

MEDICARE PART D  
MANUFACTURER DISCOUNT PROGRAM AGREEMENT

(hereinafter referred to as the “Agreement”)

Between

The Centers for Medicare & Medicaid Services

(hereinafter referred to as “CMS”)

and

The Manufacturer Identified in Section IX of this Agreement

(hereinafter referred to as “the Manufacturer”)

CMS, on behalf of the Secretary of the Department of Health and Human Services, and the Manufacturer, on its own behalf, for purposes of sections 1860D-14C and 1860D-43 of the Social Security Act (the Act), as set forth or amended in the Inflation Reduction Act of 2022, Pub. L. 117-169 (IRA), hereby agree to the following:

I. DEFINITIONS

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

(a) **“Applicable Agreement”** has the meaning given such term in section 11003 of the IRA and any applicable regulations and guidance.

(b) **“Centers for Medicare & Medicaid Services” or “CMS”** means the agency of the Department of Health and Human Services having the delegated authority to operate the Medicare Part D program.

(c) **“Labeler Codes covered by this Agreement”** means, subject to the limitation in section

II(n) below:

(1) All Labeler Codes for which the Manufacturer agrees to pay Applicable Discounts under this Agreement; and

(2) All Labeler Codes which the Manufacturer agrees are covered by this Agreement but that, under section 1860D-14C(g)(2)(B) of the Act, are for a Selected Drug not subject to Applicable Discounts under the Part D Manufacturer Discount Program.

(d) “**Medicare Part D Discount Information**” means the information sent from CMS or through the Third Party Administrator 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 this Agreement.

(e) “**Negotiation Program**” means the Medicare Drug Price Negotiation Program established pursuant to sections 1191 through 1198 of the Act and applicable regulations and guidance.

(f) “**Prescription Drug Event Record**” or “**PDE**” refers to a summary record that documents the final adjudication of a Part D dispensing event.

(g) “**Primary Manufacturer**” has the meaning given such term pursuant to applicable regulations and guidance for the Negotiation Program.

(h) “**Selected Drug**” has the meaning given such term in section 1192(c) of the Act and any applicable regulations and guidance.

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

## II. MANUFACTURER’S RESPONSIBILITIES

Pursuant to sections 1860D-14C and 1860D-43 of the Act and any applicable regulations and

guidance implementing those provisions, in order for coverage to be available under the Part D program for Applicable Drugs and Selected Drugs of the Manufacturer or for Applicable Drugs and Selected Drugs of another manufacturer whose FDA-assigned Labeler Code(s) is covered by this Agreement, the Manufacturer agrees to the following:

- (a) Comply with all the applicable requirements and conditions set forth in sections 1860D-14C and 1860D-43 of the Act, any other applicable laws, and any applicable regulations and guidance.
- (b) Reimburse all Applicable Discounts provided by Part D Sponsors on behalf of the Manufacturer for all Applicable Drugs dispensed on or after January 1, 2025 that have an NDC with a Labeler Code that the Manufacturer has provided to CMS in accordance with paragraph (c):
  - (1) within thirty-eight (38) calendar days of receipt from the TPA of the electronic invoice and Medicare Part D Discount Information for the Applicable Discounts included on the invoice, except as specified in section V(f) of this Agreement (receipt of the invoice shall be considered to be 1 calendar day after the TPA electronically transmits the invoice to the Manufacturer or otherwise notifies the Manufacturer that it is available (e.g., it is posted on a secure web site for download)); and
  - (2) which are invoiced to the Manufacturer by the TPA within thirty-seven (37) months following the end of the benefit year in which the date of service occurred based upon PDE information reported to CMS by Part D Sponsors and in accordance with instructions from CMS.

Subject to section V of this Agreement, the Manufacturer is not required to reimburse Applicable Discounts provided by Part D Sponsors for Applicable Drugs dispensed after

the NDC's marketing end date, which is the last lot expiration date, specified in a product's structured product labeling electronically submitted to the FDA, if such marketing end date was submitted to the FDA prior to the date of service.

- (c) Provide CMS with all Labeler Codes covered by this Agreement.
- (d) Ensure that the Labeler Codes that the Manufacturer provides to CMS in accordance with paragraph (c) include, at a minimum, all Labeler Codes assigned by the FDA to the Manufacturer that contain NDCs for any of the Manufacturer's Applicable Drugs or Selected Drugs, and promptly update CMS with any new Labeler Code(s) assigned to the Manufacturer by the FDA that contain NDCs for any of the Manufacturer's Applicable Drugs or Selected Drugs no later than three (3) business days after learning of a new Labeler Code assigned by the FDA to the Manufacturer.
- (e) Collect, have available, and maintain appropriate data related to the Labeler Codes covered by this Agreement, including FDA drug approvals, FDA NDC Directory listings, FDA NDC last lot expiration dates, utilization, and pricing information relied on by the Manufacturer to dispute quarterly invoices, and any other data CMS determines necessary to carry out the Part D Manufacturer Discount Program and demonstrate compliance with its requirements, for a period of not less than ten (10) years from the date of payment of the invoice.
- (f) Comply with the requirements imposed by CMS for purposes of administering the Part D Manufacturer Discount Program and monitoring compliance with such program, including providing the Manufacturer's Employer Identification Number (EIN) and other identifying information to CMS upon request.
- (g) Ensure that all electronic FDA listings for all NDCs for Applicable Drugs and Selected Drugs with Labeler Codes covered by this Agreement are up to date, including providing

information about discontinued drugs, to enable the publication of accurate information regarding what drugs, identified by NDC, are in current distribution.

- (h) Ensure that all NDC listings with the electronic database vendors to which NDCs are provided for pharmacy claims processing of all NDCs for Applicable Drugs and Selected Drugs with Labeler Codes covered by this Agreement are up to date.
- (i) Enter into and have in effect, under terms and conditions specified by CMS, an agreement with the TPA and to comply with such TPA agreement.
- (j) Comply with the TPA's instructions, processes, and requirements.
- (k) Pay quarterly invoices directly to accounts established by Part D Sponsors via electronic funds transfer through the TPA's platform, or other manner if specified by CMS, within the time period specified in paragraph (b).
- (l) Use Medicare Part D Discount Information disclosed to the Manufacturer on quarterly invoices only for purposes of paying discounts under the Part D Manufacturer Discount Program, or upon audit or dispute.
- (m) Provide and attest to information in the manner and form specified by CMS as necessary for CMS to determine eligibility for and implement the Specified Manufacturer and Specified Small Manufacturer phase-ins pursuant to sections 1860D-14C(g)(4)(B)(ii) and (g)(4)(C)(ii) of the Act, respectively, and any applicable regulations and guidance.
- (n) Agree that, no less than 30 days after the date CMS determines that a Primary Manufacturer of a Selected Drug has, consistent with the requirements in applicable regulations and guidance, provided notice to CMS of its decision not to enter into or continue its participation in the Negotiation Program and to discontinue its Applicable Agreements, none of the drugs of such Primary Manufacturer are covered by this Agreement.

### III. CMS' RESPONSIBILITIES

- (a) CMS shall administer the Part D Manufacturer Discount Program, including the determination of the amount of the Applicable Discount for an Applicable Drug of the Manufacturer pursuant to section 1860D-14C(c)(1)(A) of the Act.
- (b) CMS shall establish procedures pursuant to section 1860D-14C(c)(1)(B) of the Act that require Part D Sponsors to pay Applicable Discounts on behalf of the Manufacturer for Applicable Drugs dispensed by a pharmacy, mail order service, or other dispenser within the Applicable Number of Calendar Days beginning January 1, 2025.
- (c) CMS shall establish procedures pursuant to section 1860D-14C(c)(1)(C) of the Act to ensure that the Applicable Discount for an Applicable Drug is applied before any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of Applicable Beneficiaries.
- (d) CMS shall provide a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, Part D Sponsors, and CMS.
- (e) CMS shall monitor compliance by the Manufacturer with the terms of this Agreement, sections 1860D-14C and 1860D-43 of the Act, and any applicable regulations and guidance related to the Part D Manufacturer Discount Program pursuant to section 1860D-14C(c)(2) of the Act. CMS shall monitor compliance by Part D Sponsors and the TPA with their respective obligations in connection with the Part D Manufacturer Discount Program.
- (f) CMS shall use PDE information reported by Part D Sponsors for monitoring and tracking the Applicable Discounts for Applicable Drugs paid by Part D Sponsors and reimbursed by

the Manufacturer for Applicable Drugs, and for implementing internal control measures designed to ensure the accuracy and appropriateness of Applicable Discount payments provided by Part D Sponsors.

(g) CMS shall, or shall ensure that its TPA shall, do each of the following:

- (1) Receive and transmit information, including Medicare Part D Discount Information, among CMS, the Manufacturer, Part D Sponsors and other individuals or entities CMS determines appropriate;
- (2) Provide adequate and timely information to the Manufacturer as necessary for the Manufacturer to fulfill its obligations under this Agreement;
- (3) Calculate the invoice quarterly based upon PDEs reported to CMS by Part D Sponsors on a flow basis, which invoices may include PDEs with Dates of Dispensing from prior quarters, and reconcile any discrepancies with Applicable Discounts reported by Part D Sponsors prior to invoicing the Manufacturer;
- (4) Notify the Manufacturer of invoice errors or retroactive adjustments and make any necessary adjustments to subsequent invoices; and
- (5) Permit the Manufacturer to conduct periodic audits of the data and information used to determine the Applicable Discounts for Applicable Drugs of the Manufacturer under the Part D Manufacturer Discount Program in accordance with section V of this Agreement.

(h) CMS shall contract with a TPA to receive, distribute, and facilitate the distribution of funds of the Manufacturer to appropriate individuals or entities.

(i) In accordance with section V of this Agreement, CMS may audit the Manufacturer periodically as necessary to carry out the Part D Manufacturer Discount Program.

- (j) CMS shall make public a list of participating manufacturers and the Labeler Codes each such manufacturer has provided to CMS in accordance with section II(c).
- (k) CMS shall ensure that adjustments are made to invoices as necessary to correct errors, including information obtained as a result of CMS's audit of a Part D Sponsor or the TPA or from an audit performed by the Manufacturer of data and information made available by the TPA, as specified in section V. In the event a systemic error is discovered, CMS shall ensure that either CMS or the TPA identifies all invoices affected by the error, determines the impact of the error on invoiced discounts, notifies the Manufacturer, and adjusts the invoices of the Manufacturer if warranted (or implements an alternative reimbursement process if determined necessary by CMS) to correct any underpayment or overpayment that was requested on prior invoices.
- (l) CMS shall specify the form and manner for the Manufacturer to provide and attest to the completeness, accuracy, and truthfulness of information necessary for CMS to determine eligibility for and implement the Specified Manufacturer and Specified Small Manufacturer phase-ins pursuant to sections 1860D-14C(g)(4)(B)(ii) and (g)(4)(C)(ii) of the Act, respectively, and any applicable regulations and guidance.
- (m) CMS shall determine whether the Manufacturer qualifies as a Specified Manufacturer or Specified Small Manufacturer in accordance with sections 1860D-14C(g)(4)(B)(ii) and (g)(4)(C)(ii) of the Act, respectively, and any applicable regulations and guidance.
- (n) In the event that the Manufacturer declares bankruptcy, as described in Title 11 of the United States Code, and does not pay all invoiced amounts due for Applicable Discounts

for Applicable Drugs, including the total sum of any civil money penalties (CMPs) imposed, if necessary, CMS will file a proof of claim with the bankruptcy court to recover the unpaid amounts from the Manufacturer.

#### IV. PENALTY PROVISIONS

- (a) CMS may impose a CMP on the Manufacturer for each failure to pay Applicable Discounts for Applicable Beneficiaries for Applicable Drugs under this Agreement. For purposes of this Agreement, the Manufacturer will have failed to pay Applicable Discounts if payment has not been transmitted within thirty-eight (38) calendar days of receipt of the applicable invoice. The amount for each such failure is the amount CMS determines is commensurate with the sum of the amount that the Manufacturer would have paid with respect to such discounts under this Agreement, which will then be used to pay the Applicable Discounts that the Manufacturer failed to provide, plus an additional twenty-five (25) percent of the amount the Manufacturer would have paid with respect to such discounts under this Agreement.
- (b) The provisions of section 1128A of the Act (other than subsections (a) and (b)) shall apply to a CMP in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) of the Act.
- (c) If CMS makes a determination that it will impose a CMP as described in paragraph (a), CMS will send to the Manufacturer a written notice of its determination that will include the following:
  - (1) A description of the basis for the determination.
  - (2) The basis for the penalty.
  - (3) The amount of the penalty.

- (4) The date the penalty is due.
  - (5) A statement informing the Manufacturer of its right to hearing with an Administrative Law Judge (ALJ).
  - (6) Information about how the Manufacturer may file a request for a hearing.
- (d) (1) If the Manufacturer does not request a hearing within sixty (60) calendar days of receipt of the written notice described in paragraph (c) in accordance with the requirements set forth by CMS, CMS shall initiate the collection of the CMP.
- (2) If the Manufacturer requests a hearing within sixty (60) calendar days of receipt of the written notice described in paragraph (c) in accordance with the requirements set forth by CMS, and the ALJ upholds CMS' decision to impose a CMP, CMS may initiate collection of the CMP, unless the Manufacturer pursues further administrative appeals as detailed in the applicable regulations and guidance.

## V. AUDIT AND DISPUTE RESOLUTION

- (a) Both parties may conduct periodic audits directly or through third parties. Periodic means no more often than annual. The basis and scope of the audit must be reasonable and the information requested pursuant to an audit must be reasonably tailored to the specific purpose of the audit.
- (b) The party requesting the audit shall provide the other party with sixty (60) calendar days notice of the basis for the audit, and a description of the scope of the audit and the information required for the audit. The TPA will determine the audit schedule based upon available resources.
- (c) The Manufacturer may audit only the data specified in Exhibit B for a statistically

significant random sample size of the PDEs used to determine the Applicable Discounts for Applicable Drugs having NDCs with Labeler Codes covered by this Agreement. The Manufacturer is not permitted to audit other CMS records or the records of Part D Sponsors. The TPA will make the data available to the Manufacturer in accordance with applicable regulations and guidance and in the manner and form specified by instructions from CMS.

- (d) CMS may periodically audit appropriate data related to Applicable Drugs having NDCs with Labeler Codes covered by this Agreement, including data related to FDA drug approvals, FDA Directory listings, FDA NDC last lot expiration dates, utilization and pricing information relied on by the Manufacturer to dispute quarterly invoices and, any other data CMS determines are necessary to carry out the Part D Manufacturer Discount Program and monitor compliance with its requirements.
- (e) In the event that the Manufacturer disputes a quarterly invoice or the Medicare Part D Discount Information provided by the TPA with the quarterly invoice, the Manufacturer shall provide written notice of the issue or dispute to the TPA within sixty (60) calendar days from the date of the disputed invoice. Such notice must be accompanied by supporting evidence that is material, specific, and related to the dispute, and the manufacturer must explain why they believe the invoiced discount amount is in error.
- (f) The Manufacturer shall not withhold any invoiced discount payments pending dispute resolution with the sole exception of disputed invoiced amounts for Applicable Drugs having NDCs that do not correspond to Labeler Codes covered by this Agreement. If the Manufacturer wishes to withhold payment on this basis, the Manufacturer shall notify the TPA and applicable Part D Sponsors that payment is being withheld for this reason within thirty-eight (38) calendar days of receipt of the applicable invoice.

(g) If the Manufacturer receives a timely, unfavorable determination from CMS or the dispute is not resolved within sixty (60) calendar days of the date the initial dispute was filed, the Manufacturer may request an independent review by an entity contracted by CMS. A request for independent review must be made within thirty (30) calendar days of the date of the unfavorable determination on the initial dispute, or if no determination was made within sixty (60) calendar days of the filing date of the initial dispute, ninety (90) calendar days from the filing date of the Manufacturer's initial dispute. A party that receives an unfavorable determination from the independent review entity may request review by the CMS Administrator within thirty (30) calendar days of the date of the unfavorable determination. The decision by the CMS Administrator is final and binding.

(h) CMS shall adjust future invoices (or implement an alternative reimbursement process if determined necessary by CMS) if the dispute is resolved in favor of the Manufacturer, as applicable.

## VI. CONFIDENTIALITY AND DATA USE PROVISIONS

(a) CMS will not disclose to other parties any confidential information disclosed by the Manufacturer in connection with this Agreement in a form that identifies the Manufacturer, except as necessary to carry out provisions of section 1860D-14C of the Act or as otherwise required by law. This restriction does not limit the Office of Inspector General's authority to fulfill the Inspector General's responsibilities in accordance with applicable Federal law.

(b) The Manufacturer will observe all applicable Federal and State confidentiality statutes, regulations, and other applicable confidentiality requirements.

(c) CMS shall not disclose any direct beneficiary identifiers to the Manufacturer under the Part D Manufacturer Discount Program except as may be required by law.

(d) The parties shall comply with the data use provisions set forth in Exhibit C of this Agreement, which establish the requirements for use of Medicare Part D Discount Information specified in Exhibit A and data specified in Exhibit B of this Agreement that CMS provides to the Manufacturer either directly or through the TPA for purposes of the administration of the Part D Manufacturer Discount Program pursuant to sections 1860D-14C and 1860D-43 of the Act.

VII. TERM, RENEWAL AND TERMINATION

(a) This Agreement will be valid for an initial term of not less than twelve (12) months, and will automatically renew for a period of one (1) year on each subsequent January 1, except as otherwise provided for in paragraph (a)(2), unless terminated as described in this section.

(1) For calendar year 2025, the initial twelve (12) month term of the Agreement begins on January 1, 2025 and ends on December 31, 2025.

(2) For calendar year 2026 and subsequent years, the Agreement will become effective on the first day of a calendar quarter. The Manufacturer must enter into the Agreement no later than the last day of the first month of a calendar quarter in order for the term to begin on the first day of the next calendar quarter. If the Manufacturer enters into the Agreement after the last day of the first month of a particular calendar quarter, the initial term will begin on the first day of the second calendar quarter after the calendar quarter in which the Manufacturer entered into the Agreement.

(3) An initial term that begins on January 1 will end on December 31 of the same calendar year. An initial term that begins on April 1, July 1, or October 1 will end on

December 31 of the following calendar year.

- (b) CMS may terminate this Agreement for a knowing and willful violation of the requirements of the Agreement or other good cause shown in relation to the Manufacturer's participation in the Part D Manufacturer Discount Program. The termination will not be effective earlier than thirty (30) calendar days after the date of notice to the Manufacturer of such termination. CMS shall provide the Manufacturer with an opportunity to cure any ground for termination for cause or to show the Manufacturer is in compliance with this Agreement within thirty (30) calendar days of the Manufacturer's receipt of the written termination notice. If the Manufacturer cures the violation, or establishes that it was in compliance within the cure period, CMS shall repeal the termination notice by written notice. CMS shall provide the Manufacturer a hearing with a hearing officer concerning such termination if requested in writing within fifteen (15) calendar days of receiving notice of the termination, and such hearing must take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if CMS determines appropriate. A party that receives an unfavorable decision from the hearing officer may request review by the CMS Administrator within thirty (30) calendar days of receipt of the notification of such determination. The decision of the CMS Administrator is final and binding.
- (c) The Manufacturer may terminate this Agreement for any reason. If the Manufacturer provides notice of termination before January 31 of a calendar year, such termination shall be effective as of January 1 of the following calendar year, unless the circumstances constituting good cause described in paragraph (d) below are applicable. If the Manufacturer provides notice of termination on or after January 31 of a calendar year, such termination shall be effective as of January 1 of the second calendar year following such calendar year, unless the circumstances constituting good cause described in

paragraph (d) below are applicable.

- (d) If the Manufacturer is a Primary Manufacturer of a Selected Drug and CMS determines that the Manufacturer has, consistent with the requirements in the applicable regulations and guidance, provided notice to CMS of its decision not to enter into or continue its participation in the Negotiation Program and to terminate its Applicable Agreements, the Manufacturer's request to terminate this Agreement will trigger the good cause provision in paragraph (b).
- (e) Any termination will not affect the Manufacturer's responsibility to reimburse Part D Sponsors for Applicable Discounts for Applicable Drugs having NDCs with Labeler Codes covered by this Agreement that were incurred under this Agreement before the effective date of its 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.
- (f) The termination of this Agreement will automatically and simultaneously terminate the Manufacturer's Medicare Part D Manufacturer Discount Program Data Agreement with the TPA.
- (g) The provisions of sections IV and VI will survive termination of this Agreement. The other provisions of this Agreement necessary to effectuate the terms herein, including paragraph (e), will survive the termination of this Agreement until all invoices have been paid in full by the Manufacturer.

## VIII. GENERAL PROVISIONS

- (a) Any notice required to be given by either party pursuant to the terms and provisions of this Agreement must be sent by email. CMS shall provide the appropriate email address

for notice, and any updates to such email address thereafter, in regulations, guidance or other publications. The Manufacturer shall provide the appropriate email address(es) for notice, and any updates to such email address(es) thereafter, to CMS in a form and manner specified by CMS.

- (b) The Manufacturer will notify CMS of a change in ownership within thirty (30) calendar days after the Manufacturer executes a legal obligation for such an arrangement and no later than forty-five (45) calendar days prior to the change in ownership taking effect. In the event of a transfer in ownership of the Manufacturer, this Agreement is automatically assigned to the new owner, and all terms and conditions of this Agreement remain in effect and binding upon the new owner.
- (c) Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is found to be invalid by a court of law with competent jurisdiction, this Agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, and without any effect on any other provision.
- (d) No failure by any party to insist upon the strict performance of any requirement, obligation or condition of this Agreement shall constitute a waiver of any such requirement, obligation or condition.
- (e) Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or CMS under any applicable law.
- (f) This Agreement shall be construed in accordance with Federal law and ambiguities shall be interpreted in the manner that best effectuates the applicable statute(s). Any litigation arising from or relating to this Agreement, to the extent that jurisdiction and a cause of action would otherwise be available for such litigation, shall be resolved in Federal court.

Actions by the Manufacturer for damages are not permitted pursuant to this Agreement, and the Manufacturer's remedies for any breach are limited to termination of the Agreement or other action consistent with applicable statutes, regulations, or guidance.

- (g) In the event of any inconsistencies between this Agreement and any applicable statute, regulations, and guidance implementing the Part D Manufacturer Discount Program, the applicable statute, regulations, and guidance will take precedence.
- (h) The terms "CMS" and "Manufacturer" incorporate any contractors that fulfill responsibilities pursuant to this Agreement on behalf of such party unless specifically stated otherwise in this Agreement. Each party shall ensure that any contractor fulfilling any of such party's responsibilities under this Agreement on behalf of such party complies with the terms of this Agreement.
- (i) Except for changes in a party's address, which may be updated as set forth in paragraph (a), CMS retains the sole authority to amend this Agreement. To the extent practicable, CMS will provide the Manufacturer with sixty (60) calendar days advance written notice of any changes to this Agreement.
- (j) Nothing in this Agreement shall be construed as requiring coverage under Part D of the Manufacturer's product if that product does not otherwise meet the definition of a Covered Part D Drug.
- (k) Neither party will be liable for failure to perform its obligations under this Agreement if such failure is occasioned by a contingency beyond such party's reasonable control, including, but not limited to, lockouts, riots, wars, fires, floods or storms (a "Force Majeure Event"). A party claiming a right to excused performance under this section shall promptly notify the other party in writing of the extent of its inability to perform, which notice shall specify the Force Majeure Event that prevents such performance and include a

timeline for remediation. The party failing to perform shall use reasonable efforts to avoid or remove the cause of the Force Majeure Event and shall resume performance under the Agreement promptly upon the cessation of the Force Majeure Event.

- (l) This Agreement and the exhibits attached hereto contain the entire agreement of the parties with respect to the subject matter of this Agreement, and supersede all prior oral and written representations, agreements, and understandings with respect thereto.

IX. SIGNATURES

**FOR CMS**

By: \_\_\_\_\_ (print name)

\_\_\_\_\_ (signature)

Title: \_\_\_\_\_

Date: \_\_\_\_\_

**FOR THE MANUFACTURER**

- A. By signing this Agreement, the Manufacturer agrees to abide by all provisions set forth in this Agreement and acknowledges having received notice of potential penalties for violation of the terms of the Agreement.
  
- B. By signing this Agreement, the Manufacturer also attests that:
  - (1) the information provided in HPMS is true, complete, and accurate; and
  - (2) that the Manufacturer will timely notify CMS if any such information changes.
  
- C. The undersigned individual hereby attests that he or she is authorized by the Manufacturer to execute this Agreement with regard to the Part D Manufacturer Discount Program and to legally bind the Manufacturer on whose behalf he or she is executing the Agreement to all terms and conditions specified herein. The undersigned individual further attests that he or she has obtained access in the CMS Health Plan Management System (CMS HPMS) as an authorized representative to be signatory for the Manufacturer and that the individual's CMS HPMS access credentials contain the same information regarding the undersigned individual as the information set forth below.
  
- D. I certify that I have made no alterations, amendments or other changes to this Part D Manufacturer Discount Program Agreement.

By: \_\_\_\_\_ (print name)

\_\_\_\_\_ (signature)

Title: \_\_\_\_\_

P# \_\_\_\_\_

Name of Manufacturer: \_\_\_\_\_

Manufacturer's Mailing Address: \_\_\_\_\_

\_\_\_\_\_

Date: \_\_\_\_\_

## Exhibit A

### MEDICARE PART D DISCOUNT INFORMATION DATA ELEMENTS

1. Date of Service
2. Service Provider Identifier Qualifier
3. Service Provider Identifier
4. Prescription/Service Reference Number
5. Product/Service Identifier
6. Quantity Dispensed
7. Days Supply
8. Fill Number
9. Reported Discount
10. Low-Income Cost Sharing Amount
11. Total Gross Covered Drug Cost Accumulator
12. True Out-of-Pocket Accumulator
13. Gross Drug Cost Below Out-of-Pocket Threshold (GDCB)
14. Gross Drug Cost Above Out-of-Pocket Threshold (GDCA)

Exhibit B

PDE DATA ELEMENTS AVAILABLE UPON AUDIT ONLY

1. Contract Number
2. Plan Benefit Package Identifier
3. Ingredient Cost Paid
4. Dispensing Fee Paid
5. Total Amount Attributed to Sales Tax
6. Non-covered Plan Paid Amount
7. Vaccine Administration Fee

## Exhibit C

### DATA USE PROVISIONS

#### (a) PURPOSE

CMS agrees to provide the Manufacturer with certain data that reside in the Drug Data Processing System (DDPS), an established CMS Privacy Act System of Records. The CMS data file(s) covered under this Agreement shall include the “Medicare Part D Discount Information” as defined in section I(c) of this Agreement and shall also include the data elements in Exhibit B of this Agreement and any other data provided by CMS or the TPA to the Manufacturer, (including any derivative data(s)), any data that can be used in concert with other available information to identify beneficiaries, and any data provided in support of the resolution of payment disputes and audits pursuant to section V of this Agreement (hereinafter referred to as “Discount Information”).

The following provisions address the conditions under which CMS will disclose and the Manufacturer will obtain and use the Discount Information. These provisions supplement any and all agreements between the parties with respect to the use of Discount Information.

#### (b) MANUFACTURER’S RESPONSIBILITIES CONCERNING AND LIMITATIONS ON USE OF DISCOUNT INFORMATION

(1) The Manufacturer agrees 1) to ensure the integrity, security, and confidentiality of Discount Information by complying with the terms of this Agreement and applicable law, including the Privacy Act of 1974 and the Health Insurance Portability and Accountability Act of 1996, as amended, and its implementing regulations; and 2) to use Discount Information data

only for purposes of evaluating the accuracy of claimed discounts and resolving disputes concerning the Manufacturer's payment obligations under the Part D Manufacturer Discount Program as described in the applicable statutes, regulations, guidance, and this Agreement.

(2) The Manufacturer may not use the Discount Information to perform any functions not governed by this Agreement, including but not limited to non-Part D Manufacturer Discount Program payments to Part D Sponsors and their subcontractors, payments to other providers of health and drug benefits under any Federal health care program and marketing activities. These restrictions do not apply to the use of de-identified, aggregated, summary-level data (i.e., not prescription or claim-level data) for financial statement forecasting and accounting purposes.

(3) The parties mutually agree that CMS retains all ownership rights to the Discount Information referred to in this Agreement, and that the Manufacturer does not obtain any right, title, or interest in any of the Discount Information furnished by CMS.

(4) The Manufacturer agrees not to disclose, use, or reuse the Discount Information covered by this Agreement, except as specified in this Agreement or except as CMS shall authorize in regulations or guidance it issues in writing related to the administration of the Part D Manufacturer Discount Program or as otherwise required by law. The Manufacturer further agrees not to, sell, rent, lease, loan, or otherwise grant access to the Discount Information covered by this Agreement, with the exception that the Manufacturer may grant access to Discount Information to contracted third parties for purposes of assisting the Manufacturer in evaluating the accuracy of claimed discounts, resolving disputes, and otherwise exercising its rights and responsibilities under the Agreement, so long as such contracted third parties are subject to the same confidentiality requirements set forth in this Agreement and that the Manufacturer maintains responsibility for ensuring compliance by these third parties with the

confidentiality requirements of this Agreement.

(5) The Manufacturer agrees that, within the Manufacturer's organization and the organizations of its agents, access to the Discount Information covered by the Agreement shall be limited to the minimum amount of data necessary and minimum number of individuals who need access to the Discount Information for permitted activities, such as those described under paragraphs (2) and (4) (i.e., individual's access to Discount Information will be on a need-to-know basis).

(6) The parties mutually agree that the Discount Information may be retained by the Manufacturer for a period of up to ten (10) years from the date of payment of the invoice. The Manufacturer agrees to destroy the Discount Information as soon as no longer needed, and to maintain, and provide upon request to CMS, written documentation of the regular destruction of the files within the required timeframe. The Manufacturer may retain the data beyond the ten (10) year timeframe if the Discount Information is the subject of an unresolved audit, government investigation, or litigation, or if required by another applicable law. Such extension must be approved in advance by CMS in writing and the Manufacturer agrees to promptly destroy the Discount Information once the pending matter is resolved.

(7) The Manufacturer agrees to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the Discount Information and to prevent unauthorized use or access to it. Further, the Manufacturer (or a contracted third party) agrees that the Discount Information must not be physically moved, transmitted or disclosed in any way from or by any site(s) owned, operated, or otherwise controlled by the Manufacturer (or the contracted third party) to any sites outside of the control of the Manufacturer (or the contracted third party) without advance written approval from CMS unless such movement, transmission or disclosure is required by a law.

(8) The Manufacturer agrees to grant access to the Discount Information to authorized representatives of CMS or the U.S. Department of Health and Human Services Office of the Inspector General for the purpose of inspecting to confirm compliance with the terms of this Agreement upon reasonable notice.

(9) The Manufacturer agrees that it shall not attempt to link records included in the Discount Information to any individually identifiable source of information or for the purpose of creating any individually identifiable source of information. This includes attempts to link the Discount Information to other CMS data file(s), except that Manufacturers may link to Discount Information data from prior quarters in order to validate that a claim has not been duplicated or that retroactive adjustments have been made. CMS may establish through regulations or guidance issued separately to the Manufacturer exceptions to this prohibition that may be necessary for purposes of the administration of the Part D Manufacturer Discount Program.

(10) The Manufacturer agrees that in the event CMS determines or has a reasonable belief that the Manufacturer has made or may have made a use, reuse, or disclosure of the Discount Information that is not authorized by this Agreement, CMS, at its sole discretion, may require the Manufacturer to: (a) promptly investigate and report to CMS the Manufacturer's determinations regarding any alleged or actual unauthorized use, reuse or disclosure; (b) promptly resolve any problems identified by the investigation; (c) if requested by CMS, submit a formal response to an allegation of unauthorized use, reuse or disclosure; (d) if requested by CMS, submit a corrective action plan with steps designed to prevent any future unauthorized uses, reuses or disclosures; and (e) if requested by CMS, return Discount Information to CMS or destroy the Discount Information it received from CMS under this Agreement. The Manufacturer understands that as a result of CMS's determination or reasonable belief that

unauthorized uses, reuses or disclosures have taken place, CMS may stop releasing further Discount Information to the Manufacturer for a period of time to be determined by CMS and/or may terminate this Agreement.

(11) In the event that the Manufacturer inadvertently receives individually identifiable information, or discovers any other breach of Discount Information, loss of Discount Information or disclosure of Discount Information to any unauthorized persons, the Manufacturer agrees to report the incident to the CMS Action Desk by telephone at (410) 786- 2580 or by e-mail notification at [cms\\_it\\_service\\_desk@cms.hhs.gov](mailto:cms_it_service_desk@cms.hhs.gov) within one hour of the Manufacturer's discovery of the incident and to cooperate fully in the federal security incident process. The Manufacturer agrees not to disclose, use, or reuse Discount Information and acknowledges that the use of unsecured telecommunications, including the Internet, to transmit any individually identifiable or deducible information derived from the Discount Information is prohibited. While CMS retains all ownership rights to the Discount Information, as outlined above, the Manufacturer shall bear all cost and liability for any breaches of the Discount Information while they are in the possession of, or under the control of, Manufacturer or any of its agent or subcontractors.

(12) The Manufacturer hereby acknowledges that criminal penalties under section 1106(a) of the Social Security Act (42 U.S.C. § 1306(a)), including a fine not exceeding \$10,000 or imprisonment not exceeding five (5) years, or both, may apply to disclosures of Discount Information that are covered by § 1106 and that are not authorized by regulation or by Federal law. The Manufacturer further acknowledges that criminal penalties under the Privacy Act (5 U.S.C. § 552a(i)(3)) may apply if it is determined that the any individual employed or affiliated with the Manufacturer knowingly and willfully obtained the Discount Information under false

pretenses. Any person found to have violated section 552a(i)(3) of the Privacy Act shall be guilty of a misdemeanor and fined not more than \$5,000. Finally, the Manufacturer acknowledges that criminal penalties may be imposed under 18 U.S.C. § 641 if it is determined that the Manufacturer, or any individual employed or affiliated therewith, has taken or converted to his or her own use Discount Information, or received the Discount Information knowing that it was stolen or converted. Under such circumstances, he or she shall be fined under Title 18 or imprisoned not more than 10 (ten) years, or both; but if the value of such property does not exceed the sum of \$1,000, he or she shall be fined under Title 18 or imprisoned not more than (one) 1 year, or both.