DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 423

[CMS–4131–P2]

RIN 0938–AP64

Medicare Program; Prescription Drug Benefit Program: Payments to Sponsors of Retiree Prescription Drug Plans

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would make regulatory revisions based on a change in our interpretation of section 1860D–22(b) of the Social Security Act. We would interpret this provision as providing us with the authority to ''waive or modify'' statutory requirements pertaining to the Retiree Drug Subsidy (RDS) program in order to facilitate the offering of a prescription drug plan covering employees or retirees.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than March 13, 2009.

ADDRESSES: In commenting, please refer to file code CMS–4131–P2. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

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

2. *By regular mail*. You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4131–P2, P.O. Box 8010, Baltimore, MD 21244–8010.

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

3. *By express or overnight mail*. You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–4131–P2, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier*. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses: a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; (Because access to the interior of the Hubert H. Humphrey (HHH) Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

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

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

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

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

FOR FURTHER INFORMATION CONTACT: David Mlawsky, 410–786–6851.

SUPPLEMENTARY INFORMATION:

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

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

I. Background and Legislative History

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

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

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

The MMA also specified that implementation of the prescription drug benefit and revised MA program provisions take place by January 1, 2006. Thus, we published final rules for the MA and Part D prescription drug programs, and the RDS Program, in the January 28, 2005 **Federal Register**. (For further discussion, see (70 FR 4588 through 4741) and (70 FR 4194 through 4585), respectively.) We subsequently published revisions to these regulations in an April 15, 2008 final rule (73 FR 20486).

Since the publication of these rules, we have gained a great deal of experience with all aspects of these programs. Based on this experience, as well as on recommendations from representatives of both the organizations that provide care and the Medicare beneficiaries that they serve, we determined that proposed changes to

the existing Part C, Part D, and RDS regulations were warranted. We believed that these changes would help plans understand and comply with our policies for all three programs, and aid MA organizations and Part D and RDS plan sponsors in implementing their health care and prescription drug benefit plans in ways that will better serve the Medicare population.

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

In the September 18, 2008 **Federal Register** (73 FR 54208), we published a final rule that finalized certain marketing provisions, effective October 1, 2008, that paralleled provisions in MIPPA that are not effective until January 1, 2009. In the same issue of the **Federal Register** (73 FR 54226), we published an interim final rule that addressed the other remaining provisions of MIPPA that impacted the MA and Part D programs and were not previously addressed in the May 2008 proposed rule.

Elsewhere in this **Federal Register**, we are publishing final regulations that respond to comments on the May 16, 2008 proposed rule and finalize Part C and Part D regulations from that proposed rule that either were not impacted by MIPPA or that complement MIPPA provisions. In the same rule published today containing the foregoing final regulations, we are publishing interim final regulations, with a comment period, that respond to the comments we received on the RDS provisions proposed in the May 16, 2008 proposed rule. In the preamble discussion of these interim final regulations, we indicate that we agree with concerns expressed by commenters regarding the application to the RDS program of two Part D policies that are being finalized. These interim final regulations preserve the status quo for the RDS program with respect to these policies while we invite comment on three different legal theories under which we could potentially apply these policies (a requirement to report pass-through pricing (as opposed to lock-in pricing)) and a requirement to report rebates and other price concessions that are retained by a pharmacy benefit management company or other intermediary contracting organization to Medicare Part D plans, but not to RDS plan sponsors. Specifically, we solicit comments on the possibility of applying one or more of those legal theories. However, one of these legal theories involves interpreting the waiver authority under section 1860D–22(b) of the Act (which incorporates waiver authority under section 1857(i) of the Act) to give us the authority to modify RDS regulations in order to permit to issue a final rule that preserves the status quo in the RDS program with respect to the two policies in question. In our current regulations, however, we have interpreted section 1860D–22(b) of the Act to apply only to Medicare Part D plans, and not RDS plan sponsors. In order for us to implement this legal theory, therefore, we would have to revise the regulations to establish our interpretation that the statutory waiver provision applies to RDS plan sponsors as well. Thus, to enable us potentially to adopt this legal theory (if in fact we choose to do so), we are publishing this proposed rule inviting public comment on this proposed change. Once we have reviewed the comments received on this proposed rule and the RDS interim final regulations published today, we will determine whether to adopt any of the legal theories discussed in the preamble discussion of the RDS interim final regulations, and whether to finalize the regulatory revisions based on our change in interpretation of section 1860D–22(b) of the Act set forth in this proposed rule.

II. Provisions of the Proposed Rule

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

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

However as noted previously, we have already interpreted the waiver authority in section 1860D–22(b) of the Act as applying only to Part D prescription drug plans. The employer group waiver authority in section 1860D–22(b) of the Act is set forth in part 423 subpart J (§ 423.458) of our regulations, which governs PDPs and MA–PDs, rather than subpart R, which governs QRPDPs under the RDS program. The preamble discussion of Subpart J in the January 28, 2005 final rule states that, for purposes of the discussion that follows in Subpart J, the term ''employer sponsored group prescription drug plan'' means ''a prescription drug plan under a contract between a PDP sponsor or MA organization offering an MA–PD plan and employers, labor organizations, or the trustees of funds established by one or more employers or labor organizations (or combination thereof) to furnish prescription drug benefits under employment based retiree health coverage.'' (*See* the January 28, 2005 final rule (70 FR 4320)). In other words, the preamble expressly states in its discussion of ''terminology'' that when we use the term ''employer sponsored group prescription drug plan,'' it is referring to a PDP or MA–PD, and not to a QRPDP under the RDS program.

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

Finally, § 423.454, defines an ''employer-sponsored group prescription drug plan'' as a plan ''approved by CMS as a prescription drug plan'' (a PDP). Section 423.458(c) specifically provides only for waiving provisions that hinder the design or offering of, or enrollment in, an ''employer-sponsored group prescription drug plan.'' Thus, we believe that the current regulations unambiguously construe the authority in section 1860D–22(b) of the Act as applying only to PDPs and MA–PDs, and not to QRPDPs participating in the RDS program.

As noted previously, in a related interim final rule with comment period elsewhere in this **Federal Register**, we are soliciting public comments on whether we should adopt an interpretation of section 1860D–22(b) of the Act that would extend the scope of that provision to QRPDPs, as well as PDPs and MA–PDs. In the event that, following the review of such comments, should we decide to adopt such an interpretation, we would like to issue that interpretation as part of the rulemaking process as soon as possible. For this reason, we are publishing this proposed rule. However, we wish to reiterate that the fact that we are publishing this proposed rule does not mean that we have already decided to make this interpretation.

The proposed rule would adopt an interpretation of section 1860D–22(b) of the Act that would extend the scope of that provision to QRPDPs (as well as PDPs and MA–PDs) by revising the definition of ''employer-sponsored group prescription drug plan'' in § 423.454 and by making conforming changes to § 423.458.

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. Response to Comments

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

V. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Orders 13258 and 13422) 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). This proposed rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.0 million to $34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities.

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

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2008, that threshold is approximately $130 million. This proposed rule would have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

We draw the above conclusions because this proposed rule would give us the authority to relieve RDS sponsors of requirements/costs, rather than imposing requirements/costs on such entities.

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

List of Subjects in 42 CFR Part 423

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

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR Part 423 as set forth below:

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

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

2. Section 423.454 is amended by revising the definition ''Employer-sponsored group prescription drug plan'' to read as follows:

§ 423.454 Definitions.

* * * * *

Employer-sponsored group prescription drug plan means prescription drug coverage offered to retirees who are Part D eligible individuals under employment-based retiree health coverage. For purposes of this subpart, employment-based retiree health coverage is such coverage (as defined in § 423.882) provided through a Medicare Part D plan, or for which a plan sponsor could qualify for payments under Subpart R of this part.

* * * * *

3. Section 423.458 is amended by—

A. Republishing the heading of paragraph (c).

B. Revising paragraph (c)(1).

C. Redesignating paragraph (c)(2) as paragraph (c)(3).

D. Adding a new paragraph (c)(2).

The revision and addition read as follows:

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

* * * * *

(c) Employer group waiver. (1) *General rule for employer-sponsored group prescription drug plans that are Medicare Part D plans.* CMS may waive or modify any requirement under this part that hinders the design of, the offering of, or the enrollment in an employer-sponsored group prescription drug plan, including authorizing the establishment of separate premium amounts for enrollees of the employer-sponsored group prescription drug plan and limitations on enrollment in such plan to Part D eligible individuals participating in the sponsor's employment-based retiree health coverage. Any entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan may request, in writing, a waiver or modification of additional requirements under this Part that hinder its design of, the offering of, or the enrollment in, such employer-sponsored group prescription drug plan.

(2) *General rule for employer-sponsored group prescription drug plans for which a sponsor could qualify for payments under Subpart R of this part.* CMS may waive or modify any requirement under this Part that hinders the design of, the offering of, or the enrollment in an employer-sponsored group prescription drug plan.

* * * * *

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

Dated: November 7, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: November 13, 2008.

Michael O. Leavitt,

Secretary.

[FR Doc. E9–151 Filed 1–6–09; 4:15 pm]

BILLING CODE 4120–01–P