



THE ERISA INDUSTRY COMMITTEE

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
42 CFR Parts 423, Subpart J & R
Medicare Program; Medicare Prescription Drug Benefit
ACTION: Proposed rule**

SUMMARY OF RELEVANT EMPLOYER SECTIONS FOR TITLE I

Subpart J. Coordination Under Part D Plans with Other Prescription Drug Coverage

I. Overview and Terminology (pp. 370-375)

Subpart J of part 423 proposes the implementation of sections 1860D-2(a)(4), 1860D-2(b)(4)(C), 1860D-2(b)(4)(D), 1860D-11(j), 1860D-21(c), 1860D-22(b), 1860D-23(a), 1860D-23(b), 1860D-23(c), 1860D-24(a), 1860D-24(b), and 1860D-24(c) of the Act that were added by section 101 of the MMA.

a. Part D Plans

Wherever we mention or reference “Part D plans” we mean any or all of “MA-PD plans, prescription drug plans (PDPs) and fallback prescription drug plans”.

b. Employer-Sponsored Group Prescription Drug Plan

Section 1860D-22(b) applies to “employment-based retiree health coverage” that is defined under section 1860D-22(c)(1) of the Act. This term means coverage for individuals (or their spouses and dependents) under a group health plan based on their status as retired participants.

c. State Pharmaceutical Assistance Program

(1) provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals; (2) provides assistance to Part D eligible individuals in all Part D plans (3) meets the benefit coordination requirements

specified in this part; and (4) does not change or affect the primary payor status of a Part D plan.

II. Application of Part D Rules to MA-PD Plans on and after January 1, 2006 (§ 423.258) (pp. 375-377)

In accordance with section 1860D-21(c)(1) of the Act, and as provided under proposed § 423.458(a), the provisions of Part D apply under Part C to prescription drug coverage provided by an MA-PD plan in lieu of other Part C provisions that would apply to such coverage, unless otherwise provided.

III. Application to PACE Plan (pp. 377-378)

Section 1860D-21(f) of the Act indicates that Part D provisions shall apply to PACE organizations in a manner that is similar to those of an MA-PD local plan and that a PACE organization may be deemed to be an MA-PD local plan.

IV. Application to Employer Groups (pp. 378-388)

a. Employer Group Waivers

Section 1860D-22(b) of the Act extends the waiver authority that is provided for MA organizations related to Part C by section 1857(i) of the Act and implemented at § 422.106(c) to prescription drug plans related to Part D. This waiver authority is intended to provide prescription drug plans an opportunity, similar to the opportunity afforded MA organizations under Part C, to furnish Part D benefits to participants or beneficiaries of employment-based retiree health coverage sponsored by employers and labor organizations in the most efficient and effective manner possible.

b. Employer Options

The enactment of Title I of the MMA has provided sponsors of retiree prescription drug plans with multiple options for providing drug coverage to their retirees.

1. Provide prescription drug coverage through employment-based retiree health coverage. If those coverage is at least actuarially equivalent to the standard prescription drug coverage under Part D, the sponsor is eligible for a special Federal subsidy for each individual enrolled in the sponsor's

employment-based retiree health coverage who is eligible for Part D but elects not to enroll in Part D, directly reducing the cost of providing a high-quality drug benefit.

2. Provide prescription drug coverage that supplements, or “wraps-around,” the coverage offered under the PDP or MA-PD plans in which the retirees (and their dependents) enroll.

3. Subsidize the monthly beneficiary premium for whatever PDP or MA-PD plan in which the employer or union’s retirees (and their dependents) elect to enroll.

4. Provide a prescription drug plan (PDP) or Medicare Advantage-prescription drug plan (MA-PD plan) either under contract with a PDP sponsor or Medicare Advantage (MA) organization or by directly sponsoring a PDP or an MA-PD plan.

c. Implications for Beneficiaries

For beneficiaries, the significance of the above discussion, as well as of the earlier discussion (in Subpart C) of incurred costs that count toward the true out-of-pocket threshold, is that these rules would lead to new options for drug coverage.

- If they are eligible for a more comprehensive retiree health benefits policy sponsored by their former employer, their retiree plan sponsor may qualify for a subsidy payment.
- If they have limited income, they may be eligible for Part D low-income subsidies of premium and cost sharing through a Part D plan.
- They may be eligible for financial assistance through a State Pharmaceutical Assistance Program that can pay for an enrollee’s cost sharing and still have these payments count toward the out-of-pocket limit.
- They may qualify for charitable assistance from bona fide non-profit charities that can also pay for an enrollee’s cost sharing and still have these payments count toward the out-of-pocket limit.
- They may have access to a PDP or MA-PD (through either individual enrollment or employer group enrollment) that offers an enhanced alternative prescription drug plan for an additional premium.

V. Medicare Secondary Payer Procedures (pp. 389-392)

Section 1860D-2(a)(4) of the Act extends the Medicare secondary payer (MSP) procedures applicable to MA organizations under section 1852(a)(4) of the Act and 42 CFR 422.108 to PDP sponsors.

VI. Coordination Of Benefits With Other Providers Of Prescription Drug Coverage (pp. 392-433)

Section 1860D-23(a) of the Act authorizes us to establish procedures and requirements to promote the effective coordination of benefits between a Part D plan and a State Pharmaceutical Assistance Program with respect to payment of premiums and coverage, and payment for supplemental prescription drug benefits.

a. Coordination with SPAPs

The statute envisions a closer coordination of benefits between SPAPs and Medicare drug plans.

b. Coordination with Other Prescription Drug Coverage

Other plans providing prescription drug coverage that Part D plans would need to coordinate with are any of the following (1) Medicaid programs (including a State plan operated under a waiver under section 1115 of the Act); (2) Group health plans, as defined in § 411.101; (3) FEHBP; (4) Military Coverage (including TRICARE) under chapter 55 of title 10 of the United States Code; and (5) other prescription drug coverage as we specify.

c. Coordination of Benefits

Sections 1860D-23(a)(1) and 1860D-24(a)(1) of the Act require that, by July, 1, 2005, we establish requirements for coordination of benefits between Part D plans and SPAPs and other insurers including Medicaid programs, group health plans, the Federal Employees Health Benefits Plan (FEHBP), military coverage (including TRICARE), and other coverage we may specify at a later date.

d. Collection of Data on Third Party Coverage

Section 1860D-2(b)(4)(D)(i) of the Act authorizes us to establish procedures for determining whether a beneficiary's Part D out-of-pocket costs are actually reimbursed by a group health plan, insurance or otherwise, or another third-party arrangement.

e. Tracking True Out-of-Pocket (TrOOP) Costs

As we discuss in the preamble to subpart C of this rule, section 1860D-2(b)(4)(C) of the Act provides that beneficiary costs for covered Part D drugs are only considered incurred when those costs are incurred by a Part D enrollee for covered part D drugs covered under (or treated as covered under) a Part D plan that are not paid for under the Part D plan due to the application of any annual deductible or other cost-sharing rules for covered part D drugs prior to the Part D enrollee satisfying the out-of-pocket threshold under proposed § 423.104(e)(5)(iii), including any price differential for which the Part D enrollee is responsible under proposed § 423.120(a)(6) and §423.124(b)(2).

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

I. Overview (pp. 591-600)

Subpart R would implement section 1860D-22 of the Act, which provides for making subsidy payments to sponsors of qualified retiree prescription drug plans.

a. Options for Sponsors of Retiree Prescription Drug Programs

The enactment of Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) on December 8, 2003 has provided sponsors of retiree prescription drug plans with multiple options for providing drug coverage to their retirees.

- (1) Provide prescription drug coverage through employment-based retiree health coverage.
- (2) Contract with a PDP sponsor or Medicare Advantage (MA) organization to enroll Medicare beneficiaries covered under the retiree plan into a prescription drug plan (PDP) or Medicare Advantage-prescription drug (MA-PD) plan.
- (3) Provide prescription drug coverage that supplements, or "wraps-around," the coverage offered under the PDP or MA-PD plans in which their retirees (and retirees' spouse and dependents) enroll.

b. The Retiree Drug Subsidy Provision

By providing heavily subsidized insurance coverage of prescription drug expenditures incurred by, or on behalf of, Medicare beneficiaries, the

MMA would significantly reduce the cost of existing retiree beneficiary drug coverage.

II. Definitions (§ 423.882) (pp. 600-615)

The Act contains a number of definitions that are critical to understanding how the retiree drug subsidy functions. The terms and respective definitions are given in the document.

III. Requirements to Apply for the Retiree Subsidy (pp. 615-643)

a. General Requirements

This section outlines the general requirements related to applying for the subsidy payment described in this proposed rule.

b. Attestation of Actuarial Value Amount

1. Attestation Requirements

In § 423.884(a) of our proposed rule we would require that the sponsor submit an attestation to us that the actuarial value of the prescription drug coverage under its retiree plan or plans is at least equal to the actuarial value of standard Medicare Part D prescription drug coverage.

2. Establishing Actuarial Equivalency

Section 1860D-11(c) of the Act provides the Secretary with the authority to determine the standards and methods for determining actuarial equivalence.

c. Sponsor Application for Subsidy Payment and Required Information

A plan sponsor who wishes to be paid the retiree drug subsidy must apply annually for the subsidy. We will provide the technical details (including important system issues) to sponsors and other interested parties in the very near future in order to facilitate our developing appropriate guidance, which will, in turn, encourage sponsor participation and minimize the burden to sponsors to the maximum extent possible.

d. Creditable Coverage and Notification

Section 1860D-22(a)(2)(c) of the Act specifies that in order for a sponsor's plan to meet the definition of a qualified retiree prescription drug plan, the sponsor must provide for disclosure of whether coverage is "creditable coverage" in accordance with the proposed requirements set forth under proposed § 423.56 of our proposed rule.

IV. Retiree drug subsidy amounts (§ 423.886) (pp. 643-644)

As explained previously, § 423.886 governs the subsidy amount a sponsor of a qualifying retiree prescription drug plan receives for each qualifying covered retiree that is enrolled with the sponsor in a year. The sponsor is eligible to receive a subsidy payment for each qualifying covered retiree whose gross covered retiree plan-related prescription drug costs exceed the cost threshold. The amount of the subsidy would be 28 percent of the allowable retiree costs attributable to the gross retiree costs that are above the threshold and do not exceed the cost limit.

V. Payment Methods, Including Provision of Necessary Information (§ 423.888) (pp. 644-665)

a. Plan Year Versus Coverage (Calendar) Year

Under section 1860D-22(a)(3)(B) of the Act, the cost threshold and cost limits that determine the amount of the subsidy are calculated for "plan years that end in" 2006 and subsequent calendar years. However, section 1860D-22(a)(3)(A) of the Act refers to the subsidy amount for a qualifying covered retiree for a "coverage year," that is defined as calendar year. Thus, we believe that, in the context of section 1860D-22 of the Act, the reference to retirees enrolled in a qualified plan "during a coverage year" can be read to mean that the retiree must be enrolled during either a calendar year or plan year that ends in the specified calendar year.

c. Payment Methodology

Section 1860D-22(a)(5) of the Act specifies that payments to plan sponsors are to be made "in a manner similar to" the payment rules in section 1860D-15(d) of the Act, which apply to payments made to PDP sponsors and MA organizations under Part D. We believe that section 1860D-15(d) of the Act gives us broad discretion to determine a payment method.

d. Data Collection

Regardless of what payment methodology is ultimately chosen for the subsidy, we would need certain data from the sponsors of the plans (or the plan administrators, insurers or group health plans designated by the sponsors) in order to accurately calculate the amount of the subsidy to which the sponsor is entitled. This data would include updating of the information that was provided during the application process such as the names of the qualifying covered retirees enrolled in the plan, including the spouses and the dependents, the Health Insurance Claim (HIC) numbers (when available), social security numbers, dates of birth, sex, and relationship to the retired employees.

e. Audits

At § 423.888(d), we propose that the sponsor of the plan (or the plan administrator, insurer, or group health plan designated by the sponsor) would be required to maintain and provide access to sufficient records for our audits or audits of the OIG to assure the accuracy of the attestation regarding actuarial value and the accuracy of subsidy payments made under this subpart.

VI. Appeals (§ 423.890) (pp. 665-672)

Although the statute does not contain provisions for administrative appeals of the retiree drug subsidy amount, and although we do not believe there is a constitutional property interest in the retiree drug subsidy, we believe that it is prudent policy to allow an opportunity for review of certain agency decisions issued in relation to this subpart.

VII. Privacy (pp. 672-674)

The HIPAA Privacy Rule at 45 CFR Part 160 and Subparts A and E of Part 164 ("Privacy Rule") applies to "covered entities," which include group health plans and health insurance issuers, as defined in 45 CFR 160.103.

VIII. Change of Ownership (§ 423.892) (pp. 674-677)

Sponsors who apply for a subsidy payment would be required to comply with change of ownership requirements, similar to those set forth in proposed § 423.551 for the MA-PD and PDP plans.

IX. Construction (§ 423.894) (pp.677-678)

Sections 423.890(a) through § 423.890(d) are based on section 1860D-22(a)(6) of the Act. It provides that nothing in section 1860D-22 of the Act must be interpreted as preventing—

- An individual who is eligible for Medicare Part D and who is covered under employment-based retiree health coverage from enrolling in a prescription drug plan or in a MA-PD plan;
- The sponsor of employment-based retiree health coverage or an employer or other person from paying all or any part of any premium required for coverage under a prescription drug plan or MA-PD plan on behalf of an individual;
- Employment-based retiree health coverage from providing coverage that is supplemental to the benefits provided under a prescription drug plan or a MA-PD plan.
- Employment-based retiree health coverage from providing coverage that is better than the standard prescription drug coverage (as defined in § 423.104(e)) to retirees who are covered under a qualified retiree prescription drug plan; and
- Sponsors from providing for flexibility in benefit design and pharmacy access provisions, without regard to the requirements for basic Medicare Part D drug coverage, as long as the actuarial equivalence requirement (as defined in § 423.884(a)) is met.