
CMS Manual System

Pub. 100-18 Medicare Prescription Drug Benefit Manual

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 6

Date: November 7, 2008

SUBJECT: Chapter 12-Employer/Union Sponsored Group Health Plans

I. SUMMARY OF CHANGES: Initial release of Chapter 12 of the Medicare Prescription Drug Benefit Manual into the CMS Manual System. Normally, red italic font identifies new material. However, because this release is a new chapter, normal text font is used for the initial release. New material in subsequent releases will be identified in red, italic font.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: November 7, 2008
IMPLEMENTATION DATE: November 7, 2008

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously posted to http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage or <http://www.cms.hhs.gov/manuals/> and disseminated via the Health Plan Management System (HPMS). However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

NOTE: The Medicare Prescription Drug Benefit Manual can be accessed at http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage or <http://www.cms.hhs.gov/manuals/>. All revisions to Pub. 100-18 will be issued via HPMS.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N	12/Entire Chapter/Employer/Union Sponsored Group Health Plans

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	One-Time Notification -Confidential
	Recurring Update Notification

*Unless otherwise specified, the effective date is the date of service.

Prescription Drug Benefit Manual

Chapter 12 – Employer/Union Sponsored Group Health Plans

Table of Contents *(Rev.6, 11-07-08)*

- 10 – Introduction
 - 10.1 – Application of CMS Employer Group Waiver Authority
 - 10.2 – Employer/Union Group Health Plan Sponsorship of Employer/Union-Only Group Waiver Plans (EGWPs)
 - 10.3 – Employer/Union Group Health Plan Sponsorship of Individual PDPs
 - 10.4 – Identification of Employer/Union Sponsored Group Health Plan Enrollees
 - 10.5 – Private Reinsurance Arrangements with Employer/Union Group Health Plan Sponsors
 - 10.6 – Employer/Union-Only Group Waiver Plans and COBRA
 - 10.7 – EGWP Application Procedures
- 20 – Approved Employer/Union Sponsored Group Health Plan Waivers
 - 20.1 – Enrollment in Employer/Union Sponsored PDPs
 - 20.1.1 – Enrollment Eligibility
 - 20.1.2 - Minimum Enrollment Requirements
 - 20.1.3 - Annual Open Enrollment Period
 - 20.1.4 - Group Enrollment/Disenrollment
 - 20.1.5 - Special Enrollment Periods (SEPs)
 - 20.1.6 - Transaction Reply Code (TRC) 127 Procedures When Transitioning Employer/Union Group Health Plans from the Retiree Drug Subsidy (RDS) to Employer/Union Sponsored Individual PDPs or EGWPs
 - 20.1.7 - Beneficiary Enrollment Notification Requirements
 - 20.1.8 - Permitting Employer/Union Sponsors to Enroll Beneficiaries in Both an “800 series” Local MA-Only Coordinated Care Plan and an “800 Series” Standalone PDP (Waiver Effective Beginning Contract Year 2009)
 - 20.2 - Service Areas
 - 20.2.1 - "800 Series" EGWP Service Areas (Elimination of the "Nexus Test" Beginning In Contract Year 2008)
 - 20.2.2 - Direct Contract EGWP Service Areas
 - 20.3 – Marketing and Dissemination
 - 20.3.1 - Prior Review and Approval of Marketing Materials and Enrollment Forms
 - 20.3.2 - Timing and Content of Employer/Union Sponsored Group Health Plan Dissemination Materials
 - 20.3.2.1 - Employer/Union Sponsored Group Plans Subject to Medicare Dissemination Requirements
 - 20.3.2.1.1 - Customizing Medicare Dissemination Materials and Enrollment Forms
 - 20.3.2.1.2 - Timing for Issuance of Employer/Union Sponsored Group Plan Medicare Dissemination Materials

20.3.2.2 - Plans with Employer/Union Sponsors Eligible for Waiver of Medicare Dissemination Requirements ("Alternative Dissemination Standards Waiver")

20.3.3 - Identification Card (ID) Card Requirements

20.3.4 - "Doing Business As" (DBA) Requirements

20.3.5 - Agent and Broker Licensure and Training Requirements

20.4 - Premium Requirements

20.5 - Premium Withhold

20.6 - Providing Information to CMS about Part D

20.7 - Requirement for Part D Sponsor to Provide Specific Information via an Internet Web site

20.8 - Access to Covered Part D Drugs

20.9 - Submission of Part D EGWP Bids and Requirements Concerning Providing EGWP Supplemental Coverage

20.10 - Part D EGWP Cost Sharing

20.11 - CMS EGWP Part D Payment

20.11.1 - Direct Subsidy

20.11.2 - Reinsurance Subsidies

20.11.3 - Low-Income Subsidies

20.11.4 - Risk Sharing Arrangements ("Risk Corridors")

20.12 - Low-Income Subsidies

20.12.1 - Premium Subsidy

20.12.2 - Cost-Sharing Subsidy

20.13 - Non-Calendar Year EGWPs

20.14 - Part D Formularies

20.14.1 - Formularies for Non-Calendar Year Plans

20.15 - Beneficiary Customer Service Call Center Requirement

20.16 - Waivers Only Applicable to Direct Contract EGWPs

20.16.1 - Governmental Entities

20.16.2 - State Licensure

20.16.3 - Financial Solvency

20.16.4 - Bonding and Insurance

20.16.5 - Management and Operations

20.16.6 - Reporting Requirements

Appendix I - "800 series" EGWP Service Area Waiver Applicable for Contract Years 2006 and 2007

Appendix II - Instructions for Providing Copies of Dissemination Materials to CMS for Contract Years 2006-2008

Appendix III - HPMS Technical Plan Bidding Instructions for Organizations Offering Part D Employer/Union-Only Group Waiver Plans in Contract Year 2009

Appendix IV - Instructions for MA Organizations and PDP Sponsors Requesting Additional Waiver/Modification of Requirements

10 - Introduction

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

10.1 - Application of CMS Employer Group Waiver Authority

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

CMS has statutory authority to waive or modify requirements that hinder the design of, the offering of, or the enrollment in, employer/union sponsored standalone prescription drug plans (PDPs). This statutory authority, set forth in [section 1860D-22\(b\)](#) of the Social Security Act (the “Act”), provides:

(b) Application of MA Waiver Authority. – The provisions of section 1857(i) 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, including authorizing the establishment of separate premium amounts for enrollees in a prescription drug plan by reason of such coverage and limitations on enrollment to part D eligible individuals enrolled in such coverage.¹

Under this specific statutory authority, in order to facilitate the offering of PDPs to employer/union group health plan sponsors, CMS may grant waivers and/or modifications to PDP sponsors. When exercising its discretion to grant these waivers or modifications, each waiver or modification will be conditioned upon the PDP sponsor meeting a set of defined circumstances and complying with a set of conditions. PDP sponsors offering employer group plans must comply with all Part D requirements unless those requirements have been specifically waived or modified.

Waivers/modifications may be granted to PDP sponsors offering “individual” PDPs or PDP sponsors offering customized employer group PDPs offered exclusively to employer/union group health plan sponsors. Individual PDPs are open to both individual Medicare beneficiaries and employer/union sponsored group health plans’ Part D eligible beneficiaries. Customized employer group PDPs offered exclusively to employer/union group health plan sponsors include: (1) plans offered by PDP sponsors to employers/unions (these plans are hereinafter referred to as “800 series” plans because their plan benefit packages are enumerated in the CMS Health Plan Management System (HPMS) with identifiers in the 800s to distinguish them from individual plans offered by PDP sponsors); and (2) plans offered by employers/unions that directly contract with CMS (hereinafter referred to as “Direct Contract” plans). These “800 series” and Direct Contract PDPs are referred to collectively as employer/union-only group waiver plans (“EGWPs”).

Note that CMS’ employer group waiver authority only applies to the Part D portion of the coverage provided by Cost Plans, not Parts A and B. Thus, Cost Plans may only use the Part

¹ [Section 1857\(i\)](#) of the Act, which applies to Medicare Advantage Organizations, provides as follows: To facilitate the offering of [Medicare Advantage] plans under contracts between [Medicare Advantage] organizations and employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity’s employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations, the Secretary may waive or modify requirements that hinder the design of, the offering of, or the enrollment in such [Medicare Advantage] plans.

D waiver authority to offer Part D EGWPs as an optional supplemental benefit. Therefore, Cost Plans with supplemental Part D benefits will only qualify for the employer/union group health plan waivers applicable to Part D. See Pub. 100-16, Medicare Managed Care Manual, [Chapter 17](#) (Cost Based Payment), Subchapter F (Benefits and Beneficiary Protections), Section 60.

10.2 - Employer/Union Group Health Plan Sponsorship of Employer/Union-Only Group Waiver Plans (EGWPs)

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

As stated above, all EGWPs must restrict enrollment to employer/union group health plan Part D eligible retirees and/or their Part D eligible spouses and dependents (hereinafter referred to as “Part D eligibles”). The final benefit packages of “800 series” EGWPs are typically developed through private contractual negotiations between the PDP sponsor and employer/union group health plan sponsors of employment-based retiree coverage.

CMS has issued specific guidance waiving or modifying a number of Part D requirements that apply to these two kinds of PDPs which are detailed below. However, Direct Contract and “800 series” EGWPs must comply with all Part D requirements unless those requirements have been specifically waived or modified.

10.3 - Employer/Union Group Health Plan Sponsorship of Individual PDPs

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

As stated above, in addition to EGWPs, employer/union group health plan sponsors may choose to enroll their Part D eligibles in individual PDPs. These PDPs do not qualify for all of the employer/union group health plan waivers outlined below in this chapter. Those waivers that apply to employer/union group sponsorship of individual PDPs will be specifically identified below (e.g., group enrollment/disenrollment process, special enrollment periods (SEPs), and the annual open enrollment period waiver).

10.4 - Identification of Employer/Union Sponsored Group Health Plan Enrollees

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

The EGHP (Employer Group Health Plan) Flag field must be set to “Y” when submitting enrollment transactions for any beneficiary who is a Part D eligible retiree of an employer/union sponsored group health plan (this includes Direct Contract and “800 series” enrollments and employer/union group health plan sponsored enrollments in individual PDPs). This flag should be set to “Y” for all enrollment transaction codes (including 60, 61, 71 and 72 transactions). This designation is especially important when employer/union group health plan Part D eligibles are enrolled in individual PDPs to differentiate them from individual beneficiaries. For more details, see [Medicare Advantage and Prescription Drug Plans - Plan Communications User Guide and Appendices](#).

10.5 - Private Reinsurance Arrangements with Employer/Union Group Health Plan Sponsors

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

PDP sponsors must meet Part D state licensure and financial solvency requirements under [42 CFR 423.401](#). With regard to these requirements, all PDP sponsors are permitted to obtain reinsurance or make other arrangements for the cost of coverage provided to any enrollee (including arrangements with employers/unions) to the extent that the PDP sponsor is at risk for providing the coverage. See [42 CFR 423.401\(b\)](#). Similarly, Part D requirements do not prohibit PDP sponsors offering “800 series” or individual PDPs to employer and union group health plan sponsors from entering into these kinds of reinsurance arrangements with self-insured (i.e., self-funded) employers/unions.² Notwithstanding these arrangements, the PDP sponsor retains the responsibility for meeting all Part D requirements.

10.6 - Employer/Union-Only Group Waiver Plans and COBRA

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

The Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) requires employer group health plans with at least 20 employees to offer continuation coverage to plan enrollees who experience a COBRA qualifying event such as termination of employment, death of the participant or a divorce. COBRA requirements apply to active employee plans and retiree plans. Employer/union sponsored group Medicare plans that meet the definition of “group health plan,” as that term is defined at section 5000(b)(1) of the Internal Revenue Code, may be subject to COBRA requirements.

The standard Part D benefits are not subject to COBRA continuation of coverage requirements. Employer/Union sponsors, however, may be required by COBRA to offer continuation of coverage for supplemental benefits that are financed outside of Medicare to beneficiaries in their plans that experience a COBRA qualifying event. For example, if an employer offered additional drugs that were integrated into a customized EGWP (Direct Contract or “800 series” plan) for the employer/union sponsored PDP but was solely paid for by employer premiums, the employer/union sponsor may be required to offer continuation of coverage only for the additional drugs when a beneficiary enrolled in the plan experiences a COBRA qualifying event.

However, there is nothing in either the Medicare law or the COBRA law that prohibits an employer/union sponsor from electing to provide continuation of coverage for the entire employer sponsored group plan (the Medicare benefits along with the non-Medicare supplemental benefits). In doing so, however, an employer/union sponsor must adhere to Medicare requirements. These include the following requirements:

(1) When a PDP sponsor offering an employer/union sponsored group plan receives notification that an individual is no longer eligible for the employer/union group sponsored

² Similarly, employer group plans may enter into administrative services only (ASO) arrangements with PDP sponsors whereby the entity provides certain administrative services to a self-funded employer group plan, such as claims adjudication and enrollment services.

plan because a COBRA qualifying event has occurred, it must follow the termination procedures documented in [Pub. 100-18, chapter 3](#), section 40.6, which only allows prospective termination. Terminations can be effective only at the end of a calendar month; and

(2) Although COBRA permits a group health plan to charge up to 102% of the applicable premium for continuation of coverage, an employer/union sponsor that offers COBRA coverage can charge no more than 100% of the premium for the Medicare portion of the benefits offered (Medicare will continue to pay its portion of the cost). If an employer/union sponsor can segregate the premium for the non-Medicare supplemental benefits offered, it can charge up to 102% of the portion of the premium that is attributable to the non-Medicare supplemental benefits.

Since employer/union sponsors in some instances have up to 44 days after a qualifying event to provide a notice to an enrollee of a right to elect continuation of coverage, and an enrollee has up to 60 days after receiving the notice to elect continuation of coverage, an enrollee may make the election to continue this coverage after the effective date of termination. Under COBRA law, an enrollee who elects continuation of coverage is entitled to have coverage reinstated retroactively back to the date of the termination of coverage. For employer/union sponsors that wish to reinstate beneficiaries who elect continuation of coverage back to the effective date of termination, PDP sponsors offering such plans should submit such reinstatements using Transaction Code 60 where possible and/or by submission to the CMS retroactive adjustment contractor when necessary.

10.7 - EGWP Application Procedures

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Entities that seek to offer a Part D EGWP must enter into a contract with CMS. An applicant must meet certain requirements before CMS can consider entering into a contract with the entity. In addition, an applicant must have an acceptable bid before it may enter into a contract to offer a Part D EGWP (for bidding instructions see section 20.9 below). Information on the application process can be found at http://www.cms.hhs.gov/EmpGrpWaivers/01_Overview.asp.

20 - Approved Employer/Union Sponsored Group Health Plan Waivers

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Set forth below is a list of waivers or modifications approved for PDP sponsors offering employer/union sponsored group health plans. As noted above, as a condition of CMS granting the particular waiver or modification, PDP sponsors must demonstrate that they meet the criteria established by CMS as outlined in the specific waiver. For each waiver, CMS has noted whether the waiver/modification applies to “800 Series” PDPs, Direct Contract PDPs, or employer/union sponsored group health plan enrollments in individual PDPs. Each of these waivers/modifications will automatically apply to those PDP sponsors approved to offer EGWPs or individual plans that satisfy the applicable criteria; thus, they do not need to be granted on an individual basis. However, some waivers may be restricted to particular kinds of entities and/or a particular set of circumstances as noted below.

In addition to the waivers that have been granted, PDP sponsors have the ability to request additional waivers or modifications of Part D requirements on a case-by-case basis. If a waiver or modification is granted, it will apply to all similarly situated entities. Details on how to request additional waivers or modifications can be found in Appendix IV.

20.1 - Enrollment in Employer/Union Sponsored PDPs *(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)*

20.1.1 - Enrollment Eligibility *(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)*

“Employment-Based” Group Health Plan Requirement

Employer/union group health plan enrollment in EGWPs and individual PDPs is only available to beneficiaries who are Part D eligibles of an employer/union sponsored group health plan. Thus, a beneficiary’s enrollment in one of these PDPs must be based on receiving “employment-based” retiree health coverage from an employer/union group health plan sponsor that has entered into a contractual arrangement with a PDP sponsor to provide coverage or that has contracted directly with CMS to provide coverage for its Part D eligibles.³ Membership in a State Pharmaceutical Assistance Program (SPAP) would not make an individual eligible for enrollment into these types of plans. Similarly, coverage obtained through a professional or other type of group association would not make a beneficiary eligible for these kinds of plans, except to the extent that the coverage obtained through the association can properly be characterized as “employment-based” group health plan coverage.

Retiree Status Requirement

In accordance with the waiver authority set forth in section [1860D-22\(b\)](#) of the Act, employer-sponsored enrollments in individual PDPs and EGWPs may only be offered to Part D eligible retirees (and Part D eligible spouses and dependents of these retirees). PDP sponsors may not enroll Part D eligible current (i.e., active) employees (or their Part D eligible spouses and dependents) in employer/union sponsored individual PDPs or EGWPs. (**NOTE:** Medicare Advantage Organizations are subject to a different statutory waiver authority under [section 1857\(i\) of the Act](#), which allows these entities to enroll both current (i.e., active) employees and retirees (and their spouses and dependents) of an employer/union group health plan sponsor in individual MA plans and “800 series” and Direct Contract MA plans, provided such individuals are eligible for Medicare Parts A and B. However, when enrolling active employees into these employer/union group sponsored MA plans, MA Organizations must comply with all applicable Medicare program requirements including the

³ “Employment-based retiree health coverage” means health insurance or other coverage of health care costs for Part D eligible individuals (or for such individuals and their spouses or dependents) under a group health plan based on their status as retired participants. The term “group health plan” includes such a plan as defined in section 607(1) of the Employee Retirement Income Security Act of 1974 and also includes federal and state governmental plans, collectively bargained plans, and church plans. See Section 1860D-22(c) of the Act. See also, 42 CFR 423.454 (“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 (as defined in §423.882) approved by CMS as a prescription drug plan.”)

Medicare Secondary Payer (MSP) requirements and must ensure that employers are not allowed to enroll actives in a Medicare plan offered by MA Organizations in a manner contrary to MSP rules (see [Pub. 100-16](#), chapter 9, section 20.1.1).

Restricted Enrollment Requirement

In general, PDP sponsors have to accept all Medicare-eligible beneficiaries who reside in their service area as set forth in [42 CFR 423.104\(b\)](#). EGWPs are not subject to this requirement. Instead, under the CMS eligibility rules for these kinds of plans, EGWPs must restrict enrollment solely to those Medicare eligible individuals who are also eligible for the employer/union sponsor's employment-based retiree health coverage. See [Section 1860D-22\(b\)](#) of the Act. Note that, aside from having Medicare eligibility, the employer/union sponsor's eligibility rules exclusively govern a beneficiary's enrollment entitlement in these plans. Under the employer/union sponsor's eligibility requirements, for example, Medicare eligible spouses and dependents of participants in the employer/union sponsor's plan may be permitted to enroll in these EGWPs based on the employer/union sponsor's eligibility rules regardless of whether or not the participant is Medicare eligible.

Employer/Union Group Health Plan Part D Eligibles Must Permanently Reside In The Service Area of the PDP As Defined By The PDP sponsor Within HPMS

In addition to the above eligibility requirements, the eligibility requirements set forth in [Pub. 100-18, chapter 3](#), section 10 apply to all employer/union group health plan sponsored individual PDP and EGWP enrollments in the same manner applicable to individual enrollments in individual PDPs. Therefore, in order for a beneficiary to be eligible to enroll in an employer-sponsored individual PDP or EGWP, he/she must permanently reside in the defined service area of the individual PDP or EGWP. See also [Pub. 100-18, chapter 3](#), section 40.2 (Required Involuntary Disenrollment).

PDP sponsors offering EGWPs are eligible for extended geographic service areas for these plans under waivers issued by CMS. See section 20.2 of this chapter. Therefore, PDP sponsors offering EGWPs should ensure that their EGWP defined service area includes all geographic areas in which employer/union sponsored group health plan Part D eligibles may reside (e.g., national service area) during the contract year. No mid-year service area expansions will be permitted.

20.1.2 - Minimum Enrollment Requirements

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

In general, PDPs must meet minimum enrollment standards as set forth in [42 CFR 423.512\(a\)](#). These minimum enrollment requirements do not apply to EGWPs.

20.1.3 - Annual Open Enrollment Periods

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

CMS has waived the requirement to comply with the Medicare annual coordinated election period described in [42 CFR 423.38\(b\)](#) for employer/union group health plans sponsored enrollments in EGWPs or individual PDPs. Thus, employer/union group sponsored

enrollments in EGWPs or individual PDPs may have different annual open enrollment periods. However, such plans must accept valid requests for disenrollment at any time.

20.1.4 - Group Enrollment/Disenrollment

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

All PDP sponsors may group enroll/disenroll employer/union sponsored group health plan Part D eligibles. This waiver applies to both EGWPs and individual PDPs offered to employer/union group health plan Part D eligibles. The group enrollment/disenrollment procedures are outlined in [Pub. 100-18, chapter 3](#), sections 30.1.6 and 40.6.1.

20.1.5 - Special Enrollment Periods (SEPs)

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Employer/union members enrolled in EGWPs and individual PDPs are eligible for special enrollment periods (SEPs). These SEPs apply to employer-sponsored enrollments in an individual PDP or an EGWP. The employer/union sponsor's eligibility rules would determine when the SEP may be used. These SEPs also apply to beneficiaries disenrolling from an employer-sponsored EGWP or individual PDP in order to enroll in an individual PDP not sponsored by an employer/union. These SEP procedures are outlined in [Pub. 100-18, chapter 3](#), section 20.3.8.

20.1.6 - Transaction Reply Code (TRC) 127 Procedures When Transitioning Employer/Union Group Health Plans from the Retiree Drug Subsidy (RDS) to Employer/Union Sponsored Individual PDPs or EGWPs

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

[Pub. 100-18, chapter 3](#), section 10.4 requires a PDP sponsor to follow certain procedures when the entity receives a Transaction Reply Code (TRC) 127 after submitting an electronic enrollment transaction to CMS. TRC 127 indicates that the beneficiary is being claimed for the Retiree Drug Subsidy (RDS) by a particular employer/union during the same period of time identified in the Part D enrollment request. An employer/union group health plan sponsor cannot claim the RDS for a beneficiary simultaneously enrolled in a PDP. In accordance with CMS instructions, before effectuating the enrollment request, a PDP that receives TRC 127 is required to contact the beneficiary to prevent inadvertent Part D enrollments and potential loss of employer/union coverage caused by the required notification to the employer/union of the beneficiary's enrollment in Part D.

Where the PDP sponsor is working directly with an employer/union group health plan sponsor to enroll its Part D eligibles into an individual PDP or EGWP and receives TRC 127 for these Part D eligibles, the notification procedures identified above are not needed to protect these beneficiaries from possible loss of that employer/union group health plan coverage. Accordingly, the PDP sponsor in this situation is not required to provide each beneficiary with the notification letter or other contact specified in CMS enrollment guidance. The PDP sponsor can immediately resubmit the enrollment with the proper employer subsidy override flag. PDP sponsors should maintain records to support the use of this alternate process for these Part D eligibles.

Note that, in some rare instances, the employer/union group health plan Part D eligible may have other drug coverage through another employer/union group health plan sponsor receiving the RDS (i.e., as a spouse or dependent of a retired participant). In these instances, the employer/union group health plan Part D eligible may potentially lose this other coverage upon enrollment in Part D. CMS strongly recommends that the PDP sponsor work closely with employer/union group health plan sponsors to communicate about this possibility, identify affected Part D eligibles (if possible) prior to enrollment into the PDP, and properly communicate with all Part D eligibles about their opt-out rights in accordance with the CMS group enrollment notification procedures.

20.1.7 - Beneficiary Enrollment Notification Requirements

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

In general, the notice requirements contained in Appendix 1 (Summary of Notice Requirements) of chapter 3 of this manual apply to all employer/union group health plan sponsored enrollments in individual PDPs or EGWPs, with the following clarifications:

- Each of the model beneficiary notices which are applicable to employer/union sponsored group health plans can be customized to the extent the modifications will more clearly and accurately reflect the employer group plan being offered by each individual employer/union group health plan sponsor (in accordance with the waivers/modifications set forth in section 20.3.2.1.1 of this chapter).
- The PDP sponsor retains the ultimate responsibility for the proper and timely dissemination of the notices. However, the PDP sponsor and the employer/union group health plan sponsor can enter into an agreement where the employer/union group health plan sponsor agrees to disseminate particular notices to its Part D eligibles on behalf of the PDP sponsor.

Note that certain notices contained in Appendix 1 are not applicable to employer/union group health plan sponsored enrollments in individual PDPs or EGWPs, as identified below:

- Exhibit 5a – Model Notice to Potential Auto-Enrollee with RDS
- Exhibit 13a – PDP Model Notice for Auto-Enrollments Provided by CMS with Recent Deceased Code
- Exhibit 24 – Confirmation of Auto-enrollment
- Exhibit 25 – Confirmation of Facilitated Enrollment
- Exhibit 27 – Auto and Facilitated Enrollees Who Permanently Reside in Another Region Where the PDP sponsor Offers Another PDP at or Below the Low-Income Premium Subsidy Amount for that Region
- Exhibit 28 – Auto and Facilitated Enrollees Who Permanently Reside in Another Region Where the PDP sponsor Does Not Offer Another PDP at or Below the Low-Income Premium Subsidy Amount for that Region
- Exhibit 29 – Reassignment Confirmation

- Exhibit 30 – Optional Notice for “Losing Plan” to LIS Beneficiaries Re-Assigned to a Different PDP sponsor (in lieu of ANOC)

20.1.8 – Permitting Employer/Union Sponsors to Enroll Beneficiaries in Both an “800 series” Local MA-Only Coordinated Care Plan and an “800 Series” Standalone PDP (Waiver Effective Beginning Contract Year 2009) *(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)*

Subject to certain exceptions, a Part D eligible person who is enrolled in a Medicare Advantage (MA) plan may not be simultaneously enrolled in a stand-alone PDP. See [Section 1860D-1\(a\)\(1\)\(B\)\(ii\)](#) of the Act, and [42 CFR 423.30\(b\)](#). Beginning in 2009, CMS has granted a modification of a previously issued 2007 waiver policy which will permit all employer/union sponsors to enroll beneficiaries in both an EGWP (i.e., “800 series”) local coordinated care MA-Only plan and an “800 series” standalone PDP.

Beginning with the 2007 contract year, CMS granted a limited waiver for certain public employers to simultaneously enroll their Part D eligibles in an “800 series” local coordinated care MA-Only plan and an “800 series” standalone PDP under certain limited circumstances (see [Pub. 100-16](#), chapter 9, section 20.1.10). In order to be eligible for the waiver, the public employer was required to have a longstanding, pre-existing partnership with separate vendors. Also, the vendors were required to have been working closely with the employer to provide coordinated care and disease management services between the medical and prescription drug portions of the benefit similar to the kind of coordination that would be offered if the employer purchased the medical coverage and drug coverage from a single MA-PD vendor.

Beginning with the 2009 contract year, all employer/union group health plan sponsors will be allowed to enroll their Part D eligibles in both an “800 series” local coordinated care MA-Only plan (i.e., HMO, HMO/POS, Local PPO) and an “800 series” standalone PDP. Like the previous waiver, as a condition of this expanded waiver, CMS will require the separate medical and prescription drug vendors to work closely together with the employer/union sponsor to provide coordinated care and disease management services between the MA and PD portions of the benefit. This coordination is similar to the kind that would be offered if the employer/union purchased the medical coverage and the drug coverage from a single local MA-PD vendor.

20.2 - Service Areas

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

20.2.1 - “800 series” EGWP Service Areas (Elimination of the “Nexus Test” Beginning in Contract Year 2008)

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

For contract years 2006 and 2007, CMS employer group waiver policy required PDP sponsors to offer plans to individual Medicare beneficiaries as a condition of being able to offer “800 series” plans associated with the same contract. Also, if the PDP offered individual coverage in the PDP region where the most substantial portion of an employer’s employees reside, PDP sponsors were permitted to extend their “800 series” plan service area and enroll an

employer/union sponsor's retirees that resided outside of the individual plan service area. (This service area extension policy is commonly known as the "nexus test").

Beginning with the 2008 contract year, PDP sponsors offering prescription drug plans are not required to offer these plans to individual beneficiaries as a condition of offering associated "800 series" plans. This change includes the elimination of the "nexus test." The changes described above will apply to entities renewing "800 series" plan benefit packages in 2008, as well as to entities offering "800 series" plans for the first time in 2008.

Notwithstanding these changes, entities offering these plans will continue to have to meet all CMS requirements that are not otherwise waived or modified, including the requirement to be licensed as a risk bearing entity eligible to offer health insurance or health benefits. For entities that choose to only offer "800 series" plans for a particular PDP sponsor contract, this requirement will be met if the entity is licensed in at least one state.

For more details on the service area waiver policies (including the "nexus test" policy) that applied to EGWPs in contract years 2006 and 2007, see Appendix I below.

20.2.2 - Direct Contract EGWP Service Areas

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

In general, PDP sponsors can only cover beneficiaries in the service areas in which they operate. However under CMS waiver authority, for employers/unions which directly contract with CMS to sponsor their own PDP, coverage can extend to all of their Part D eligibles, regardless of whether they reside in one or more other PDP regions in the nation. However, in order to meet the enrollment eligibility requirements described in [Pub. 100-18, chapter 3](#), section 10, which includes the requirement that the beneficiary must permanently reside in the EGWP-specific service area, all Direct Contract PDPs should ensure their defined service area includes all geographic areas in which their plan Part D eligibles may reside (e.g., national service area).

20.3 - Marketing and Dissemination

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

20.3.1 - Prior Review and Approval of Marketing Materials and Enrollment Forms

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Direct Contract and "800 series" Plans

CMS has waived the prior review and approval requirements for marketing materials and enrollment forms contained in [42 CFR 423.2262](#), [423.2264](#), [423.2266](#), and [423.2268](#) for all EGWPs. These include all "800 series" plans as well as Direct Contract plans. This waiver applies to all marketing materials, including the marketing materials requirements contained in the Medicare Marketing Guidelines.

Note that as a result of this waiver, Direct Contract plans and PDP sponsors offering “800 series” EGWPs or employer-sponsored individual PDPs are not subject to the annual restriction against communicating to Medicare eligible beneficiaries before October 1st. Rather, CMS strongly encourages employer/union sponsors and entities offering these plans to employers/unions to begin the communication process early with these beneficiaries and to continue to communicate about their benefits as frequently as possible prior to their particular annual open enrollment period (which may differ from Medicare’s annual coordinated election period). More specifically, employers/unions and/or entities that offer employer-sponsored “800 series” or individual plans to employers/unions should be prepared to direct beneficiaries to available resources and should explain their coverage and how it works with Medicare.

Employer/Union Group Plan Sponsored Individual PDPs

Note that the waiver of prior review and approval requirements for marketing materials and enrollment forms contained in 42 CFR [423.2262](#), [423.2264](#), [423.2266](#), and [423.2268](#) will also apply to a PDP sponsor that elects to use the waiver outlined in section 20.3.2.1.1 below which allows PDP sponsors to customize dissemination materials. More specifically, the waiver will apply to those PDP sponsors that elect to customize dissemination materials for a particular employer/union group health plan sponsor that offers coverage to its Part D eligibles using an individual PDP (e.g., individual PDP paired with a non-Medicare supplemental drug coverage designed to “wrap around” or enhance the individual PDP).

20.3.2 - Timing and Content of Employer/Union Sponsored Group Health Plan Dissemination Materials

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

20.3.2.1 - Employer/Union Sponsored Group Plans Subject to Medicare Dissemination Requirements

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

In general, dissemination materials for employer/union sponsored enrollees in Direct Contract plans, “800 series” plans or individual PDPs are subject to all applicable Medicare dissemination regulatory requirements ([42 CFR 423.128](#)) and sub-regulatory guidance (including any requirements related to the timing and content of these materials) unless waived or modified as outlined below. This also includes all of the dissemination requirements contained in the Medicare Marketing Guidelines unless those requirements have been explicitly waived or modified.

20.3.2.1.1 - Customizing Medicare Dissemination Materials and Enrollment Forms

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

In order to meet the requirements of [42 CFR 423.128\(a\)\(2\)](#), which require a Part D sponsor to disclose information about the plan in a clear, accurate and standardized form, PDP sponsors should provide customized dissemination materials to “800 series” and Direct Contract PDP enrollees to reflect the modified/supplemental benefits being provided to that particular

employer/union group health plan enrollees, if any. More specifically, CMS has waived any rules that would otherwise prohibit these entities from offering customized dissemination materials to the extent those customized materials will more clearly and accurately describe the benefits available to employer/union group Part D eligibles (for example, when the supplemental coverage is taken into account). Note that this waiver also allows customization of dissemination materials for employer-sponsored enrollments in individual PDPs (e.g., where an employer/union group health plan sponsors coverage to its retirees using an individual PDP and a non-Medicare supplemental plan designed to “wrap around” or enhance the individual PDP or where the employer/union sponsor is subsidizing or paying premium amounts for its Part D eligibles enrolled in an individual PDP).

With regard to premium amounts (including premium amounts for low-income premium subsidy eligible individuals) that are required to be accurately reflected on any customized beneficiary dissemination materials (e.g., Evidence of Coverage, LIS Rider), PDP sponsors should ensure these materials accurately reflect the actual premium amount the beneficiary pays when the supplemental coverage, if any, and any corresponding employer/union premium subsidization (or subsidization by CMS in the case of low-income premium subsidy eligible beneficiaries) is taken into account. Alternatively, if accurate premium information concerning the amount the beneficiary actually pays is not available to the PDP sponsor, the PDP sponsor may substitute language in lieu of providing actual premium amounts (e.g., “For information concerning the actual premiums you will pay, please contact [insert employer/union group health plan sponsor name] or your employer group benefits plan administrator.”)

As provided in section 20.3.1 above, all customized employer/union group health plan materials are not required to be submitted for review and approval by CMS prior to use. Customized materials must not be submitted through HPMS.

Also, beginning with contract year 2009, PDP sponsors are no longer required to submit informational copies of these dissemination materials to CMS at the time of use (for details on the previous waiver policies in effect for contract years 2006 through 2008 requiring informational copies of employer/union group health plan dissemination materials to be submitted to CMS, see Appendix II). However, as a condition of CMS providing these particular waivers or modifications, CMS reserves the right to request and review these materials in the event of beneficiary complaints or for any other reason it determines to ensure the information accurately and adequately informs Medicare beneficiaries about their rights and obligations under the plan.

PDP sponsors also will be required to retain these dissemination materials and provide access to these written materials to CMS (or its designees) in accordance with [42 CFR 423.504\(d\)](#) and [423.505\(d\)](#) and (e). If the materials for multiple employer/union sponsors are identical except for employer group sponsor identifier information, CMS will not require a PDP sponsor to retain materials for each employer group (i.e., retention of one “template” version of dissemination materials used for particular employer groups is permissible).

20.3.2.1.2 - Timing for Issuance of Employer/Union Sponsored Group Plan Medicare Dissemination Materials

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Employer sponsored “800 series” plans, Direct Contract plans or individual PDPs that are subject to Medicare marketing and dissemination requirements are also subject to any applicable timing requirements for issuance of these materials. However, CMS has waived or modified applicable timing requirements in certain circumstances. These include those circumstances where a particular employer/union sponsor has an open enrollment period that differs from Medicare’s Annual Coordinated Election Period (ACEP). In this situation, the timing for issuance of any dissemination materials that are based on the ACEP should be based instead on the employer/union sponsor’s open enrollment period. For example, for contract year 2008, in accordance with applicable timing requirements for these materials, if an employer/union sponsor’s open enrollment period began on December 1, 2007, the ANOC and Summary of Benefits (SB), LIS Rider and Formulary must have been received by beneficiaries no later than November 16, 2007 (15 days before the beginning of the employer/union group health plan’s open enrollment period). Beginning in 2009, a combined Annual Notice of Change/Evidence of Coverage (ANOC/EOC), LIS rider, and Formulary are required to be received by beneficiaries no later than 15 days before the beginning of the ACEP. Therefore, for contract year 2009, if an employer/union sponsor’s open enrollment period begins on December 1, 2008, these documents must be received by beneficiaries no later than November 16, 2008 (15 days before the beginning of the employer/union group health plan’s open enrollment period). The timing for other dissemination materials that may be based on the start of the Medicare plan (i.e., calendar) year should be appropriately based on the employer/union sponsor’s plan year. If the employer/union sponsor does not have an open enrollment period, then dissemination materials that are based on the ACEP must be received by beneficiaries no later than 15 days before the beginning of the plan year.

20.3.2.2 - Plans with Employer/Union Sponsors Eligible for Waiver of Medicare Dissemination Requirements (“Alternative Dissemination Standards Waiver”)

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

CMS has waived the specific dissemination requirements of [42 CFR 423.128](#) for employer/union group health plan beneficiaries when the employer/union sponsor is subject to alternative dissemination requirements (e.g., those required by the Employee Retirement Income Security Act of 1974 (“ERISA”)), and the employer/union sponsor complies with such alternative requirements. However, these alternative dissemination materials (including summary plan descriptions and all other beneficiary communications that provide descriptions of the Medicare benefit offerings) must be provided by the Direct Contract PDP or the PDP sponsor offering the “800 series” plan or employer-sponsored individual PDP to beneficiaries on a timely basis.

Similarly, for an employer/union sponsor plan eligible for the alternative dissemination standards waiver referenced above in section 20.3.2.1.2, a PDP sponsor that offers “800 series” plans to these employer/union sponsors must retain copies of these alternative dissemination materials or, alternatively, the information that would be necessary to satisfy its reporting and disclosure obligations under [42 CFR 423.514\(d\)](#). 42 CFR 423.514(d) provides that entities must furnish, upon request, the information that any employees’ health benefits plan needs to fulfill its reporting and disclosure obligations under ERISA.

However, as a condition of CMS providing these particular waivers or modifications, CMS reserves the right to request and review these materials in the event of beneficiary complaints or for any other reason it determines to ensure the information accurately and adequately informs Medicare beneficiaries about their rights and obligations under the plan. PDP sponsors also will be required to retain these dissemination materials and provide access to these written materials to CMS (or its designees) in accordance with [42 CFR 423.504\(d\)](#) and [423.505\(d\)](#) and (e).

20.3.3 - Identification Card (ID) Card Requirements

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Direct Contract PDPs and PDP sponsors that offer “800 series” plans may provide enrollees with one combination member Identification (ID) card which incorporates the medical, Part D, and employer sponsored non-Medicare supplemental medical and/or drug benefits. However, entities must comply with all other CMS ID card requirements, including the requirements contained in the Medicare Marketing Guidelines. Note that this same waiver applies when a PDP sponsor elects to use the waiver outlined in section 20.3.2.1.1 above to customize dissemination materials for a particular employer/union sponsor that offers coverage to its retirees using an individual Medicare plan paired with a non-Medicare supplemental plan designed to “wrap around” or enhance the individual Medicare plan.

Note that it is also permissible to include the name and/or logo of the employer/union sponsor on the ID card. This activity is not considered “co-branding”.

20.3.4 - “Doing Business As” (DBA) Requirements

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

PDPs that offer “800 series” plans may use different names for “doing business as” purposes. However, for HPMS purposes only, these entities will be restricted to entering one “doing business as” name.

20.3.5 - Agent and Broker Licensure and Training Requirements

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

All agents and brokers (employed and contracted) selling “800 series” plans to employer/union group plan sponsors on behalf of a PDP sponsor must be licensed to sell these products as required by state law. However, representatives of a PDP sponsor or those representatives of employer/union group plan sponsors or others acting on their behalf (e.g., their employees, benefit consultants, third party administrators) who conduct educational, enrollment or informational events for retirees of employer/union sponsors are not required to

be licensed for these purposes as these activities would not constitute marketing or sales activities.

To ensure that employer/union group sponsors are receiving accurate and reliable information to make informed decisions on behalf of its retirees, it is critical that health plan representatives such as agents and brokers (employed and contracted) performing these marketing and sales activities are knowledgeable about the products they are selling, including “800 series” plans. CMS expects that PDP sponsors will ensure that brokers and agents are knowledgeable about the products they are selling by requiring they are trained on Medicare rules and regulations, as well as on plan details specific to the plan products being sold. However, the broker/agent testing requirements at 42 CFR 423.2274(c) do not apply under these circumstances.

Note that beginning with the 2007 contract year, the marketing and dissemination guidance contained in this chapter (section 20.3) supersedes the EGWP Marketing and Disclosure/Dissemination guidance located in Pub. 100-18, Chapter 2, section 13 (released on July 25, 2006).

20.4 - Premium Requirements

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Waiver of Uniform Premium Requirement

The uniform premium requirement (see [42 CFR §423.286\(a\)](#)) has been waived for entities offering “800 series” plans under certain circumstances. Under this waiver of the uniform premium requirement, entities offering “800 series” plans serving multiple regions or the nation will be allowed to vary premium and cost sharing between defined market areas within the same employer/union sponsored group plan. This waiver is contingent on the requirement that the market areas (geographic areas) within the employer sponsored group plan with premium variation are based on objective market information demonstrating verifiable differences in drug costs between these market areas. The PDP sponsor must have documentation validating the drug cost variation in these market areas comprising the plan. PDP sponsors will be required to retain all of these documents and must provide access to this documentation for inspection or audit by CMS (or its designee) in accordance with the requirements of [42 CFR 423.504\(d\)](#) and [423.505\(d\)](#) and (e).

Premium Subsidization by Employer/Union Group Health Plan Sponsors

Under its waiver authority, CMS will allow the employer/union sponsoring the PDP flexibility in determining how much of a plan enrollee’s Part D monthly beneficiary premium it will subsidize, subject to the conditions set forth below.

First, an employer/union sponsor can subsidize different amounts for different classes of enrollees in a plan provided such classes are reasonable and based on objective business criteria, such as years of service, date of retirement, business location, job category, and nature of compensation (e.g., salaried vs. hourly). Different classes cannot be based on eligibility for the Part D Low-Income Subsidy. Second, the premium cannot vary for individuals within a given class of enrollees. Third, with regard to the Part D premium, an

employer/union cannot charge an enrollee for prescription drug coverage provided under the PDP more than the sum of his or her monthly beneficiary premium attributable to basic prescription drug coverage and 100% of the monthly beneficiary premium attributable to his or her non-Medicare Part D benefits (if any). The employer/union must pass through any direct subsidy payments received from CMS to reduce the amount that the beneficiary pays (or in those instances where the subscriber to or participant in the employer/union-only plan pays premiums on behalf of a Medicare eligible spouse or dependent, the amount the subscriber or participant pays).

As a condition of CMS providing these particular waivers, PDP sponsors that offer “800 series” PDPs to employers/unions will be required to obtain in writing from such employers/unions their agreement that they will satisfy the requirements of this waiver with respect to the premiums charged to their participants. Also, PDP sponsors will be required to retain these agreements with employers/unions and provide access to these written agreements to CMS (or its designees) in accordance with [42 CFR 423.504](#)(d) and [423.505](#)(d) and (e).

Charging Different Premiums to Different Employer/Union Group Health Plan Sponsors

In addition to the flexibilities outlined above for employers/unions to subsidize different amounts of an enrollee’s premium contribution, “800 series” PDPs have the flexibility to negotiate with and vary the premium charged to particular employer/union group health plan sponsors. This includes the ability to “experience rate” “800 series” employer/union group health plan sponsors in determining these premiums.

20.5 - Premium Withhold

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

PDP sponsors must permit their enrollees, at their option, to pay their premium through deductions from their Social Security checks, Railroad Retirement checks, or Federal annuity. When employers/unions also contribute to the beneficiary’s premium, in whole or in part, it is not feasible for both PDP sponsors and CMS to factor in the employer/union sponsor’s contribution and adjust the amount of the premium that should be deducted from the beneficiary’s Social Security or other check.

Because of these operational obstacles, as a condition of sponsoring an EGWP, CMS has waived the requirement that PDP sponsors offering “800 series” and Direct Contract EGWPs must provide beneficiaries the option to pay their premium through withholding. Thus, the premium withhold option will not be available for enrollees in EGWPs. PDP sponsors offering these plans will be required to bill the beneficiary and/or the employer/union directly. This waiver is not applicable to employer-sponsored enrollments in individual PDPs (employer-sponsored group beneficiaries enrolled in these PDPs will have the option to pay premiums through withholding).

20.6 - Providing Information to CMS about Part D

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

CMS has waived the requirements contained in [42 CFR 423.48](#) for all EGWPs. These regulatory provisions require plans to report certain information annually to CMS to enable it

to provide current and potential beneficiaries the information they need to make informed decisions concerning their available choices for Part D coverage. This would include information to be included in the CMS “Medicare and You” publications and on the CMS Web site (e.g., “Medicare Prescription Drug Plan Finder”). Since these kinds of employer-sponsored PDPs are not available for general enrollment, these requirements do not apply and are therefore waived.

20.7 - Requirement for Part D Sponsor to Provide Specific Information via an Internet Web site

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

To the extent a PDP sponsor has a Web site or provides information through the Internet, [42 CFR 423.128\(d\)\(2\)](#) requires them to provide certain Part D information on an Internet Web site (e.g., current formulary, notice regarding the removal or change in the preferred or tiered cost sharing status of a Part D drug on its formulary, etc.).

CMS has waived the requirements of 42 CFR 423.128(d)(2) for all “800 series” plans. PDP sponsors will not be required to provide any information concerning these EGWPs on the PDP sponsor’s Internet Web site. Since these kinds of employer-sponsored PDPs are not available for general enrollment, these requirements do not apply and are therefore waived.

20.8 - Access to Covered Part D Drugs

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

PDPs cannot limit coverage to only mail order prescription drugs and must meet specific standards in 42 CFR 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 employer/union group health plan coverage as compared to other PDPs. For example, an employer/union arrangement may have only a small number of Part D eligibles concentrated in a local area within a large region. Employers/unions also have an interest in ensuring their Part D eligibles have adequate pharmacy access.

To facilitate the offering of such plans and maximize flexibility, CMS has waived the specific Part D retail pharmacy access standards contained in 423.120(a)(1) for “800 series” and Direct Contract EGWPs as long as the PDP sponsor attests that its networks are and will continue to be sufficient to meet the needs of its Part D eligibles, including situations involving emergency access. 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 in order to ensure that the plan’s network is sufficient to meet the needs of its enrollee population.

Note that other than the waiver of the retail pharmacy access requirements described above, no other waivers or modifications of the Part D pharmacy access requirements have been granted for EGWPs. Thus, all PDP sponsors offering EGWPs must adhere to all other CMS pharmacy access requirements (e.g., the requirements for long term care, home infusion, and I/T/U pharmacy access). See 42 CFR 423.120(a) and [chapter 5](#), section 50, of this manual.

20.9 - Submission of Part D EGWP Bids and Requirements Concerning Providing EGWP Supplemental Coverage

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Note that beginning with the 2008 contract year, PDP sponsors are no longer required to submit Part D EGWP bids. PDP sponsors are still required to take certain actions with the PBP software. See Appendix III for detailed bidding instructions for Part D EGWPs. For the 2006 and 2007 contract years, PDP sponsors submitted Part D bids for “800 series” and Direct Contract EGWPs in a manner similar to the flexible method offered to Medicare Advantage Organizations offering “800 series” plans in the past. Under this approach, CMS required PDP sponsors to submit bids for EGWPs only for the standardized Part D coverage. Entities were not required to submit separate bids for each employer/union benefit design variation.

For “800 series” EGWPs, any supplemental (i.e., additional non-Medicare Part D) prescription drug coverage is provided separately pursuant to a private agreement between the PDP sponsor and the employer/union sponsor. However, any EGWP supplemental coverage offered cannot reduce the value of the basic standardized Part D benefit design. For example, supplemental coverage cannot impose a cap that would preclude employer group health plan Part D eligibles from realizing the full value of coverage under the standard Part D benefit. To assure that the actuarial equivalence of the standard Part D benefit design is maintained, CMS requires all PDP sponsors offering EGWPs to ensure that the total employer/union sponsored plan (including adjusting for any supplemental coverage) provides at least the standard Part D coverage, including a deductible no higher than that of defined standard Part D (for 2008 - \$275), and catastrophic coverage after the true out-of-pocket limit (for 2008 - \$4,050) is met.

Beginning in 2006, no employer/union Part D EGWP bids were included in the calculation of the Part D national average monthly bid amount or in the low-income regional benchmark premium amounts.

20.10 - Part D EGWP Cost Sharing

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

In general, a PDP offered to individual Medicare beneficiaries can offer actuarially equivalent standard, basic alternative or enhanced alternative prescription drug coverage (i.e., coverage that differs from defined standard prescription drug coverage) if certain actuarial equivalence standards are met. For example, [42 CFR 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) (\$2,510 in 2008) that is equal to or greater than what a PDP offering defined standard prescription drug coverage would pay between such limit and the deductible at section 42 CFR 423.104(d)(1) (\$275 in 2008). (Throughout that range, defined standard prescription drug coverage covers on average 75 percent of the costs and beneficiaries pay on average 25 percent.) See [Pub. 100-18, chapter 5](#), sections 20.3.2, 20.4.1 and 20.4.2, for more information.

Employer/union group health plan coverage 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 deductible

and the initial coverage limit range, these designs may provide somewhat less coverage than defined standard prescription drug coverage under Part D. Therefore, to provide beneficiaries with more choices and enable employer/union group health plans to continue offering Part D eligibles their familiar coverage, CMS has waived the 42 CFR 423.104(e)(5) prong of the actuarial equivalence test for EGWPs offered exclusively to employer/union group health plan Part D eligibles. Absent this waiver, this provision requires defined standard coverage for costs incurred between the deductible and initial coverage limit.

However, this guidance is not intended to waive other actuarial equivalence standards in 42 CFR 423.104(e), including (but not limited to) the requirement in 42 CFR 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 42 CFR 423.104(e)(2) regarding catastrophic reinsurance coverage. Thus, for example, an EGWP 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.

20.11 - CMS EGWP Part D Payment

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

20.11.1 - Direct Subsidy

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

The Part D risk adjusted direct subsidy payment for all EGWPs will be based on the national average monthly bid amount and the national base beneficiary premium (not on bids amounts as for plans offered to individual Medicare beneficiaries).

20.11.2 - Reinsurance Subsidies

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

In addition, CMS will modify the way catastrophic reinsurance is paid for all EGWPs. CMS will not make a prospective payment for reinsurance, and instead will include all EGWPs in the normal Part D reinsurance reconciliation at year end. Since no prospective payments will have been made during the year, the year-end process will result in the full reinsurance payment being paid to the plan. Since most employers/unions will be providing enhanced drug coverage through supplemental arrangements (which raises the threshold for catastrophic coverage), the reinsurance payments to these PDP sponsors are expected to be small as a result of the application of the True Out of Pocket Costs (TrOOP) rule. See [chapter 5](#), section 30 (Incurred / “True Out-of-Pocket” (TrOOP) Costs), of this manual.

20.11.3 - Low-Income Subsidies

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Information concerning low-income subsidy requirements as they relate to EGWPs is set forth in section 20.12.

20.11.4 - Risk Sharing Arrangements (“Risk Corridors”)

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Risk corridor payments assist PDP sponsors entering a new market without any experience in mitigating any losses or gains by sharing these losses or gains with Medicare. Risk corridor payments are not available for EGWPs.

The following table summarizes the differences in payment between EGWPs and plans offered to individual Medicare beneficiaries.

	<u>Part D EGWP Payments</u>			
<u>Plan Types</u>	Direct Subsidy	Low-Income Premium Subsidy and Cost Sharing Amounts	Reinsurance	Risk-Sharing
	42 CFR 423.329(a)(1)	42 CFR 423.780 42 CFR 423.329(c)	42 CFR 423.329(c)	42 CFR 423.336
Part D Calendar Year Plans	The national average monthly bid amount is multiplied by the individual's risk score. This amount is then reduced by the rounded base beneficiary premium (\$27.90 for 2008)	Payment methodology is the same as for plans offered to individual Medicare beneficiaries, except that the rounded base beneficiary premium (\$27.90 for 2008), will be used in the low-income premium subsidy regional benchmark comparison. Note that beginning in 2008, because of the elimination of the requirement to submit Part D EGWP bids, Low-Income Cost Sharing (LICS) amounts will be paid retrospectively at year-end reconciliation (rather than prospectively as in 2006 and 2007). See section 20.12.2 below.	Reinsurance is paid retrospectively at year-end reconciliation (rather than being paid prospectively).	Not Available
Part D Non-Calendar Year Plans	Same as above (payments are on calendar year basis; plan may be administered on non-calendar year basis)	Same as above	No reinsurance payments.	Not Available

20.12 - Low-Income Subsidies

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

For each beneficiary entitled to the low-income subsidy (LIS), CMS pays the beneficiary's premium (up to the plan's low-income premium subsidy amount) and cost sharing obligations minus the beneficiary's cost-sharing responsibilities under the LIS rules. However, for EGWPs there are a number of important additional requirements that must be adhered to concerning both the low-income premium subsidy and the low-income cost-sharing subsidy as set forth below.

20.12.1 - Premium Subsidy

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Low-Income Premium Subsidy Pass Through Requirements

PDP sponsors offering EGWPs are required to comply with the same low-income premium subsidy amount requirements that apply to PDP sponsors offering plans to individual Medicare beneficiaries. See [42 CFR 423.800\(b\)](#). Thus, EGWP Part D sponsors are responsible for identifying employer/union group health plan LIS Part D eligibles and passing through the low-income premium subsidy amount payments made by CMS on behalf of these Part D eligibles to reduce their premium contributions.

Premiums charged (to the beneficiary and/or the employer/union) for a particular “800 series” PDP plan benefit package can vary between different employer/union group health plan sponsors and also among a particular employer group health plan’s Part D eligibles based on legitimate criteria such as years of service. See section 20.4 of this chapter. CMS does not take into account these variations in premiums because CMS does not receive information on these variations during the annual Part D bidding process. Even though premium amounts may vary among and between employer/union group health plan enrollees as described above, the LIS premium subsidy amounts paid by CMS to all EGWPs for all enrollees of a particular “800 series” or Direct Contract plan benefit package do not vary.

As a condition of receiving the waivers and modifications described above, CMS requires that all PDP sponsors offering EGWPs ensure that any low-income premium subsidy amount paid on behalf of an LIS beneficiary accrues first to the benefit of the LIS-eligible employer/union group health plan Part D eligible. Specifically, the low-income premium subsidy must first be used to reduce any portion of the monthly beneficiary premium paid by the Part D eligible (or in those instances where the subscriber to or participant in the employer/union plan pays premiums on behalf of a low-income eligible spouse or dependent, the amount the subscriber or participant pays), with any remaining portion of the premium subsidy amount then applied toward the portion of any monthly premium paid for by the employer/union. However, if the sum of the enrollee’s monthly premium (or the subscriber’s/participant’s monthly premium, if applicable) and the employer/union sponsor’s monthly premiums (i.e., total monthly premium) is less than the monthly low-income premium subsidy amount, any portion of the low-income premium subsidy amount above the total monthly premium must be returned directly to CMS.

Similarly, if there is no monthly premium charged to the beneficiary (or subscriber/participant, if applicable) or employer/union, the entire low-income premium subsidy amount must be returned directly to CMS and cannot be retained by the PDP sponsor, the employer/union, or the employer/union group Part D eligible (or the subscriber/participant, if applicable). If low-income premium subsidy amounts need to be returned to CMS for any employer/union group sponsor enrollees that meet the above criteria,

PDP sponsors are required to immediately contact their CMS account manager for instructions on how to return these amounts.

As stated in section 10.5, PDP sponsors may enter into reinsurance or administrative services arrangements with self-insured (i.e., self-funded) employers/unions. Therefore, instead of paying an insurance premium to the PDP sponsor, the employer/union group typically pays an administrative fee to the PDP sponsor. In these kinds of arrangements, in order to properly administer the low-income premium subsidy requirements outlined above, the PDP sponsor must develop an “illustrative premium.” The “illustrative premium” is equal to the premium the employer/union group plan sponsor would have paid if they had purchased an equivalent product offered by the PDP sponsor. The same rules outlined above would be applied using the illustrative premium in the place of actual premium. The PDP sponsor will be required to develop and apply an “illustrative premium” for each self-insured or self-funded employer/union group plan sponsor.

Note that if the low-income premium subsidy amount for which an enrollee is eligible is less than the portion of the monthly beneficiary premium paid by the Part D eligible (or subscriber/participant, if applicable), then the employer/union should communicate to the Part D eligible (or subscriber/participant) the financial consequences of the low-income subsidy eligible individual enrolling in the employer/union sponsored group health plan as compared to enrolling in another PDP with a monthly beneficiary premium equal to or below the low-income premium subsidy amount.

Ability to Refund Low-Income Premium Subsidy Amounts

In accordance with [42 CFR 423.800](#), where the PDP sponsor offering the EGWP directly bills the employer/union sponsor’s Part D eligibles for their premium contributions, the Part D sponsor is required to reduce up-front the premiums charged to reflect the low-income premium subsidy payments paid to the PDP sponsor by CMS on behalf of these individuals.

If, however, the PDP sponsor does not or cannot directly bill an employer/union group health plan’s Part D eligibles, CMS will waive this up-front reduction requirement and permit the PDP sponsor to directly refund the amount of the low-income premium subsidy to the LIS beneficiary. This refund must meet the above requirements concerning beneficiary premium contributions; specifically, that the amount of the refund not exceed the amount of the monthly premium contribution by the Part D eligible (or subscriber/participant, if applicable) and/or the employer/union sponsor. In addition, the PDP sponsor must refund these amounts to the beneficiary within a reasonable time period. However, under no circumstances may this time period exceed 45 days from the date that the PDP sponsor receives from CMS the low-income premium subsidy amount payment for the low-income subsidy eligible enrollee.

Alternatively, the PDP sponsor and the employer/union may agree that the employer/union will be responsible for reducing up-front the premium contribution required for its Part D eligibles that are eligible for the Low-Income Subsidy. In those instances where the employer/union is not able to reduce up-front the premiums paid by the enrollee (or subscriber/participant, if applicable), the PDP sponsor and the employer/union may agree that the employer/union shall directly refund to the Part D eligible (or subscriber/participant, if applicable) the amount of the low-income premium subsidy up to the monthly premium

contribution previously collected from the Part D eligible (or subscriber/participant, if applicable). The employer/union is required to complete the refund on behalf of the PDP sponsor within 45 days of the date the PDP sponsor receives from CMS the low-income premium subsidy amount payment for the low-income subsidy eligible enrollee.

Note that in some cases the LIS beneficiary may not be the subscriber to or participant in an employer/union sponsored group health plan, but the spouse or dependent of the subscriber/participant. In these instances, where the PDP sponsor or employer/union refunds low-income premium subsidy amounts to LIS enrollees, it may refund such amounts directly to the employer/union group health plan subscriber/participant on behalf of a spouse or dependent who is an LIS-eligible beneficiary.

Requirement to Retain and Provide Documents

As a condition of receiving the waivers and modifications described above and to support the PDP sponsor's compliance with the low-income pass-through requirements, CMS requires that all PDP sponsors offering EGWPs retain documents and/or working papers that support their adherence to these requirements. These include documents evidencing that low-income premium subsidy amounts were properly passed through or refunded by either the PDP sponsor or the employer/union group plan sponsor and documents or working papers evidencing the calculation of "illustrative premium" for each self-insured/self-funded employer/union group plan sponsor. Also, PDP sponsors will be required to retain all of these documents and must provide access to this documentation for inspection or audit by CMS (or its designee) in accordance with the requirements of [42 CFR 423.504\(d\)](#) and [423.505\(d\)](#) and (e).

Requirement to Obtain and Provide Written Agreements With Employer/Union Group Plan Sponsors

As a condition of receiving the waivers and modifications described above, CMS also requires that all PDP sponsors offering EGWPs enter into written agreements with employers/unions which require the employer/union to comply with the above requirements and to retain and provide documents upon request to the PDP sponsor evidencing the employer/union group plan sponsor's adherence to such requirements. This includes the requirement that any low-income premium subsidy amount paid to the employer/union sponsor on behalf an LIS beneficiary is first used to reduce any portion of the monthly PDP premium paid for by the Part D eligible (or subscriber/participant, if applicable). Also, if the employer/union assumes responsibility for either reducing up-front LIS beneficiaries' monthly premiums or refunding to LIS beneficiaries their monthly premium contributions, the PDP sponsor shall ensure that its written agreement with the employer/union also reflects the employer/union sponsor's assumption of these duties consistent with the above requirements (including a provision requiring that any refunds to an LIS beneficiary be completed within 45 days of the date the PDP sponsor receives the low-income premium subsidy amount payment for that beneficiary from CMS). PDP sponsors will be required to retain all of these written agreements with employers/unions and must provide access to these written agreements for inspection or audit by CMS (or its designee) in accordance with [42 CFR 423.504\(d\)](#) and [423.505\(d\)](#) and (e).

CMS Payment of LIS Premium Amounts to All EGWPs

Beginning in 2007, HPMS included a new table that provides all Part D sponsors with the monthly payments they are receiving to subsidize their low-income enrollees' premiums. These same payment amounts are reflected in the electronically generated reports received by all PDP sponsors on a regular basis from CMS. HPMS will continue to have a separate table providing the low-income premiums that beneficiaries pay in the plans. However, HPMS will no longer display the low-income premiums for EGWP enrollees in this table. These amounts will be reflected as "N/A" for all EGWPs because, as stated above, the premiums for beneficiaries enrolled in these plans can vary, and CMS does not collect this information.

Note that beginning in 2007, the following rounding rules were used in determining EGWP LIS premium payment amounts: the base beneficiary premium (\$27.35) was rounded to the nearest \$.10 (\$27.40) and was used as the Direct Contract or "800 series" plan premium. See [42 CFR 423.780\(b\)\(1\)](#). The rounded base beneficiary premium was compared to the unrounded low-income benchmark premium amount for the PDP region. If the low-income benchmark premium amount was less than the rounded base beneficiary premium, the low-income benchmark premium amount was rounded to the nearest \$.10 to derive the low-income premium subsidy amount.

20.12.2 - Cost-Sharing Subsidy

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Benefits provided to EGWP enrollees cannot vary based on the Part D eligible's LIS eligibility. In addition, for an LIS Part D eligible enrollee in an EGWP, CMS will subsidize only those cost-sharing obligations actually imposed on the Part D eligible under the plan, which includes any supplemental prescription drug coverage offered by the employer/union group health plan sponsor, with the supplemental coverage primary to the LIS program.

For example, an "800 series" PDP that provides benefits exclusively to employer X's Part D eligibles has a \$100 deductible. For expenses incurred by a full subsidy eligible individual, CMS' payments to the plan will be determined based on that \$100 deductible (minus any minimal co-pays an individual is responsible for under [42 CFR 423.782\(a\)](#)). CMS payments will not be based on the plan having a \$265 deductible (as reflected in Part D defined standard prescription drug coverage).

As noted above, beginning with the 2008 contract year, PDP sponsors are no longer required to submit Part D EGWP bids. As a result, beginning in 2008, CMS will not pay interim prospective LIS cost sharing amounts to EGWPs because these amounts are directly derived from Part D bids. Instead, as a condition of the waiver of the requirements to submit a Part D bid, CMS will make LICS payments during the normal year-end reconciliation process.

20.13 - Non-Calendar Year EGWPs

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Many employers, particularly public employers, determine benefits and enroll individuals in plan years that differ from the calendar year. Many of these plan years are mandated by state laws, federal law or union contracts.

CMS has granted a waiver to permit PDP sponsors offering EGWPs to establish non-calendar year plan benefit packages in HPMS in order to allow employer groups to determine benefits (including deductibles, out-of-pocket limits, etc.) on a non-calendar year basis. However, for these non-calendar year plan benefit packages, most submissions to CMS, along with CMS payments, will be determined on a calendar year basis in a process similar to the process historically used for “800 series” MA plans.

Non-calendar year EGWPs will be subject to the following rules:

- All required submissions to CMS, including applications and formularies for such plans, must be submitted at the same time as calendar-year EGWPs.
- With regard to Part D coverage, the plan must be actuarially equivalent to defined standard coverage for the portion of its plan year that falls in a given calendar year. A plan will meet this standard if it is actuarially equivalent for the calendar year in which the plan year starts and no design change is made for the remainder of the plan year. In no event can a plan increase during the plan year the out-of-pocket limit at which catastrophic coverage begins.
- Medicare direct subsidy payments will be based on the national average monthly bid amount for the calendar year for which the direct subsidy is being paid.
- Part D LIS payments and reconciliations will be determined based on the calendar year for which the payments are made.
- Prescription Drug Event (PDE) data will be reported to CMS on a plan year (i.e., non-calendar year) basis. Reconciliation, however, will be done on a calendar year basis.
- Certain benefits parameters (e.g., premium, cost sharing amounts) may be administered on a non-calendar plan year basis; however, other items such as formulary, deductible, gross covered drug spend and TrOOP may be administered on a calendar year basis.
- Like all other EGWPs, CMS will allow Part D eligibles of an employer/union sponsored group PDP that operates on a non-calendar year basis to disenroll from such plan and enroll in another plan through a special enrollment period (SEP) (see section 20.1.5).

Reinsurance and Risk Sharing Payments Not Available

With regard to Part D coverage, catastrophic reinsurance payments and risk corridor payments will not be made available to non-calendar year EGWPs (risk corridor payments are also not paid to calendar year EGWPs). However, the waiver of catastrophic reinsurance payments does not change the requirement for such plans to provide catastrophic coverage comparable to the standard benefit, though eligibility for such catastrophic coverage under the plan can be determined on a plan year basis.

Administration of Non-Calendar Year Plans

With regard to TrOOP and gross covered drug cost balance transfer requirements under the current TrOOP balance transfer process, two TrOOP and gross covered drug cost accumulations are necessary for Part D EGWPs. Plans must report TrOOP and gross covered drug cost balance transfers to a new plan of record as a calendar year accumulation when a beneficiary switches plans mid-year. However, plans will also be required to track TrOOP and gross covered drug costs on a non-calendar plan year basis in order to properly administer the non-calendar year benefit. If a beneficiary joins a non-calendar year plan during the middle of the plan year, any TrOOP and gross covered drug cost accumulation for costs incurred under a different plan between the beginning of the non-calendar plan year and the effective date of enrollment in the plan and within the same calendar year must carry over with the beneficiary. (Refer to the discussion of non-calendar year plans and sample scenarios in the guidance on automated TrOOP balance transfer dated October 20, 2008.) Explanation of Benefit (EOB) beneficiary dissemination materials must reflect the benefit design and TrOOP and gross covered drug cost accumulation coinciding with the non-calendar plan benefit year. Note that once the new Financial Reporting Transaction process is implemented, non-calendar year EGWPs will no longer need to track TrOOP and gross covered drug cost accumulations on a separate, calendar year track since this new method of TrOOP balance transfer will involve tracking these amounts on a month-by-month basis

Note that if an employer/union group sponsor's year starts mid-calendar year and ends on December 31st, renewing on January 1 of the subsequent year, the EGWP is **not** considered a non-calendar year plan. Also, PDP sponsors are not allowed to extend an employer/union only group health plan year longer than 12 months. The PDP sponsor must offer the EGWP for a portion of the contract year which ends on December 31st and renews on January 1st of the subsequent year.

20.14 - Part D Formularies

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

PDP sponsors will not be required to submit to CMS every formulary variation offered to Part D eligibles enrolled in EGWPs. Rather, PDP sponsors are permitted to submit a base formulary for use with its employer/union sponsored group health plans. After submission and approval of a base formulary, PDP sponsors may enhance the formulary (add new drugs or make positive changes to cost sharing) without having to resubmit the formulary for review and approval by CMS. These formularies may not be modified to remove any drugs from the list, or to add any restrictions or limitations unless these modifications or removals are otherwise consistent with CMS requirements.

20.14.1 - Formularies for Non-Calendar Year Plans

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

CMS allows PDP sponsors to offer prescription drug benefits on a calendar year and on a non-calendar year basis (if PDP sponsors are approved to offer non-calendar year Part D EGWP plan benefit packages). Negative formulary change requests for non-calendar year Part D EGWPs are required to follow the same review and approval process as calendar year plans. Thus, the time frame for non-calendar year Part D EGWPs to make negative changes is the same as calendar year plans.

Non-calendar year Part D EGWPs may elect to convert to the conditionally approved formulary for the next calendar year on January 1st. PDP sponsors offering non-calendar year EGWPs that choose this option must provide appropriate beneficiary notice as specified in 423.120(b)(5). Alternatively, PDP sponsors offering non-calendar year Part D EGWPs whose plan start date occurs after conditional approval of the formulary for the following calendar year (CY) may elect to use that formulary for the entire non-calendar plan year. Any further changes for the rest of the non-calendar year would have to be consistent with the process for updating CY 2008 formularies and requesting negative formulary changes as described in the HPMS memorandum, Updating CY 2008 Formularies, November 28, 2007.

The following example illustrates the above-stated policy. A non-calendar year Part D EGWP with a start date of October 1, 2008, could either:

- Use its CY 2008 conditionally approved formulary throughout the employer/union sponsor's plan year (October 1, 2008 –September 30, 2009) and make no negative changes;
- Use its CY 2008 conditionally approved formulary from October 1, 2008 – December 31, 2008 and its CY 2009 conditionally approved formulary from January 1, 2009 – September 30, 2009) and request negative changes through July 31, 2009, in accordance with the above-stated policy; or
- Use its CY 2009 conditionally approved formulary throughout the employer/union sponsor's plan year (October 1, 2008 – September 30, 2009) and request negative changes through July 31, 2009, in accordance with the above-stated policy.

20.15 - Beneficiary Customer Service Call Center Requirements

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

CMS has granted a waiver of the Part D beneficiary customer service call center hour requirements for all Direct Contract and “800 series” EGWPs offered by PDP sponsors. See Addendum 2 - Customer Service Call Center Requirements of the Medicare Marketing Guidelines (as revised 7/25/06). These entities will be allowed to operate beneficiary customer service call center hours for their employer/union group health plan only enrollees that differ from the Part D requirements for plans offered to individual beneficiaries. These entities must ensure that a sufficient mechanism is available to respond to beneficiary inquiries and must provide customer service call center services to these Part D eligibles during normal business hours. However, CMS may review the adequacy of these call center hours and potentially require expanded beneficiary customer service call center hours in the event of beneficiary complaints or for other reasons in order to ensure that the entity's customer service call center hours are sufficient to meet the needs of its enrollee population. Also, CMS has granted a waiver of the Part D call center performance requirements for all Direct Contract and “800 series” EGWPs.

20.16 - Waivers Only Applicable to Direct Contract EGWPs

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

20.16.1 - Governmental Entities

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

In general, in accordance with section [1860D-41\(a\)\(13\)](#) of the Act, governmental entities are not permitted to be PDP sponsors. However, CMS waived this prohibition for governmental entities, such as for state retirement funds and municipal or local government plans, applying to sponsor a Direct Contract EGWP for their retirees.

20.16.2 - State Licensure

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

In general, a Part D sponsor must be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers coverage ([42 CFR 423.401\(a\)\(1\)](#) and [42 CFR 423.504 \(b\)\(2\)](#)). However, an employer/union Direct Contract EGWP applying to become a PDP solely for purposes of providing prescription drug coverage to its retirees will not have to meet the state licensing requirements set forth in 42 CFR 423.401(a)(1) and 42 CFR 423.504(b)(2) as a condition of being a Medicare prescription drug plan sponsor. CMS waived the licensure requirement for employer/union Direct Contract EGWPs that provide coverage to their own retirees. However, as a condition of this waiver, CMS requires that these entities meet certain financial solvency standards (see section 20.16.3).

20.16.3 - Financial Solvency

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

The financial solvency requirements for employer/union Direct Contract EGWPs are set forth in Appendix I of the 2009 Solicitation for Applications for New Employer/Union Direct Contract Prescription Drug Plans (PDP) Sponsors, dated January 24, 2008. CMS requires that the entity demonstrate 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/union sponsor's contracts and sub-contracts contain beneficiary hold harmless provisions as described in Appendix I and in other CMS guidance. The employer/union may request waivers/modifications of the requirements in Appendix I by completing Appendix III ("HPMS Technical Plan Bidding Instructions for Organizations Offering Part D Employer/Union-Only Group Waiver Plans in Contract Year 2009). CMS may, at its discretion, approve requests for such waivers/modifications on a case-by-case basis.

20.16.4 - Bonding and Insurance

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

An employer/union Direct Contract EGWP must meet the bonding and insurance standards described in [42 CFR 423.504\(b\)\(4\)\(iv\)-\(v\)](#). However, CMS may, on a case-by-case basis, provide flexibility to an employer/union directly contracting with CMS as a Part D sponsor by waiving these requirements upon a demonstration that different federal or state legal standards (such as ERISA bonding requirements) are satisfied.

20.16.5 - Management and Operations

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

In general, an entity seeking to contract with CMS as a Part D sponsor must have administrative and management arrangements that demonstrate the following pursuant to [42 CFR 423.504 \(b\)\(4\)\(i\)-\(iii\)](#): policy-making bodies exercising oversight and control to ensure that management 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.

An employer/union Direct Contract EGWP may be subject to other potentially different standards governing its management and operations, such as fiduciary requirements under the Employee Retirement Income Security Act of 1974 (“ERISA”), state law standards, and certain oversight standards created under the Sarbanes-Oxley Act. To reflect these issues and avoid imposing additional (and potentially conflicting) government oversight that may hinder employers/unions from considering Part D direct contracts with CMS, the requirements of 42 CFR 423.504(b)(4)(i)-(iii), as noted above, are waived if the employer/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 set forth in [42 CFR 423.505\(d\)](#).

20.16.6 - Reporting Requirements

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

In general, PDP 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/union sponsored group health plans, CMS will modify these reporting requirements for Direct Contract EGWPs to allow information be reported to enrollees and to the general public to the extent required by other law (including ERISA or securities laws), or by contract.

Appendix I

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

“800 series” EGWP Service Area Waiver Applicable for Contract Years 2006 and 2007 (superseded by subsequent Contract Year employer group waivers):

“800 series” EGWP Service Areas (The “Nexus Test”)

A PDP sponsor is permitted to offer an EGWP to employers/unions in a given PDP region of the country if the sponsor - either itself or through subcontractors or other partners - provides PDP coverage to Part D eligible individuals in that region. Through its waiver authority, however, CMS will permit PDP sponsors of EGWPs to expand coverage to an employer/union sponsor’s Part D eligibles residing in other regions through contracts and other arrangements provided that the most substantial portion of the employer/union sponsor’s employees live in a region where the PDP is offering plans to individual Medicare beneficiaries. This requirement is known as the “nexus test”.

Example 1: An employer has 600,000 employees, of whom 400,000 live in California and 200,000 live in Florida. A PDP sponsor that serves the non-group market in California (or that contracts or partners with an entity serving the non-group market in California) can offer a PDP sponsored by the employer that not only serves the employer’s California retirees, but also those retirees in Florida or any other state in the nation.

Example 2: An employer has 100,000 employees, of whom 45,000 live in New York, with the remainder spread out in smaller numbers among 20 other states. A PDP sponsor that serves the non-group market in New York (or that contracts or partners with an entity serving the non-group market in New York) can offer a PDP sponsored by the employer that not only serves the employer’s New York retirees, but also the retirees residing in the other 20 states where they reside.

A PDP sponsor that does not meet the most substantial portion test described above for a given employer/union may provide retiree-only PDP coverage for the retirees in any region where the PDP provides PDP coverage to individuals.

The foregoing service area rules are summarized in this table:

Region (Service Area) for Individual Medicare Beneficiary Coverage	Largest Region (Service Area) for Employer/Union Retiree Group Coverage
No coverage offered to individual Medicare beneficiaries.	Employer/union sponsored PDP coverage prohibited. However, other MMA options are available for nationwide coverage, including the 28% retiree drug subsidy for qualifying retiree prescription drug plans. (Entities can offer prescription drug coverage that qualifies for

	the 28% subsidy without being a PDP sponsor).
Region where most substantial portion of employees (or for union funds, participants) reside.	Nationwide
Region other than where most substantial portion of employees (or for union funds, participants) reside.	Limited to that same region where it provides coverage to individual Medicare beneficiaries.

Appendix II

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Instructions for Providing Copies of Dissemination Materials to CMS for Contract Years 2006-2008

What Materials to Send

For contract years 2006, 2007 and 2008, all Direct Contract PDPs and PDPs that offer “800 series” plans must provide copies of all dissemination materials to the CMS Central Office at the time of use. If the materials for multiple employer/union sponsors are identical except for sponsor identifier information, CMS will not require duplicate submissions of such materials (i.e., submission of one “template” version is permissible). Note that these same requirements to provide copies of customized dissemination materials at the time of use will apply to PDP sponsors that elect to utilize the waiver outlined in section 20.3.2.1.1 above on behalf of employers/unions that sponsor an individual PDP (e.g., use an individual Medicare plan paired with a non-Medicare supplemental plan designed to “wrap around” or enhance the individual Medicare plan to provide coverage to retirees).

For an employer/union sponsor plan eligible for the alternative dissemination standards waiver referenced above in section 20.3.2.2, a PDP Sponsor that offers “800 series” plans to these employer/union sponsors may provide copies to CMS of the alternative dissemination materials or, alternatively, the information that would be necessary to satisfy its reporting and disclosure obligations under [42 CFR 423.514\(d\)](#). 42 CFR 423.514(d) provides that entities must furnish, upon request, the information that any employees’ health benefits plan needs to fulfill its reporting and disclosure obligations under ERISA. All information intended to satisfy 423.514(d) must be provided to CMS prior to November 1st.

How to Send the Materials

All marketing and dissemination materials must be sent to CMS via e-mail (in Microsoft Word or PDF format) to the following e-mail address: EGWPdisclosure@cms.hhs.gov. If the materials are subject to Medicare standards, include in the subject line of the e-mail “Medicare Dissemination Materials for Contract #xxxxxx”. If the materials are subject to alternative dissemination standards in accordance with the waiver outlined in section 20.3.2.2 above, include in the subject line of the e-mail “Alternative Dissemination Materials for Contract #xxxxxx”. For all materials, also provide in the body of the e-mail the type of document being submitted (e.g., Summary Plan Description, Information Required to Satisfy 42 CFR 423.514(d), etc.) and contact information (a contact name, phone number and e-mail address) if there are questions concerning the materials.

Materials must not be submitted through HPMS for any Direct Contract or “800 series” plan. Employer group plan sponsored materials also must not be submitted through HPMS when a PDP sponsor elects to use the waiver outlined in section 20.3.2.1.1 above to customize dissemination materials for a particular employer/union sponsor that offers coverage to its retirees using an individual Medicare plan paired with a non-Medicare supplemental plan designed to “wrap around” or enhance the individual Medicare plan.

Appendix III

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

HPMS Technical Plan Bidding Instructions for Organizations Offering Part D Employer/Union-Only Group Waiver Plans in Contract Year 2009

Starting in contract year (CY) 2008, Part D entities that offer employer/union-only group waiver plans (EGWPs) were no longer required to complete Part D Bid Pricing Tool (BPT) submissions. See 2008 Employer Group Waiver Policy – Elimination of the Requirement for Entities Offering EGWPs to Submit Part D Bids, February 28, 2007. This waiver policy has been extended to CY 2009. As noted in the memo, this waiver policy applies to all MA, PDP, and 1876 Cost organizations offering Part D EGWPs (i.e., “800 series” EGWPs) as well as to employers/unions that directly contract with CMS to offer Part D benefits to their retirees (i.e., “Direct Contract” EGWPs).

NOTE: CMS’ employer group waiver authority applies only to Part D, not to Parts A or B of the Cost Plan. Thus, section 1876 Cost Plan sponsors may only offer “800 series” Part D coverage as an optional supplemental benefit and may not offer customized “800 series” A/B benefits.

CMS has also modified the corresponding Plan Benefit Package (PBP) submission requirement for all EGWPs offering Part D.

The following table outlines the HPMS PBP and BPT submission requirements for each type of Part D EGWP for the 2009 contract year:

	A	B
PBP Section/BPT	MA-PD “800 series” EGWP and Direct Contract MA-PD EGWP	PDP and 1876 Cost “800 series” EGWP and Direct Contract PDP EGWP
PBP Section A	Yes	Yes
PBP Sections B, C, and D	Yes	No
PBP Rx Section	No	No
MA BPT	Yes	No
PD BPT	No	No

Plans that fall under column A will download and install the 2009 PBP software, create their 2009 plans, and download their plan-specific data into the software, per the usual process. Column A plans will complete sections A, B, C, and D of the 2009 PBP software, but the Rx Section of the PBP will be disabled. Column A plans will also complete the MA BPT.

Plans that fall under column B will download and install the 2009 PBP software, create their 2009 plans, and download their plan-specific data into the software, per the usual process. While no actual data entry is required in Section A of the PBP for PDP plan types, plans are still required to open Section A, review the plan information, and exit Section A with validation.

All plans outlined in column A and B are required to upload their plans into HPMS, per the usual process. In addition, these plans are still required to meet all applicable pre-upload submission requirements to upload plans into HPMS.

NOTE: Plans that fall under column B are required to complete the upload process as a mechanism for establishing their official set of plan IDs for the 2009 contract year in HPMS.

Appendix IV

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Instructions for MA Organizations and PDP Sponsors Requesting Additional Waiver/Modification of Requirements.

MA organizations and PDP sponsors may submit individual waiver/modification requests at any time to CMS. The Applicant should submit these additional waiver/modification requests to their Account Manager.

These requests must be identified as requests for additional waivers/modifications and must fully address the following items:

- Specific provisions of existing statutory, regulatory, and/or CMS policy requirement(s) the entity is requesting to be waived/modified (identify the specific requirement (e.g., “42 CFR 422.66,” or “Pub. 100-16, Medicare Managed Care Manual chapter 2, section 40.4, ”) and whether you are requesting a waiver or a modification of these requirements);
- How the particular requirements hinder the design of, the offering of, or the enrollment in, the employer-sponsored group plan;
- Detailed description of the waiver/modification requested including how the waiver/modification will remedy the impediment (i.e., hindrance) to the design of, the offering of, or the enrollment in, the employer-sponsored group plan;
- Other details specific to the particular waiver/modification that would assist CMS in the evaluation of the request; and
- Contact information (contract number, name, position, phone, fax and email address) of the person who is available to answer inquiries about the waiver/modification request.