

**MEDICARE PART D MANUFACTURER DISCOUNT PROGRAM DATA AGREEMENT**  
**(hereinafter referred to as the “Agreement”)**

**Between**

**The Third Party Administrator**  
**(hereinafter referred to as “the TPA”)**

**and**

**The Manufacturer Identified in Section VIII of this Agreement**  
**(hereinafter referred to as “the Manufacturer”)**

The TPA, as a contractor to the Centers for Medicare & Medicaid Services (“CMS”), and the Manufacturer, on its own behalf, and per the Medicare Part D Manufacturer Discount Program (“Discount Program”) Agreement the Manufacturer signed with CMS for purposes of sections 1860D-14C and 1860D-43 of the Social Security Act (“the Act”), hereby agree to the following:

**I DEFINITIONS**

The terms defined in this section, for purposes of this Agreement, will have the meanings specified as follows:

- (a) “Medicare Part D Discount Information” means the information sent from CMS or through the TPA to the Manufacturer along with each quarterly invoice that is derived from applicable data elements available on PDEs as determined by CMS. The Medicare Part D Discount Information data elements are set forth in Exhibit A of the Program Agreement.
- (b) “Medicare Part D Discount Information Data Transmission” means automated transfer or exchange of Medicare Part D Discount Information.
- (c) “Medicare Part D Manufacturer Discount Program Agreement” or “Program Agreement” means the agreement signed by the Secretary and the Manufacturer as described in section 1860D-14C(b) of the Act.
- (d) “TPA Contract” means the contract between CMS and the TPA for the TPA to perform certain CMS duties in administering the Discount Program.

Except where such terms are expressly defined in this Agreement, all other terms used in this Agreement will have the meanings given to them under the provisions of sections 1860D-1 through 1860D-43 of the Act, any applicable regulations and guidance implementing those provisions, and Section I of the Program Agreement.

**II MANUFACTURER’S RESPONSIBILITIES**

Consistent with the terms of the Program Agreement, the Manufacturer agrees to the following:

- (a) To establish, identify and maintain personnel contact(s) as specified by CMS who are responsible for establishing and maintaining electronic connectivity between the Manufacturer and the TPA

for the purpose of timely Medicare Part D Discount Information Data Transmission and transmission of other Discount Program information, including but not limited to, audit and dispute information. The POC will notify the TPA in advance of connectivity changes.

- (b) If the Manufacturer contracts with a third party for electronic file transmission, the Manufacturer shall ensure that the third party complies with all terms and conditions of this Agreement and the Program Agreement.
- (c) To receive Medicare Part D Discount Information from the TPA and send information to the TPA as directed by the TPA.
- (d) To fully reimburse each Part D sponsor within thirty-eight (38) calendar days of receipt from the TPA of the electronic invoice and Medicare Part D Discount Information for the quarterly applicable discount amounts included on the invoice and paid by such Part D sponsor on behalf of the Manufacturer for all of the applicable drugs having National Drug Codes (NDC) with labeler codes covered by the Program Agreement.

### **III TPA'S RESPONSIBILITIES**

Consistent with the terms of the TPA Contract between CMS and the TPA, the TPA will perform the following:

- (a) Provide customer support to the Manufacturer (or a third party with whom the Manufacturer has contracted for file transmission) to assist in establishing and maintaining connectivity to the TPA.
- (b) Establish, identify and maintain personnel contact(s) who are responsible for providing and maintaining the systems to enable electronic connectivity between the Manufacturer and the TPA for the purpose of timely Medicare Part D Discount Information Data Transmission and transmission of other Discount Program information, including but not limited to, audit and dispute information. The personnel will notify the Manufacturer in advance of connectivity changes.
- (c) Prepare and distribute Medicare Part D Discount Information and quarterly invoices to the Manufacturer.
- (d) Verify that the Manufacturer reimbursed the applicable discount amounts in full as directed by the TPA.
- (e) Collect and maintain Part D Sponsor electronic funds transfer ("EFT") information and appropriately apply applicable discount amounts due from the Manufacturer to each Part D sponsor.
- (f) Facilitate audit requests from the Manufacturer by scheduling audits, making workspace available on site at the TPA, and providing audit data described in Exhibit B of the Program Agreement as necessary.

### **IV MUTUAL OBLIGATIONS**

The Manufacturer and the TPA agree to the following:

- (a) Establishing Roles. Prior to the initial Medicare Part D Discount Information Data Transmission, the Manufacturer and the TPA will confirm the validity of their personnel contacts via contact from the TPA to the Manufacturer. Access codes for the Discount Program portal will be subsequently issued and a login test should be executed to test successful access. This process must be completed prior to the first Medicare Part D Discount Information Data Transmission in accordance with instructions from the TPA. For the Manufacturer, the duties of the personnel

contact(s) include relaying general information regarding the Discount Program; receiving all Discount Program related notifications distributed by the TPA; and communicating with the TPA to address payment matters.

- (b) Establishing EFT information. Prior to the initial Medicare Part D Discount Information Data Transmission, the Manufacturer and the TPA will coordinate to establish which of the Manufacturer's bank accounts(s) are to be used for sending and/or receiving payments. This process must be completed in accordance with the TPA's instructions prior to the first Medicare Part D Discount Information Data Transmission in order to allow for validating bank account information.
- (c) Medicare Part D Discount Information Data Transmission Accuracy. The Manufacturer and the TPA will ensure that Medicare Part D Discount Information Data Transmission is timely, complete and accurate to the best of their knowledge.
- (d) Medicare Part D Discount Information Data Transmission Security. The TPA will issue security access codes to the Manufacturer. The Manufacturer and the TPA will employ security measures necessary to protect Medicare Part D Discount Information Data Transmission between them, including authentication, encryption, password use, or other security measures in compliance with the section 1173(d) of the Act and any U.S. Department of Health and Human Services implementing regulations or guidelines and as set forth in Section V of this Agreement.
- (e) Security Access Codes. The Manufacturer and the TPA agree that the security access codes that the TPA issues to the Manufacturer will, when affixed to Medicare Part D Discount Information Data Transmission, be legally sufficient to verify the identity of the transmitter and to authenticate the Medicare Part D Discount Information Data Transmission and therefore establish the Medicare Part D Discount Information Data Transmission's validity.

## **V CONFIDENTIALITY PROVISIONS**

The Manufacturer shall comply with the confidentiality and data use provisions outlined in Section VI and Exhibit C of the Program Agreement for all files and information, including Medicare Part D Discount Information and the data elements specified in Exhibit B of the Program Agreement, that it receives under the terms of this Agreement. The TPA shall comply with the requirements regarding confidentiality and data security contained in the TPA Contract.

## **VI ORDER OF PRECEDENCE**

In the event of any inconsistencies between this Agreement and any applicable statute, regulations, and guidance implementing the Discount Program, the applicable statute, regulations, and guidance will take precedence. As related to the Manufacturer, in the event of any inconsistencies between this Agreement and the Program Agreement, the Program Agreement will take precedence.

## **VII TERMINATION**

This Agreement will only terminate upon the termination of the Program Agreement. Upon the effective date of the termination of this Agreement, the TPA and CMS will cease releasing data to the Manufacturer under this Agreement, except as necessary to ensure that the Manufacturer reimburses applicable discounts for previous time periods in which the Agreement was in effect. The Manufacturer agrees to destroy the Medicare Part D Discount Information it has received under this Agreement in accordance with Exhibit C of the Program Agreement. The provisions of Section V will survive termination of this Agreement. The other provisions of this Agreement necessary to effectuate the terms herein and the terms of the Program Agreement will survive the termination of this Agreement until all invoices have been paid in full by the Manufacturer.

