PATIENT ASSISTANCE PROGRAM (PAP)

DATA SHARING PARTNER AGREEMENT

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 AND THEIR IMPACT ON PATIENT ASSISTANCE PROGRAM DATA SHARING PARTNERS

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) was enacted in 2003 and 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, under 1860 D-4 (c) requires PDP sponsors to put in place appropriate arrangements that will facilitate medication therapy management, drug utilization review and quality assurance.

II. PURPOSE OF AGREEMENT

The purpose of this Agreement is to establish conditions under which (1) the Patient Assistance Program Data Sharing Partner, as defined in Section IV, agrees to provide prescription drug coverage data to the CMS, as more specifically set forth in Attachment A and in the User Guide; and (2) the CMS agrees to provide the Patient Assistance Program Data Sharing Partner with Medicare Part D enrollment data, as more specifically set forth in Attachment B and the User Guide on enrollees for whom the Patient Assistance Program data sharing partner provides prescription drug coverage. This exchange of information will (1) assist CMS in flagging PAPs participating outside the Part D benefit as non-TrOOP eligible payers so that Part D Plans do not pay for prescription drugs covered by the Part D plan that are provided to the Part D enrollee at no cost by the PAP, (2) alert the Part D Plan that they need to communicate and coordinate coverage with the PAP regarding the particular free prescription drug product provided by the PAP to the Part D enrollee and (3) help facilitate plan safety coordination through drug utilization review and quality assurance activities.

III. PATIENT ASSISTANCE PROGRAM DATA SHARING USER GUIDE

A "User Guide" has been produced to accompany this Agreement and is incorporated herein by reference as the User Guide. The User Guide is designed to accommodate the ordinary process changes and revisions that result from monthly program operations. Current operational versions of the input and response data illustrated in Attachments A through C can be found in the User Guide.

IV. DEFINITIONS

1. "Patient Assistance Program (PAP)"— a program in which pharmaceutical manufacturers provide financial or medication assistance (pharmaceuticals) to low-income individuals.

2. "Covered Individual"— an individual who is eligible for and enrolled in a Patient Assistance Program, receives medications through such a plan and has authorized or provided consent to the PAP for the disclosure by CMS of Medicare eligibility information.

3. "Medicare Part D Plan" — a PDP, MA-PD, or a Pace Plan offering qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage.

4. "Medicare Part D Enrollee" — a Medicare beneficiary who is enrolled in a Medicare Part D plan and receives coverage through such plan.

5. "Medicare Part D Enrollment" — refers to information about the enrollment of a Medicare beneficiary in a Medicare Part D plan.

6. "Agent"— an individual or entity authorized by the data sharing partner to act on the partner'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 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 PATIENT ASSISTANCE PROGRAM COVERED INDIVIDUALS

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

B. PREPARATORY PERIOD AND TEST PROCEDURES FOR CONTINUING ELECTRONIC DATA EXCHANGE FOR PATIENT ASSISTANCE PROGRAM 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 Patient Assistance Program 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 Patient Assistance Program Data Sharing Partner is unable to meet the specified timeframe of the Preparatory Period, the Patient Assistance Program Data Sharing Partner shall notify the CMS in writing of this delay.

Within five (5) business days of receipt of this notice from the Patient Assistance Program Data Sharing Partner, the CMS will contact the Patient Assistance Program 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 Patient Assistance Program 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 Patient Assistance Program 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 PATIENT ASSISTANCE PROGRAM COVERED INDIVIDUALS

1. Within forty-five (45) days of the completion of the process described in Section B hereof (the "Preparatory Period"), the Patient Assistance Program Data Sharing Partner shall provide to the CMS a file containing the data elements listed in Attachment A, in the record layout prescribed in the User Guide, with respect to Patient Assistance Program covered individuals ("Initial Input File"). The data provided by the Patient Assistance Program in the Initial Input File shall cover all the periods of coverage for the above-mentioned Patient Assistance Program 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 Patient Assistance Program covered individuals identified on the Patient Assistance Program's Initial Input File. Where a match occurs, the CMS shall annotate its Medicare Part D enrollment files to identify the Patient Assistance Program as a supplemental prescription drug payer to the Medicare Part D plan for these Patient Assistance Program covered individuals.

3. Within fifteen (15) days of the CMS' receipt of the Patient Assistance Program's Initial Input File, the CMS shall provide to the Patient Assistance Program a file (the "Response File") containing the data elements listed in Attachment B, in the record layout prescribed in the User Guide, for individuals identified under the electronic match conducted pursuant to Section C.2., above.

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

   a. examined the Response File it received to determine whether the CMS was able to apply to the CMS enrollment files the Patient Assistance Program's prescription drug coverage contained in the Input Records;

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 Patient Assistance Program's covered individuals, or from applying the Patient Assistance Program'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 Patient Assistance Program's covered individuals and apply all Patient Assistance Program prescription drug coverage contained in the Input Records where the Patient Assistance Program's covered individual was identified as a Medicare Part D enrollee in subsequent Input Files; and

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

Monthly Input Files shall contain records of all Patient Assistance Program covered individuals whose Patient Assistance Program participation is current and ongoing, and records of Patient Assistance Program covered individuals who have begun participation since the submission date of the previous Input File. Monthly Input Files may also include participation records of former (inactive) Patient Assistance Program covered individuals for the purpose of keeping such records active on CMS databases.

D. CORRECTION OF ERROR RECORDS

Upon receipt of the Patient Assistance Program's Initial and Monthly Input Files, 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). When it detects errors and/or defects with submitted data, the CMS shall provide to the Patient Assistance Program a Response File containing the data elements listed in Attachment B and in the record layout prescribed in the User Guide, identifying the errors detected on the Initial or Monthly Input Files. The Patient Assistance Program 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 those records on the next Input File.

E. DUTY TO OBTAIN DATA

The Patient Assistance Program may be in possession of some, but not all, of the data elements identified in Attachment A and the User Guide. The Patient Assistance Program acknowledges that knowingly submitting inaccurate patient data to the BCRC is inconsistent with the purpose of the PAP Data Sharing Agreement. With respect to data not now in its possession, the Patient Assistance Program shall use its best efforts to obtain such data as soon as reasonably possible. With respect to data not now in its possession or known to be incorrect, where the data cannot be quickly obtained the Patient Assistance Program shall use its best efforts to obtain necessary and accurate data as soon as reasonably possible. The Patient Assistance Program shall include data corrections received in response in the next Monthly Input File delivered to the CMS.

After following the procedures detailed above for collection/correction of data, if the Patient Assistance Program is still unable to obtain a certain data element, with the exception of the Social Security Number, or Health Insurance Claim Number or Medicare Beneficiary Identifier, one of which is always mandatory, the Patient Assistance Program should still provide the CMS with as many of the other data elements as it can obtain for that Patient Assistance Program covered individual.

F. TERM OF AGREEMENT

The Patient Assistance Program and the CMS are dedicated to developing and implementing a process for exchanging data that provides the CMS with monthly Input Files and the Patient Assistance Program with monthly Response Files on a regular and consistent basis with minimal interruption to the administration of the Patient Assistance Program 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 Patient Assistance Program of the Patient Assistance Program's repeated failure to perform its obligations pursuant to this Agreement, and the Patient Assistance Program'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 Patient Assistance Program 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.

G. 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 Patient Assistance Program 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 Patient Assistance Program 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 Patient Assistance Program 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 Patient Assistance Program 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 Patient Assistance Program 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 Patient Assistance Program 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.

H.   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 Patient Assistance Program wishes to use the data and information provided by the CMS under this Agreement for any purpose other than those outlined above, the Patient Assistance Program 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 Patient Assistance Program request to use the data and information provided hereunder is acceptable, the CMS shall provide written approval to the Patient Assistance Program of the additional purpose for use of the data.

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

I.   PATIENT ASSISTANCE PROGRAM CONTACTS

<u>Administrative Contact:</u> The Patient Assistance Program 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 Patient Assistance Program changes its administrative contact person, the Patient Assistance Program 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 Patient Assistance Program 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 Patient Assistance Program changes its technical contact person, the Patient Assistance Program 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)

J. 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 Patient Assistance Program 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 Patient Assistance Program 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 Patient Assistance Program 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 Patient Assistance Program within thirty (30) working days of the transfer and provide the new EDI Rep contact information.

K. 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 Patient Assistance Program 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 Patient Assistance Program 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 Patient Assistance Program agrees that it will inform its related entities, to the extent necessary, to pay prescription drug claims in accordance with the MMA provisions. The Patient Assistance Program 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.

L. 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 Patient Assistance Program Representative Name)

_____

By: (Insert Patient Assistance Program Representative Name)   DATE

       (Insert Title)

       Duly Authorized Representative