DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

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Subject: Employer Prescription Drug Coverage that Supplements Medicare Part D Coverage provided through an Employer Group Waiver Plan

Market: Group

Purpose

The purpose of this Bulletin is to provide guidance on how the requirements of title XXVII of the Public Health Service Act (PHS Act), Part 7 of the Employee Retirement Income Security Act (ERISA) and Chapter 100 of the Internal Revenue Code (the Code) apply when an Employer Group Waiver Plan, authorized under the Medicare statute, supplements standard Medicare Part D prescription drug coverage. These requirements, originally added by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and later amended by various statutes including the Affordable Care Act, are essentially the same in all three statutes. Therefore, for ease of reference, we refer to the relevant PHS Act, ERISA, and Code provisions, collectively, as the "federal health coverage requirements." This also helps distinguish those requirements from Medicare provisions. The Departments of Labor and the Treasury have reviewed and concur in the discussion in this Bulletin of the application of the federal health coverage requirements.

Background

Medicare in General

The Medicare program established under title XVIII of the Social Security Act has four parts. Part A (hospital insurance) and Part B (medical insurance) benefits are provided to Medicare beneficiaries either directly by the government, under "Original Medicare," or through private entities that contract with Medicare, called "Medicare Advantage" plans, established under Part C of Medicare. Part D is an optional prescription drug benefit, also provided by private entities that are generally referred to as "Part D plans." Part D benefits can either be provided by "stand-alone" Prescription Drug Plans (PDPs) that are available to beneficiaries enrolled in Original Medicare, or it can be provided by a Medicare Advantage (MA) plan, to beneficiaries who are enrolled in the plan to get their Part A and B benefits. An MA plan that provides Part D coverage is referred to as a Medicare Advantage Prescription Drug or "MA-PD" plan.

Part D coverage, at a minimum, includes a "standard" Part D benefit. However, organizations offering PDPs or MA-PD plans are also permitted to offer "supplemental" Part D drug coverage that is more generous than that offered under the standard benefit. Thus for most purposes, the term "Medicare Part D plan coverage" includes both the standard Part D benefit and any Part D supplemental benefits offered by the Part D plan. For most MA-PD plans and PDPs, CMS must be able to distinguish what is in the basic benefit, and what is in the supplemental benefit. The way this is accomplished is to require plans to submit a document called a "bid." This "bid" includes the PDP's or MA-PD plan's price for the standard Part D benefit, as well as the charge for supplemental Part D coverage (or, in the case of an MA-PD plan, the amount of Medicare dollars allocated to covering the cost of the supplemental coverage). The bid must be submitted to CMS for approval.

Standard Part D coverage historically has included a "coverage gap," which means that after beneficiaries and the plan together incur a specified amount of expenses for prescription drugs (the "initial coverage limit"), beneficiaries pay the full cost of their prescriptions out-of-pocket until they reach a "catastrophic" limit. Supplemental Part D benefits often include at least some coverage during the coverage gap.

Under the Affordable Care Act, the coverage gap is being closed over a period of years. Once the coverage gap is closed, under standard benefit coverage beneficiaries will pay the same levels of cost sharing throughout the period that starts when they satisfy the deductible and ends when they reach the catastrophic limit. To cover a portion of the beneficiary's costs in the coverage gap, section 3301 of the Affordable Care Act has established the Medicare Coverage Gap Discount Program, under which pharmaceutical manufacturers must pay for some of the out-of-pocket costs of drugs that would otherwise be **covered** under Medicare Part D, but are not **reimbursable** while the beneficiary is in the gap. The amount the manufacturer must pay is based on the coverage gap amounts that the beneficiary still owes after all Part D plan coverage (including both the standard benefit and any supplemental Part D coverage provided for in the bid) has been applied, but before any coverage provided outside the scope of the Part D plan has been taken into account.

Medicare and Group Health Plans

In addition to Part D plans (i.e., MA-PD plans and PDPs) that are generally available to any individual Medicare beneficiary who lives in the plan's service area, Part D plans can also be provided through employer or union group health plans[1] for their employees or retirees who are Medicare beneficiaries. Because these plans can only be offered by employers pursuant to waiver authority in the Social Security Act, they are referred to as "Employer Group Waiver Plans" or "EGWPs." We use this term to encompass Part D plans provided by employers. When we discuss distinctions between the two types of plans (because PDPs can only be provided to retirees, while MA-PD coverage can be provided to both retirees and active

[1] MA-PD plans and PDPs may be sponsored by an employer, an employee organization, or both. For simplicity, this bulletin refers to employers. This bulletin, however, is equally applicable to MA-PD plans and PDPs sponsored by an employee organization or jointly by employers and employee organizations.

employees) we will specify whether we are talking about "employment-based MA-PD plans" or "employment-based PDPs."

As noted above, the supplemental coverage that is included in a bid is considered part of the Medicare Part D coverage offered by the MA-PD plan or PDP. We refer to it here as "supplemental Part D coverage" to distinguish it from any other supplemental coverage a beneficiary might have, such as through an employer, that might also help defray expenses not covered by the Part D plan.

In the case of the usual Part D plan (not offered under an employer group waiver) for which CMS reviews and approves the "bid," the supplemental Part D plan benefits are readily identifiable. However, in the case of EGWPs, whose enrollees are limited to members of an employer or union group health plan under waiver authority provided for under the Part D statute, CMS does not receive or review bids because CMS believes that applying the bid requirement to EGWPs would hinder the design, offering, or enrollment in employer-sponsored coverage given the additional complexity and level of effort that would be required of EGWPs to submit all applicable information on all of their employment-based benefit packages. Thus, for EGWPs, CMS does not have a way of distinguishing supplemental Part D coverage under the PDP or MA-PD plan from non-Medicare drug coverage that may be offered by the employer. Consequently, in order to be able to distinguish Part D benefits (including both basic and supplemental Part D benefits) from non-Medicare supplemental benefits provided by an EGWP, CMS issued a final regulation that defined **any** supplemental benefits offered by an employer or union to enrollees in an EGWP as a non-Medicare benefit.[2] This change means that the manufacturer's liability for a discount under an EGWP is always calculated based on the standard Part D benefit (i.e., the minimum provided by any Part D plan), without taking into account **any** supplemental benefits provided by the employer or union to those eligible to enroll in the plan. This provides CMS with a consistent way to calculate the appropriate discount amount for EGWPs.

Discussion

Retiree-only plans

The federal health coverage requirements generally do not apply to group health plans with less than two participants who are current employees (such as plans in which only retirees participate). See, ACA Implementation FAQs Part III, issued on October 12, 2010 (which can be found at http://cciio.cms.gov/resources/factsheets/aca_implementation_faqs3.html). As explained above, for this purpose there is a distinction between EGWPs that are PDPs and those that are MA-PDs. The employment-based PDPs can **only** be provided to retirees, and will, by definition, never enroll any current employees. Accordingly, all employment-based PDPs are exempt from the federal health coverage requirements. In addition, any employment-based MA-PD plans in which only retirees participate, or that do not otherwise cover at least **two**

[2] See 42 CFR 423.100, 77 Fed. Reg. 22072 (April 12, 2012). This rule represented an exercise of CMS's discretion to decide the circumstances under which to approve an EGWP by effectively conditioning such an approval on the plan not offering Part D supplemental benefits.

employees who are current employees, are exempt from the federal health coverage requirements.

Plans that Cover at Two or More Current Employees - Insured Coverage

Sponsors of self-insured plans generally bear the risk associated with paying their plan's covered health expenses. In contrast, sponsors of fully-insured plans generally pay premiums to insurers and transfer all such risk to them. EGWPs can either be self-insured or be fully insured. For MA-PD plans, a separate basis for exemption from the federal health coverage requirements exists if a benefit meets the requirements to be an excepted benefit under PHS Act section 2722(c)(3). For the reasons that follow, to the extent that non-Medicare supplemental drug coverage is provided to enrollees through an **insured** EGWP MA-PD plan, we believe that the coverage would qualify as an excepted benefit.

Pursuant to PHS Act section 2791(c)(4) and implementing regulations at 45 CFR 146.145(c)(5), coverage that is provided under a separate policy, certificate, or contract of insurance and is either Medicare supplemental health insurance (Medigap),[3] TRICARE supplemental programs, or similar supplemental coverage provided to coverage under a group health plan is an excepted benefit, and the federal health coverage requirements do not apply.[4] In Insurance Standards Bulletin No. 08-01 (May 2008) and parallel guidance issued by Labor and Treasury, the Departments set forth criteria for an enforcement safe harbor for determining whether coverage can be considered "similar supplemental coverage" and thus an excepted benefit.[5] The following analysis explains why supplemental prescription drug coverage offered to active employees enrolled in an employer-sponsored MA-PD plan provided through insurance is considered to satisfy these criteria:

- First, the coverage must supplement coverage provided under a group health plan. While coverage under EGWPs that are MA-PD plans is considered Medicare coverage because enrollment is based on eligibility for Medicare benefits, enrollment in these plans is, by definition, limited to employees or retirees who are also eligible for benefits under the group health plan sponsoring the employment-based MA-PD plan.

- Second, the supplemental coverage must be provided through a separate policy, certificate, or contract of insurance. To the extent the employer plan is an insured plan, the insured MA-PD is considered coverage provided by an EGWP through a separate policy, certificate, or contract of insurance.

- Third, the supplemental coverage must be independent of the primary coverage, meaning that it must be issued by an entity other than the entity providing the primary coverage

[3] Medigap policies are private health insurance that Medicare beneficiaries can buy to cover certain Medicare cost-sharing amounts, and provide some additional benefits.
[4] This language is also contained in ERISA section 733(c)(4) and 29 CFR 2590.732(c)(5), and Code section [9833(c)(4) and 26 CFR 54.9831-1(c)(5)].
[5] See also Department of Labor Field Assistance Bulletin 2007-04, available at http://www.dol.gov/ebsa/regs/fab2007-4.html .

under the plan.[6] In this case, even though the same issuer may be *contracting* to deliver both, it is contracting with two different entities, based on two different sources of eligibility for coverage. The supplemental prescription drug benefits are offered by the employer through an insurance policy based on an individuals' status as an employee or retiree, while the standard Part D drug coverage provided under the MA-PD plan is offered by the Federal government through a tax-funded program (Medicare) for which one is eligible under the Social Security Act, without regard to whether the enrollee is an employee or retiree. CMS believes this situation is precisely analogous to Medigap coverage supplementing Medicare Part A and Part B benefits. Therefore, the Medicare Part D and supplemental prescription drug benefits meet the criterion of being offered by separate entities, even if they are offered through a common contractor.

- Fourth, the coverage must be specifically designed to fill "gaps" in the primary coverage, such as coinsurance or deductibles, but may not become secondary or supplemental only under a coordination-of-benefits provision. While some EGWPs that are MA-PD plans may incidentally cover items excluded under Medicare Part D, such as over-the-counter medications, the vast majority of supplemental benefits in EGWPs that are MA-PD plans are for reducing the cost-sharing for prescription drugs covered under the Medicare Part D standard benefit. Accordingly, CMS considers this criterion satisfied with respect to EGWPs that are MA-PDs.

- Fifth, the cost of supplemental coverage must not exceed 15 percent of the cost of primary coverage. The Office of the Actuary at CMS has determined that it is highly unlikely for the cost of supplemental prescription drug benefits provided in addition to those provided by MA-PD plans to exceed 15 percent of the cost of the Part C and Part D benefits. Accordingly, CMS considers this criterion to be met for all EGWPs that are MA-PD plans.

- Finally, the supplemental coverage must not differentiate among individuals in eligibility, benefits, or premiums based on any health factor of an individual (or any dependent of the individual). Since supplemental drug benefits offered by employer sponsored MA-PD plans are closely integrated with the standard Medicare Part D benefits, beneficiaries are protected against potential discrimination based on health status since there is no medical underwriting used in connection with enrollment and premium setting and there is no separate medical necessity or claims determination for the supplemental benefits.

Accordingly, non-Medicare drug benefits provided by an insured EWGP that is a MA-PD constitute an excepted benefit and are not subject to the federal health coverage requirements.

Plans that Cover at Two or More Current Employees - Self-Insured Coverage

[6] For this purpose, the guidance states that entities that are part of the same controlled group of corporations or part of the same group of trades or businesses under common control, within the meaning of section 52(a) or (b) of the Code, are considered a single entity.

EGWPs that are MA-PD plans can also be self-insured by an employer or employee organization (or both), rather than insured through an issuer. Although the supplemental non-Medicare drug coverage provided through self-insured MA-PD plans is technically subject to the federal health coverage requirements, CMS, the Departments of Labor and the Department of the Treasury have recently released an FAQ that provides an enforcement safe harbor for such plans. See, ACA Implementation FAQs Part XI, issued on January 24, 2013 (which can be found at http://cciio.cms.gov/resources/factsheets/aca_implementation_faqs11.html).

Beneficiary Protections

Although CMS has clarified that any prescription drug benefit provided by an EGWP that supplements the standard Part D benefit is a non-Medicare benefit, group health plans and health insurance issuers are encouraged to apply Part D beneficiary protections to the supplemental benefits as well. In fact, most of the supplemental coverage consists of cost sharing reductions that are, as a practical matter, directly controlled by the Part D requirements because they flow directly from the determination of the basic benefits. Because the Affordable Care Act has increased basic Part D benefits in the coverage gap, as of 2013 there will be very few claims that do not contain some basic Part D benefits and would not ultimately be governed (as a practical matter) by the Part D regulations.

Where to get more information:

If you have any questions regarding this Bulletin, please e-mail phig@cms.hhs.gov or call 877-267-2323, ext. 1565.