



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Centers for Medicare &amp; Medicaid Services

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500 Security Boulevard  
Baltimore, Maryland 21244

Date: October 6, 2005

To: Medicare Prescription Drug Plan Sponsor

From: Cynthia Tudor, Acting Director, Medicare Drug Benefit Group

Subject: Approval of Medicare Prescription Drug Plan Contract

The Centers for Medicare & Medicaid Services (CMS) is pleased to inform you that your organization meets the eligibility requirements for a Medicare Part D Prescription Drug Plan contract. CMS has based this finding on a review of your application submitted in response to the Solicitation for Applications from Prescription Drug Plans (PDPs), January 21, 2005 (as Revised on March 9, 2005), as well as your bid proposal and other materials submitted to document your qualification to operate a PDP.

CMS has approved your organization for a contract effective from the date of the signature of the CMS official's signature through December 31, 2006, and renewable for successive one-year periods. The contract, along with the Medicare Part D regulations and CMS policy guidance, articulates the responsibilities of your organization and CMS under this program. Please note that your contract with CMS consists only of the terms stated in the contract CMS provided to you and the bid certification as you downloaded it from HPMS. CMS does not consider any statements made in a cover letter that you may have submitted with your Medicare contract to be part of the agreement between CMS and your organization.

We have enclosed an executed copy of the PDP contract. Please review all of the information carefully and notify Scott Nelson at 410-786-1038 or [Scott.Nelson2@cms.hhs.gov](mailto:Scott.Nelson2@cms.hhs.gov) if you find any discrepancies or have any questions.

CMS will continue to provide Part D program information (including information about your CMS Central Office and Regional Office contacts) to PDP sponsors through the Health Plan Management System (HPMS) and the CMS web site. As a result, we remind you to make certain that your organization's contact information in HPMS remains accurate.

Congratulations on your Medicare Part D contract, and we look forward to working with you on making affordable prescription drugs available to Medicare beneficiaries.

**Contract with Approved Entity Pursuant to Sections 1860D-1 through 1860D-42 of  
the Social Security Act for the Operation of a Voluntary Medicare Prescription  
Drug Plan**

Between

Centers for Medicare & Medicaid Services (hereinafter referred to as "CMS")

And

Sierra Health and Life Insurance Company, Inc.(S5917)  
(a Prescription Drug Plan Sponsor, hereinafter referred to as the "PDP Sponsor")

CMS and the PDP Sponsor, an entity that has been determined eligible to operate a Voluntary Medicare Prescription Drug Plan by the Administrator of CMS under 423 CFR §423.503, agree to the following for the purposes of sections 1860D-1 through 1860D-42 (with the exception of sections 1860D-22(a) and 1860D-31) of the Social Security Act (hereinafter referred to as "the Act.")

**Article I**  
**Medicare Voluntary Prescription Drug Benefit**

- A. PDP Sponsor agrees to operate one or more Medicare Voluntary Prescription Drug Plans (hereinafter referred to as a "PDP"), as described in its application and related materials, including but not limited to all the attestations contained therein and all supplemental guidance, for Medicare approval and in compliance with the provisions of this contract, which incorporates in its entirety the Solicitation For Applications from Prescription Drug Plans released on January 21, 2005(as revised on March 9, 2005) (hereinafter collectively referred to as "the contract"). The PDP Sponsor also agrees to operate in accordance with the regulations at 42 CFR §423.1 through 42 CFR §423.910 (with the exception of Subparts Q, R, and S), sections 1860D-1 through 1860D-42 (with the exception of sections 1860D-22(a) and 1860D-31) of the Social Security Act, and the solicitation, as well as all other applicable Federal statutes, regulations, and policies. This contract is deemed to incorporate any changes that are required by statute to be implemented during the term of this contract and any regulations or policies implementing or interpreting such statutory provisions.
- B. CMS agrees to perform its obligations to the PDP Sponsor consistent with the regulations at 42 CFR §423.1 through 42 CFR §423.910 (with the exception of Subparts Q, R and S), sections 1860D-1 through 1860D-42 of the Social Security Act (with the exception of sections 1860D-22(a) and 1860D-31) and the solicitation, as well as all other applicable Federal statutes, regulations, and policies.
- C. CMS agrees that it will not implement, other than at the beginning of a calendar year, regulations under 42 CFR Part 423 that impose new, significant regulatory requirements on the PDP Sponsor. This provision does not apply to new requirements mandated by statute.
- D. This contract is in no way intended to supersede or modify 42 CFR, Part 423. Failure to reference a regulatory requirement in this contract does not affect the applicability of such requirements to the PDP Sponsor and CMS.

**Article II**  
**Functions to be Performed by the PDP Sponsor**

- A. ENROLLMENT
  - 1. PDP Sponsor agrees to accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments, as described in 42 CFR, Part 423, Subpart B.
  - 2. PDP Sponsor agrees to comply with the prohibition in 42 CFR 423.104(b) on discrimination in beneficiary enrollment.

## B. PRESCRIPTION DRUG BENEFIT

1. PDP Sponsor agrees to provide the basic prescription drug coverage as defined under 42 CFR §423.100 and, to the extent applicable, supplemental benefits as defined in 42 CFR §423.100 and in accordance with Subpart C of 42 CFR Part 423. PDP Sponsor also agrees to provide Part D benefits as described in the PDP Sponsor's bid(s) approved each year by CMS (as referenced in Attachment A, to be replaced each year upon renewal of the contract to reflect the Sponsor's approved bids for the succeeding contract year).
2. PDP Sponsor agrees to calculate and collect beneficiary premiums in accordance with 42 CFR §§423.286 and 423.293.

## C. DISSEMINATION OF PLAN INFORMATION

1. PDP Sponsor agrees to provide the information required in 42 CFR §423.48.
2. PDP Sponsor agrees to disclose information to beneficiaries in the manner and the form specified by CMS under 42 CFR §§423.128, 423.50 and in the "Marketing Materials Guidelines for Medicare Advantage-Prescription Drug Plans (MA-PDs) and Prescription Drug Plans (PDPs)," and to comply with requirements in 42 CFR §423.50 requiring certain approvals of marketing materials prior to distribution.
3. PDP Sponsor certifies that all materials it submits to CMS under the File and Use Certification authority described in the Marketing Materials Guidelines are accurate, truthful, not misleading, and consistent with CMS marketing guidelines.

## D. QUALITY ASSURANCE/UTILIZATION MANAGEMENT

PDP Sponsor agrees to operate quality assurance, drug utilization management, and medication therapy management programs, and to support electronic prescribing in accordance with Subpart D of 42 CFR Part 423.

## E. APPEALS AND GRIEVANCES

PDP Sponsor agrees to comply with all requirements in Subpart M of 42 CFR Part 423 governing coverage determinations, grievances and appeals, and formulary exceptions.

## F. PAYMENT TO PDP SPONSOR

1. PDP Sponsor and CMS agree that payment under this contract will be governed by the rules in Subpart G of 42 CFR Part 423.

2. If the PDP Sponsor is participating in the Part D Reinsurance Payment Demonstration, described in 70 FR 9360 (Feb. 25, 2005) it affirms that it will not seek payment under the demonstration for services provided to employer group enrollees.
3. PDP Sponsor agrees that it is bound by all applicable federal laws and regulations, guidance, and authorities pertaining to claims and debt collections. In the event that the government determines that the PDP Sponsor has been overpaid, the PDP Sponsor agrees to return those overpaid monies back to the federal government.

#### G. BID SUBMISSION AND REVIEW

If the PDP Sponsor intends to participate in the Part D program for the next program year, PDP Sponsor agrees to submit the next year's bid, including all required information on premiums, benefits, and cost-sharing, by the applicable due date, as provided in Subpart F of 42 CFR Part 423 so that CMS and the Part D plan sponsor may conduct negotiations regarding the terms and conditions of the proposed bid and benefit plan renewal.

#### H. STATE LAW AND LICENSURE REQUIREMENTS

1. PDP Sponsor agrees to comply with State law to the extent that it is not preempted by Federal law as described in Subpart I of 42 CFR Part 423.
2. PDP Sponsor agrees that where it is operating in a State using a waiver granted pursuant to 42 CFR §423.410, such waiver shall be valid for three consecutive program years. PDP Sponsor agrees that expiration of the licensure waiver (and the failure to obtain a license from the relevant State) may be the basis for CMS deleting from the PDP Sponsor's service area those PDP Regions affected by the waiver expiration. CMS may terminate or non-renew the PDP Sponsor's contract where the expiration of the waiver results in the PDP Sponsor not being qualified to offer a PDP plan in any PDP Region.
3. PDP Sponsor agrees that where it is operating in a State using a waiver granted pursuant to 42 CFR §423.415, such waiver shall be valid for the period that the Secretary of the Department of Health and Human Services determines is appropriate for timely processing of the PDP Sponsor's license application by the State, but in no case no more than one year only, beginning on January 1 of the contract year for which CMS granted the waiver.

#### I. COORDINATION WITH OTHER PRESCRIPTION DRUG COVERAGE

1. PDP Sponsor agrees to comply with the coordination requirements with State Pharmacy Assistance Programs (SPAPs) and plans that provide other prescription drug coverage as described in Subpart J of 42 CFR Part 423.

2. PDP Sponsor agrees to comply with Medicare Secondary Payer procedures as stated in 42 CFR §423.462.

#### J. SERVICE AREA AND PHARMACY ACCESS

1. The PDP Sponsor agrees to provide Part D benefits in the service area for which it has been approved by CMS utilizing a pharmacy network and formulary approved by CMS that meet the requirements of 42 CFR §423.120.
2. The PDP Sponsor agrees to provide Part D benefits through out-of-network pharmacies according to 42 CFR §423.124.
3. PDP Sponsor agrees to provide benefits by means of point of service systems to adjudicate prescription drug claims in a timely and efficient manner in compliance with CMS standards, except when necessary to provide access in underserved areas, I/T/U pharmacies (as defined in 42 CFR §423.100), and long-term care pharmacies (as defined in 42 CFR §423.100).
4. PDP Sponsor agrees to contract with any pharmacy that meets the PDP Sponsor's reasonable and relevant standard terms and conditions.

#### K. COMPLIANCE PLAN/PROGRAM INTEGRITY

1. PDP Sponsor agrees that it will develop and implement a compliance plan that applies to its Part D-related operations, consistent with 42 CFR §423.504(b)(4)(vi).
2. The PDP sponsor agrees to provide notice based on best knowledge, information, and belief to CMS of any integrity items related to payments from governmental entities, both federal and state, for healthcare or prescription drug services that would have been reported as part of 3.1.4 of the PDP application. These items include any investigations, legal actions or matters subject to arbitration brought involving the sponsor (or sponsor's firm if applicable) and its subcontractors (excluding contracted network providers), including any key management or executive staff, or any major shareholders (5% or more), by a government agency (state or federal) on matters relating to payments from governmental entities, both federal and state, for healthcare and/or prescription drug services. In providing the notice, the sponsor shall keep the government informed of when the integrity item is initiated and when it is closed. Notice should be provided of the details concerning any resolution and monetary payments as well as any settlement agreements or corporate integrity agreements.
3. The PDP Sponsor agrees to provide notice based on best knowledge, information, and belief to CMS in the event the Sponsor or any of its subcontractors is criminally convicted or has a civil judgment entered against it for fraudulent activities or is sanctioned under any Federal program involving the provision of

health care or prescription drug services.

L. LOW-INCOME SUBSIDY

PDP Sponsor agrees that it will participate in the administration of subsidies for low-income individuals according to Subpart P of 42 CFR Part 423.

M. COMMUNICATION WITH CMS

PDP Sponsor agrees that it shall maintain the capacity to communicate with CMS electronically in accordance with CMS requirements.

N. BENEFICIARY FINANCIAL PROTECTIONS

The PDP Sponsor agrees to afford its enrollees protection from liability for payment of fees that are the obligation of the PDP Sponsor in accordance with 42 CFR §423.505(g).

O. RELATIONSHIP WITH RELATED ENTITIES, CONTRACTORS, AND SUBCONTRACTORS

1. The PDP Sponsor agrees it maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of this contract with CMS.
2. The PDP Sponsor shall ensure that any contracts or agreements with subcontractors or agents performing functions on the PDP Sponsor's behalf related to the operation of the Part D benefit are in compliance with 42 CFR §423.505(i).
3. The PDP Sponsor agrees to act in accordance with 45 CFR Part 76 and agrees that it will not contract with or employ entities or individuals that are excluded by the Department of Health and Human Services, Office of the Inspector General or included on the Excluded Parties List System maintained by the General Services Administration.

P. CERTIFICATION OF DATA THAT DETERMINE PAYMENT

PDP Sponsor must provide certifications in accordance with 42 CFR §423.505(k).

Q. ENROLLMENT RELATED COSTS

PDP Sponsor agrees to payment of fees established by CMS for cost sharing of enrollment related costs in accordance with 42 CFR §423.6.

### **Article III**

#### **Record Retention and Reporting Requirements**

##### **A. RECORD MAINTENANCE AND ACCESS**

PDP Sponsor agrees to maintain records and provide access in accordance with 42 CFR §§423.504(d), and 423.505(d) and (e).

##### **B. GENERAL REPORTING REQUIREMENTS**

The PDP Sponsor agrees to submit information to CMS according to 42 CFR §§423.505(f), 423.514, and the "Final Medicare Part D Reporting Requirements," a document issued by CMS and subject to modification each program year.

##### **C. LICENSURE-RELATED REPORTING REQUIREMENTS**

1. If the PDP Sponsor is operating under a CMS-granted licensure waiver in any State, the PDP Sponsor agrees to notify CMS in writing of the State's disposition of the Sponsor's license application within ten business days of the date that it receives notice of the State's action.
2. For those States where the PDP Sponsor is operating under a risk-bearing license, the Sponsor agrees to provide written notice to CMS of the State's non-renewal of the Sponsor's license within ten days of receiving notice of the State's action.
3. In the event that a State regulator imposes a sanction against the PDP Sponsor or requires the implementation of a corrective action plan, the Sponsor agrees to provide written notice to CMS of such sanction or corrective action requirement (including basis for the sanction and/or timeline for corrective action) within ten days of receiving notice of the State's action.
4. In the event that there is a change in the status of the PDP Sponsor's risk-bearing license in any State (e.g., suspension, revocation), the Sponsor agrees to provide written notice to CMS of the change in status (including basis for the change in status and effective date) within ten days of receiving notice of the State's action.
5. If the PDP Sponsor is operating a Part D benefit under a CMS-granted waiver in every State in its service area, and the Sponsor is terminating or reducing the amount of an existing letter of credit obtained for the purposes of funding projected losses, the Sponsor shall provide written notice to CMS of such action 30 days prior to its effective date. The PDP Sponsor agrees that it must obtain CMS approval prior to terminating or reducing the amount of a letter of credit obtained for the purposes of funding projected losses under Appendix X of the PDP Solicitation.

##### **D. CMS License For Use of Plan Formulary**

PDP Sponsor agrees to submit to CMS each plan's formulary information, including any changes to its formularies, and hereby grants to the Government<sup>^</sup> and any person or entity who might receive the formulary from the Government,]



a non-exclusive license to use all or any portion of the formulary for any purpose related to the administration of the Part D program, including without limitation publicly distributing, displaying, publishing or reconfiguration of the information in any medium, including www.medicare.gov, and by any electronic, print or other means of distribution.

#### **Article IV HIPAA Provisions**

##### **HIPAA TRANSACTIONS/PRIVACY/SECURITY**

- A. PDP Sponsor agrees to comply with the confidentiality and enrollee record accuracy requirements specified in 42 CFR §423.136.
- B. PDP Sponsor agrees to enter into a business associate agreement with the entity with which CMS has contracted to track Medicare beneficiaries' true out-of-pocket costs.

#### **Article V Requirements of Other Laws and Regulations**

The PDP Sponsor agrees to comply with (a) applicable Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. §§3729 et seq.), and the anti-kickback provision of section 1128B of the Act; (b) applicable HIPAA Administrative Simplification Security and Privacy rules at 45 CFR parts 160, 162, and 164; and (c) all other applicable Federal statutes and regulations.

#### **Article VI Contract Term and Renewal**

##### **A. TERM OF CONTRACT**

This contract is effective from the date of CMS' authorized representative's signature through December 31, 2006. This contract shall be renewable for successive one-year periods thereafter according to 42 CFR §423.506. PDP Sponsor shall not conduct Part D-related marketing activities prior to October 1, 2005 and shall not process enrollment applications prior to November 15, 2005. PDP Sponsor shall begin delivering prescription drug benefit services on January 1, 2006.

##### **B. QUALIFICATION TO RENEW A CONTRACT**

- 1. In accordance with 42 CFR §423.507, the PDP Sponsor will be determined

- qualified to renew its contract annually only if—
- (a) CMS informs the PDP Sponsor that it is qualified to renew its contract; and
  - (b) The PDP Sponsor has not provided CMS with a notice of intention not to renew in accordance with Article VII of this contract.
2. Although PDP Sponsor may be determined qualified to renew its contract under this Article, if the PDP Sponsor and CMS cannot reach agreement on the bid under Subpart F of 42 CFR Part 423, no renewal takes place, and the failure to reach agreement is not subject to the appeals provisions in Subpart N of 42 CFR Part 423.

## **Article VII**

### **Nonrenewal of Contract**

#### **A. NONRENEWAL BY THE PDP SPONSOR**

- 1. The PDP Sponsor may elect not to renew its contract with CMS, effective at the end of the term of the contract for any reason as long as PDP Sponsor provides proper notice of the decision according to the required timeframes.
- 2. If the PDP Sponsor does not intend to renew its contract, it must notify -
  - (a) CMS in writing by the first Monday of June in the year in which the current contract period ends;
  - (b) Each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective. This notice must include a written description of alternatives available for obtaining qualified prescription drug coverage within the PDP region, including Medicare Advantage-Prescription Drug plans, Medicare cost plans offering a Part D plan, and other PDPs, and must receive CMS approval prior to issuance; and
  - (c) The general public, at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.
- 3. If the PDP Sponsor does not renew a contract CMS cannot enter into a contract with the organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS.
- 4. If the PDP Sponsor does not renew a contract, it must ensure the timely transfer of any data or files in accordance with CMS instructions.

#### **B. NONRENEWAL BY CMS**

- 1. CMS may determine that the PDP Sponsor is not qualified to renew its contract for any of the following reasons:
  - (a) The reasons listed in 42 CFR §423.509(a) that also permit CMS to terminate the contract.
  - (b) The PDP Sponsor has committed any of the acts in 42 CFR §423.752 that

support the imposition of intermediate sanctions or civil money penalties under 42 CFR §423.750.

2. CMS will provide notice of its decision whether the PDP Sponsor is qualified to renew its contract as follows:
  - (i) To the PDP Sponsor by May 1 of the current contract year,
  - (ii) If CMS decides that the PDP Sponsor is not qualified to renew its contract, to the PDP Sponsor's Medicare enrollees by mail at least 90 days before the end of the current calendar year,
  - (iii) If CMS determines that the PDP Sponsor is not qualified to renew its contract, to the general public at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the PDP Sponsor's service area,
  - (iv) CMS will provide the notice described in (B)(2)(ii) and (iii) of this Article where a non-renewal results because CMS and the PDP Sponsor are unable to reach agreement on the bid under 42 CFR Part 423, Subpart F. CMS shall give the PDP Sponsor written notice of its right to appeal the decision that the sponsor is not qualified to renew its contract in accordance with 42 CFR §423.642(b).

## **Article VIII**

### **Modification or Termination of Contract**

#### **A. CONTRACT MODIFICATION OR TERMINATION BY MUTUAL CONSENT**

1. This contract may be modified or terminated at any time by written mutual consent of the parties.
2. If this contract is terminated by mutual consent, the PDP Sponsor must provide notice to its Medicare enrollees and the general public in accordance with CMS's instructions.
3. If the contract is modified by mutual consent, the PDP Sponsor must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification according to the process and timeframes specified by CMS.
4. If a contract is terminated under section A of this Article, the PDP Sponsor must ensure the timely transfer of any data or files.

#### **B. TERMINATION OF CONTRACT BY CMS**

CMS may terminate the contract in accordance with 42 CFR §423.509.

#### **C. TERMINATION OF CONTRACT BY THE PDP SPONSOR**

The PDP Sponsor may terminate the contract only in accordance with 42 CFR §423.510.

**Article IX**  
**Intermediate Sanctions**

Consistent with Subpart O of 42 CFR Part 423, the PDP Sponsor shall be subject to sanctions and civil money penalties.

**Article X**  
**Severability**

Severability of the contract shall be in accordance with 42 CFR 423.504(e).

**Article XI**  
**Miscellaneous**

**A. DEFINITIONS**

Terms not otherwise defined in this contract shall have the meaning given to such terms in 42 CFR Part 423.

**B. ALTERATION TO ORIGINAL CONTRACT TERMS**

The PDP Sponsor agrees that it has not altered in any way the terms of the PDP contract presented for signature by CMS. PDP Sponsor agrees that any alterations to the original text the PDP Sponsor may make to this contract shall not be binding on the parties.

**C. ADDITIONAL CONTRACT TERMS**

The PDP Sponsor agrees to include in this contract other terms and conditions in accordance with 42 CFR §423.505(j).

**D. CMS APPROVAL TO BEGIN MARKETING AND ENROLLMENT ACTIVITIES**

PDP Sponsor agrees that it must complete CMS operational requirements prior to receiving CMS approval to begin Part D marketing and enrollment activities. Such activities include, but are not limited to, establishing and successfully testing connectivity with CMS systems to process enrollment applications (or contracting with an entity qualified to perform such functions on PDP Sponsor's behalf) and successfully demonstrating capability to submit accurate and timely price comparison data. To establish and successfully test connectivity, the PDP Sponsor must, 1) establish and test physical connectivity to the CMS data center, 2) acquire user identifications and passwords, 3) receive, store, and maintain data necessary to

perform enrollments and send and receive transactions to and from CMS,  
and 4) check and receive transaction status information.

In witness whereof, the parties hereby execute this contract.

**FOR THE PDP SPONSOR**

Jonathon W. Bunker  
Printed Name

President  
Title

/S/ Jonathon W. Bunker

September 7, 2005  
Date

Sierra Health and Life Insurance Company, Inc. (S5917)  
Organization

2720 North Tenaya Way  
Las Vegas, Nevada 89128  
Address

**FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES**

/S/ Robert Donnelly

Robert Donnelly  
Director  
Medicare Drug Benefit Group  
Center for Beneficiary Choices

Date