

STATE PHARMACEUTICAL ASSISTANCE PROGRAM

DATA SHARING AGREEMENT

This State Pharmaceutical Assistance Program (SPAP) Data Sharing Agreement (the “Agreement”) for the exchange of enrollment information is entered into between [insert data sharing partner name], with its principal address at [insert data sharing partner address] and the United States Department of Health & Human Services, acting by and through the Centers for Medicare & Medicaid Services (“CMS”) (the “Parties”) on this _____ day of _____, 20 _____ (the “Effective Date”).

RECITALS

I. **MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003 AND SUBSEQUENT REGULATIONS AND THEIR IMPACT ON SPAPS**

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) was enacted in 2003. It includes a new prescription drug benefit, referred to as Medicare Part D. Part D plans, which include private prescription drug plans (PDPs), and Medicare Advantage plans (MA-PDs) will administer the Medicare Part D prescription drug benefit. The MMA introduces a new concept called “true out-of-pocket” (TrOOP) costs. TrOOP refers to the incurred out-of-pocket costs a Medicare Part D beneficiary must spend in a calendar year on Part D covered drugs in order to reach the Part D catastrophic coverage threshold. Any payments made by an SPAP, as defined in Section IV, on behalf of a Part D beneficiary, will be considered incurred costs by the Part D beneficiary and will therefore count toward the beneficiary’s TrOOP. Part D Plans require up-to-date, validated information about other prescription drug coverage to accurately calculate a beneficiary’s TrOOP spending. SPAPs require similar information about the Medicare Part D enrollment of SPAP Enrollees.

II. **PURPOSE OF THIS AGREEMENT**

The purpose of this Agreement is to establish conditions under which (1) the SPAP, as defined in Section IV, agrees to provide SPAP prescription drug enrollment data to the Centers for Medicare & Medicaid Services (CMS), as more specifically set forth in the User Guide; and (2) the CMS agrees to provide the SPAP with Medicare Part D enrollment data, as more specifically set forth in the User Guide, regarding SPAP Enrollees for whom the SPAP provides prescription drug coverage. The Parties to this Agreement seek to more efficiently coordinate the payment of prescription drug benefits and premiums with Medicare Part D plans in accordance with the MMA and subsequent regulations.

III. **SPAP DATA SHARING USER GUIDE**

An “SPAP User Guide,” incorporated herein by reference as the “User Guide,” has been produced to accompany this Agreement.

Current operational versions of the input and response data files can be found in the User Guide. The User Guide is designed to accommodate the ordinary process changes and revisions that result from ongoing program operations.

IV. DEFINITIONS

1. “State Pharmaceutical Assistance Program (SPAP)” – A State program which meets the requirements as set forth in 1860 D23(b) of the MMA and subsequent regulations and has been verified by the CMS as specified in Section V of this Agreement.
2. “SPAP Enrollee” – An individual who is eligible for and enrolled in an SPAP and receives coverage through such a plan.
3. “Medicare Part D Enrollment” – Reference to information about the Medicare Part D plan enrollment of the Medicare Part D beneficiary.
4. “Medicare Part D Beneficiary” – A Part D-entitled individual who is enrolled in a Medicare Part D plan and who receives coverage through such plan.
5. “Medicare Part D Plan” – A PDP, MA-PD, or Pace Plan offering qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage.
6. “Standard BIN/PCN” – The standard codes assigned to network pharmacy payers used when electronically routing pharmacy claims information.
7. “TrOOP Facilitation Rx BIN/PCN” – Unique codes assigned to network pharmacy payers used to electronically route pharmacy claims information. A TrOOP Facilitation Rx BIN or PCN will identify prescription drug coverage that is supplemental to Medicare Part D.
8. “Agent” – An individual or entity authorized by the SPAP to act on the SPAP’s behalf for purposes of administering this Agreement. For purposes of this Agreement, all actions undertaken by the agent in administering this Agreement on behalf of the SPAP shall be binding on the SPAP.

V. TERMS AND CONDITIONS

In consideration of the mutual promises and representations set forth in this Agreement, the Parties agree as follows:

A. MEDICARE PART D ENROLLMENT DETERMINATION FOR SPAP ENROLLEES

In accordance with the process described in “C,” below, the SPAP shall identify those SPAP Enrollees, as defined in Section IV of this Agreement, and the CMS shall identify those SPAP Enrollees that are Medicare Part D beneficiaries or that have been approved for the Low Income Subsidy. The SPAP further agrees that a completed copy of the SPAP Data Sharing Agreement Implementation Questionnaire will accompany the copy(s) of this Agreement delivered to the CMS.

B. PREPARATORY PERIOD AND TEST PROCEDURES FOR CONTINUING ELECTRONIC DATA EXCHANGE FOR SPAP ENROLLEES

Within ten (10) business days after the effective date of the Agreement, the CMS, the CMS Benefits Coordination & Recovery Center (BCRC), and the SPAP will begin to discuss the operational terms of the Agreement. This shall include discussions on data requirements, file submissions, review of error codes, and any other issues. This Preparatory Period shall be completed within thirty (30) business days after the

effective date of the Agreement. If the SPAP is unable to meet the timeframe specified for the Preparatory Period, the SPAP shall notify the CMS in writing. Within five (5) business days of receipt of this notice from the SPAP, the CMS will contact the SPAP to agree on a mutually acceptable time frame in which to complete the Preparatory Period.

Prior to submitting its Initial Input File, the SPAP shall conduct tests of its ability to provide to the CMS a “Test” Initial Input File, receive a “Test” Response File, correct errors identified in the Test Initial Input File, and add new SPAP Enrollees in a second “Test” Input File. This testing process is described in detail in the User Guide.

After successfully completing the Test process, the Initial Input File (the first regular production file) shall be submitted in accordance with the provisions of Section C hereof.

C. CONTINUING ELECTRONIC DATA EXCHANGE FOR SPAP ENROLLEES

1. Within forty-five (45) days of the completion of the process described in Section B hereof (the “Preparatory Period”), the SPAP shall provide to the CMS a file containing the data elements listed in the record layout prescribed in the User Guide, with respect to SPAP Enrollees (“Initial Input File”). The data provided by the SPAP in the Initial Files shall cover all the periods of coverage for the above-mentioned SPAP Enrollees from [insert date] through the first day of the month following the Initial File Date.
2. The CMS shall search its Medicare enrollment files for the SPAP Enrollees identified on the SPAP’s Initial Input File. Where a match occurs, the CMS shall annotate its Medicare Part D enrollment files to identify the SPAP as a supplemental prescription drug payer to the Medicare Part D plan for these SPAP Enrollees.
3. Within fifteen (15) days of the CMS’ receipt of the SPAP’s Initial Input File, the CMS shall provide to the SPAP a file (the “Response File”) containing the data elements listed in the record layout prescribed in the User Guide for individuals identified under the electronic match conducted pursuant to Section B.2 above.
4. Within fifteen (15) days of the SPAP’s receipt of CMS’ Response File, the SPAP shall submit the next monthly Input File, having:
 - a. examined the Response File to determine whether the CMS were able to apply the SPAP prescription drug coverage contained in the Input Records to the CMS enrollment files;
 - b. examined the Response File to determine whether there were errors in the Input Records that prevented the CMS from determining the Medicare Part D enrollment of the SPAP Enrollees or from applying the SPAP prescription drug coverage contained in the Input Records to the CMS enrollment files;

- c. corrected all errors identified in the data in the Input Records, so that the CMS can determine the Medicare Part D enrollment of the SPAP Enrollees and, in subsequent Input Files, apply all SPAP prescription drug coverage included in the Input Records where the SPAP Enrollee was identified as a Medicare Part D Beneficiary; and
- d. updated the SPAP's internal records with all corrections made by the CMS during processing of the Input File, and with corrections made by the SPAP after receiving the Response File.

Ongoing Input File shall contain records of all SPAP Enrollee whose SPAP enrollment terminated up to thirty-six (36) months prior to the first day of the month in which the Ongoing Input File is generated.

D. CORRECTION OF ERROR RECORDS

Upon receipt of the SPAP's Initial and Ongoing Input Files, the CMS shall analyze the files to identify errors and defects in the data provided (e.g., data that is not readable or data that does not comply with the terms of the Agreement). When it detects errors and/or defects with the submitted data, the CMS shall provide to the SPAP a Response File containing the data elements listed in the record layout prescribed in the User Guide, identifying the errors detected on the Initial or Ongoing Input Files. The SPAP shall undertake the steps necessary to correct any error records identified on a Response File, provided such records can be corrected by the Parties, and resubmit the records on the next Input File.

E. Rx BIN AND Rx PCN CODES

Both the Rx BIN and Rx PCN are numbers used in the electronic routing of pharmacy benefit reimbursement information. The Prescription Benefit Identification Number (Rx BIN) and the Pharmacy Benefit Processor Control Number (PCN) are assigned to network pharmacy payers by the American National Standards Institute (ANSI) or the National Coalition for Prescription Drug Programs (NCPDP). All network pharmacy (point-of-sale) payers have an Rx BIN. Many, though not all, have an Rx PCN. The Input and Response File used by the SPAP Data Sharing Agreement program includes data fields for both Rx BIN and Rx PCN reporting.

To participate in the TrOOP Facilitation process, SPAPs should obtain a unique Rx BIN and Rx PCN number to code for coverage that is supplemental to Medicare Part D. This unique coding will assure that the supplemental paid claims captured by the TrOOP Facilitation contractor in the claims response from the payer to the pharmacy provider. The "TrOOP Facilitation" Rx BIN(s) or Rx PCN(s) will be separate and distinct from the SPAP's standard Rx BIN(s) and Rx PCNs. The TrOOP Facilitation Rx BIN and Rx PCN are the appropriate routing numbers for Input Records.

When the CMS identifies an SPAP Enrollee on the Input Files as a Medicare Part D beneficiary, the prescription drug coverage and TrOOP Facilitation Rx BIN and Rx PCN routing information will be provided to the Part D plan and the TrOOP Facilitation contractor. By signing this Agreement, the SPAP must provide the CMS with a list of all its Standard and TrOOP Facilitation Rx BIN and Rx PCN no later than ten (10) business days prior to the submission of the Initial Input File.

F. DUTY TO OBTAIN DATA

The SPAP may be in possession of some, but not all, of the data elements identified in the User Guide. With respect to data not now in its possession, the SPAP shall use its best effort to obtain such data as soon as reasonably possible. With respect to data not now in its possession, or incorrect, and where the data cannot be obtained because an enrollment, re-enrollment, or renewal data of the SPAP will not occur in the next six (6) months, the SPAP shall individually contact each SPAP Enrollee with respect to whom data is missing or incorrect, to obtain or correct such data within thirty (30) days of becoming aware, or being notified, that the information is missing or is incorrect. The SPAP shall include data corrections received in response to such contact in the next Ongoing Input File delivered to the CMS.

After following the procedures detailed above for collection or correction of the data, if the SPAP is still unable to obtain a certain data element – excluding the Social Security Number, or Health Insurance Claim Number or Medicare Beneficiary Identifier, one of which is always mandatory – the SPAP should still provide the CMS with as many of the other data elements as it can obtain for that SPAP Enrollee. The SPAP shall follow up requests for data that remain unresolved for more than thirty (30) days.

G. TERM OF AGREEMENT

The SPAP and the CMS are dedicated to developing and implementing a process for exchanging data that provides the CMS with monthly Input Files and the SPAP with monthly Response Files on a regular and consistent basis with minimal interruption to the administration of the SPAP or the CMS. Accordingly, the initial term of this Agreement shall be twenty-four (24) months from the Effective Date unless earlier terminated as set forth below and shall automatically renew for successive twelve (12) month terms unless, not less than ninety (90) days prior to the end of any term, a Party provides the other Party with written notice of its intent not to renew the Agreement. During the initial term of the Agreement, the Parties shall diligently and in good faith evaluate the data exchange process and discuss and endeavor to implement modifications to the process in order to achieve the efficiency described in Section II hereof as a principal purpose of the Agreement.

During the initial term or any succeeding term of this Agreement, the CMS may terminate this Agreement upon sixty (60) days prior written notice to the SPAP of the SPAP's repeated failure to perform its obligations pursuant to this Agreement, and the SPAP's failure during such sixty (60) day period to cure such breach of its obligations by satisfying the conditions set forth in such notice.

During the initial term or any succeeding term of this Agreement, the SP AP may terminate this Agreement upon sixty (60) days prior written notice to the CMS of the CMS' repeated failure to perform its obligations pursuant to this Agreement, and the CMS' failure during such sixty (60) day period to cure such breach of its obligations by satisfying the conditions set forth in such notice.

Except as the Parties may otherwise agree, this Agreement shall terminate in the event of enactment of any new Medicare Part D legislation which contradicts or is inconsistent with the terms of the data exchange portions of this Agreement.

H. SAFEGUARDING & LIMITING ACCESS TO EXCHANGED DATA

The Parties agree to establish and implement proper safeguards against unauthorized use and disclosure of the data exchanged under this Agreement. Proper safeguards shall include the adoption of policies and procedures to ensure that the data obtained under this Agreement shall be used solely in accordance with the authorization/ consent provided by the beneficiary. The SPAP shall establish appropriate administrative, technical, procedural, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized access to the data provided by the CMS. The SPAP agrees that the authorized representatives of the CMS shall be granted access to the premises where the Medicare data is being kept for the purpose of inspecting security arrangements and confirming whether the SPAP is in compliance with the security requirements specified above.

Access to the records matched and to any records created by the matching process shall be restricted to authorized employees, agents, and officials of the CMS and the SPAP who require access to perform their official duties in accordance with the uses of the information as authorized in this Agreement.

Such personnel shall be advised of (1) the confidential nature of the information; (2) safeguards required to protect the information, and (3) the administrative, civil, and criminal penalties for noncompliance contained in applicable Federal laws.

The CMS and the SPAP agree to limit access to, disclosure of, and use of all data exchanged between the Parties. The information provided may not be disclosed or used for any purpose other than to implement the Part D coordination of benefits provisions of the MMA and subsequent regulations, and coordinate benefit payments between the SPAP and the Medicare Part D plans. The Parties agree that the enrollment files exchanged by the Parties shall not be duplicated or disseminated beyond updating the Parties current enrollment files.

I. PRIVACY ACT

Data that are protected in a Privacy Act System of Records (SOR) shall be released from the CMS in accordance with the Privacy Act (5 U.S.C. § 552a) and the CMS data release policies and procedures. There appropriate Privacy Act disclosure exception for these releases is found in System No. 09-70-0536 (Medicare Beneficiary Database). The Parties agree and acknowledge that they are performing “covered functions” as that term is defined in the Standards for Privacy of Individually Identifiable Health Information (the “Privacy Rule”) under the HIPAA at 45 C.F.R. § 164.501. The Parties further agree that the use and disclosure of Protected Health Information between the Parties pursuant to this Agreement is for payment as defined in the Privacy Rule. The Parties further agree that the Protected Health Information be used or disclosed pursuant to this Agreement is the minimum necessary to accomplish the intended purposes of this Agreement. The Parties agree to abide by all requirements of the Privacy Rule with respect to Protected Health Information used or disclosed under the Agreement.

J. RESTRICTION ON USE OF DATA

All data and information provided by the Parties shall be used solely for the purposes outlined in Section II of the Recitals. If the SPAP wishes to use the data and information provided by the CMS under this Agreement for any purpose other than those outlined above, the SPAP shall make a written request to the CMS outlining the additional purposes for which it seeks to use the data. If the CMS determine that the SPAP request to use the data and information provided hereunder is acceptable, the CMS shall provide written approval to the SPAP of the additional purpose for use of the data.

The terms of this Section J shall not apply to the SPAP with respect to data contained in any Ongoing Input Files, excluding any Medicare data which are provided by CMS to the SPAP in any Response Files.

K. PENALTIES FOR UNAPPROVED USE OR DISCLOSURE OF DATA

The SPAP acknowledges that criminal penalties under section 1106(a) of the Social Security Act [42 U.S.C. § 1306 (a)], including possible imprisonment, may apply with respect to any disclosure of data received from the CMS that is inconsistent with the purposes and terms of the Agreement. The SPAP acknowledges that criminal penalties under the Privacy Act [5 U.S.C., § 552a (I) (3)] may apply if it is determined that the SPAP, or any individual employed or affiliated therewith, knowingly and willfully obtained the data under false pretenses. The SPAP also acknowledges that criminal penalties may be imposed under 18 U.S.C. § 641 if the SPAP, or any individual employed or affiliated therewith, has taken, or converted to its own use date file(s), or received the file(s) knowing that (it) they were stolen or converted. The SPAP further acknowledges that civil and criminal penalties under HIPAA (PL 104-191) may apply if it is determined that a person wrongfully discloses protected health information/individually identifiable health information.

L. SPAP CONTACTS

Administrative Contact: The SPAP designates the individual listed below as the contact person for administrative or other implementation coordination issues under this Agreement. The contact person shall be the point of contact for the CMS for any administrative questions that may arise during the term of this Agreement. If the SPAP changes its administrative contact person, the SPAP shall notify the CMS in writing within thirty (30) working days of the transfer and provide the information listed below for the new contact person.

Name: (Insert Name)
Address: (Insert mailing address)
Phone #: (Insert Phone #)
Email: (Insert Email address)

Technical Contact: The SPAP designates the individual listed below as the contact person for technical or other implementation coordination issues under this Agreement. The contact person shall be the point of contact for the CMS for any technical questions that may arise during the term of this Agreement. If the SPAP

changes its technical contact person, the SPAP shall notify the CMS in writing within thirty (30) working days of the transfer and provide the information listed below for the new contact person.

Name: (Insert Name)
Address: (Insert mailing address)
Phone #: (Insert Phone #)
Email: (Insert Email address)

M. CMS CONTACTS

Administrative Contact: The CMS designates the individuals listed below as the contacts for administrative or other implementation coordination issues under this Agreement. The contacts shall be the point of contact for the SPAP for any administrative questions that may arise during the term of this Agreement. If the CMS changes the administrative contact person(s), the CMS shall notify the SPAP in writing within thirty (30) working days of the transfer and provide the information listed below for the new contact person.

Name: Gerald A. Brozyna Jr.
Phone#: (410) 786-7953
Email: Gerald.Brozyna@cms.hhs.gov
Address: Centers for Medicare & Medicaid Services
Office of Financial Management
Division of Medicare Secondary Payer Operations
Mail Stop: C3-14-16
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Technical Contact: Upon signature of this Agreement by both Parties, the CMS will designate an Electronic Data Interchange Representative (EDI Rep) as the contact for technical or other implementation coordination issues under this Agreement. The EDI Rep shall be the point of contact for the SPAP for any technical questions that may arise during the term of this Agreement. If CMS changes the technical contact person, the CMS shall notify the SPAP within thirty (30) working days of the transfer and provide the new EDI Rep contact information.

N. MISCELLANEOUS

1. The Parties agree that their respective representatives, whose signatures appear below, have the authority to execute this Agreement and to bind each of the Parties, respectively, to every promise or covenant contained in this Agreement. The Effective Date of this Agreement shall be the last date of execution by the Parties.
2. No alteration, amendment, modification, or other change to the Agreement shall be effective without the written consent of the affected Party or Parties. No waiver of this Agreement or of any of the promises, obligations, terms, or conditions contained herein shall be valid unless it is written and signed by the Party against whom the waiver is to be enforced. This applies only to alterations, amendments,

modifications, or other changes to information contained in this Agreement and not to the User Guide.

3. The Parties agree that this Agreement, together with the User Guide, includes all material representations, understandings, and promises of the Parties with respect to this Agreement. This Agreement shall be binding upon the Parties, their successors, and assigns.
4. In the interest of protecting confidentiality of SPAP covered individual data, information received by the Parties hereto that does not result in a match relevant to this Agreement shall be destroyed within twelve (12) months following a Party's completion of the matching process. Each Party to this Agreement shall provide written confirmation to the other Party that all data and information that does not result in a match has been destroyed within that time frame if requested by either Party. The Parties further agree that the medium by which the Parties exchange stored data (e.g., round-reel tapes, cartridges, CDs) shall be destroyed within twelve (12) months of receipt.
5. The Parties may transmit the data required to be exchanged under this Agreement electronically, provided the Parties agree on a methodology and format within which to exchange such documentation as required by the User Guide, and the transmission is secure.
6. The SPAP shall provide a header and trailer for each file submitted using the data elements in the record layout as prescribed in the User Guide.
7. The SPAP agrees that it will inform its related entities, to the extent necessary, to pay prescription drug claims in accordance with the MMA provisions. The SPAP shall share the Medicare Part D entitlement information, identified as a result of this data exchange, with these entities for their use in paying prescription drug claims in accordance with the Medicare Part D provisions.
8. No fees are payable by either Party with respect to this Agreement.
9. Except as specifically provided herein, the rights and/or obligations of either Party to this Agreement may not be assigned without the other Party's written consent. This Agreement shall be binding upon and shall inure to the benefit of and be enforceable by the successors, legal representatives, and permitted assigns of each Party hereto.
10. If either Party cannot release its respective file in a timely manner, it must notify the other Party at least one week prior to the scheduled release of the file that the submission shall be late. A date as to when the file will be released shall be provided at that time.
11. The SPAP has attested that it meets the definition of a Qualified SPAP in 42 CFR 423.454.
12. The SPAP agrees to provide to the CMS a list of all its standard and TrOOP facilitation BINs and PCNs no later than ten (10) days prior to submission of the Initial Input File. The SPAP further agrees to update this list within thirty (30) days of receiving any new numbers.

