supplies associated with insulin administration or our clarification relating to the timely delivery of home infusion medications place any additional cost burden on Part D plans. We had initially estimated the gross costs of inhaled insulin for Fiscal Year 2008 would be \$10 million. Given this product's current status, we now believe it will be substantially lower

in costs. As discussed elsewhere in this analysis, our requirement for the timely delivery of home infusion drugs is consistent with an existing standard with which sponsors should be familiar. Consequently, we do not believe it will increase sponsors' costs.

### C. Alternatives Considered

We considered not issuing regulations to address the policy clarifications and technical changes we proposed in our May 2007 proposed rule. However, we believed that in order to ensure public awareness of our policies, as well as to avoid potential confusion regarding those policies, we should codify our clarifications as well as make certain technical corrections to the January 2005 final rule. In addition, we wished to codify a few new clarifications for Part D plans as a result of our experience in implementing Part D. Finally, we wanted to codify certain changes made by Congress to the statutory definition of a Part D drug since the publication of the January 2005 final rule.

### D. Accounting Statement

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

<b>Table D1: Accounting Statement: Classification of Estimated Expenditures for Policy and Technical Changes to the Medicare Prescription Drug Benefit, Final Rule</b>	
<i>Category</i>	<i>TRANSFERS (\$ Millions)</i>
<b>Vaccine Administration, FYs 2008 - 2017</b>	
Undiscounted Annualized Monetized Transfers	\$340
Annualized Monetized Transfers Using 7% Discount Rate	\$387
Annualized Monetized Transfers Using 3% Discount Rate	\$360
From Whom To Whom?	Federal Government To Part D Plans

E. Conclusion

Given that we expect the cost of implementing vaccine administration under Part D will exceed the \$100 million threshold in FY 2008, we conducted an economic impact analysis with regard to those entities potentially involved in administering Part D vaccines. As we stated previously, we expect that entities such as private physician practices and pharmacies will benefit from this change in FY 2008, whereas other entities, such as Part D sponsors, will experience no or little difference in their costs as a result of the implementation of this statutory change. We conducted a full analysis of the impact of this final rule’s technical corrections and substantive clarifications for the final regulations implementing the Part D provisions of Medicare Prescription Drug Improvement and Modernization Act of 2003, which were published on January 28, 2005. For reasons cited previously, we believe that these additional clarifications either do not require further analysis or are in practice today and, as such, will not have an economically significant impact.

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



**List of Subjects**

**42 CFR Part 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 amends 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 §403.205 of this chapter.

\* \* \* \* \*

**Subpart C--Benefits and Beneficiary Protections**

4. Section 423.100 is amended by revising the definitions of “contracted pharmacy network,” and “Part D drug” to 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.

\* \* \* \* \*

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 and for vaccine administration on or after January 1, 2008, its administration.

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

(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 24 hours of discharge from an acute care setting, or later if so prescribed.

\* \* \* \* \*

**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 rules. Part D sponsors must--

(1) 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).

(2) Permit payment of monthly Part D premiums (if any) under the timing of payments established in §422.262(e) of this chapter; and

(3) 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. 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 one of the following:

(i) For risk adjustment, the date of the final reconciled payment under §423.343(b) of this subpart.

(ii) For reinsurance, the date of the final reconciled payment under §423.343(c) of this subpart; for low-income cost sharing subsidies, the date of the final reconciled payment under §423.343(d) of this subpart.

(iii) For risk-sharing payments, the date of the final payments under §423.336 of

this subpart.

\* \* \* \* \*

**Subpart I--Organizational Compliance with State Law and Preemption by Federal Law**

8. 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**

9. 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 sections 1894 and 1934 of the Act, with the benefits under Part D.

10. Section 423.464 is amended by--

(A) Revising paragraphs (f)(1)(vii) and (f)(1)(viii).

(B) Adding new paragraphs (f)(1)(ix), (f)(5), and (f)(6).

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**

11. 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 of this part 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.

\* \* \* \* \*

12. 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).

\* \* \* \* \*

13. 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 either of the following:

(i) Marketing requirements in §423.50.

(ii) Information dissemination requirements of §423.128 of this part.

\* \* \* \* \*

**Subpart M--Grievances, Coverage Determinations, and Appeals**

14. Section 423.560 is amended by revising the definitions of “appointed representative” and “projected value” to read as follows:

**§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.

\* \* \* \* \*

15. 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.

\* \* \* \* \*

16. 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) of this subpart also apply to expedited redeterminations.

\* \* \* \* \*

17. 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) of this part; 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**

18. Section 423.780 is amended by revising paragraphs (b)(1) and (e) to 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 PDP 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 PDP region.

\* \* \* \* \*

(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 §423.4 6 of this part 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**

19. Section §423.884 is amended by--

- A. Revising paragraphs (c)(5)(i), (c)(7)(i).
- B. Revising paragraphs (d)(5)(iii)(B)(2), (d)(5)(iii)(C), and (d)(5)(iii)(D).
- C. Revising the last sentence of paragraph (d)(5)(iv).
- D. Revising paragraph (d)(6)(ii).
- E. Adding a new paragraph (d)(7).

The revisions and addition read as follows:

**§423.884 Requirements for qualified retiree prescription drug plans.**

\* \* \* \* \*

(c) \* \* \*

(5) \* \* \*

(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 through 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 CY 2007, or the amounts announced for CY 2008. However, in order to use the amounts applicable in CY 2007, the sponsor must submit the attestation within 60 days after the publication of the Part D coverage limits for CY 2008. If the attestation is submitted more than 60 days after the 2008 coverage limits have been published, the CY 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).

(6) \* \* \*

(ii) Submission following material change. The attestation must be provided no

later than 90 days before the implementation of a material change to the drug coverage of the sponsor’s retiree prescription drug plan. For purposes of this clause, the term “material change” means the addition of a benefit option that does not impact the actuarial value of the retiree prescription drug coverage under the sponsor’s plan such that it no longer meets the standards set forth in paragraph (d)(1)(i) or (ii) of this section.

(7) Notice of failure to continue to satisfy the actuarial equivalence standards. A sponsor must notify CMS, in a form and manner specified by CMS, no later than 90 days before the implementation of a change to the drug coverage that impacts the actuarial value of the retiree prescription drug coverage under the sponsor’s plan such that it no longer meets the standards set forth in paragraph (d)(1)(i) or (ii) of this section.

\* \* \* \* \*

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

20. Section 423.902 is amended by adding the definition of “noncovered drugs” in alphabetical order to read as follows:

**§423.902 Definitions.**

\* \* \* \* \*

Noncovered 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.

\* \* \* \* \*

21. Section 423.906 is amended by revising paragraphs (b)(1), (b)(2), and (c) to 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) Noncovered 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.

22. 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.

\* \* \* \* \*

CMS-4130-F

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

Dated: \_\_\_\_\_

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**Kerry Weems**

Acting Administrator,

Centers for Medicare & Medicaid Services.

Approved: \_\_\_\_\_

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**Michael O. Leavitt,**

Secretary.

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