



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, Maryland 21244

TO: Current and Future Medicare Advantage Organizations, Prescription Drug Plan Sponsors, Direct Contract Employer/Union Prescription Drug Plan Sponsors, Cost Based Plans, and PACE organizations

FROM: Patricia Smith, Director, Medicare Advantage Group
Cynthia Tudor, Acting Director, Medicare Drug Benefits Group
Mark Hamelburg, Director, Employer Policy and Operations Group

RE: Posting of Draft 2007 Medicare Advantage Applications and Prescription Drug Plan Solicitations for Public Comment

DATE: December 7, 2005

Today, we are posting draft Medicare Advantage applications and Prescription Drug Plan solicitations for public comment. CMS welcomes comments from the public on all items set forth in these documents. This posting includes the specific applications and solicitations listed below. Comments are most useful if organized by the application or solicitation and section/header to which they apply (see below).

Comments on these materials must be received via email at the indicated addresses no later than 5:00 PM EST, December 14, 2005.

Send comments on the following applications to PARTCappcomments@cms.hhs.gov:

- Draft 2007 Coordinated Care Plan (CCP) Application
- Draft 2007 Private Fee-for-Service Plan (PFFS) Application
- Draft 2007 Regional Preferred Provider Organization (RPPO) Application
- Draft 2007 Medical Savings Account (MSA) Application
- Draft 2007 Service Area Expansion (SAE) Application

Send comments on the following applications to PARTDappcomments@cms.hhs.gov:

- Draft 2007 Solicitation for Applications for New Prescription Drug Plan (PDP) Sponsors
- Draft 2007 Solicitation for New Medicare Advantage-Prescription Drug Plan (MA-PD) Sponsors
- Draft 2007 Solicitation for Applications for New Cost Based Plan-Prescription Drug Plan Sponsors

- Draft 2007 Part D Service Area Expansion Application for PDP and MA-PD Sponsors

Send comments on the following applications to EMPLOYERappcomments@cms.hhs.gov:

- Draft 2007 Solicitation for Application for New Direct Contract Employer/Union-Only Group Waiver (Direct EGWP) Prescription Drug Plans
- Draft 2007 Application for MA Organizations to Offer Employer/Union-Only Group Waiver Plans (EGWPs)
- Draft 2007 Application for PDP Sponsors to Offer Employer/Union-Only Group Waiver Plans (EGWPs)
- Draft 2007 Application for Cost Based Plan Sponsors to Offer Employer/Union-Only Part D Group Waiver Plans (EGWPs)
- Draft 2007 Service Area Expansion Application for MA Organizations, PDP Sponsors and Cost Based Plan Sponsors

The Draft 2007 Solicitation for Applications for New PACE-Prescription Drug Plan Sponsors will be posted for comment in the near future.

Information Regarding Expiration of Web Addresses Within Posted Draft Documents

CMS will be transitioning to a new web design on December 15, 2005. While this transition will occur after the close of the comment period on the draft applications/solicitations, this action will affect the draft documents in several ways.

- Effective December 15, 2005, the web page containing the links to the draft application/solicitation documents will have a new web address which is not known at this time. We recommend that you use the search feature on the new CMS website to locate these draft documents until we can post a link on the appropriate pages.
- After December 14, 2005, the web addresses referred to in the draft application/solicitation documents will expire. Typing these web addresses into your browser after December 14, 2005 will likely result in an error message.
- As soon as possible after December 14, 2005, CMS will post a revised draft of these documents that will include functioning web addresses. You will be able to differentiate the revised drafts from the current draft versions because the cover page of the revised drafts will indicate they are revised.

If you have questions during this comment period, please contact the following individuals:

For Medicare Advantage issues – Gloria Parker at (410) 786-9281 or gloria.parker@cms.hhs.gov

For Prescription Drug Plan issues – Marla Rothouse at (410) 786-8063 or marla.rothouse@cms.hhs.gov

For PACE issues – Brenda Hudson at (410) 786-4085 or brenda.hudson@cms.hhs.gov

Draft SAE 11/16/05

For Employer/Union-Only Group Waiver issues – Brenda Tranchida at (410) 786-2001 or brenda.tranchida@cms.hhs.gov.

We look forward to receiving your comments and appreciate your efforts to help us prepare for the 2007 application/solicitation season.

**2007 PART D SERVICE AREA EXPANSION
APPLICATION**

FOR

PRESCRIPTION DRUG PLAN (PDP) SPONSORS

AND

**MEDICARE ADVANTAGE PRESCRIPTION DRUG PLAN
(MA-PD) SPONSORS**

Department of Health and Human Services
Centers for Medicare and Medicaid Services (CMS)
Center for Beneficiary Choices (CBC)
Medicare Drug Benefit Group (MDBG)

December 7, 2005

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1. General Information

1.1 Purpose of Solicitation

The Centers for Medicare & Medicaid Services is seeking applications from existing Part D Benefit organizations seeking to expand the current service area to which they are offering qualified prescription drug coverage. Please submit your service area applications (SAEs) according to the process described below.

This solicitation represents an abbreviated version of the Part D Sponsor Application that is used for organizations seeking to participate in the Part D benefit for the first time. The sections below must be completed for the new service area for which your organization is seeking to expand the Part D benefit. Existing Part D Sponsors who offer either a PDP or MA-PD plan may expand their regional coverage. CMS has identified 26 MA Regions and 34 PDP Regions; in addition, each territory is its own PDP region. Additional information about the regions can be found at <http://www.cms.hhs.gov/medicarereform/mmaregions>.

While CMS approval of a service area expansion requires completion of the sections below, Part D Sponsors are assumed to be able to maintain all requirements for the new service area related to Part D as included in their existing Part D contract or contract addendum. For instance, Part D sponsors will be held to the attestations made for their existing contract for the new service area. In addition, Part D sponsors are still required to provide to CMS formulary and bid submissions on the appropriate dates.

1.2 Notice of Intent for Service Area Expansion

To ensure clear and timely communication with CMS, all existing Part D Sponsors intending to expand their Part D service area should notify CMS of their intention to apply by 5:00 p.m. EST on **January 17, 2006**.

Part D Sponsors are encouraged to submit the Notice of Intent for Service Area Expansion (Appendix I) if they intend to offer the Part D drug benefit in service areas other than those contracted for 2006. Part D Sponsors with multiple Part D contract numbers should submit only one Notice of Intent for service area expansion.

The Notice of Intent for Service Area Expansion is designed to accomplish three things:

1. Make CMS aware of a Part D Sponsor's intention to expand their service area.
2. Obtain contact information for individuals coordinating the Part D Sponsor's service area expansion.
3. Confirm Part D Sponsor identifier, licensure, and solvency information.

To submit a Notice of Intent for service area expansion, Part D Sponsors should complete a Notice of Intent for Service Area Expansion and email and mail it to CMS. Applicants

must email the Notice of Intent for Service Area Expansion to drugbenefitimpl@cms.hhs.gov with “NOI SERVICE AREA EXPANSION” indicated in the subject field. Mail 1 hard copy of the Notice of Intent for Service Area Expansion with original signature to:

Centers for Medicare & Medicaid Services
Attention: Service Area Expansion
Mail Stop C1-26-12
7500 Security Boulevard
Baltimore, Maryland 21244-1850

1.3 Instructions

In preparing your application in response to the tables in this solicitation, please mark “Yes” or “No” in sections organized with that format.

Additional supporting documentation is notated in the following manner throughout the application and is to be submitted as follows:

1. Appendices: documents supplied by CMS that are contained at the end of this application. They are to be completed by the Part D Sponsor and returned to CMS as indicated.
2. Attachments: documents that are to be created and/or supplied by the Part D Sponsor and sent to CMS with the application. Attachments are to be used only when the application does not indicate to respond directly below the question.

CMS will check the application for completeness shortly after its receipt. We will notify Part D Sponsors of any deficiencies and afford them the opportunity to amend their applications.

CMS has established that all aspects of program that the Part D Sponsor attests to must be ready for operation by the contract signature date. As with all aspects of a Part D sponsor’s operations under its contract with CMS, we may verify a sponsor’s compliance with qualifications it attests it will meet, through on-site visits at the Part D sponsor’s facilities as well as through other program monitoring techniques. Failure to meet the requirements attested to in this solicitation and failure to operate its Part D plan(s) consistent with the requirements of the applicable statutes, regulations, and the Part D contract may delay a Part D sponsor’s marketing and enrollment activities or, if corrections cannot be made in a timely manner, the Part D sponsor will be disqualified from participation in the Part D program.

An individual with legal authority to bind the Part D Sponsor shall sign and submit the certification found in Appendix III. CMS reserves the right to request clarifications or corrections to a submitted application. Failure to provide requested clarifications within a 2-day period could result in the applicant receiving a notice of intent to deny the

application, in which case, the Part D Sponsor will then have 10 days to seek to remedy its application.

This solicitation does not commit CMS to pay any cost for the preparation and submission of an application.

1.4 Format

- To assure that each CMS review panelist receives the application in the manner intended by the Part D Sponsor, Part D Sponsor should deliver a total of two (2) hard copies of the written application and supporting documentation.
- Part D Sponsor must include a cover letter with the following elements:
 - Organization Name
 - Parent organization if any
 - Organization Address
 - Organization Phone #
 - Contract ID # (or #s if applicable)
 - Contact Person(s)
 - Contact Person(s) Phone Number(s)
 - Contact Person(s) Email Address(es)

Note: It is important that Part D Sponsor provide 2 separate contact persons and applicable contact information for SAE Application submission(s). This will help to avoid delays in the processing of an application.

- All responses should be completed in Microsoft Word (in a version that is compatible with Office 2003). Attachments (such as existing contracts) can be submitted in Microsoft Word (in a version that is compatible with Windows 2003) or as a PDF file.
- Both hard copies should be in separate 3-ring binders. Tab indexing should be used to identify all of the major sections of the application. Page size should be 8 ½ by 11 inches and the pages should be numbered. Font size should be 12 point.
- One application should be clearly marked, “Original” and contain all original signed certifications requested in the application.
- Additionally, the Part D Sponsor must submit the cover letter, written application, appendices, attachments and all supporting documentation electronically on 4 duplicate (CDs). This will support the review of the application by different CMS components.
- Each CD must be clearly labeled with the information in the table below:

Part D Sponsor's Organization Name
CMS Identification Number (Contract ID #s)
CD Number (Copy 1, Copy 2, Copy 3, Copy 4) Note: If multiple CDs are required to include written application, appendices, attachments and other supporting documentation, label the CDs as follows: Copy 1 (1 of 2), Copy 1 (2 of 2); Copy 2 (1 of 2), Copy 2 (2 of 2), etc.

Failure to submit a service area expansion application consistent with these instructions may delay its review by CMS and could result in the sponsor receiving a notice of intent to deny.

- Applications must be sent to:
 Centers for Medicare & Medicaid Services (CMS)
 Mail Stop: XX-XX-XX
 Attn: Service Area Expansion Part D Application
 7500 Security Boulevard
 Baltimore, Maryland 21244-1850

In order for CMS to receive your application in a timely manner, please note that Federal Express and the US Postal Service possess a CMS Security Clearance. Applications mailed through carriers that do not have CMS Security Clearance could be delayed due to clearance processing.

CMS will accept SAE applications beginning January 24, 2006, **BUT** will not review **ANY** SAE applications received after 5:00 P.M. EST on March 20, 2006

2. Application

2.1 Contract Number:

Provide the contract number for which the service area expansion will apply. _____

2.2 Service Area

Provide as an attachment, the table below, indicating the MA or PDP region(s) (including territories) you plan to serve. Regional information may be found at the following website: www.cms.hhs.gov/medicarereform/mmaregions/pdpmaosum.asp. Be sure to list both the MA or PDP region name and associated number.

MA or PDP Region	MA or PDPRegion Number
Territory	

--

2.3 Licensure and Solvency

Note: MA-PD Sponsors seeking to expand into another MA region may skip this section and proceed directly to Pharmacy Access.

A. Only PDP Sponsors seeking to expand into another PDP region must complete the table below:

NOTE: APPLICANT CAN ONLY BE APPROVED FOR CONTRACT IF: ITEM #3 IS ANSWERED 'YES' <u>OR</u> ITEM #4 BELOW IS ANSWERED 'YES' <u>AND</u> CMS APPROVES THE REQUEST <u>AND</u> ITEM #5 IS ANSWERED 'YES' <u>AND</u> THE APPLICANT SATISFIES THE REQUIREMENT "B" BELOW, IF APPROPRIATE. ATTEST 'YES' OR 'NO' TO THE FOLLOWING STATE LICENSURE REQUIREMENTS.	YES	NO	DOES NOT APPLY
1. Applicant is licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in at least one State.			
2. Applicant is currently under some type of supervision, corrective action plan or special monitoring by the State licensing authority in any State.			
3. Applicant is licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which the Applicant proposes to offer Part D drug benefits.			
4. If the Applicant does not meet Requirement #3, then the Applicant has or will have completed and provided to CMS the <i>State Licensure Waiver Request Form</i> (Appendix I) for each State in which it is not licensed but seeks to offer Part D drug benefits.			
5. If Applicant is seeking a waiver of the licensure requirement, the Applicant meets the CMS-published financial solvency and capital adequacy requirements.			

B. If the answer to item A1 above is "NO", the Applicant must submit the *Financial Solvency Documentation* (Appendix II), as a separate attachment.

C. If the answer to item A2 is "YES", include a separate attachment explaining the specific actions taken by the State license regulator. In these cases, CMS reserves the right to require the Applicant to demonstrate that it meets the CMS-published financial solvency and capital adequacy requirements.

D. If the answer to item A1 is "YES," then please provide documentation (e.g, licensing certificate or letter) from each State licensing authority of your organization's status as an entity licensed to bear risk.

2.4 Pharmacy Access

Part D Sponsors must complete the Pharmacy Guidance Submission for **ONLY** the new service area. The Pharmacy Guidance Submission may be found at www.cms.hhs.gov/

3. CERTIFICATION

I, the undersigned, certify to the following:

- 1) 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 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 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.
- 3) I agree that if my organization meets the minimum qualifications and is Medicare-approved, and my organization enters into a Part D contract with CMS for the expanded service area, I will abide by the requirements contained in this Application and provide the services outlined in my application.
- 4) I agree that CMS may inspect any and all information necessary including inspecting of the premises of the Part D Sponsor's organization or plan to ensure compliance with stated Federal requirements including specific provisions for which I have attested. I further agree to immediately notify CMS if despite these attestations I become aware of circumstances which preclude full compliance by January 1, 2007 with the requirement stated here in this application as well as in Part 423 of 42 CFR of the regulation.
- 5) 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.
- 6) I further certify that I am an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for qualification to enter into a Part D contract with CMS.
- 7) I acknowledge, that for the Part D program requirements described in this solicitation where CMS has issued operational policy guidance that provides more detailed instructions to Part D sponsors, that they are also representing to CMS that they have reviewed the associated guidance materials posted on the CMS web site and will comply with such guidance should they be approved for a SAE to their existing contract.

Authorized Representative Name (printed)

Title

Authorized Representative Signature

Date (MM/DD/YYYY)

4. Appendices

Appendix I

Notice of Intent for Service Area Expansion

Complete this form to indicate your intent to expand your service area beyond your contracted 2006 service area.

Applicant Organization's Legal Entity Name:

Applicant Organization's Corporate Address (*Street, City, State, Zip – No Post Office Boxes*):

Type of Medicare Prescription Drug Benefit Contract Request (check all that apply):
 PDP MA-PD cost plan EPOG direct Medical Savings Account

Indicate whether your organization intends to offer a Special Needs Plan proposal (check all that apply):
 Institutional Dual Eligible Chronic Care

PROVIDE THE INFORMATION BELOW REGARDING YOUR PHARMACY BENEFITS			
Pharmacy Benefit Management Organization's Full Name. <i>Note: If Applicant contracts with multiple Pharmacy Benefit Management Organizations, be sure to list all:</i>			
PROVIDE THE INFORMATION BELOW FOR THE PERSON WHO WILL ACT AS THE MAIN CONTACT			
Name of Individual:		Title:	
Address of Individual: (<i>Street, City, State, Zip – No Post Office Boxes</i>):			
Direct Telephone Number:		Fax Number:	
Email Address:			
PROVIDE THE INFORMATION BELOW FOR THE PERSON WHO WILL ACT AS A BACKUP FOR THE MAIN CONTACT			
Name of Individual:		Title:	
Address of Individual: (<i>Street, City, State, Zip – No Post Office Boxes</i>):			
Direct Telephone Number:		Fax Number:	
Email Address:			
COMPLETE THIS SECTION FOR ALL PDP AND MA-PD REQUESTS. IDENTIFY THE REGION(S) and CONTRACT NUMBERS ASSOCIATED FOR EACH AREA PART D SPONSOR INTENDS TO EXPAND SERVICE FOR PART D:			
<i>Note: MA & PDP region number information may be found at the following website:</i>			
www.cms.hhs.gov/medicarereform/mmregions/pdpmaosum.asp			
If Part D Sponsor is a PDP, identify PDP regions to be served using region numbers. Also include name of territories if included:	Identify corresponding contract number for the service area expansion	If Part D Sponsor is a MA-PD offering regional PPO, identify MA regions to be served using region numbers:	Identify corresponding contract number for the service area expansion
Ex. Region 3	Sxxxx	Ex. Region 3	Ex. Hxxxx
If MA-PD Sponsor offering local plan(s.) identify state, county, and zip code. Include name of territories if any:			
PDP AND MA-PD SPONSORS ONLY SHOULD PROVIDE THE INFORMATION BELOW ON LICENSURE			
Are you licensed (or is your application pending at the state) to be a risk-bearing entity in any state in which you propose to expand Part D drug benefits? <input type="checkbox"/> Yes <input type="checkbox"/> No			

If yes, please complete the table below. Add additional rows as necessary.					
List State(s) in which you Already Possess or Have Applied for License	Status of License		Dates of License		
	<i>Indicate the status using an "x" to mark the appropriate column</i>		<i>Complete either Effective and Expiration Dates or Application Submission Date</i>		
	Licensed	License Application Submitted	Effective Date	Expiration Date	Submission Date

PDP AND MA-PD SPONSORS ONLY SHOULD PROVIDE THE INFORMATION BELOW ON STATE LICENSURE REQUIREMENT WAIVERS. ADD ADDITIONAL ROWS AS NECESSARY.					
List the State(s) for Which a Licensure Requirement Waiver has Been or will be Requested	Status of License Requirement Waiver				
	<i>Use the key below to indicate your response.</i> X = Waiver application is to be submitted. A = Waiver application submitted and approved. Provide date approved. P = Waiver application submitted and pending. Provide date submitted. D = Waiver application denied. Provide date denied.				
	Status		Date		

Note: This Notice of Intent for Service Area Expansion must be emailed to drugbenefitimpl@cms.hhs.gov by 5:00 p.m. EST on January 17, 2006. Be sure to indicate "NOI SERVICE AREA EXPANSION" in the subject line.

APPENDIX II

Application to Request Federal Waiver of State Licensure Requirement for Prescription Drug Plan (PDP)

A. COMPLETE THE TABLE BELOW **Contract#** _____

IDENTIFY THE CORPORATION SEEKING WAIVER OF STATE LICENSURE REQUIREMENT FOR PDP PLAN	
Full Legal Corporate Name:	D.B.A:
Full Address of Corporation: <i>(Street, City, State, Zip – No Post Office Boxes)</i> :	
Corporation Telephone Number:	Corporation Fax Number:
PROVIDE THE CORPORATION'S CONTACT INFORMATION FOR THE PERSON WHO WILL ACT AS THE MAIN CONTACT	
Name of Individual:	Title:
Address of Individual: <i>(Street, City, State, Zip – No Post Office Boxes)</i> :	
Direct Telephone Number:	Fax Number:
Email Address:	

B. REQUEST

I, on behalf of the legal entity identified in Section A, above, hereby request that the Secretary of the Department of Health and Human Services, pursuant to the authority granted under Section 1855(a) (2) and Section 1860D-12(c) of the Social Security Act, grant a waiver of the requirement that our organization be licensed under (Name of State or for Regional Plan Waiver, States) _____ State laws as a risk-bearing entity eligible to sponsor prescription drug benefits coverage.

D. CERTIFICATION

The undersigned officer has read this completed request for federal waiver form and does hereby declare that the facts, representations, and statements made in this form together with any attached information are true and complete to the best of my knowledge, information, and belief. The information herein declared by me represents matters about which I am competent, qualified, and authorized to represent the corporation. If any events, including the passage of time, should occur that materially change any of the answers to this request for federal waiver, the corporation agrees to notify the Centers for Medicare & Medicaid services immediately.

Corporate Name: _____
 By: _____
 Print Name: _____
 Title: _____
 Witness/Attest: _____

E. SUBMITTING FORM

If submitting separately from Part D, send 3 copies of this waiver request form to the below address. Applicants must send no sooner than January 17, 2006 and no later than March 20, 2006.

Centers for Medicare & Medicaid Services (CMS)
 Center for Beneficiary Choices
 Attention: Part D Service Area Expansion Application
 7500 Security Boulevard
 Mail Stop C1-26-12/Location C1-26-12
 Baltimore, Maryland 21244-1850

F. INSTRUCTIONS FOR COMPLETING COVER SHEET OF LICENSURE WAIVER APPLICATION

Section A

Contract # _____

- Enter the corporate name
- Enter the name under which your PDP will do business (D.B.A)
- Enter the street address, telephone number and facsimile number of the Corporation at its corporate headquarters
- Enter the name, title, telephone number, fax number, and email address of the main contact person

Section B

- Indicate the State for which you are requesting a waiver or the States for which you are requesting a Regional Plan Waiver.

Section C

- Have a duly appointed corporate officer sign this form in the presence of a witness

If you have any questions regarding this form please contact:

Joseph Millstone
410-786-2976

INSTRUCTIONS FOLLOW

(THIS SECTION FOR OFFICIAL USE ONLY)

Supporting Documentation for Request of Federal Waiver of State Licensure Requirement for Prescription Drug Plan (PDP) Sponsors

I. BACKGROUND AND PURPOSE

This waiver request form is for use by Applicants who wish to enter into a contract with the Centers for Medicare and Medicaid Services (CMS) to become Prescription Drug Plan (PDP) sponsors and provide prescription drug plan benefits to eligible Medicare beneficiaries without a State risk-bearing entity license.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) generally requires Applicants who wish to become PDP sponsors to be licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which the Applicant wishes to offer a PDP. However, the MMA created several exceptions to this State licensure requirement. These exceptions are similar to those applying to Provider Sponsored Organizations under the Balanced Budget Act of 1997.

In general, there are 2 types of waivers – both of which are more fully explained in Section II below. The waivers are: (1) Single State waivers. For these waivers, the Applicant should submit a separate waiver request for each State, and the waiver is effective only with respect to the single State. For applications submitted for plan years 2006 and 2007, special waivers are available as discussed more fully in Section II below. (2) Regional plan waivers. These waivers may be obtained if an Applicant is licensed in one State in a region and wishes to receive a waiver for all the other States in the region in which it is not licensed. In this case, the entity need only submit one waiver request – not one for each and every State in which it is not licensed. Waiver requests should be submitted to CMS using the criteria described in the remainder of this paper.

Approval of a waiver request, in no way suggests that the Applicant is approved for a Medicare contract with CMS. Following approval of a waiver request, the Applicant will be required to submit a Medicare contract application that demonstrates that the Applicant can meet the Federal definition of a PDP sponsor and that the prescription drug plan being offered will meet all plan requirements for PDPs.

Applicants who receive a waiver from State licensure must also comply with CMS standards for financial solvency and capital adequacy if they wish to receive a PDP contract.

II. WAIVER ELIGIBILITY

The following constitute the waivers available to Applicants. These are the sole grounds for receiving waivers.

A. SINGLE STATE WAIVER

The Applicant is requesting a single state waiver for the following state: _____. Please indicate the grounds upon which you are requesting a waiver (check all applicable areas).

1. The State has failed to complete action on a licensing application within 90 days of the date of the State's receipt of a substantially complete application. 42 CFR 423.410(b) (1).
2. The State does not have a licensing process in effect with respect to PDP sponsors. 42 CFR 423.410(c).

3. For applications for plan years 2006 and 2007 only, the Applicant has submitted a substantially complete licensure application to each State for which it requests a waiver. 42 CFR 423.410(d).
4. The State has denied the license application on the basis of one of the following: (a) material requirements, procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or (b) the State requires, as a condition of licensure, the Applicant to offer any product or plan other than a PDP. 42 CFR 423.410(b)(2).
5. The State has denied the licensure application, in whole or in part, for one of the following reasons: (a) on the basis of the Applicant's failure to meet solvency requirements that are different from the solvency standards developed by CMS; or (b) the State has imposed, as a condition of licensing, any documentation or information requirements relating to solvency that are different from the information or documentation requirements in the solvency standards developed by CMS. 42 CFR 423.410(b)(3).
6. The State has denied the licensure application on the basis of grounds other than those required under Federal law. 42 CFR 423.410(b)(4).

B. REGIONAL PLAN WAIVERS

The Applicant is State-licensed in the State(s) of _____ and is applying for a regional plan waiver in the following region(s): _____ as provided under 42 CFR 423.415(a). The Applicant must demonstrate that it submitted a substantially complete licensure application in each State in the region for which it does not already have State licensure, except that no such application is necessary if CMS determines that the State does not have a licensing process for potential PDP sponsors.

III. WAIVER DURATION

A. SINGLE STATE WAIVER

The Single State waiver listed in II.A is effective for up to 36 months only and cannot be renewed unless CMS determines that the State in question does not have a licensing process in effect with respect to PDP sponsors. Thus, by the end of the three-year waiver period the PDP sponsor must be State-licensed if it wishes to continue as a PDP sponsor, unless CMS determines that the State in question has chosen not to create a licensing process for PDP sponsors – in which case the waiver can continue until CMS determines that a licensure process has been created. The special waivers for 2006 and 2007 will not be available for Applications submitted for 2008 and thereafter. Single State waivers automatically terminate if the PDP sponsor obtains State licensure.

B. REGIONAL PLAN WAIVERS

The Regional Plan waivers expire at the end of the time period the Secretary determines is appropriate for timely processing of the licensure application, but in no case will a waiver extend beyond the end of the calendar year. For both Single State and Regional Plan waivers, the waiver will terminate if the contract with Medicare terminates.

IV. INFORMATION TO BE INCLUDED IN THIS REQUEST

While the applicant should provide information concerning each of the following areas, the specific information and documentation requested below are not necessarily all inclusive for CMS to approve or deny the request. Applicants should provide any information and all documentation necessary to substantiate their request.

- a) Provide a written summary of the PDP entity or, if a line of business, a description of the entire organization. Also include information about management structure and the health care provider or group of affiliated health care providers that control the PDP. Discuss legal history, predecessor corporations, recent mergers or re-organizations, recent change-of-ownerships; any State licenses held, any previous or current contractual involvement with the Medicare program either directly with CMS or by contract with an HMO.
- b) Provide a narrative of the circumstances leading to the PDP's eligibility for a waiver based on one of the grounds listed in section II. Include information about the State risk-bearing entity license for which the PDP applied, the application process that the PDP followed, and any relevant interaction with the State.
- c) Provide documentation to substantiate the narrative required in (b). Depending on the grounds for waiver eligibility, this documentation should include but is not necessarily limited to the list below. For Regional Plan Waivers, group response to numbers 1-6, as they apply, by state:

1. Evidence of State's failure to act on a licensure application on a timely basis

Copy of the dated cover sheet to the application submitted to the State, State confirmation of the receipt and completeness of the application, State requests for additional information, and all pertinent correspondence with the State relating to the status of the application, etc.

2. Evidence that Applicant submitted licensure application to the State (special 2006/2007 waiver)

Copy of cover letter to appropriate State authority that accompanied Applicant's licensure application and proof of delivery.

3. Evidence of denial of the application based on discriminatory treatment

Copy of denial letter from the State, copy of "discriminatory" material requirements (including, State laws and regulation), procedures or standards to which the PDP was required to comply that are not generally applicable to other entities engaged in a substantially similar business, a copy of State licensure requirements that the PDP offer a particular product or plan in addition to a Medicare Advantage plan, and any supplemental material received from the State explaining their rationale for the denial, etc.

PDPs seeking a waiver on the grounds that they are subject to requirements, procedures and standards not applicable to entities engaged in a "substantially similar business" must demonstrate through submission of these and other appropriate materials:

- a) The types of entities subject to the different requirements, procedures and standards are engaged in a "substantially similar business".

b) The State requirements, procedures and standards imposed on the PDP entity are not applicable to other “substantially similar business” entities.

4. Evidence of denial of the application based on solvency requirements

Copy of denial letter from the State, copy of State solvency requirements, demonstration of the difference between State solvency requirements, procedures and standards and Federal PDP solvency requirements, procedures and standards, any other State information regarding documentation, information, and other material requirements, procedures or standards relating to solvency, or any correspondence detailing the reason the application was denied, etc.

5. Evidence of State licensure standards other than those required by Federal law

Memo identifying the State licensure standards by reference to relevant State law, regulation, or policy guidance and describing the how those standards differ from those required by Federal law.

6. Regional Plan Waiver

Evidence of licensure in one State within a regional plan and evidence that a substantially complete application has been submitted to the other States in the region – unless CMS determines that there is no PDP licensing process in effect in a State.

- d) Provide the name, address and telephone number of all State regulatory officials involved in the State application and/or denial proceedings.
- e) Provide any other information that you believe supports your request for a waiver under Section II.

V. OVERVIEW OF WAIVER REQUEST PROCESS

For single-state waivers, section 1860D-12(c) and section 1855(a)(2) of the Act requires the Secretary to grant or deny this waiver request within 60 days after the date the Secretary determines that a substantially complete application has been filed. Upon receipt of a waiver request, CMS will review it to determine whether it contains sufficient information to approve or deny the request. The 60-day review period begins at the time CMS determines that the applications is substantially complete. For those applications deemed incomplete, CMS will work with the applicant to identify the remaining information necessary to either approve or deny the request.

APPENDIX III
Financial Solvency Documentation
For Applicant Not Licensed as a Risk-bearing Entity in Any State

I. DOCUMENTATION

A. Net Worth - Minimum Net Worth: \$1.5 million

1. Documentation of Minimum Net Worth

At the time of application, the potential PDP Sponsor not licensed in any state must show evidence of the required minimum net worth. The PDP Sponsor must demonstrate this through an independently audited financial statement if it has been in operation at least twelve months.

If the organization has not been in operation at least twelve months it may choose to 1) obtain an independently audited financial statement for a shorter time period; or 2) demonstrate that it has the minimum net worth through presentation of an unaudited financial statement that contains sufficient detail that CMS may verify the validity of the financial presentation. The unaudited financial statement must be accompanied by an actuarial opinion by a qualified actuary regarding the assumptions and methods used in determining loss reserves, actuarial liabilities and related items.

A qualified actuary for the purposes of this application means a member in good standing of the American Academy of Actuaries or a person recognized by the Academy as qualified for membership, or a person who has otherwise demonstrated competency in the field of actuarial determination and is satisfactory to CMS.

B. Financial Plan

1. Plan Content and Coverage

At the time of application, the PDP Sponsor must submit a business plan (with supporting financial projections and assumptions, satisfactory to CMS), covering the first twelve months of operation under the Medicare contract and meeting the requirements stated below. If the plan projects losses, the business plan must cover the period for twelve months past the date of projected break-even.

The business plan must include a financial plan with:

- a. A detailed marketing plan;
- b. Statements of revenue and expense on an accrual basis;
- c. A cash flow statement;
- d. Balance sheets;
- e. The assumptions in support of the financial plan;
- f. If applicable, availability of financial resources to meet projected losses; (if no projected losses this does not preclude applicant from calculating projected losses as prescribed by CMS in 2. b. below)and
- g. Independent actuarial certification of business plan assumptions and plan feasibility by a qualified actuary.

2. Funding for Projected Losses

(a) Allowable sources of funding:

In the financial plan, the PDP Sponsor must demonstrate that it has the resources available to meet the projected losses for time-period to breakeven. Except for the use of guarantees as provided in section (a) below, letters of credit as provided in section (b) below, and other means as provided in section (c) below, the resources must be assets on the balance sheet of the PDP Sponsor in a form that is either cash or is convertible to cash in a timely manner (i.e. cash or cash equivalents), pursuant to the financial plan.

(i) Guarantees will be acceptable as a resource to meet projected losses under the conditions detailed in Section III, Guarantees.

(ii) An irrevocable, clean, unconditional, evergreen letter of credit may be used in place of cash or cash equivalents if prior approval is obtained from CMS. It must be issued or confirmed by a qualified United States financial institution as defined in Section II.B, Insolvency, below. The letter of credit shall contain an issue date and expiration date and shall stipulate that the beneficiary need only draw a sight draft under the letter of credit and present it to obtain funds and that no other document need be presented.

“Beneficiary” means the PDP sponsor for whose benefit the credit has been established and any successor of the PDP sponsor by operation of law. If a court of law appoints a successor in interest to the named beneficiary, then the named beneficiary includes the court appointed bankruptcy trustee or receiver. The letter of credit also shall indicate that it is not subject to any condition or qualifications any other agreement, documents or entities.

CMS must be notified in writing thirty days prior to the expiration without renewal or the reduction of a proposed or existing letter of credit or replacement of a letter of credit by one for a reduced amount.

Prior written approval of CMS should be secured by the PDP sponsor of any form of proposed letter of credit arrangements before it is concluded for purposes of funding for projected losses.

(iii) If approved by CMS, based on appropriate standards promulgated by CMS, a PDP sponsor may use the following to fund projected fund losses for periods after the first year: lines of credit from regulated financial institutions, legally binding agreements for capital contributions, or other legally binding contracts of a similar level of reliability.

NOTE: A plan needs to maintain its \$1.5 million in net worth to meet the net worth standard (Section A, above) and may not use any portion of the \$1.5 million in net worth to fund the projected losses. Net worth in excess of \$1.5 million, which is funded through the forms allowable for meeting projected losses (i.e., cash, or cash equivalents,..) may be counted in the projected losses funding however the minimum \$750,000 liquidity requirement (Section C, below) must still be met and may not be used to meet the projected losses.

(b) Calculation of projected losses:

An applicant that has had state licensure waived must demonstrate that in order to cover projected losses, the applicant possesses allowable sources of funding sufficient to cover the greater of:

- (i) 7.5 percent of the aggregated projected target amount for a given year (aggregated projected target amount is calculated by estimating the average monthly per capita cost of benefits (excluding administrative costs) and multiplying that amount by member months for a 12 month period), or
- (ii) Resources to cover 100% of any projected losses, if the business plan projects losses greater than 7.5% of the aggregated projected target amount.

The applicant must include with the application, a worksheet calculating the aggregated projected target amount as defined above.

C. Liquidity

The PDP Sponsor must have sufficient cash flow to meet its financial obligations as they become due. The amount of minimum net worth requirement to be met by cash or cash equivalents is \$750,000. Cash equivalents are short term highly liquid investments that can be readily converted to cash. To be classified as cash equivalents these investments must have a maturity date not longer than 3 months from the date of purchase. In determining the ability of a PDP Sponsor to meet this requirement, CMS will consider the following:

- (a) The timeliness of payment,
- (b) The extent to which the current ratio is maintained at 1:1 or greater, or whether there is a change in the current ratio over a period of time, and
- (c) The availability of outside financial resources.

CMS may apply the following corresponding corrective action remedies:

- (a) If the PDP Sponsor fails to pay obligations as they become due, CMS will require the PDP Sponsor to initiate corrective action to pay all overdue obligations.

- (b) CMS may require the PDP Sponsor to initiate corrective action if any of the following are evident:
 - (1) the current ratio declines significantly; or
 - (2) a continued downward trend in the current ratio. The corrective action may include a change in the distribution of assets, a reduction of liabilities or alternative arrangements to secure additional funding to restore the current ratio to at least 1:1.
- (c) If there is a change in the availability of the outside resources, CMS will require the PDP Sponsor to obtain funding from alternative financial resources.

D. Methods of Accounting

The PDP Sponsor may use the standards of Generally Accepted Accounting Principles (GAAP) or it may use the standards of Statutory Accounting Principles (SAP) applicable to the type of organization it would have been licensed as at the state level if a waiver were not granted by CMS. Whether GAAP or SAP is utilized however, there are certain additional differences cited below for waived PDP Sponsors.

Generally Accepted Accounting Principles (GAAP) are those accounting principles or practices prescribed or permitted by the Financial Accounting Standards Board. Statutory Accounting Principles are those accounting principles or practices prescribed or permitted by the domiciliary State insurance department in the State that the PDP Sponsor operates.

Waivered organizations should note that the maximum period of waiver is limited by Federal regulation. At such time as the waiver expires, the PDP Sponsor would have to obtain a risk bearing license.

Waivered PDP Sponsors should adjust their balance sheets as follows:

1. Calculation-Assets

The following asset classes will not be admitted as assets:

- Good will
- Acquisition costs
- Other similar intangible assets

2. Calculation- Liabilities

Net worth means the excess of total admitted assets over total liabilities, but the liabilities shall not include fully subordinated debt.

Subordinated debt means an obligation that is owed by an organization, that the creditor of the obligation, by law, agreement, or otherwise, has a lower repayment rank in the hierarchy of creditors than another creditor. The creditor would be entitled to repayment only after all higher ranking creditor's claims have been satisfied. A debt is fully subordinated if it has a lower repayment rank than all other classes of creditors and is payable out of net worth in excess of that required under Section IA, Net Worth and under Section IC, Liquidity above.

In order to be considered fully subordinated debt for the purpose of calculating net worth, the subordinated debt obligation must be a written instrument and include:

- a) The effective date, amount, interest and parties involved.
- b) The principal sum and/or any interest accrued thereon that are subject to and subordinate to all other liabilities of the PDP sponsor, and upon dissolution or liquidation, no payment of any kind shall be made until all other liabilities of the PDP sponsor have been paid.
- c) The instrument states that the parties agree that the PDP sponsor must obtain written approval from CMS prior to the payment of interest or repayment of principal.

E. Financial Indicators and Reporting

The PDP Sponsor must file a Health Blank Form (in the same format as utilized by the National Association of Insurance Commissioners) to CMS. The portion of the Health Blank Form submitted to CMS will be limited to the following pages:

- Jurat Page
- Assets
- Liabilities, Capital and Surplus
- Statement of Revenue and Expenses
- Capital and Surplus Account
- Cash Flow
- Actuarial Opinion (the actuarial opinion is required only of annual report filings). In addition, the PDP Sponsor shall submit an annual independently audited financial statement with management letter.

Note: Future frequency of reporting will be both quarterly (first, second, and third quarters only) and annually to CMS. CMS may choose to initiate monthly reporting from certain PDP Sponsors who because of their financial status CMS deems may require additional monitoring.

Reporting shall be on the following schedule:

Quarterly reporting PDP sponsors shall report within 45 days of the close of a calendar quarter ending on the last day of March, June and September. No separate quarterly report shall be required for the final quarter of the year.

Annually reporting and quarterly reporting PDP sponsors shall report annually within 120 days of the close of the calendar year i.e. by April 30th or within 10 days of the receipt of the annual audited financial statement, whichever is earlier.

Financial reporting may be the under the principles of General Accepted Accounting Principles (GAAP) or under Statutory Accounting Principles (SAP) applicable to similar

organizations of similar type within the state where the organization is based. However, if an organization chooses to report under GAAP, it may not report under GAAP for a period longer than 36 months unless a state has chosen to not license such organizations.

II. INSOLVENCY

A. Hold Harmless and Continuation of Coverage/Benefits

PDP Sponsors shall be subject to the same hold harmless and continuation of coverage/benefit requirements as other Medicare Advantage contractors.

B. Insolvency Deposit \$100,000 held in accordance with CMS requirements by a qualified U. S. Financial Institution. A qualified financial institution means an institution that:

1. Is organized or (in the case of a U. S. office of a foreign banking organization) licensed, under the laws of the United States or any state thereof; and
2. Is regulated, supervised and examined by U. S. Federal or State authorities having regulatory authority over banks and trust companies.

III. GUARANTEES

A. General policy.

A PDP Sponsor, or the legal entity of which the PDP Sponsor is a Component, may apply to CMS to use the financial resources of a Guarantor for the purpose of meeting the requirements of a PDP Sponsor. CMS has the discretion to approve or deny approval of the use of a Guarantor.

B. Request to use a Guarantor.

To apply to use the financial resources of a Guarantor, a PDP Sponsor must submit to CMS:

1. Documentation that the Guarantor meets the requirements for a Guarantor under paragraph (C) of this section; and
2. The Guarantor's independently audited financial statements for the current year-to-date and for the two most recent fiscal years. The financial statements must include the Guarantor's balance sheets, profit and loss statements, and cash flow statements.

C. Requirements for Guarantor.

To serve as a Guarantor, an organization must meet the following requirements:

1. Be a legal entity authorized to conduct business within a State of the United States.
2. Not be under Federal or State bankruptcy or rehabilitation proceedings.
3. Have an adjusted net worth (not including other guarantees, intangibles and restricted reserves) equal to three times the amount of the PDP Sponsor guarantee.
4. If a State insurance commissioner regulates the Guarantor, or other State official with authority for risk-bearing entities, it must meet the adjusted net worth requirement in this document with all guarantees

and all investments in and loans to organizations covered by guarantees excluded from its assets.

5. If the Guarantor is not regulated by a State insurance commissioner, or other similar State official it must meet the adjusted net worth requirement in this document with all guarantees and all investments in and loans to organizations covered by a guarantee and to related parties (subsidiaries and affiliates) excluded from its assets and determination of adjusted net worth.

D. Guarantee document.

If the guarantee request is approved, a PDP Sponsor must submit to CMS a written guarantee document signed by an appropriate Guarantor. The guarantee document must:

1. State the financial obligation covered by the guarantee;
2. Agree to:
 - a. Unconditionally fulfill the financial obligation covered by the guarantee; and
 - b. Not subordinate the guarantee to any other claim on the resources of the Guarantor;
3. Declare that the Guarantor must act on a timely basis, in any case not more than 5 business days, to satisfy the financial obligation covered by the guarantee; and
4. Meet other conditions as CMS may establish from time to time.

E. Reporting requirement.

A PDP Sponsor must submit to CMS the current internal financial statements and annual audited financial statements of the Guarantor according to the schedule, manner, and form that CMS requests.

F. Modification, substitution, and termination of a guarantee.

A PDP Sponsor cannot modify, substitute or terminate a guarantee unless the PDP Sponsor:

1. Requests CMS's approval at least 90 days before the proposed effective date of the modification, substitution, or termination;
2. Demonstrates to CMS's satisfaction that the modification, substitution, or termination will not result in insolvency of the PDP Sponsor; and
3. Demonstrates how the PDP Sponsor will meet the requirements of this section.

G. Nullification.

If at any time the Guarantor or the guarantee ceases to meet the requirements of this section, CMS will notify the PDP Sponsor that it ceases to recognize the guarantee document. In the event of this nullification, a PDP Sponsor must:

1. Meet the applicable requirements of this section within 15 business days; and

2. If required by CMS, meet a portion of the applicable requirements in less than the time period granted in paragraph (G.1.) of this section.

