

MEDICARE PRESCRIPTION DRUG BENEFIT

2009 Application Instructions for PDP Sponsors to Offer New Employer/Union-Only Group Waiver Plans (EGWPs)

January __, 2008

PUBLIC REPORTING BURDEN: According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0936. The time required to complete this information collection is estimated to average 4 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, C4-26-05, Baltimore, Maryland 21244-1850.

BACKGROUND:

The Medicare Modernization Act (MMA) provides employers and unions with a number of options for providing coverage to their Medicare-eligible members. Under the MMA, those options include purchasing benefits from sponsors of prescription drug-only plans (PDPs), making special arrangements with Medicare Advantage Organizations (MAOs) and Section 1876 Cost Plans to purchase customized benefits, including drug benefits, for their members; and directly contracting with CMS to become Part D or MAO plan sponsors themselves. Each of these approaches involves the use of CMS waivers authorized under Sections 1857(i) or 1860D-22(b) of the Social Security Act (SSA). Under this authority, CMS may waive or modify requirements that “hinder the design of, the offering of, or the enrollment in” employer-sponsored group plans. CMS may exercise its waiver authority for PDPs, MAOs and Cost Plan Sponsors that offer employer/union-only group waiver plans (EGWPs). EGWPs are also known as “800 series” plans because of the way they are enumerated in CMS systems.

Which Applicants Should Complete This Application?

This application is to be used by new PDP Sponsors or existing PDP Sponsors (i.e., those with an existing contract) who are seeking to offer new “800 series” plans in 2009. All applications are required to be submitted electronically in the Health Plan Management System (HPMS). Please follow the application instructions below and submit the required material in support of your application to offer new “800 series” EGWPs.

Elimination of the Requirement to Offer Individual Plans (i.e., the “Nexus Test”)

For Contract Years 2006 and 2007, CMS employer group waiver policy required all PDP Sponsors to offer plans to individual Medicare beneficiaries as a condition of being able to offer “800 series” EGWPs to employers and unions. Beginning in 2008, this requirement was eliminated for all PDP Sponsors. Pursuant to CMS employer group waiver policy, PDP Sponsors will be permitted to offer “800 series” plans to employer and union group beneficiaries without being required to offer plans to individual Medicare beneficiaries. All new PDP Sponsors that are applying to only offer “800 series” plans (i.e., no plans will be offered to individual Medicare beneficiaries under the applicant’s contract number) will be required to designate their application as one which only offers “800 series” plans when completing the application.

APPLICATION INSTRUCTIONS:

This application must be submitted electronically through HPMS by March __, 2008, by the following entities applying to offer new “800 series” EGWPs:

- New PDP Sponsor Applicants seeking to offer new “800 series” EGWPs – with or without corresponding individual plans. New PDP Sponsors include Applicants that have not previously applied to offer plans to individual beneficiaries or “800 series” EGWPs.

Note: All new PDP Sponsor Applicants must complete the *2009 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors* in addition to this application. The *2009 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors* is also required to be submitted electronically through HPMS. These requirements are also applicable to any new PDP Sponsor Applicants that do not intend to offer individual plans in 2009. Together these two documents will comprise a completed application for new PDP Sponsors. Failure to complete the *2009 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors* will result in a denial of the EGWP application.

- Existing PDP Sponsors that currently offer plans to individual beneficiaries under an existing contract but that have not previously applied to offer “800 series” EGWPs under this same contract.

Note: Existing PDP Sponsors are only required to complete this application.

Using HPMS to Submit an Application

In order to submit an application, please log on to HPMS and follow the instructions. To complete the application, please access the following link in HPMS:

Contract Management > Contract Management > Select Contract Number > Online Applications/EGWP Attestation

Separate Applications Required For Each Contract Number

A separate application must be submitted for *each contract number* under which the PDP Sponsor is applying to offer new “800 series” EGWPs.

PDP EGWP SERVICE AREA AND PHARMACY ACCESS REQUIREMENTS:

EGWP Service Areas:

New PDP Sponsor Applicants and existing PDP Sponsors will be able to enter their EGWP service areas directly into HPMS during the application process.

PDP Sponsor Applicants may provide coverage to employer group members wherever they reside (i.e., nationwide). However, in order to provide coverage to retirees wherever they reside, PDP Sponsor Applicants must set their service areas to include all areas where retirees may reside during the plan year (i.e., set national service areas). **No mid-year service area expansions will be permitted.**

New PDP Sponsors Offering Individual and “800 Series” Plans – Pharmacy Access:

PDP Sponsors offering both individual and “800 series” plans are not required to submit separate GeoNetworks® retail pharmacy reports (Appendix X - Retail Pharmacy Network Access Instructions) or other pharmacy access submittals (mail order, home infusion, long-term care, I/T/U) for their “800 series” service areas in addition to those required to be submitted for their individual plan service areas. PDP Sponsors will not initially be required to have retail and other pharmacy networks in place for those designated EGWP service areas outside of their individual plan service areas. However, in accordance with employer group waiver pharmacy access policy, pharmacy access sufficient to meet the needs of enrollees must be in place once the PDP Sponsor enrolls members of an employer or union group residing in particular geographic locations outside of its individual plan service area.

New PDP Sponsors Only Offering “800 Series” Plans – Pharmacy Access:

PDP Sponsors that intend to only offer “800 series” plans (i.e., no plans will be offered to individual Medicare beneficiaries under this contract number) will be required to submit retail and other pharmacy access information (mail order, home infusion, long-term care, I/T/U) for the entire defined EGWP service area during the application process and demonstrate sufficient access in these areas in accordance with employer group waiver pharmacy access policy.

**REQUEST FOR ADDITIONAL WAIVER/MODIFICATION OF
REQUIREMENTS (OPTIONAL):**

As a part of the application process, Applicants may submit individual waiver/modification requests to CMS. The Applicant should submit these additional waiver/modifications via hard copy to:

Centers for Medicare & Medicaid Services (CMS)
Mail Stop: C1-22-06
Attn: 2009 Additional Waiver Request (Contract #: SXXXX)
7500 Security Blvd.
Baltimore, MD 21244-1850

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 (please identify the specific requirement (e.g., 42 CFR 423.32, Section 30.4 of the Part D Enrollment Manual) 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 prescription drug 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.

ASSISTANCE:

If you have any questions about this application, please contact:

Julian Nadolny by email at Julian.Nadolny@cms.hhs.gov or by phone at 410-786-2274.

Usree Bandyopadhyay by email at Usree.Bandyopadhyay@cms.hhs.gov or by phone at 410-786-6650.

DESIGNATION OF APPLICATION AS “800 SERIES” EGWP ONLY (NO INDIVIDUAL PLANS WILL BE OFFERED)

Checking the box below is optional. Only check the box below if you are applying to only offer “800 series” plans under this contract (no plans to individual beneficiaries will be offered). Do not check the box below if you intend to offer plans to individual beneficiaries and “800 series” plans under this contract number.

☐ I am hereby designating this application as one which will only offer “800 series” plans. No plans will be offered to individual Medicare beneficiaries under this contract number.

{Entity MUST complete if it is applying to only offer “800 series” EGWPs (no plans will be offered to individual Medicare beneficiaries under this contract number).}

EGWP Attestation for Contract _____

1. EGWP SERVICE AREA & PHARMACY ACCESS REQUIREMENTS

PDP Sponsor Applicants may provide coverage to employer group members wherever they reside (i.e., nationwide). However, in order to provide coverage to retirees wherever they reside, PDP Sponsor Applicants must set their service areas to include all areas where retirees may reside during the plan year (i.e., set national service areas). **No mid-year service area expansions will be permitted.**

New PDP Sponsors Offering Individual and “800 Series” Plans – Pharmacy Access:

PDP Sponsors offering both individual and “800 series” plans are not required to submit separate GeoNetworks® retail pharmacy reports (Appendix X - Retail Pharmacy Network Access Instructions) or other pharmacy access submittals (mail order, home infusion, long-term care, I/T/U) for their “800 series” service areas in addition to those required to be submitted for their individual plan service areas. PDP Sponsors will not initially be required to have retail and other pharmacy networks in place for those designated EGWP service areas outside of their individual plan service areas. However, in accordance with employer group waiver pharmacy access policy, pharmacy access sufficient to meet the needs of enrollees must be in place once the PDP Sponsor enrolls members of an employer or union group residing in particular geographic locations outside of its individual plan service area.

New PDP Sponsors Only Offering “800 Series” Plans – Pharmacy Access:

PDP Sponsors only offering “800 series” plans (i.e., no plans will be offered to individual Medicare beneficiaries under this contract number) will be required to submit retail and other pharmacy access information (mail order, home infusion, long-term care, I/T/U) for the entire defined EGWP service area during the application process and demonstrate sufficient access in these areas in accordance with employer group waiver pharmacy access policy.

☐ I certify that I am an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for qualification to offer employer/union-only group waiver plans in association with my organization’s Prescription Drug Plan Contract with CMS. I have read, understand, and agree to comply with the above statement about service areas and pharmacy access. If I need further information, I will contact one of the individuals listed in the instructions for this application.

{Entity MUST complete for a complete application.}

2. CERTIFICATION

For new PDP Sponsors, this application, along with the *2009 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*, comprises the entire “800 series” EGWP application for PDP Sponsor. All provisions of the *2009 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors* apply to all employer/union-only group waiver plan benefit packages offered by PDP Sponsor except where the provisions are specifically modified and/or superseded by particular employer/union-only group waiver guidance, including those waivers/modifications set forth below (specific sections of the *2009 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsor* that have been waived or modified for new PDP Sponsor Applicants are noted in parentheses).

For existing PDP Sponsors, this application comprises the entire “800 series” EGWP application for PDP Sponsor. All provisions of the PDP Sponsor’s existing contract with CMS will apply to all employer/union-group waiver plan benefit packages offered by PDP Sponsor except where the provisions are specifically modified and/or superseded by particular employer/union-only group waiver guidance, including those waivers/modifications set forth below.

I, the undersigned, certify to the following:

- 1) Applicant is applying to offer new employer/union-only group waiver (“800 series”) prescription drug plans (PDPs) and agrees to be subject to and comply with all CMS employer/union-only group waiver guidance.
- 2) In order for new PDP Sponsors to be eligible for the CMS employer group waiver that allows PDP Sponsors to offer employer/union-only group waiver plan benefit packages without offering plans to individual beneficiaries, Applicant understands and agrees that it must complete and submit the corresponding *2009 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors* in addition to this application. The *2009 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors* and this document comprise new PDP Sponsor Applicant’s entire application.
- 3) In order for new PDP Sponsors to be eligible for the CMS employer group waiver that allows PDP Sponsors to offer employer/union-only group waiver plan benefit packages without offering plans to individual beneficiaries, Applicant understands and agrees that it must be licensed in at least one state. (Section 3.1.3.B of the *2009 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*).

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- 4) Applicant understands and agrees that it is not required to submit a 2009 Part D bid (i.e., bid pricing tool) to offer its employer/union-only group waiver plans. (Section 3.2.6.A.1 of the *2009 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*)
- 5) In order for new PDP Sponsors to be eligible for the CMS employer group waiver that allows PDP Sponsors to offer employer/union-only group waiver plan benefit packages without offering plans to individual beneficiaries, Applicant understands and agrees that as part of its completion of the *2009 Solicitation for Applications for New Prescription Drug Plan (PDP) Sponsors*, it will submit GeoNetworks® retail pharmacy reports (Appendix X - Retail Pharmacy Network Access Instructions) and other pharmacy access submissions (mail order, home infusion, long-term care, I/T/U) required at the time of application in Section 3.4 of the *2009 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors* for its entire designated service area. (Sections 3.3.B and 3.4 of the *2009 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*)
- 6) PDP Sponsor Applicants applying to offer employer/union-only group waiver plans and plans to individual beneficiaries understand and agree that it will not initially be required to have networks in place for those designated EGWP service areas outside of their individual plan service areas or submit GeoNetworks® retail pharmacy reports (Appendix X - Retail Pharmacy Network Access Instructions) and other pharmacy access submissions (mail order, home infusion, long-term care, I/T/U) required in Section 3.4 of the *2009 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors* for its designated EGWP service area. However, access sufficient to meet the needs of enrollees must be in place once an Applicant enrolls members of an employer or union group residing in particular geographic locations outside of its individual plan service area. (Section 3.4 of the *2009 Solicitation for Applications for New Prescription Drug Plan Plans (PDP) Sponsors*)
- 7) In order to be eligible for the CMS retail pharmacy access waiver of 42 CFR 423.120(a)(1) (i.e., application of “TRICARE” standards), Applicant attests that its retail pharmacy network is sufficient (or will be sufficient prior to enrollment) to meet the needs of its enrollees throughout the employer/union-only group waiver PDP’s service area, including situations involving emergency access, as determined by CMS. Applicant acknowledges and understands that CMS may review the adequacy of the plan’s pharmacy networks and potentially require expanded access in the event of beneficiary complaints or for other reasons it determines in order to ensure that the plan’s network is sufficient to meet the needs of its employer group population. (Section 3.4.1.A of the *2009 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*)
- 8) Applicant agrees to restrict enrollment in its employer/union-only group waiver PDPs to those Part D eligible individuals eligible for the employer’s/union’s employment-based retiree prescription drug coverage. (Section 3.5.A.3 of the *2009 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*)
- 9) Applicant understands that its employer/union-only group waiver PDPs will not be included in the processes for auto-enrollment (for full-dual eligible beneficiaries) or facilitated enrollment (for other low income subsidy eligible beneficiaries). (Section

3.5.A.4 of the *2009 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*)

10) Applicant understands that its employer/union-only group waiver plans will not be subject to the requirements contained in 42 CFR 423.48 to submit information to CMS, including the requirements to submit information (e.g., pricing and pharmacy network information) to be publicly reported on www.medicare.gov and the Medicare Prescription Drug Plan Finder. (Sections 3.7.A and 3.16.A.20 of the *2009 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*.)

11) Applicant understands that dissemination materials for its employer/union-only group waiver PDPs are not subject to the requirements contained in 42 CFR 423.50 to be submitted for review and approval by CMS prior to use. However, Applicant agrees that it will submit these materials to CMS at the time of use in accordance with the procedures outlined in Chapter 12 of the Prescription Drug Benefit Manual. Applicant also understands CMS reserves the right to 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. (Section 3.13.A.1 of the *2009 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*).

12) Applicant understands that its employer/union-only group waiver PDPs will not be subject to the requirements regarding the timing for issuance of certain dissemination materials, such as the Annual Notice of Change/ Evidence of Coverage (ANOC/EOC), Summary of Benefits (SB), Formulary, and LIS rider when an employer’s or union’s open enrollment period does not correspond to Medicare’s Annual Coordinated Election Period. For these employers and unions, the timing for issuance of the above dissemination materials should be appropriately based on the employer/union sponsor’s open enrollment period. For example, the Annual Notice of Change/Evidence of Coverage (ANOC/EOC), Summary of Benefits (SB), LIS rider, and Formulary are required to be received by beneficiaries no later than 15 days before the beginning of the employer/union group health plan’s open enrollment period. The timing for other dissemination materials that are based on the start of the Medicare plan (i.e., calendar) year should be appropriately based on the employer/union sponsor’s plan year. (Section 3.13.A.10 of the *2009 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*)

13) Applicant understands that the dissemination requirements set forth in 42 CFR 423.128 will not apply to its employer/union-only group waiver PDPs when the employer/union sponsor is subject to alternative disclosure requirements (e.g., the Employee Retirement Income Security Act of 1974 (“ERISA”)) and complies with such alternative requirements. Applicant agrees to comply with the requirements for this waiver contained in employer/union-only group waiver guidance, including those requirements contained in Chapter 12 of the Prescription Drug Benefit Manual. (Sections 3.13.A.1-2, 8 of the *2009 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*)

14) Applicant understands that its employer/union-only group waiver plans will not be subject to the Part D beneficiary customer service call center hours and call center performance requirements. Applicant attests that it will ensure that a sufficient mechanism is available to respond to beneficiary inquiries and will provide customer service call center services to these members 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. (Section 3.13.A.5 of the *2009 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*)

15) Applicant understands that CMS has waived the requirement that the employer/union-only group waiver plans must provide beneficiaries the option to pay their premium through Social Security withholding. Thus, the premium withhold option will not be available for enrollees in Applicant’s employer/union-only group waiver plans. (Sections 3.5.A.19 and 3.22.A.2-4 of the *2009 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*)

16) This Certification is deemed to incorporate any changes that are required by statute to be implemented during the term of the contract, and any regulations and policies implementing or interpreting such statutory provisions.

17) I have read the contents of the completed application and the information contained herein is true, correct, and complete. If I become aware that any information in this application is not true, correct, or complete, I agree to notify CMS immediately and in writing.

18) I authorize CMS to verify the information contained herein. I agree to notify CMS in writing of any changes that may jeopardize my ability to meet the qualifications stated in this application prior to such change or within 30 days of the effective date of such change. I understand that such a change may result in termination of the approval.

19) I understand that in accordance with 18 U.S.C. § 1001, any omission, misrepresentation or falsification of any information contained in this application or contained in any communication supplying information to CMS to complete or clarify this application may be punishable by criminal, civil, or other administrative actions including revocation of approval, fines, and/or imprisonment under Federal law.

20) I acknowledge that I am aware that there is operational policy guidance, including the forthcoming 2009 Call Letter, relevant to this application that is posted on the CMS website and that it is continually updated. Organizations submitting an application in response to this solicitation acknowledge that they will comply with such guidance should they be approved to offer employer/union-only group waiver plans in association with the organization’s PDP Contract with CMS.

☐ I certify that I am an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for qualification to offer

PDP (“800 series”) EGWP

employer/union-only group waiver plans (“800 series” EGWPs) in association with my organization’s PDP Contract with CMS. I have read and agree to comply with the above certifications.

{Entity MUST check box for a complete application.}

{Entity MUST create 800-series PBPs during plan creation and designate EGWP service areas.}