ADAP DATA SHARING AGREEMENT

SUPPLEMENTAL DRUG PROGRAM DATA SHARING

FOR USE BY STATE AIDS DRUG ASSISTANCE PROGRAMS (ADAPs)

This 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 and 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, THE AFFORDABLE CARE ACT, AND THEIR IMPACT ON PATIENT ASSISTANCE PROGRAM DATA SHARING PARTNERS**

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) was enacted in 2003. It includes a prescription drug benefit, referred to as Medicare Part D. Part D insurance plans, which include private prescription drug plans (PDPs) and Medicare Advantage plans (MA-PDs), administer the Medicare Part D prescription drug benefit. The MMA introduced a 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. As defined in Section IV, any payments made by an ADAP on behalf of a Part D-enrolled beneficiary supplement the Part D Plan benefit. For the Part D-enrolled Medicare beneficiary, these ADAP supplements are considered incurred costs and therefore count toward the beneficiary's Part D TrOOP. The Part D Plan has the responsibility to keep the record of the Plan member's TrOOP spending. As a consequence, Part D Plans require up-to-date, validated information about financial support of the benefits being provided to an enrollee in the Part D Program.

The Affordable Care Act (ACA, Public Law111-148) expanded TrOOP payments that are to count towards the Part D out-of-pocket threshold. Effective January1, 2011, ADAPs became TrOOP eligible payers. Medicare Part D Plan sponsors are now required to include ADAP expenditures for covered Part D drugs towards the TrOOP limit of Medicare Part D enrollees.

II. **PURPOSE OF AGREEMENT**

The purpose of this Agreement is to establish conditions under which (1) an AIDS Drug Assistance Program (ADAP) Data Sharing Partner, as defined in Section IV, agrees to provide prescription drug coverage data to the CMS, as specifically set forth in the User Guide; and (2) the CMS agree to provide the Data Sharing Partner with Medicare Part D enrollment data, as specifically set forth in the User Guide, regarding Enrollees for whom the ADAP Data Sharing Partner provides access to prescription drug coverage. ADAPs that offer prescription drug coverage that supplements Medicare Part D are to be included in the point-of-sale coordination of benefits process which was developed to support

administration of the Medicare Part D benefit. ADAPs providing financial support that can be considered part of a Medicare beneficiary's Part D TrOOP are to have this financial support coordinated with the applicable Part D Plan benefit. As a result, there is a need by both Medicare and ADAPs to exchange beneficiary eligibility information. This will facilitate the coordination of benefit coverages among the programs and help to assure accurate TrOOP accounting. The Parties to the Agreement seek to more efficiently coordinate the payment of prescription drug benefits, premiums, and other TrOOP expenditures with Medicare Part D plans in accordance with applicable law and regulations.

III. ADAP DATA SHARING USER GUIDE

An "ADAP Data Sharing Agreement User Guide" has been produced to accompany this Agreement and is incorporated herein by reference. This ADAP User Guide is designed to also accommodate the ordinary process changes and revisions that result from monthly program operations. Current operational versions of the input and response data files can be found in the User Guide.

IV. DEFINITIONS

1. "AIDS Drug Assistance Program (ADAP)" – a program funded under the Ryan White Care Fund and administered by state governments which provides drug coverage assistance for HIV/AIDS patients.

2. "Covered Individual" – an individual who is eligible for and enrolled in an ADAP and who receives coverage through such a plan.

3. "Medicare Part D Enrollment" – information about the Medicare Part D plan enrollment of a Medicare Part D enrollee.

4. "Medicare Part D Enrollee" – a Medicare beneficiary who is enrolled in a Medicare Part D Plan and who receives Part D Plan coverage.

5. "Medicare Part D Plan" – a PDP or MA-PD, a Medicare Pace Plan which includes qualified prescription drug coverage, or a Medicare Cost Plan offering incorporating prescription drug coverage.

6. "TrOOP Facilitation Rx BIN or Rx PCN" – unique code numbers used in the electronic network routing of pharmacy claims information. "TrOOP Facilitation" codes are used by network pharmacy payers to identify benefit coverage that is supplemental to Medicare Part D.

7. "Standard Rx BIN or Rx PCN" – unique code numbers used in the electronic network routing of pharmacy claims information. "Standard" codes are used by network pharmacy payers to identify their own primary benefit coverage.

8. "Agent" – an individual or entity authorized by the Data Sharing Agreement partner to act on the partner's behalf for purposes of administering this Agreement. All actions undertaken by the agent in administering this Agreement on behalf of the data sharing partner shall be binding on the data sharing partner.

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 ADAP COVERED INDIVIDUALS

In accordance with the process described in "C," below, the AIDS Drug Assistance (ADAP) Data Sharing Partner shall identify those ADAP covered individuals, as defined in Section IV of this Agreement, and the CMS shall identify the ADAP covered individuals who are Medicare Part D enrollees. The ADAP Data Sharing Partner further agrees that a completed copy of the ADAP Implementation Questionnaire will accompany the copies of this Agreement delivered to CMS.

B.   PREPARATORY PERIOD AND TEST PROCEDURES FOR CONTINUING ELECTRONIC DATA EXCHANGE FOR ADAP COVERED INDIVIDUALS

Within ten (10) business days after the effective date of the Agreement, the CMS, the CMS Benefits Coordination & Recovery Center (BCRC) and the ADAP Data Sharing Partner 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 ADAP Data Sharing Partner is unable to meet the specified timeframe of the Preparatory Period, the ADAP Data Sharing Partner shall notify the CMS in writing of this delay.

Within five (5) business days of receipt of this notice from the ADAP Data Sharing Partner, the CMS will contact the ADAP Data Sharing Partner to agree on a mutually acceptable time frame in which to complete the Preparatory Period.

Prior to submitting its Initial Input File, the ADAP Data Sharing Partner shall conduct tests of its ability to provide to the CMS a "Test" Initial Input File, receive a "Test" Response File, and correct errors identified in the Test Initial Input File and add new ADAP Data Sharing Partner Covered individuals in a "Test" Monthly Input File. The Test process is described in detail in the User Guide.

After successfully completing the Test process, the Initial Input File shall be submitted in accordance with the provisions of Section C hereof.

C.   CONTINUING ELECTRONIC DATA EXCHANGE FOR ADAP COVERED INDIVIDUALS

1. Within forty-five (45) days of the completion of the process described in Section B hereof (the "Preparatory Period"), the ADAP Data Sharing Partner shall provide to the CMS a file containing the data elements listed in the record layout prescribed in the User Guide, with respect to ADAP covered individuals ("Initial Input File"). The data provided by the ADAP in the Initial Input File shall cover all the periods of coverage for the above-mentioned ADAP covered individuals from [*insert date no earlier than January 1, 2006*] through the first day of the month following the Initial File Date.

2. The CMS shall search its Medicare enrollment files for the ADAP covered individuals identified on the ADAP's Initial Input File. Where a match occurs, the CMS shall annotate its Medicare Part D enrollment files to identify the ADAP as a supplemental payer to the Medicare Part D plan for these ADAP covered individuals.

3. Within fifteen (15) days of the CMS' receipt of the ADAP's Initial Input File, the CMS shall provide to the ADAP a file (the "Response File") containing the data elements listed in the record layout prescribed in the User Guide.

4. Within fifteen (15) days of the ADAP's receipt of the CMS' Response File, the ADAP shall submit the next monthly Input File, having:

   a. examined the Response File to determine whether the CMS was able to apply the ADAP's 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 ADAP's covered individuals, or from applying the ADAP's prescription drug coverage contained in the Input Records to the CMS enrollment files;

   c. corrected all errors originally contained in the Input Records, so that the CMS can correctly determine the Medicare Part D enrollment of the ADAP's covered individuals and apply all ADAP prescription drug coverage contained in the Input Records where the ADAP's covered individual was identified as a Medicare Part D enrollee in subsequent Input Files; and

   d. updated the ADAP's internal records with all corrections made by the CMS during processing of the Input File and by the ADAP after receiving the Response File.

Monthly Input Files shall contain records of all ADAP covered individuals whose ADAP enrollment terminated up to thirty-six (36) months prior to the first day of the month in which the Monthly Input File is generated.

D. CORRECTION OF ERROR RECORDS

Upon receipt of the ADAP's Initial and Monthly Input Files, in the course of its standard processing activity the CMS shall analyze the files to identify any 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). If it detects errors and/or defects with submitted data, in the regular Response File CMS shall provide to the ADAP the data elements listed in the Response File record layout prescribed in the User Guide and will identify the errors detected on the Initial or Monthly Input Files. The ADAP shall undertake the steps necessary to correct any error records identified in a Response File, provided such records can be corrected by the Parties, and resubmit the corrected records on the next Input File.

E. RX BIN AND RX PCN CODES

ADAPs must obtain a unique, TrOOP-specific Rx BIN and Rx PCN number to code for coverage that is supplemental to Medicare Part D. This unique coding will assure

that a copy of the supplemental paid claim is captured by the Transaction Facilitation Contractor as the claims data moves through the health care billing and reimbursement EDI networks. "TrOOP Facilitation" Rx BIN(s) and Rx PCN(s) are required and must be separate and distinct from the ADAP's standard Rx BIN(s) and Rx PCN(s).

On an Input file, when CMS identifies an ADAP covered individual as a Medicare Part D enrollee, the prescription drug coverage and TrOOP Facilitation Rx BIN and Rx PCN routing information will be made available to the Part D Plan and the Transaction Facilitation Contractor. By signing this Agreement, the ADAP agrees to obtain a TrOOP Facilitation Rx BIN and Rx PCN. In addition, the ADAP must provide CMS with a list of all its Standard and TrOOP Facilitation Rx BINs and Rx PCNs no later than ten (10) business days prior to the submission of the Initial Input File.

F.   DUTY TO OBTAIN DATA

The ADAP may be in possession of some, but not all, of the data elements identified in the Input File and the User Guide. With respect to data not now in its possession, the ADAP shall use its best efforts to obtain such data as soon as reasonably possible. With respect to data not now in its possession or incorrect, where the data cannot be obtained because an enrollment, re-enrollment, or renewal date of the ADAP will not occur in the next six (6) months, the ADAP shall individually contact each program client from 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 ADAP shall include data corrections received in response to such contact in the next Monthly Input File delivered to the CMS.

If, after following the procedures detailed above for collection/correction of data, the ADAP is still unable to obtain a certain data element, excluding the Social Security Number, or Medicare Health Insurance Claim Number or Medicare Beneficiary Identifier, one of which is always mandatory, the ADAP should still provide the CMS with as many of the other data elements as it can obtain for the program client.

The ADAP shall follow-up requests for data that remain unresolved for more than thirty (30) days.

G.   TERM OF AGREEMENT

The ADAP and the CMS are dedicated to developing and implementing a process for exchanging data that provides the CMS with monthly Input Files and the ADAP with monthly Response Files on a regular and consistent basis with minimal interruption to the administration of the ADAP 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 ADAP of the ADAP's repeated failure to perform its obligations pursuant to this Agreement, and the ADAP'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 ADAP 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 Section 1106 of the Social Security Act [42 U.S.C. § 1306], Section 1874(b) of the Social Security Act [42 U.S.C. § 1395k (b)], Section 1862(b) of the Social Security Act [42 U.S.C. § 1395y (b)], and the Privacy Act of 1974, as amended [5 U.S.C. § 552a]. The ADAP 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 ADAP 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 ADAP 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 ADAP 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 ADAP 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 ADAP 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 ADAP wishes to use the data and information provided by the CMS under this Agreement for any purpose other than those outlined above, the ADAP 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 ADAP's request to use the data and information provided hereunder is acceptable, the CMS shall provide written approval to the ADAP of the additional purpose for use of the data.

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

K. PENALTIES FOR UNAPPROVED USE OF DISCLOSURE OF DATA

The ADAP 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 ADAP acknowledges that criminal penalties under the Privacy Act [5 U.S.C., § 552a (I) (3)] may apply if it is determined that the ADAP, or any individual employed or affiliated therewith, knowingly and willfully obtained the data under false pretenses. The ADAP also acknowledges that criminal penalties may be imposed under 18 U.S.C. § 641 if the ADAP, 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 ADAP 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. AIDS DRUG ASSISTANCE PROGRAM CONTACTS

<u>Administrative Contact</u>: The ADAP 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 ADAP changes its administrative contact person, the ADAP 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)

<u>Technical Contact</u>: The ADAP 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 ADAP changes its technical contact person, the ADAP 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

<u>Administrative Contact</u>: The CMS designates the individuals listed below as the contact for administrative or other implementation coordination issues under this Agreement. The contact shall be the point of contact for the ADAP 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 ADAP 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 ADAP 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 ADAP 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 ADAP 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 ADAP 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 ADAP agrees that it will inform its related entities, to the extent necessary, to pay prescription drug claims in accordance with the MMA provisions. The ADAP 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 ADAP agrees to provide to the CMS a list of all its standard and TrOOP Facilitation Rx BINs and Rx PCNs no later than ten (10) days prior to submission of the Initial Input File. The ADAP further agrees to update this list no more than thirty (30) days after receiving any new coding numbers.

O.   SIGNATURE OF THIS AGREEMENT

IN WITNESS WHEREOF, the Parties have signed this Agreement as indicated below.

Centers for Medicare & Medicaid Services

_____

By: Director, Financial Services Group   DATE

        Office of Financial Management

        Duly Authorized Representative

(Insert ADAP Representative Name)

_____

By: (Insert ADAP Representative Name)   DATE

        (Insert Title)

        Duly Authorized Representative