

**CONTRACT WITH APPROVED EMPLOYER/UNION ENTITY PURSUANT TO  
SECTIONS 1860D-1 THROUGH 1860D-42 OF THE SOCIAL SECURITY ACT FOR  
THE OPERATION OF A VOLUNTARY MEDICARE PRESCRIPTION DRUG PLAN**

CONTRACT (<<CONTRACT\_ID>>)

Between

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

And

<<CONTRACT\_NAME>>

(a Prescription Drug Plan Sponsor, hereinafter referred to as “PDP Sponsor”)

CMS and PDP Sponsor, an entity that has been determined eligible to operate a Voluntary Medicare Prescription Drug Plan offered exclusively to PDP Sponsor’s Part D eligible individuals enrolled in its employment-based retiree health coverage (as defined at 42 CFR §423.882) by the Administrator of CMS under 42 CFR §423.503, agree to the following for the purposes of §§1860D-1 through 1860D-43 (with the exception of §§1860D-22(a) and 1860D-31) of the Social Security Act (hereinafter referred to as “the Act”).

**Article I**  
**Voluntary Medicare Prescription Drug Plan**

- A. In accordance with the waivers granted by CMS under section 1860D-22(b) of the Act, PDP Sponsor agrees to operate one or more Medicare Voluntary Prescription Drug Plans offered exclusively to Part D eligible individuals enrolled in its employment-based retiree prescription drug coverage (hereinafter referred to as “PDPs”), as described in its application and related materials submitted to CMS for Medicare approval, including but not limited to all the attestations contained therein and all supplemental guidance, and in compliance with the provisions of this contract, which incorporates in its entirety the *Solicitation for Applications for Medicare Prescription Drug Plan 2014 Contracts*, released on January 10, 2013 (hereinafter collectively referred to as “the contract”).
- B. PDP Sponsor agrees to operate in accordance with the regulations at 42 CFR Part 423 (with the exception of Subparts Q, R, and S), §§1860D-1 through 1860D-43 (with the exception of §§1860D-22(a) and 1860D-31) of the Act, and the solicitation, as well as all other applicable Federal statutes, regulations, and policies, and any employer/union-only group waiver guidance issued by CMS, including, but not limited to, those requirements set forth in Chapter 12 of the Prescription Drug Benefit Manual (hereinafter referred to as “employer/union group waiver guidance”). 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 or regulatory provisions.
- C. CMS agrees to perform its obligations to PDP Sponsor consistent with the regulations at 42 CFR Part 423 (with the exception of Subparts Q, R and S), §§1860D-1 through 1860D-43 of the Act (with the exception of §§1860D-22(a) and 1860D-31) and the solicitation, as well as all other applicable Federal statutes, regulations, and policies, including any employer/union group waiver guidance.
- D. 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 PDP Sponsor. This provision does not apply to new requirements mandated by statute.
- E. If PDP Sponsor had a contract with CMS for Contract Year 2013 under the contract ID number designated above, this document is considered a renewal of the existing contract. While the terms of this document supersede the terms of the 2013 contract, the parties’ execution of this contract does not extinguish or interrupt any pending obligations or actions that may have arisen under the 2013 or prior year contracts.
- F. This contract is in no way intended to supersede or modify 42 CFR Part 423, except as to any requirements set forth in 42 CFR Part 423 that are specifically waived or modified for PDP sponsors offering PDPs exclusively to Part D eligible individuals enrolled in employment-based retiree prescription drug coverage as provided in applicable employer/union group waiver guidance and/or in this contract. Failure to reference a regulatory requirement in this contract does not affect the applicability of such requirements to PDP Sponsor and CMS.

- G. In the event of any conflict between the employer/union group waiver guidance issued prior to the execution of the contract, the provisions of this contract shall control. In the event of any conflict between the employer/union group waiver guidance issued after the execution of the contract, the provisions of the employer/union group waiver guidance shall control.

## **Article II**

### **Functions to be Performed by 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 restrict enrollment in its PDPs to those Part D eligible individuals eligible for its employer's/union's employment-based retiree prescription drug coverage. PDP Sponsor agrees not to enroll active employees in its PDPs.
3. CMS agrees that PDP Sponsor is not subject to the requirement in 42 CFR §423.104(b) that requires PDP Sponsor to offer its plans to all Part D eligible beneficiaries residing in PDP Sponsor's service area.
4. PDP Sponsor will not be subject to the minimum enrollment requirements set forth in 42 CFR §423.512(a).
5. If PDP Sponsor elects to enroll Part D eligible individuals eligible for its PDPs through a group enrollment process, PDP Sponsor will not be subject to the individual enrollment requirements set forth in 42 CFR §423.32(b). PDP Sponsor agrees that it will comply with all of the requirements for group enrollment contained in CMS guidance, including those requirements contained in Chapter 3 of the Prescription Drug Benefit Manual.

#### **B. PRESCRIPTION DRUG BENEFIT**

1. Except as provided in this subsection, PDP Sponsor agrees to provide basic prescription drug coverage, as defined under 42 CFR §423.100, under any PDP, in accordance with Subpart C of 42 CFR Part 423.
  - (a) CMS agrees that PDP Sponsor will not be subject to the actuarial equivalence requirement set forth in 42 CFR §423.104(e)(5) with respect to any PDP and may provide less than the defined standard coverage between the deductible and initial coverage limit. PDP Sponsor agrees that its basic prescription drug coverage under any PDP will satisfy all of the other actuarial equivalence standards set forth in 42 CFR §423.104, including but not limited to the requirement set forth in 42 CFR §423.104(e)(3) that the plan has a total or gross value that is at least equal to the total or gross value of defined standard coverage.

- (b) CMS agrees that nothing in this Addendum prevents PDP Sponsor from offering prescription drug benefits in addition to basic prescription drug coverage. Such additional benefits will be considered non-Medicare Part D benefits (“non-Medicare Part D benefits”). PDP Sponsor agrees that such additional benefits may not reduce the value of basic prescription drug coverage (e.g., additional benefits cannot impose a cap that would preclude enrollees from realizing the full value of such basic prescription drug coverage).
  - (c) PDP Sponsor agrees that any additional non-Medicare Part D benefits will always pay primary to the subsidies provided by CMS to low-income subsidy eligible individuals under Subpart P of 42 CFR Part 423 (the “Low-Income Subsidy”).
- 2. Except as provided in this subsection and subsection 3 of this section, PDP Sponsor agrees to calculate and collect beneficiary premiums in accordance with 42 CFR §§423.286 and 423.293.
  - (a) PDP Sponsor agrees that enrollees of its PDPs shall not be charged more than the sum of his or her monthly beneficiary premium attributable to basic prescription drug coverage and 100% of the monthly beneficiary premium attributable to his or her non-Medicare Part D benefits (if any). PDP Sponsor must pass through the direct subsidy payments received from CMS to reduce the amount that the beneficiary pays (or, in those instances where the subscriber to or participant in the employer plan pays premiums on behalf of a Medicare eligible spouse or dependent, the amount the subscriber or participant pays).
  - (b) PDP Sponsor agrees enrollees of its PDPs will not be permitted to make payment of premiums under 42 CFR §423.293(a) through withholding from the enrollee’s Social Security, Railroad Retirement Board, or Office of Personnel Management benefit payment.
- 3. PDP Sponsor agrees it may determine how much of an enrollee’s Part D monthly beneficiary premium it will subsidize, subject to the restrictions set forth in this subsection.
  - (a) PDP Sponsor can subsidize different amounts for different classes of enrollees in the PDP provided such classes are reasonable and based on objective business criteria, such as years of service, date of retirement, business location, job category, and nature of compensation (e.g., salaried v. hourly). Different classes cannot be based on eligibility for the Low Income Subsidy.
  - (b) PDP Sponsor cannot vary the premium subsidy for individuals within a given class of enrollees.
  - (c) PDP Sponsor cannot charge an enrollee for prescription drug coverage provided under the plan more than the sum of his or her monthly beneficiary premium

- attributable to basic prescription drug coverage and 100% of the monthly beneficiary premium attributable to his or her non-Medicare Part D benefits (if any). PDP Sponsor must pass through direct subsidy payments received from CMS to reduce the amount that the enrollee pays (or, in those instances where the subscriber to or participant in the employer plan pays premiums on behalf of a Medicare eligible spouse or dependent, the amount the subscriber or participant pays).
- (d) For all enrollees eligible for the Low Income Subsidy, the low income premium subsidy amount will first be used to reduce any portion of the monthly beneficiary premium paid by the enrollee (or in those instances where the subscriber to or participant in the employer plan pays premiums on behalf of a low-income eligible spouse or dependent, the amount the subscriber or participant pays), with any remaining portion of the premium subsidy amount then applied toward the portion of any monthly beneficiary premium paid by the employer/union. However, if the sum of the enrollee's monthly premium (or the subscriber's/participant's monthly premium, if applicable) and PDP Sponsor's monthly premium contribution (i.e., total monthly premium) are less than the monthly low-income premium subsidy amount, any portion of the low-income subsidy premium amount above the total monthly premium must be returned directly to CMS. Similarly, if there is no monthly premium charged the beneficiary (or subscriber/participant, if applicable) or premium contribution made by PDP Sponsor, the entire low-income premium subsidy amount must be returned directly to CMS and cannot be retained by PDP Sponsor or the beneficiary (or the subscriber/participant, if applicable).
  - (e) If the low income premium subsidy amount for which an enrollee is eligible is less than the portion of the monthly beneficiary premium paid by the enrollee (or subscriber/participant, if applicable), then PDP Sponsor should communicate to the enrollee (or subscriber/participant) the financial consequences of the low-income subsidy eligible individual enrolling in the PDP as compared to enrolling in another Part D plan with a monthly beneficiary premium equal to or below the low income premium subsidy amount.
4. For non-calendar year employer group only PDPs, PDP Sponsor may determine benefits (including deductibles, out-of-pocket limits, etc.) on a non-calendar year basis subject to the following requirements:
- (a) Applications, formularies and other submissions to CMS must be submitted on a calendar year basis;
  - (b) The prescription drug coverage under the PDP must be at least actuarially equivalent to defined standard coverage for the portion of its plan year that falls in a given calendar year. A PDP will meet this standard if its prescription drug coverage is at least actuarially equivalent for the calendar year in which the plan year starts and no design change is made for the remainder of the plan year. In no event can PDP Sponsor increase during the plan year the annual out-of-pocket threshold;

- (c) After an enrollee's incurred costs exceed the annual out-of-pocket threshold, PDP Sponsor must provide prescription drug coverage that is at least actuarially equivalent to that provided under standard prescription drug coverage; eligibility for such coverage can be determined on a plan year basis.
- 5. PDP Sponsor agrees to maintain administrative and management capabilities sufficient for the organization to organize, implement, and control the financial, marketing, benefit administration, and quality assurance activities related to the delivery of Part D services as required by 42 CFR §423.505(b)(25).
- 6. PDP Sponsor agrees to provide applicable beneficiaries applicable discounts on applicable drugs in accordance with the requirements of 42 CFR Part 423 Subpart W.

#### C. DISSEMINATION OF PLAN INFORMATION

- 1. CMS agrees that PDP Sponsor will not be subject to the information requirements set forth in 42 CFR §423.48 and the prior review and approval of dissemination materials and enrollment forms requirements set forth in 42 CFR 423, Subpart V. Except as provided in subsection 2 of this section., PDP Sponsor will be subject to all other dissemination requirements contained in 42 CFR §423.128 and in CMS guidance, including those requirements contained in Chapter 12 of the Prescription Drug Benefit Manual.
- 2. CMS agrees that the dissemination requirements set forth in 42 CFR §423.128 will not apply with respect to PDP Sponsor when PDP Sponsor is subject to alternative disclosure requirements (e.g., the Employee Retirement Income Security Act of 1974 ("ERISA")), and fully complies with such alternative requirements. PDP Sponsor agrees to comply with the requirements for this waiver contained in employer/union group waiver guidance, including those requirements contained in Chapter 12 of the Prescription Drug Benefit Manual.
- 3. PDP Sponsor certifies that all of its dissemination materials are accurate, truthful, not misleading, and consistent with CMS employer/union group waiver guidelines.
- 4. CMS agrees that with respect to any PDPs, PDP Sponsor will not be subject to the Part D beneficiary customer service call center hour and performance requirements. PDP Sponsor agrees to operate beneficiary customer service call center hours for any PDPs that ensure a sufficient mechanism is available to respond to beneficiary inquiries and provide customer service call center services to these members during normal business hours. However, PDP Sponsor agrees that CMS may review the adequacy of these call center hours and potentially require expanded beneficiary customer service call center hours in the event of beneficiary complaints or for other reasons in order to ensure that the customer service call center hours are sufficient to meet the needs of its enrollee population.

#### D. QUALITY ASSURANCE/UTILIZATION MANAGEMENT

1. 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.
2. PDP sponsor agrees to address complaints received by CMS against the Part D sponsor as required in 42 CFR §423.505(b)(22) by:
  - (a) Addressing and resolving complaints in the CMS complaint tracking system; and
  - (b) Displaying a link to the electronic complaint form on the Medicare.gov Internet Web site on the Part D plan's main Web page.

#### 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 and the relevant provisions of Subpart U governing reopenings.

#### F. PAYMENT TO PDP SPONSOR

1. Except as provided in this subsection, PDP Sponsor and CMS agree that payment under this contract will be governed by the rules in Subpart G of 42 CFR Part 423.
  - (a) PDP Sponsor is not required to submit a Part D bid and will receive a monthly direct subsidy for each PDP enrollee equal to the amount of the national average monthly bid amount, adjusted for health status (as determined under 42 CFR §423.329(b)(1)) and reduced by the base beneficiary premium, as adjusted under 42 CFR §423.286(d)(3), if applicable. The further adjustments to the base beneficiary premium contained in 42 CFR §423.286(d)(1) and (2) will not apply.
  - (b) PDP Sponsor agrees that the risk-sharing payment adjustment described in 42 CFR §423.336 is not applicable for any PDP enrollee.
  - (c) PDP Sponsor will not receive monthly reinsurance payment or low-income cost-sharing subsidy amounts in the manner set forth in 42 CFR §423.329(c)(2)(i) and 42 CFR §423.329(d)(2)(i) for any PDP enrollee but instead will receive the full reinsurance and low-income cost-sharing subsidy payments following the end of year reconciliation as described in 42 CFR §423.329(c)(2)(ii) and 42 CFR §423.329(d)(2)(ii) respectively.
  - (d) For non-calendar year plans:
    - (i) CMS payments will be determined on a calendar year basis;

- (ii) Low income subsidy payments and reconciliations will be determined based on the calendar year for which the payments are made; and
  - (iii) PDP Sponsor acknowledges that it will not receive reinsurance payments under 42 CFR §423.329(c).
- 2. 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 PDP Sponsor has been overpaid, PDP Sponsor agrees to return those overpaid monies back to the federal government.

#### G. STATE LAW AND LICENSURE REQUIREMENTS

- 1. CMS agrees that PDP Sponsor will not be subject to the state licensure requirements set forth in 42 CFR §423.401(a)(1) and 42 CFR §423.504(b)(2).
- 2. PDP Sponsor agrees to meet the financial solvency requirements set forth in 42 CFR §423.420(a) and as in the *2013 Solicitation For Applications For New Employer/Union Direct Contract Prescription Drug Plans (PDP) Sponsors*, released on January 4, 2012 and the bonding and insurance requirements set forth in 42 CFR §423.504(b)(4)(iv) and (v) unless CMS notified PDP Sponsor in writing prior to the execution of this contract that any particular requirements were waived and/or modified.
- 3. 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.

#### H. 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.

#### I. SERVICE AREA AND PHARMACY ACCESS

- 1. CMS agrees that PDP Sponsor has a national service area.
- 2. 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, with the following exception: CMS agrees that the retail pharmacy access requirements set forth in 42 CFR §423.120(a)(1) will not apply when the PDP's pharmacy network is sufficient to meet the needs of its enrollees throughout PDP's service area, as determined by CMS. CMS may periodically review the adequacy of the PDP's pharmacy network and require PDP Sponsor to expand access



if CMS determines that such expansion is necessary in order to ensure that the PDP's network is sufficient to meet the needs of its enrollees.

3. PDP Sponsor agrees to provide Part D benefits through out-of-network pharmacies according to 42 CFR §423.124.
4. 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) according to 42 CFR §423.505(b)(17).
5. PDP Sponsor agrees to contract with any pharmacy that meets PDP Sponsor's reasonable and relevant standard terms and conditions according to 42 CFR §423.505(b)(18).

#### J. EFFECTIVE COMPLIANCE PROGRAM/PROGRAM INTEGRITY

1. PDP Sponsor agrees that it will develop and implement an effective compliance program that applies to its Part D-related operations, consistent with 42 CFR §423.504(b)(4)(vi).
2. 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 Table A. of the Business Integrity section 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. PDP Sponsor agrees to provide notice based on best knowledge, information, and belief to CMS in the event PDP 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.
4. PDP Sponsor agrees to provide organizational conflict of interest reports to CMS, pursuant to CMS instructions and consultations.

#### L. LOW-INCOME SUBSIDY

PDP Sponsor agrees that it will participate in the administration of subsidies for low-income subsidy eligible individuals according to Subpart P of 42 CFR Part 423, except as waived or

modified by employer/union group waiver guidance and II.B.1(c) and II.B.3 of this contract.

#### 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

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

#### O. RELATIONSHIP WITH FIRST TIER, DOWNSTREAM, AND RELATED ENTITIES

1. PDP Sponsor agrees that it maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of this contract with CMS.
2. PDP Sponsor shall ensure that any contracts or agreements with first tier, downstream, and related entities performing functions on PDP Sponsor's behalf related to the operation of the Part D benefit are in compliance with 42 CFR §423.505(i).
3. PDP Sponsor agrees to act in accordance with 45 CFR Part 79 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.

#### R. ADMINISTRATIVE AND MANAGEMENT ARRANGEMENTS REQUIREMENTS

CMS agrees that the administrative and management arrangements requirements set forth in 42 CFR §423.504(b)(4)(i)-(iii) will not apply when PDP Sponsor is subject to other statutory standards governing its management and operations, such as ERISA fiduciary requirements, state law standards, or oversight standards created under the Sarbanes-Oxley Act, and PDP Sponsor fully complies with such alternative requirements.

#### S. PDP SPONSOR REIMBURSEMENT TO PHARMACIES

1. If a PDP Sponsor uses a standard for reimbursement of pharmacies based on the cost of a

drug, PDP Sponsor will update such standard not less frequently than once every 7 days, beginning with an initial update on January 1 of each year, to accurately reflect the market price of the drug.

2. PDP Sponsor will issue, mail, or otherwise transmit payment with respect to all claims submitted by pharmacies (other than pharmacies that dispense drugs by mail order only, or are located in, or contract with, a long-term care facility) within 14 days of receipt of an electronically submitted claim or within 30 days of receipt of a claim submitted otherwise.
3. PDP Sponsor must ensure that a pharmacy located in, or having a contract with, a long-term care facility will have not less than 30 days (but not more than 90 days) to submit claims to PDP Sponsor for reimbursement.

### **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 §§ 423.505(b)(10) and 423.505(i)(2).

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

1. PDP Sponsor agrees to submit information to CMS according to 42 CFR §§423.505(f) and 423.514, the “Final Medicare Part D Reporting Requirements,” a document issued by CMS and subject to modification each program year and any employer/union group waiver guidance.
2. Notwithstanding the foregoing, CMS agrees:
  - (a) PDP Sponsor will not be subject to the general public reporting requirements contained in 42 CFR §423.514(a) to the extent such information is required to be reported to enrollees and to the general public under other federal law (including ERISA or securities laws) or by a separate contractual agreement and PDP Sponsor fully complies with such requirements; and
  - (b) PDP Sponsor will not be subject to a specific reporting requirement related to financial solvency, bonding or insurance if PDP Sponsor was notified in writing by CMS during the application review and approval process that a specific reporting requirement was waived and/or modified for PDP Sponsor.

#### **C. 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, 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**

- 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**

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 §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, 2014. This contract shall be renewable for successive one-year periods thereafter according to 42 CFR §423.506.

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

- 1. In accordance with 42 CFR §423.507, PDP Sponsor will be determined qualified to renew its contract annually only if:
  - (a) PDP Sponsor has not provided CMS with a notice of intention not to renew in accordance with Article VII of this contract, and
  - (b) CMS has not provided PDP Sponsor with a notice of intention not to renew.
- 2. Although PDP Sponsor may be determined qualified to renew its contract under this Article, if 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 PDP SPONSOR**

1. 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. PDP Sponsor does not intend to renew its contract, it must notify CMS in writing by the first Monday of June in the year in which the current contract period ends.
3. If PDP Sponsor does not renew a contract CMS cannot enter into a contract with PDP Sponsor or with an organization whose covered persons, as defined in 42 CFR §423.507(a)(4), also served as covered persons for the nonrenewing sponsor for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS.
4. If PDP Sponsor does not renew this 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 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) 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 shall give PDP Sponsor written notice of its right to appeal the decision that the sponsor is not qualified 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, PDP Sponsor must provide notice to its Medicare enrollees in accordance with CMS's instructions.
3. As set forth in 42 CFR §423.508, if the contract is modified by mutual consent, 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 this section, 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 PDP SPONSOR**

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, 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**

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 that PDP Sponsor may make to this contract shall not be binding on the parties.

#### **C. ADDITIONAL CONTRACT TERMS**

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 ENROLLMENT ACTIVITIES**

PDP Sponsor agrees that it must complete CMS operational requirements prior to receiving CMS approval to begin Part D 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). To establish and successfully test connectivity, 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.

- E. Pursuant to §13112 of the American Recovery and Reinvestment Act of 2009 (ARRA), PDP Sponsor agrees that as it implements, acquires, or upgrades its health information technology systems, it shall utilize, where available, health information technology systems and products that meet standards and implementation specifications adopted under §3004 of the Public Health Service Act, as amended by §13101 of the ARRA.
- F. PDP sponsor agrees to maintain a fiscally sound operation by at least maintaining a positive net worth (total assets exceed total liabilities) as required in 42 CFR §423.505(b)(23).

In witness whereof, the parties hereby execute this contract.

This document has been electronically signed by:

FOR PDP SPONSOR

<<CONTRACTING\_OFFICIAL\_NAME >>

Contracting Official Name

<<DATE\_STAMP>>

Date

<<CONTRACT\_NAME>>

Organization

<<ADDRESS>>

Address

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

<<CYNTHIA\_TUDOR\_ESIG>>

Cynthia Tudor, Ph.D.

Director

Medicare Drug Benefit  
and C & D Data Group,  
Center for Medicare

<<DATE\_STAMP>>

Date