

MEDICARE COVERAGE GAP DISCOUNT PROGRAM DATA AGREEMENT

Between

Third Party Administrator

(hereinafter referred to as “TPA”)

and

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

The Third Party Administrator, as a contractor to the Centers for Medicare & Medicaid Services (CMS), and the Manufacturer, on its own behalf, and per the Medicare Coverage Gap Discount Program Agreement the Manufacturer signed with CMS for purposes of sections 1860D-14A and 1860D-43 of the Social Security Act (the Act), hereby agree to the following:

I DEFINITIONS

The terms defined in this section will, for purposes of this Agreement, have the meanings specified in section 1860D-1 through 1860D-43 of the Act as interpreted and applied herein:

- (a) “Medicare Coverage Gap Discount Program Agreement (Program Agreement)” means the agreement signed by the Secretary and the Manufacturer as described in 1860D-14A(b).
- (b) “Medicare Part D Discount Information Data Transmission” means automated transfer or exchange of data as described in this agreement.

All other terms used in this Agreement will have the same meanings specified in 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 and maintain a Point-of-Contact (POC) responsible for establishing and maintaining connectivity between the Manufacturer and the TPA. The POC will notify the TPA in advance of connectivity changes. If the Manufacturer contracts with a third party for file transmission, the Manufacturer maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of this Agreement and the Program Agreement.
- (b) To provide electronic connectivity to receive and send Medicare Part D Discount Information.
- (c) To receive Medicare Part D Discount Information from and send Medicare Part D Discount Information to the TPA using CMS-approved record formats.

- (d) To pay each Part D sponsor within 38 calendar days of receipt from the TPA of the electronic invoice and Medicare Part D Discount Information for the quarterly applicable discounts included on the invoice provided by such Part D sponsor on behalf of the Manufacturer for all of the applicable drugs having National Drug Codes (NDC) with the Manufacturer's Food and Drug Administration (FDA)-assigned labeler code(s).

III TPA RESPONSIBILITIES

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

- (a) Provide customer support to Manufacturer (or a third party with whom it has contracted for file transmission) to assist in establishing and maintaining connectivity to the TPA.
- (b) Provide and maintain connectivity between the Manufacturer and TPA.
- (c) Prepare and distribute Medicare Part D Discount Information and quarterly invoices to the Manufacturer.
- (d) Receive verification from Manufacturer that discount amounts were paid in full as directed by CMS.
- (e) Maintain Part D Sponsor electronic funds transfer (EFT) information and appropriately apply discount amounts due from the Manufacturer.
- (f) Facilitate audits by the Manufacturer by receiving requests for audit, scheduling audits, making work space available on site at the TPA and providing audit data.

IV Mutual Obligations.

Manufacturer and the TPA agree to the following:

- (a) Establishing Roles. Prior to the initial Medicare Part D Discount Information Transmission, the Manufacturer and the TPA will confirm the validity of the TPA Liaison and CGDP Payment Contact roles as stated in HPMS via completion of TPA Welcome Letter. The TPA Liaison is the primary point of contact for general information regarding the CGDP. This person receives all CGDP related notifications distributed by TPA. The CGDP Payment Contact is the manufacturer contact that the TPA communicates with to address payment issues and to whom payment communications are sent. Access Codes for the CGDP Portal will be subsequently issued and a login test should be executed to test successful access. This process must be completed no less than ten (10) days prior to the first Medicare Part D Discount Information Data Transmission.
- (b) Establishing EFT information. Prior to the initial Medicare Part D Discount Information Transmission, the Manufacturer will coordinate with the TPA 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 no less than twenty (20) days 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 Transmissions are 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 Transmissions between them, including authentication, encryption, password use, or other security measures in compliance with the Social Security Act § 1173(d) and any HHS implementing regulations or guidelines and as set forth in Article V of this Agreement.
- (e) Security Access Codes. The Security Access Codes that the TPA issues to the Manufacturer will, when affixed to Medicare Part D Discount Information Data Transmissions, 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 be subject to the same confidentiality provisions outlined in Section VI of the Program Agreement and in the Data Use Agreement attached to the Program Agreement and in Exhibit C, Data Use Provisions, of the Program Agreement for all Medicare Part D Discount Information it receives under the terms of this Agreement. The TPA shall be subject to the requirements regarding confidentiality and data security contained in the Third Party Administrator Contract between CMS and the TPA.

VI ORDER OF PRECEDENCE

As related to CMS and the Manufacturer, in the event of any inconsistencies between this Agreement between the TPA and the Manufacturer and the Program Agreement, the Program Agreement shall take precedence.

VII TERMINATION

Upon the effective date of the termination of this Agreement, 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 upon notification by CMS. The provisions of section V shall survive termination of this Agreement.

VIII. SIGNATURES

FOR THE TPA

By: _____
(please print name) (signature)

Title: _____

Date: _____

FOR THE MANUFACTURER

A. By signing this Agreement, the Manufacturer agrees to abide by all provisions set out in this Agreement and acknowledges having received notice of potential criminal or administrative penalties for violation of the terms of the Agreement.

B. On behalf of the Manufacturer the undersigned individual hereby attests that he or she is authorized to legally bind the Manufacturer to the terms of this Agreement and agrees to all the terms specified herein.

I certify that I have made no alterations, amendments or other changes to this Medicare Coverage Gap Discount Program Data Agreement.

By: _____
(please print name) (signature)

Title: _____

P# _____

Name of Manufacturer: _____

Manufacturer's Mailing Address: _____

Date: _____