

Additional Part D Waiver Guidance for Employer/Union Retiree Coverage
March 9, 2005

Introduction

Employer Options

The MMA provides employers and unions with a number of options for providing prescription drug coverage to their retirees.

- An employer or union sponsor with coverage that is at least as good as Medicare's Part D defined standard prescription drug benefit can receive a tax-free retiree drug subsidy that pays 28 percent of a retiree's drug costs (as defined by the regulation) between \$250 and \$5,000 in 2006. The subsidy only applies to retirees eligible for but not enrolled in a Medicare Prescription Drug Plan or a Medicare Advantage (MA) Plan (such as an HMO or PPO), cost plan, or PACE plan with prescription drug coverage (collectively, a "Part D plan"). Under the subsidy rules described in 42 CFR 423.880 et. seq., sponsors have substantial flexibility to qualify for subsidy payments under the existing health plans.
- Another available option is for an employer or union to encourage its retirees to enroll in a plan providing Part D benefits and then provide them with additional coverage. There are several ways that sponsors could supplement the standard Medicare drug benefit, such as:
 - Retaining substantial flexibility to design and offer their own separate supplemental coverage that coordinates benefits with the coverage provided by the Part D plans their retirees enroll in, in much the same way they currently lower non-prescription drug costs by supplementing the standard Medicare Part A and B benefits;
 - Paying for enhanced coverage offered under a Part D plan that subsidizes more of their retirees' cost-sharing and provides additional benefits;
 - Making special arrangements with MA plans to purchase customized benefits, including drug benefits, for their retirees pursuant to CMS waivers (discussed in more detail below), or to rely on such waivers to purchase customized benefits from other Part D sponsors (defined in 42 CFR 423.4) that provide prescription drug-only plans; and
 - Providing the customized Part D plan benefits for their retirees by contracting with CMS to become Part D plan sponsors themselves and obtaining CMS waivers.

Waiver Authority

CMS has the authority under sections 1860D-22(b) and 1857(i) of the Social Security Act (Act) to waive or modify Part D requirements that hinder the design of, the offering of, or the enrollment in an employer or union Part D retiree plan. In considering the extent to which it will exercise its waiver authority, CMS will consider a number of important goals, including:

- Providing group plan sponsors with maximum flexibility and minimum administrative burden with regard to requirements that would hinder the design of, the offering of, or the enrollment in, Part D plans offered to their retirees so they will keep offering --- and retirees can retain -- high quality retiree prescription drug coverage;
- Recognizing and supporting the goal of employers to offer coordinated care plans to their Medicare-eligible retirees like they do for other retired (and active) health plan participants;
- Adhering to budgetary constraints; and
- Considering the appropriate protections that Medicare enrollees may expect when enrolling in a Part D plan.

Scope of Guidance

This guidance waives or modifies Part D requirements and elements of the Part D application process that CMS believes hinder the design, offering of or enrollment in employer or union retiree Part D coverage. Given the erosion of retiree coverage over time, the different ways in which employer and union retiree coverage have historically been regulated and designed as compared to standards for Part D benefits, and the limited time available for employers, unions and Part D sponsors to consider available options under the MMA, CMS believes the guidance is needed to ensure that the customized Part D benefit is a viable option for employers and unions seeking to retain high quality retiree coverage. At the same time, the guidance has been designed to take into account important policy goals and beneficiary protections built into the Part D rules, and budgetary considerations.

The waivers listed below are in addition to those described in the waiver guidance for employer/union retiree coverage issued on February 11, 2005 at http://www.cms.hhs.gov/EmpGrpWaivers/01_Overview.asp. The waivers will automatically apply and will not need to be granted to each employer or union Part D plan on an individual basis. Waivers are not applicable to the other MMA options described above for employers and unions, and this guidance is not intended to address standards that apply under any of those other options.

CMS will release further guidance relating to Medicare Part D waivers that will be granted automatically to employer or union retiree group plans. CMS will also consider additional waiver requests relating to specific requirements not addressed in this document or in future guidance on a case-by-case basis.

For the waivers described below, references are provided to relevant sections of the PDP application at <http://www.cms.hhs.gov/> and Part D regulation. The guidance also indicates which waivers apply only to arrangements involving employer or union direct contracts with CMS, and which waivers apply both to the direct contract arrangements and to employer or union plans offered by other Part D sponsors.

Part D Employer Group Waivers in Addition to Those in CMS February 11, 2005 Guidance

Management and Operations Requirements

Application Sections 3.1 and 3.16

Available for Employer/Union Direct Contracts Only

In general, an entity seeking to contract with CMS as a Part D sponsor must have policy-making bodies exercising oversight and control to ensure actions are in the best interest of the organization and its enrollees, appropriate personnel and systems relating to prescription drug services, administration and management, and an executive manager whose appointment and removal are under the control of the policy-making body, pursuant to 42 CFR 423.504 (b) (4)(i)-(iii). An employer or union directly contracting with CMS as a Part D sponsor may be subject to other, potentially different standards governing its management and operations, such as ERISA fiduciary requirements, state law standards, and certain oversight standards created under the Sarbanes-Oxley Act. In most cases they will also contract with business associates to provide the prescription drug benefit services. To reflect these issues and avoid imposing additional (and potentially conflicting) government oversight that may hinder employers and unions from considering direct Part D contracts with CMS, the requirements of 423.504(b)(4) noted above are waived if the employer or union (or to the extent applicable, the business associate with which it contracts for prescription drug benefit services) is subject to ERISA fiduciary requirements or similar state or federal law standards. However, such entities (or their business associates) are not relieved from the record retention standards applicable to other Part D sponsors in 42 CFR 423.505(d). (section 3.16 of the PDP application)

In addition, Part D sponsors must meet bonding and insurance standards described in 42 CFR 423.504(b)(4)(iv)-(v). CMS may, on a case-by-case basis, provide flexibility to an employer or union directly contracting with CMS as a Part D sponsor upon a demonstration that different federal or state legal standards (such as ERISA bonding requirements) are satisfied.

Cost Sharing Requirements

Regulation Sections 423.104(d) and (e)

Available for Employer/Union Direct Contracting Plans and MA-PD and PDP Retiree-only Plans

In general, a Part D plan can offer alternative or enhanced prescription drug coverage (i.e., coverage that differs from defined standard prescription drug coverage) if certain actuarial equivalence standards are met. For example, section 423.104(e)(5) requires that the coverage be designed to provide for the payment of costs incurred for covered part D drugs equal to the initial coverage limit defined in 42 CFR 423.104(d)(3) (\$2,250 in 2006) that is equal to or greater than what a part D plan offering defined standard prescription drug coverage would pay between such limit and the deductible at section 423.104(d)(1) (\$250 in 2006). (Throughout that range, defined standard prescription drug

coverage covers on average 75 percent of the costs and beneficiaries pay on average 25 percent.)

Retiree coverage offered by employers and unions has often differed from the defined standard benefit design in Part D. For example, many arrangements offer lower deductibles or provide coverage for claims incurred in the Part D coverage gap. By contrast, within the range between the deductible and the initial coverage limit, these designs may provide somewhat less coverage than defined standard prescription drug coverage under Part D. To provide beneficiaries with more choices and enable employers and unions to continue offering retirees their familiar coverage, CMS will waive the section 423.104(e)(5) actuarial equivalence test for Part D plans offered exclusively to employer or union retirees. (This waiver applies to employer/unions directly contracting with CMS as Part D sponsors, and Part D plans offered by other Part D sponsors).

However, this guidance is not intended to waive other actuarial equivalence standards in section 423.104(e), including (but not limited to) the requirement in section 423.104(e)(3) that the total or gross value of the coverage be at least equal to the total or gross value of defined standard coverage and the requirement in 423.104(e)(2) regarding catastrophic coverage. Thus, for example, a retiree Part D plan that requires beneficiary coinsurance that on average is greater than 25 percent may still satisfy actuarial equivalence by instead offering a lower deductible, or by providing coverage above the initial coverage limit, if the gross value coverage standard, the catastrophic coverage, and other requirements are satisfied.

Solvency Requirements

Application Section 3.1.3 and Appendix X

Available for Employer/Union Direct Contracts Only

Under certain circumstances, Part D sponsors are permitted to operate without state licensure for certain periods. If they do, they are subject to specified solvency standards and other requirements described in appendix X of the PDP application (See http://www.cms.hhs.gov/PrescriptionDrugCovContra/04_RxContracting_ApplicationGuidance.asp). In the February 11, 2005 guidance, CMS noted that in regards to an employer/union applying to become a Part D sponsor for purposes of providing prescription drug coverage to its retirees, certain solvency and other standards will be required if state licensure is waived for that entity.

This guidance clarifies that if the employer or union does not meet the standards described in appendix X of the PDP application, CMS may in its discretion approve, on a case-by-case basis, waivers of such requirements upon a demonstration from the entity that its fiscal soundness is commensurate with its financial risk and that through other means the entity can assure that claims for benefits paid for by CMS and beneficiaries will be covered. In all cases, CMS will require that the employer or union's contracts and sub-contracts provide beneficiary hold harmless provisions described in appendix X and other CMS guidance.

Pharmacy Access Requirements

Application Section 3.4

Available for Employer/Union Direct Contracting Plans and MA-PD and PDP Retiree-only Plans

Part D plans cannot limit coverage to only mail order prescription drugs. In addition, Part D plans must meet specific standards in section 423.120(a)(1) regarding the assembling of broad networks of retail pharmacies to provide convenient access to beneficiaries. While waivers of the mail order only-prohibition will not be granted, CMS also recognizes different circumstances surrounding retiree coverage as compared to other Part D plans. For example, an employer or union arrangement may have only a small numbers of retirees concentrated in a local area within a large region. Employers and unions also have an interest in ensuring their retirees have adequate pharmacy access. To facilitate the offering of such plans and maximize flexibility, CMS will waive other specific Part D retail pharmacy access standards in 423.120(a) for Part D plans for employer or union retirees upon receipt of an attestation that the plan's networks are sufficient to meet the needs of its retiree population, including situations involving emergency access. For example, this might be the case if a sponsor provides similar or identical provider networks to pre-Medicare eligible health plan participants. However, CMS may review the adequacy of the pharmacy networks and potentially require expanded access in the event of beneficiary complaints or for other reasons it determines in order to ensure that the plan's network is sufficient to meet the needs of its retiree population.

Marketing/Beneficiary Communications Requirements

Application Section 3.10

Available for Employer/Union Direct Contracting Plans and MA-PD and PDP Retiree-only Plans

In general, CMS establishes guidelines on the content and format of beneficiary plan documents, including marketing materials, and requires CMS prior approval (423.50 (a)). Additional standards governing the disclosure of Part D plan information are described or cross-referenced in section 423.128. Many Part D plans offered only to employer/union retirees are subject to alternative disclosure standards under other laws (e.g., under ERISA). To avoid subjecting such plans to unnecessary/conflicting standards of review, CMS will waive such specific Part D marketing/beneficiary communications requirements upon receipt of an attestation that the plans comply with the alternative disclosure standards. However, such materials must be provided to CMS at the time of use and to beneficiaries on a timely basis, and CMS may review these materials in the event of beneficiary complaints or for other reasons it determines to ensure the information adequately informs Medicare beneficiaries about their rights and obligations under the plan.

Reporting Requirements

Application Section 3.13

Available for Employer/Union Direct Contracts Only

In general, Part D plan Sponsors must report certain information to CMS, to their enrollees, and to the general public, such as the cost of their operations and financial statements, under 42 CFR 423.514 (a). To avoid imposing additional and possibly conflicting public disclosure obligations that would hinder the offering of employer or union direct contract arrangements, CMS will modify these reporting requirements to require information regarding such arrangements be reported to enrollees and to the general public to the extent required by other law (including ERISA or securities laws) or by contract.

Timetable for Employer Plans

The February 11 guidance provided extended timetables for submission of notice of intent to apply, applications, and formularies with respect to employer/union Part D plans. This guidance clarifies that MA-PDs and PDPs serving the non-employer or union group market already file notices of intent to apply (for new plans), and thus it will not be necessary for these plans that wish to offer customized employer/union-only plans to file additional notices of intent to apply. Also, they will not need to file separate applications for the employer or union group coverage but will file by April 18, 2005 an addendum (to be supplied by CMS) identifying certain provisions of the Part D application expected to differ for their employer customers, and/or provisions for which they are requesting additional waivers. Further, separate formulary submissions will be required to the extent a formulary differs for a given product. Information relating to bids for employer or union retiree plans will be addressed separately in other guidance.

Process to File a Notice of Intent for Direct Contract Plans: As stated in the February 11 guidance, the deadline for submission for of a Notice of Intent to Apply for employer/union direct contracts has been extended to March 23, 2005. The process involves submission of three documents that can be located on the employer page of the CMS Website <http://www.cms.hhs.gov>. These documents include: 1) Notice of Intent Form for an Employer/Union PDP Direct Contract; 2) CMS Connectivity Request Form; and 3) Application for Access to CMS Computer Systems. This information was posted on March 4, 2005.

For More Information

A significant amount of information regarding Part D plans (including applications, formulary information, a place to register for user group calls, and other implementation materials) can be found at: <http://www.cms.hhs.gov/>.