

CENTERS FOR MEDICARE AND MEDICAID SERVICES

Requirements for and Contracts with Prescription Drug Plan (PDP) Sponsors:

Federal Solvency Standards for PDP Sponsors who Meet Standards for Waiver of State Licensure

Background

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, commonly referred to as the Medicare Modernization Act (MMA) created the opportunity for several new types of entities to contract with the Centers for Medicare and Medicaid Services (CMS) for services under Title XVIII of the Social Security Act (Medicare). Most of the new types of entities continued the past practice of the current Medicare + Choice program in the requirement for State licensure as a risk bearing entity in the jurisdictions where the entity proposes to serve Medicare beneficiaries.

Title I of the MMA created requirements for a new type of organization called Prescription Drug Plans. The base requirement for Contracts with Prescription Drug Plan (PDP) Sponsors also requires State licensure as a risk bearing entity in the jurisdictions where the entity proposes to serve Medicare beneficiaries. However, the MMA also created the opportunity for the organization to apply for a waiver of state licensure under certain criteria very similar to that of Provider Sponsored Organizations created under the Balance Budget Act of 1997.

Proposed Federal regulations to implement Title I, Subpart I were published by the Office of the Federal Register on August 3, 2004. Statutory authority resides in the MMA itself in Section 1860D-12(c) Waiver of Certain Requirements to Expand Choice, which provides that:

(1) Authorizing Waiver

(A) In General-In the case of an entity that seeks to offer a prescription drug plan in a State, the Secretary shall waive the requirement of subsection (a)(1) that the entity be licensed in that State if the Secretary determines, based on the application and other evidence presented to the Secretary, that any of the grounds for approval of the application described in paragraph (2) have been met.

Paragraph (2) of the MMA references certain grounds for approval of waivers including:

- The State has failed to complete action on a licensing application of the organization within 90 days of the date of the State's receipt of a substantially complete application. 42CFR423.410(b)(1)
- The standards or review process imposed by the State as a condition of approval of the license imposes any material requirements, procedures, or standards (other than solvency requirements) to such organizations that are not generally applicable to other entities engaged in a substantially similar business. 42CFR423.410(b)(2)
- The State has denied the licensure application, in whole or in part, on the basis of the PDP Sponsor's failure to meet solvency requirements that are different from the solvency standards developed by CMS. 42CFR423.410(b)(3)
- The State has applied grounds other than those required under Federal law. 42CFR423.410(b)(4)

We would further accept as a basis for waiver of the State licensure requirement, notice that the appropriate State licensing authority has notified the PDP Sponsor in writing that it will decline to accept their licensure application and/or there is no State requirement to review the application.

Requirement for CMS Consultation with the NAIC

The MMA also states that CMS must consult with NAIC on the financial solvency and capital adequacy standards.

In Section 1860D-12(d) Solvency Standards for Non-Licensed Entities—

(1) ESTABLISHMENT AND PUBLICATION-The Secretary, in consultation with the National Association of Insurance Commissioners, shall establish and publish, not later than January 1, 2005, financial solvency and capital adequacy standards for entities described in paragraph (2).

(2) COMPLIANCE WITH STANDARDS-A PDP Sponsor that is not licensed by a State under subsection (a)(1) and for which a waiver application has been approved shall meet solvency and capital adequacy standards established under paragraph (1). The Secretary shall establish certification procedures for such Sponsors with respect to such solvency standards in the manner described in 1855(c)(2).

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I. INITIAL APPLICATION AND ONGOING OPERATIONS

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

1. Documentation of Minimum Net Worth

At the time of application, the PDP Sponsor 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 (which has received a waiver under 42CFR423.410) 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; and,
- (F) If applicable, availability of financial resources to meet projected losses.

(G) Independent actuarial certification of business plan assumptions and plan feasibility by a qualified actuary

2. Funding for Projected Losses:

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. current assets), pursuant to the financial plan.

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

(b) 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 outside the letter of credit. In addition, the letter of credit itself shall not contain reference to 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.

(c) 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.

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 those that meet the definition of current assets that can be converted to cash in one year or less.

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 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 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 come into compliance with applicable state law.

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 I.A. Net Worth and under Section I.C Liquidity above.

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.

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.

PDP sponsors should note the correlation between the expiration of the CMS granted waiver of state licensure; the expiration of their Medicare contract; and the date of mandatory SAP method of accounting as follows:

Waivers granted anytime in 2006 shall expire with the CMS contract period ending 12/31/2008. Reporting under SAP must begin no later than the period beginning January 1, 2009.

Waivers granted anytime in 2007 shall expire with the CMS contract period ending 12/31/2009. Reporting under SAP must begin no later than the period beginning January 1, 2010.

Waivers granted anytime in 2008 shall expire with the CMS contract period ending 12/31/2010. Reporting under SAP must begin no later than the period beginning January 1, 2011.

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. WAIVER REQUEST AND APPROVAL PROCESS

A. The organization must submit a substantially complete waiver request that clearly demonstrates its eligibility for a waiver under 42CFR423.410.

B. The organization will be notified in writing within 60 days of having submitted to CMS a substantially complete waiver request whether the waiver request has been granted or denied.

C. An organization that has had a waiver request denied, may submit subsequent waiver requests. Waiver requests submitted after an initial waiver denial must contain substantial changes from the previously submitted and denied application. CMS will indicate in any waiver denial decision the reasons for the denial. Subsequent waiver requests may be deemed non-responsive and rejected if they do not respond to previous CMS denial reasons in a substantive manner.

IV. 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.