

**Centers for Medicare & Medicaid Services**  
**2006 Part D Application Instructions for Employer/Union Sponsored Retiree Group Plans**  
**(Employer/Union Direct Contractors and PDP/MA-PD/Cost Plan Sponsors Offering Employer/Union Retiree Group Plans)\*\***

**(Revised -04/19/2005)**

Employers and unions that currently offer retiree medical coverage that includes prescription drug benefits have several options under the Medicare Modernization Act (MMA). These options include becoming Part D plans themselves through direct contracting or obtaining customized coverage for their retirees through special arrangements with Part D sponsors. Both options involve the use of CMS waivers authorized under Sections 1857(i) and 1860D-22(b) of the Social Security Act (*see* February 11, March 9, and April 6, 2005 CMS waiver guidance located at: <http://www.cms.hhs.gov/medicarereform/pdbma/employer.asp>).

The chart below summarizes the instructions employer/union direct contractors and Prescription Drug Plan (PDP), Medicare Advantage Prescription Drug Plan (MA-PD) and Cost Plan sponsors must follow during the application process in order to be eligible to offer employer/union retiree Part D plans through the use of these waivers. The chart summarizes the waivers that are available to each entity, where in the corresponding application the waiver applies to modify the application submission requirements and, when applicable, what information must be submitted in support of the waiver with the entity's application. Please note that the chart is a summary designed to assist applicants in the application process and it does not in any way modify and/or supersede the official waiver guidance documents issued previously. Also included are waiver checklists for each kind of application (Attachments A & B), sample attestations (Attachments C, D, E, F, G), and more specific guidance on what needs to be submitted in a request for additional individual waivers not already approved by CMS (Attachment H). Also included is information in a question and answer format about the employer group application process (Attachment I).

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**Employer/Union Direct Contract Applications:**

For direct employer/union applications, please complete the same PDP solicitation for application (March 9, 2005 version located at <http://www.cms.hhs.gov/pdps/>) that applies to the non-group (individual) market. Follow all of the same directions in the application (including how applications materials must be packaged, the number of copies and how and to whom the application must be sent; *see* Section 2.6 of solicitation for application), unless any sections of the application requirements have been modified by particular waivers (*see* chart below). In addition, the employer/union sponsor must:

- Submit a cover sheet with the PDP application that indicates that the application is an employer/union direct contract application;
- Include with the cover sheet:
  - the contract number received in the Notice of Intent process (“S number”) (**If you did not receive a contract number, please send an email to: [employerwaivers@cms.hhs.gov](mailto:employerwaivers@cms.hhs.gov) immediately**);
  - how many different formularies the sponsor intends to submit on June 6, 2005;
  - whether the plan will operate on a non-calendar year and if so, the exact dates on which the plan will operate;
  - a checklist of each of the waivers in the chart below that the employer/union sponsor is intending to utilize (*see* waiver checklist – Attachment A); and
- For those waivers that require materials to be submitted, include these materials with the section of the application to which they apply (*see* chart below and Attachments).
- The following attachments apply to this waiver application:
  - (A) Waiver Checklist
  - (D) Retail Pharmacy Access Attestation
  - (E) Marketing/Beneficiary Communications Attestation
  - (G) Management/Operations Attestation
  - (H) Case by Case Waiver Instructions.

**Also, please remember that employer/union direct contract applications must be received by 5:00 EDT on Monday, April 25, 2005. It also would help to speed the processing of these applications for employer/union sponsors to note in the attention line of the mailing label addressed to Ms. Mack (“Attention Marietta Mack: Employer Group Direct Contract”)**

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**PDPs, MA-PDs and Cost Plan Employer/Union Retiree Group Applications:**

PDPs, MA-PDs and Cost Plan sponsors<sup>1</sup> seeking to apply to offer employer/union retiree group plans are not required to submit another full solicitation for application in addition to the one already submitted for the non-group market on March 23, 2005. Instead, these Part D sponsors must submit additional application materials in support of their request to offer a Part D plan to the employer group market through the use of CMS waivers.

The sponsor must:

- Submit a cover sheet that indicates that the application is an employer/union-only group waiver application;
- Include with the cover sheet:
  - the contract number provided for the corresponding individual market application (“S” (PDP), “H” (Local MA-PD), or “R” (Regional MA-PD) number); **(It is very important to submit a correct contract number in order to properly associate this employer group waiver application with your non-group market contract. If you do not know your contract number or need assistance, please send an email to: [employerwaivers@cms.hhs.gov](mailto:employerwaivers@cms.hhs.gov) immediately);**
  - how many new formularies the sponsor intends to submit on June 6, 2005 for the employer group market that are different from what the sponsor intends to submit on April 18, 2005 for the non-group market;
  - indicate whether the sponsor expects to offer any non-calendar year plans (specific dates are not needed); and
  - A checklist of each of the waivers in the chart below that the plan sponsor is intending to utilize (*see* waiver checklist – Attachment B).
- For those waivers that require materials to be submitted, include these materials with your application (*see* chart below and Attachments).
- Attach an additional executed certification (*see* Attachment C for sample attestation language) which will apply to these waiver application materials submitted by the sponsor;
- Indicate all of the areas the sponsor intends to offer employer group coverage to retirees (for local MA-PD plans - the state(s) and county (if partial counties, indicate zip codes); for regional MA-PDs – the MA regions; for PDP plans – the PDP regions).

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<sup>1</sup> For Cost Plans, Part D coverage is an optional supplemental benefit and CMS’ employer group waiver authority applies only to Part D, not to Parts A or B.

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- Submit an original and three (3) hard copies of all of these waiver application materials and send to the same mailing address that was identified in the non-group application (*see* note below for modification to ATTN: line).
- The following Attachments apply to this waiver application:
  - (B) Waiver Checklist
  - (C) Certification to Employer Group Waiver Application Materials
  - (D) Retail Pharmacy Access Attestation
  - (E) Marketing/Beneficiary Communications Attestation
  - (F) Service Area Requirements Attestation (PDPs only)
  - (H) Case by Case Waiver Instructions.

**Also, please remember that employer/union-only group waiver applications must be received by 5:00 EDT on Monday, April 25, 2005. It also would help to speed the processing of these applications for plan sponsors to note in the attention line of the mailing label addressed to Ms. Mack (“Attention Marietta Mack: Employer Group Plan: [insert] PDP, MA-PD or Cost Plan” [depending on applicant type])”**

If you have questions about these application instructions or employer group waivers, please send your questions via email to: [employerwaivers@cms.hhs.gov](mailto:employerwaivers@cms.hhs.gov). Also, CMS will be holding several special user group calls to assist employer/union sponsors with these instructions. Call-in information and instructions for these calls will be posted at: <http://www.cms.hhs.gov/medicarereform/pdbma/employer.asp>.

In addition, at the bottom right hand corner of this same page, there is a link to subscribe to our LISTSERV for future employer group announcements.

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(Revised -04/19/2005)

Available Part D Employer/Union Sponsored Group Waiver	General Description of Waiver	Waiver available for Employer/Union Direct Contracts?	Waiver available for PDP/MA-PD/Cost Plans?	Corresponding section(s) of non-group PDP application affected by waiver	Corresponding section(s) of non-group MA-PD application affected by waiver	Corresponding section(s) of non-group Cost Plan application affected by waiver	Actions Needed By Employers/Union Group Plan Sponsors To Utilize Waiver
Modification of the timeframes for submission of application materials	<p><b>March 23, 2005:</b> Notice of intent to apply due (Direct contract PDPs only)</p> <p><b>April 25, 2005:</b> Employer/union sponsored group applications due</p> <p><b>June 6, 2005:</b> Employer/union sponsored group formularies due</p> <p>Employer/union sponsored group Regional MA-PD bids due</p> <p><i>(see February 11 and April 6, 2005 guidance)</i></p> <p><b>July 1, 2005:</b> Employer/union sponsored group PDP and Local MA-PD bids due <i>(see April 6, 2005 guidance)</i></p>	<p>YES</p> <p>YES</p> <p>YES</p> <p>N/A</p> <p>YES</p>	<p>N/A</p> <p>YES</p> <p>YES</p> <p>YES</p> <p>YES</p>	<p>All references to corresponding timeframes in sections 1 and 2 are modified</p>	<p>All references to corresponding timeframes in sections 1 and 2 are modified</p>	<p>All references to corresponding timeframes in sections 1 and 2 are modified</p>	<p>To comply with the particular requirements for submission of an employer group application, formularies and bids within the deadlines established by the applicable timeframes.</p>

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Ability to Restrict Enrollment To Retirees Only	Employer/union sponsored group plans may restrict enrollment solely to their retirees (i.e., do not have to comply with the requirements of 42 CFR 423.104(b)).  (see February 11, 2005 guidance)	YES	YES	<u>Section 3.5</u> A1, A2, A3	MA-PD enrollment requirements are detailed in the Part C solicitation for application	<u>Section 3.4</u> A1, A2	None – upon approval as a Part D employer/union sponsored plan, may automatically restrict enrollment to retirees only.
Minimum Enrollment Requirements	Employer/union sponsored group plans do not have to comply with the minimum enrollment standards listed in 42 CFR 423.512(a).  (see February 11, 2005 guidance)	YES	YES	Not contained in PDP solicitation for application	MA-PD minimum enrollment requirements are detailed in the Part C solicitation for application	Not contained in Cost Plan solicitation for application	None – upon approval as a Part D employer/union sponsored plan, will automatically not be subject to minimum enrollment requirements.

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Service Area Requirements	<p><u>Employer/Union direct contracts:</u> Coverage can be extended to all retirees regardless of where they reside. (see February 11, 2005 guidance)</p> <p><u>PDPs offering employer/union-only group plans:</u> In order to qualify for a waiver of the service area requirements of 42 CFR 423.112(a), the PDP must offer non-retiree coverage (either itself or through subcontractors or other partners) in the area where the most substantial portion of the employer's/union's total number of <i>employees</i> (or, for union funds, <i>participants</i>) reside. Coverage may then be offered to all of the employer's/union's retirees regardless of where in the country they reside. If the PDP only offers non-retiree coverage in a region other than where the most substantial portion of employees/participants reside then coverage for retirees is limited to that same region.</p> <p>(see April 6, 2005 guidance)</p>	YES	N/A	<u>Section 3.3</u> A2 <u>Section 3.5</u> A2	N/A	N/A	None – waiver automatically applies.
		N/A	YES	<u>Section 3.3</u> A2 <u>Section 3.5</u> A2	N/A	N/A	The plan must provide an attestation that it has conducted or will conduct an actual review of where the substantial portion of an employer's/union's employees reside and that area corresponds to the area that the plan (either itself or through subcontractors or other partners) offers non-group coverage. (See Attachment F for sample attestation language). The plan must also maintain adequate supporting documentation to demonstrate that this review was actually undertaken for each employer/union.

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<b>Available Part D Employer/Union Sponsored Group Waiver</b>	<b>General Description of Waiver</b>	<b>Waiver available for Employer/Union Direct Contracts?</b>	<b>Waiver available for PDP/MA-PD/Cost Plans?</b>	<b>Corresponding section(s) of non-group PDP application affected by waiver</b>	<b>Corresponding section(s) of non-group MA-PD application affected by waiver</b>	<b>Corresponding section(s) of non-group Cost Plan application affected by waiver</b>	<b>Actions Needed By Employers/Union Group Plan Sponsors To Utilize Waiver</b>
Service Area Requirements (Cont.)	<p><u>MA-PDs offering employer/union-only group plans</u>: The service area rules for MA plans prior to passage of the MMA will continue to apply to Local MA-PD plans (and MA-only plans). Thus, if a Local MA-PD sponsor provides coverage to individuals in any part of a State, it can offer retiree-only coverage for an employer or union throughout that State.</p> <p>For Regional MA-PD plans, the MA-PD sponsor can provide retiree-only coverage in any area within, or throughout the MA region in which it provides coverage to individuals. CMS may, on a case-by-case basis, grant a waiver to permit a regional MA or MA-PD providing coverage under an employer or union-sponsored retiree plan to extend coverage to the employer or union retirees living outside such region.</p> <p><b>(see April 6, 2005 guidance)</b></p>	N/A	YES	N/A	<u>Section 3.3 A1</u>	Not contained in Cost Plan solicitation for application	None – waiver automatically applies.

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State Licensure	<p>For employer/union sponsored group plans that directly contract with CMS, the state licensure requirement of 42 CFR 423.401(a)(1) and 42 CFR 423.504(b)(2) will be waived, thus allowing an unlicensed employer or union group to sponsor their own PDP. However, certain financial solvency requirements must be satisfied (<i>see</i> financial solvency waiver below).</p> <p>(<i>see</i> February 11, 2005 guidance)</p>	YES	NO	<u>Section 3.1.3</u> A, C, D	N/A	N/A	Must submit necessary documentation that demonstrates the entity meets certain financial solvency standards ( <i>see</i> Financial Solvency Requirements waiver summary below).

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Financial Solvency Requirements	<p>For employer/union groups directly contracting with CMS, certain solvency and other standards will be required if state licensure is waived for that entity. If the employer or union does not meet the standards described in appendix X of the PDP application (requirements of 42 CFR 423.420), CMS may in its discretion approve, on a case-by-case basis, waivers of such requirements upon a demonstration from the entity that its fiscal soundness is commensurate with its financial risk and that through other means the entity can assure that claims for benefits paid for by CMS and beneficiaries will be covered.</p> <p><b>(see March 9, 2005 guidance)</b></p>	YES	NO	<u>Section 3.1.3 B</u>	N/A	N/A	<p>Financial solvency requirements will be reviewed and approved on a case-by-case basis. Documentation must be submitted to CMS which demonstrates that the solvency standards described in appendix X of the PDP application are satisfied, or alternately, documentation must be provided that demonstrates that the entity's 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's or union's contracts and subcontracts contain beneficiary hold harmless provisions described in appendix X and other CMS guidance.</p>

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Available Part D Employer/Union Sponsored Group Waiver	General Description of Waiver	Waiver available for Employer/Union Direct Contracts?	Waiver available for PDP/MA-PD/Cost Plans?	Corresponding section(s) of non-group PDP application affected by waiver	Corresponding section(s) of non-group MA-PD application affected by waiver	Corresponding section(s) of non-group Cost Plan application affected by waiver	Actions Needed By Employers/Union Group Plan Sponsors To Utilize Waiver
Management and Operations Requirements	<p>Employer/union groups directly contracting with CMS may be subject to other standards governing its management and operations, such as ERISA fiduciary requirements, state law standards, and certain oversight standards created under the Sarbanes-Oxley Act. CMS waives the requirements of 42 CFR 423.504(b)(4)(i)-(iii) to the extent that an employer or union (or to the extent applicable, the business associate with which it contracts for prescription drug services) is subject to ERISA or similar state or federal law standards.</p> <p>CMS may waive bonding and insurance standards under 42 CFR 504(b)(4)(iv)-(v) on a case by case basis for a direct contract employer or union upon a demonstration that different legal standards (such as ERISA bonding standards) are satisfied.</p> <p><b>(see March 9, 2005 guidance)</b></p>	YES	NO	Section 3.1.1 A2, A4, A5, A6, C, D	N/A	N/A	<p>Must identify and attest to the fact that the entity (or to the extent applicable, the business associate with which it contracts for prescription drug services) is subject to ERISA fiduciary requirements or similar state or federal laws. (See Attachment G for sample attestation language).</p> <p>Must request an additional case by case waiver (see Attachment H).</p>

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Available Part D Employer/Union Sponsored Group Waiver	General Description of Waiver	Waiver available for Employer/Union Direct Contracts?	Waiver available for PDP/MA-PD/Cost Plans?	Corresponding section(s) of non-group PDP application affected by waiver	Corresponding section(s) of non-group MA-PD application affected by waiver	Corresponding section(s) of non-group Cost Plan application affected by waiver	Actions Needed By Employers/Union Group Plan Sponsors To Utilize Waiver
Public Reporting Requirements	<p>In general, Part D plan Sponsors must report certain information to CMS, to their enrollees, and to the general public, such as the cost of their operations and financial statements, under 42 CFR 423.514 (a). To avoid imposing additional and possibly conflicting <u>public</u> disclosure obligations that would hinder the offering of employer or union direct contract arrangements, CMS will modify these public reporting requirements to require information regarding such arrangements be reported to enrollees and to the general public to the extent required by other law (including ERISA or securities laws) or by contract.</p> <p><i>(see March 9, 2005 guidance)</i></p>	YES	NO	<u>Section 3.13, A20</u>	N/A	N/A	None – waiver automatically applies.

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Non-Governmental Entities Requirements	In order to allow governmental entities to directly contract with CMS for their retirees, the non-governmental requirement in Section 1860D-41(a)(13) of the MMA that prohibits governmental entities from being PDP or MA-PD sponsors will be waived.  (see February 11, 2005 guidance)	YES	NO	<u>Section 3.1.1 A2</u>	N/A	N/A	None – waiver automatically applies.

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Requirement to Operate on a Calendar Year Basis	(Section 1860D-1(a)(2) of the MMA requires Part D plans to operate on a calendar year basis. Employer/union sponsored group plans will be allowed to operate on a non-calendar year basis. These plans are permitted to determine benefits (including deductibles, out-of-pocket limits, etc.) on a non-calendar year basis. However, bids and other submissions to CMS, along with CMS payments, will be determined on a calendar year basis, in a process similar to the process currently used for employer and union-sponsored MA plans.  <b>(see April 6, 2005 guidance)</b>	YES	YES	N/A	N/A	N/A	For Direct Contracts, must identify whether the plan will operate on a non-calendar year basis and the exact dates on which the plan will operate.  For PDP/MA-PD/Cost Plan sponsors, indicate whether sponsor expects to offer any non-calendar year plans.  Non-calendar plans must comply with all the specific CMS benefit administration and enrollment requirements for these plans <b>(see April 6, 2005 guidance)</b> .

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Requests for Waiver of Additional Requirements	42 CFR 423.458(c)(1) provides that CMS may waive or modify any Part D requirement that hinders the design of, the offering of, or the enrollment in an employer-sponsored group prescription drug plan.	YES	YES	N/A	N/A	N/A	Any entity seeking to offer, sponsor, or administer an employer-sponsored group prescription plan may request, in writing, a waiver or modification of additional requirements under this Part that hinder its design of, the offering of, or the enrollment in, such employer-sponsored group prescription drug plans. Waivers or modifications approved by CMS apply to any similarly situated entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan, meeting the conditions of the waiver or modification. 42 CFR 423.458(c)(2) (see Attachment H for specific details)

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**ATTACHMENT A**

**(WAIVER CHECKLIST: EMPLOYER/UNION DIRECT CONTRACTS)**

Employer/Union Direct Contractor Name: \_\_\_\_\_

Contract Number: \_\_\_\_\_

Available Part D Employer/Union Sponsored Group Waiver	Requesting Waiver for Employer/Union Direct Contracts?		Attachments Needed for Application Materials?
	Yes	No	
Ability to restrict enrollment to retirees only			No
Minimum enrollment requirements			No
Retail Pharmacy access requirements			Yes (See Attachment D)
Marketing / Beneficiary communications requirements			Yes (See Attachment E)
Service area requirements			No
State licensure requirements			No
Financial solvency requirements			Yes (see March 9 <sup>th</sup> guidance)
Management and Operations requirements			Yes (See Attachment G)
Public Reporting requirements			No
Non-governmental entities requirements			No
Requirement to operate on a calendar year basis			Yes (dates the plan will operate)
Requests for waiver of additional requirements			Yes (See Attachment H)

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**ATTACHMENT B**

**(WAIVER CHECKLIST: PDP/MA-PD/COST PLAN SPONSORS)**

PDP/MA-PD/Cost Plan Sponsor Name: \_\_\_\_\_

Contract Number: \_\_\_\_\_

<b>Available Part D Employer/Union Sponsored Group Waiver</b>	<b>Requesting Waiver for PDP/MA-PD/Cost Plan?</b>		<b>Attachments Needed for Application Materials?</b>
	Yes	No	
Ability to restrict enrollment to retirees only			No
Minimum enrollment requirements			No
Retail Pharmacy access requirements			Yes (See Attachment D)
Marketing /Beneficiary communications requirements			Yes (See Attachment E)
Service area requirements			Yes (if PDP) (See Attachment F)
Requirement to operate on a calendar year basis			Yes (indicate whether plan expects to offer non-calendar year plans)
Requests for waiver of additional requirements			Yes (See Attachment H)

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**ATTACHMENT C**

**(SAMPLE CERTIFICATION: PDP/MA-PD/COST PLAN EMPLOYER GROUP  
APPLICATION MATERIALS)**

**CERTIFICATION**

**I, the undersigned, certify to the following:**

- 1) I have read the contents of the completed employer/union group waiver application materials and the information contained herein is true, correct, and complete. If I become aware that any information in these application materials is not true, correct, or complete, I agree to notify the Centers for Medicare & Medicaid Services (CMS) immediately and in writing.
- 2) 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 requirements stated in these employer/union group waiver application materials 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.
- 3) I understand that in accordance with 18 U.S.C. § 1001, any omission, misrepresentation or falsification of any information contained in these employer/union group waiver application materials 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.
- 4) I further certify that I am an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for employer/union group waivers with CMS.

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Authorized Representative Name (printed)

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Title

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Authorized Representative Signature

---

Date (MM/DD/YYYY)

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**ATTACHMENT D**

**(SAMPLE)**

**RETAIL PHARMACY ACCESS ATTESTATION**

**(Contract Number: \_\_\_\_\_)**

(Date)

\_\_\_\_\_ (Employer/Union Direct Contractor or PDP/MA-PD/Cost  
Plan Sponsor Name) attests that the employer/union group plan's retail pharmacy  
networks are sufficient to meet the needs of its retiree population, including situations  
involving emergency access.

\_\_\_\_\_  
Authorized Representative Name (printed)

\_\_\_\_\_  
Title

\_\_\_\_\_  
Authorized Representative Signature

\_\_\_\_\_  
Date (MM/DD/YYYY)

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**ATTACHMENT E**

**(SAMPLE)**

**MARKETING/BENEFICIARY COMMUNICATIONS ATTESTATION**

**(Contract Number: \_\_\_\_\_)**

(Date)

\_\_\_\_\_ (Employer/Union Direct Contractor or PDP/MA-PD/Cost  
Plan Sponsor Name) attests that the plan complies with the following alternative  
disclosure standards [**insert standard here – e.g., ERISA disclosure standards**].

\_\_\_\_\_  
Authorized Representative Name (printed)

\_\_\_\_\_  
Title

\_\_\_\_\_  
Authorized Representative Signature

\_\_\_\_\_  
Date (MM/DD/YYYY)

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**ATTACHMENT F**

**(SAMPLE)**

**SERVICE AREA REQUIREMENT ATTESTATION FOR PDP OFFERING AN  
EMPLOYER/UNION ONLY PLAN**

**(Contract Number: \_\_\_\_\_)**

(Date)

\_\_\_\_\_ (PDP) attests that it has conducted or will conduct an actual review of where the substantial portion of the employer's/union's total number of employees (or, for union funds, participants) reside and that the area corresponds to the area that the plan (either itself or through subcontractors or other partners) offers non-group coverage. The plan also attests that it will maintain adequate supporting documentation to demonstrate that this review was actually undertaken for each employer/union.

\_\_\_\_\_  
Authorized Representative Name (printed)

\_\_\_\_\_  
Title

\_\_\_\_\_  
Authorized Representative Signature

\_\_\_\_\_  
Date (MM/DD/YYYY)

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**ATTACHMENT G**

**(SAMPLE)**

**MANAGEMENT/OPERATIONS ATTESTATION**

**(Contract Number: \_\_\_\_\_)**

(Date)

\_\_\_\_\_ (Employer/Union Direct Contractor) attests that the plan complies with the following alternative management and operations standards **[insert standard here – e.g., ERISA fiduciary requirements, state law standards, Sarbanes-Oxley standards]**.

\_\_\_\_\_  
Authorized Representative Name (printed)

\_\_\_\_\_  
Title

\_\_\_\_\_  
Authorized Representative Signature

\_\_\_\_\_  
Date (MM/DD/YYYY)



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**ATTACHMENT H**

**Instructions for Additional Employer/Union Sponsored Plan Waiver Requests**

Individual waiver requests must include the name of the employer/union direct contract, PDP, MA-PD or Cost Plan sponsor (refer to contract number), and fully address the following items:

- Provisions of existing statutory and/or regulatory requirement the entity is requesting to be waived/modified (please be explicit as to 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;
- Executive summary of the requested waiver/modification;
- 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 that would assist CMS in the evaluation of the request; and
- Contact information (name, position, phone, fax and email address) of the person who is available to answer inquiries about the waiver/modification request.

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**ATTACHMENT I**

Part C Application Information

- Q1:** For Part C coverage, what if anything do MA organizations need to submit on April 25, 2005 in support of their employer/union-only (“800-series”) plans?
- A1:** MA-only and MA-PD employer/union group plans (employer/union-only or “800 series plans”) must notify CMS by April 25, 2005 of the Part C service areas they intend to offer employer/union group coverage (for Regional MA-only and MA-PDs identify the regions; for Local MA-only and MA-PDs identify the states and counties). Please note that for current MA plans, no submission is necessary if no changes to the current service area(s) will be made. Also please note that service area information does not need to be employer-specific. Include with this submission the assigned current or pending “H” or “R” number. Please mail a hard copy of this information to the following address with a cc: to the local Regional Office contact:

Gloria Parker, Director Division of Plan Management  
Medicare Advantage Group/Center for Beneficiary Choices  
Centers for Medicare & Medicaid Services  
Mail Stop C4-23-07  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Part D Application Information

- Q2:** May an employer/union who wishes to be a direct contract PDP still submit an application on April 25, 2005 if the entity did not submit a notice of intent on March 23, 2005?
- A2:** Yes, but please note that the employer/union must still follow the Notice of Intent procedures on our website and submit the necessary forms to the proper recipients by April 25, 2005, in order to ensure a contract number is assigned and access to CMS systems is obtained.
- Q3:** For uniform premium and low income subsidy requirements as they apply to employer/union groups, do the written agreements that Part D plans must obtain from employers/unions have to be in place when the plan applies on April 25, 2005? Must these written agreements be submitted to CMS?

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- A3:** No. These written agreements do not have to be in place when the plan applies and do not have to be submitted to CMS during the solicitation for application process.
- Q4:** What is included in the attestation to be provided for the PDP service area waiver? Also, must separate attestations be provided for each of the actual reviews conducted for each employer/union?
- A4:** The plan must provide one attestation that it has conducted or will conduct an actual review of where the substantial portion of an employer's/union's employees/participants reside and that this area corresponds to the area that the plan (either itself or through subcontractors or other partners) offers non-group coverage. Although a separate attestation is not required for each employer/union, the plan must also maintain adequate supporting documentation to demonstrate that this review was actually undertaken for each employer/union, the date it was undertaken, by whom the review was undertaken, etc., in the event of a CMS audit and review of this requirement.
- Q5:** Do I need to meet the April 18, 2005 deadline for Section 3.2.3, A8 and A10 (Quality Assurance and Patient Safety) in the PDP, MA-PD, and Cost Plan application?
- A5:** No. Since these materials were intended to be submitted along with the applicant's formulary, we will extend the due date for these requirements to coincide with the employer group formulary submission date of June 6, 2005.
- Q6:** Do I need to meet the April 18, 2005 deadline for Section 3.2.4, A5 and A10 (Medication Therapy Management) in the PDP, MA-PD, and Cost Plan application?
- A6:** No. We will extend the due date for these requirements to June 6, 2005.
- Q7:** Did I need to meet the March 23, 2005 deadline for Section 3.4.5, A3 for long-term care pharmacy contracting in the PDP and MA-PD application (Section 3.3.5 of the Cost Plan Application)?
- A7:** No. We will extend that timeframe to April 25, 2005. However, if these pharmacy access contracting standards are not met by April 25, 2005, the applicant must resubmit the analysis by August 1, 2005.
- Q8:** When a PDP/MA-PD/Cost Plan is submitting the additional application materials on April 25, 2005 for the employer-only (800-series) plans they wish to offer, is it

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necessary to submit employer-specific materials for each employer/union group for which the plan intends to offer coverage?

**A8:** No. These additional application materials are not required to be employer/union specific.

Employer Group Formularies

**Q9:** Can formularies for employer/union group Part D plans be modified after submission and approval?

**A9:** Part D plans may enhance these employer/union group formularies subsequent to submission without further review by CMS if the entity is adding new drugs or changing the cost sharing to lower cost sharing. However, these formularies may not be modified after submission to add restrictions or limitations. CMS will require that all Part D plans sign a letter certifying that the employer/union group formularies used comply with these guidelines.