DRAFT MEDICARE TRANSACTION FACILITATOR PAYMENT MODULE CONTRACTOR AGREEMENT

(hereinafter referred to as the "MTF PM Agreement" or "this Agreement")

Between

The Medicare Transaction Facilitator Payment Module Contractor
(hereinafter referred to as the "MTF Payment Module Contractor")

And

[FULL NAME OF MANUFACTURER]
(hereinafter referred to as "the Manufacturer")

WHEREAS, the MTF Payment Module Contractor is intended to accomplish the following tasks in the administration of the Medicare Drug Price Negotiation Program (hereinafter referred to as the "Negotiation Program") in a ministerial role:

(1) Facilitate effectuation of maximum fair price (hereinafter referred to as "MFP") refund payments between the Manufacturer and dispensing entities by passing through payment of an MFP retrospective refund on MFP eligible claims of selected drugs from the Manufacturer to dispensing entities (hereafter referred to as the "selected drug(s)" or each "selected drug"). If a manufacturer opts into the MTF PM, the manufacturer shall typically use the MTF PM for all selected drugs; however, the manufacturer may come to a mutually agreed with process for effectuating the MFP outside the MTF PM with dispensing entities.

(2) Provide an efficient and unified payment flow by connecting the Manufacturer and dispensing entities.

(3) Support implementation of the Ledger System as defined in section I(c) of this Agreement.

WHEREAS, the MTF Payment Module Contractor shall serve only to transfer funds of the Manufacturer to dispensing entities as directed by the Manufacturer and in the amounts authorized by the Manufacturer, as indicated by the Manufacturer to the MTF Data Module Contractor, as defined in section I(f) of this Agreement, and passed along to the MTF Payment Module Contractor, and will not collect funds for any other use;

WHEREAS, the MTF Payment Module's (hereinafter the "MTF Payment Module" or "MTF PM," as defined in section I(h) of this Agreement) ministerial role in facilitating the transfer of refund payments from the Manufacturer to dispensing entities shall not supersede or alter the Manufacturer's statutory obligation to effectuate the MFP;

WHEREAS, the MTF PM shall only facilitate transactions between the Manufacturer and dispensing entities;

WHEREAS, the MTF PM shall not accrue any interest on funds held by the MTF PM during the period before the funds are transferred to dispensing entities;

WHEREAS, the MTF PM shall not settle disputes between the Manufacturer and dispensing entities (or provide the appearance of adjudication) when there has been an allegation of over or under payment;

NOW THEREFORE, the MTF Payment Module Contractor, as a contractor to the Centers for Medicare & Medicaid Services ("CMS"), and the Manufacturer, on its own behalf, and per the MTF Program Agreement the Manufacturer signed with CMS (as defined in section I(i) of this Agreement), for purposes of sections 1191 through 1198 of the Social Security Act ("the Act"), and for purposes of implementing section II of the Medicare Drug Price Negotiation Program Agreement(s) between CMS and the Manufacturer (hereinafter referred to as the "Negotiation Program Agreement(s)," as defined in section I(j) of this Agreement), hereby agree to the following:

I   DEFINITIONS

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

(a) **"Claim-level data elements"** means the data, as described in applicable guidance, regulations, and technical instruction, that CMS transmits to the Manufacturer via the MTF Data Module for each claim for a selected drug that is dispensed to an MFP-eligible individual.

(b) **"Claim-level payment elements"** means the data, as described in applicable guidance, regulations, and technical instructions, that the Manufacturer transmits to CMS via the MTF Data Module indicating the Manufacturer's response to the claim-level data elements for each claim for a selected drug dispensed to an MFP-eligible individuals.

(c) **"Ledger System"** means the system within the MTF PM as described in applicable guidance, regulations, and technical instructions to track credits and debits for MFP refund payments for each of the selected drug(s) at the dispensing entity National Provider Identifier ("NPI")-level on behalf of participating manufacturers.

(d) **"Manufacturer MTF Enrollment Information"** means the Manufacturer's identifying, and, if applicable, financial information as described in CMS' instruction for MTF enrollment. As described in the CMS instructions for MTF enrollment, if the Manufacturer elects not to participate in the MTF PM, then certain financial information is not required enrollment information.

(e) "**MTF Data Module" or "MTF DM"** means the system that provides MTF claim-level data elements to manufacturers, receives claim-level payment elements from manufacturers, operates the user interface for dispensing entities and manufacturers, and provides an Electronic Remittance Advice ("ERA") that uses the X12 835 standard adopted under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") for electronic transfer of funds or remittances for paper checks to dispensing entities.

(f) **"MTF Data Module Contractor"** means a contractor to CMS retained to establish and maintain the MTF Data Module and to execute on the data exchange, user interface functionality, and issuance of the remittance or ERA for manufacturers and dispensing

entities.

(g) **"MTF DM Agreement"** means the agreement between the Manufacturer and the MTF Data Module Contractor.

(h) "**MTF Payment Module" or "MTF PM"** means the voluntary system to pass through MFP refund payments from a participating manufacturer to dispensing entities per the Manufacturer's direction in the transmitted claim-level payment elements received from the MTF Data Module Contractor to effectuate MFP in connection with the MTF Program Agreement.

(i) "**MTF Program Agreement**" means the agreement between the Manufacturer and CMS on behalf of the Secretary of the United States Department of Health and Human Services with respect to the respective parties' obligations in connection with the MTF.

(j) **"Negotiation Program Agreement" or "Negotiation Program Agreement(s)"** means the agreement(s) between CMS and the Manufacturer as established under section 1193 of the Act with respect to the Manufacturer's participation in the Negotiation Program for a selected drug(s).

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 1191 through 1198 of the Act, any applicable regulations and guidance implementing those provisions, and section I of the MTF Program Agreement.

II   MANUFACTURER'S RESPONSIBILITIES

Pursuant to the Negotiation Program Agreement(s), including any applicable guidance, regulations, and technical instructions describing the obligations thereunder, and the MTF Program Agreement:

(a)   Manufacturer shall utilize the MTF PM for all selected drug(s) except in instances where the Manufacturer and dispensing entities have a mutually agreed upon alternative process to effectuate the MFP outside of the MTF PM.

(b) Manufacturer shall authorize the MTF PM to send to the dispensing entities or parties authorized by dispensing entities to receive payment on their behalf, payment equal to the total refunds to be paid by returning the claim-level payment elements to the MTF DM within the 14-day prompt MFP payment window. The Manufacturer's return of the claim-level payment elements is the authorization for the MTF PM to transfer the appropriate amount from the bank account the Manufacturer has on file with the MTF DM for the purposes of transferring such funds to dispensing entities as directed by the Manufacturer.

(c) Manufacturer shall ensure that electronic funds transfers or other payments to dispensing entities are timely, complete, and accurate to the best of their knowledge, including maintaining sufficient funds in the identified bank account(s) to complete the transfer of the amount authorized by the Manufacturer's claim-level payment elements.

(d) Manufacturer shall provide the MTF Data Module Contractor with banking information via the MTF DM and keep this information up to date, including updating the Manufacturer's bank account information in the MTF Data Module no less than thirty (30) calendar days prior to the effective date of any changes to such banking information.

(e) Manufacturer shall receive payment confirmation from the MTF PM via the MTF DM demonstrating effectuation of payment and close-out of the open transaction.

(f) Manufacturer shall ensure that any third party with which the Manufacturer has contracted to support payment facilitation complies with the requirements of this Agreement, the MTF Program Agreement, and the Negotiation Program Agreement(s).

(g) Manufacturer shall comply with any instructions, processes, and requirements as directed by the MTF Payment Module Contractor.

(h) Manufacturer shall utilize the MTF PM consistent with the Manufacturer's MFP Effectuation Plan and make any updates to the MFP Effectuation Plan within the timelines and in accordance with all requirements established by applicable guidance, regulations, and technical instructions.

III   MTF PAYMENT MODULE CONTRACTOR'S RESPONSIBILITIES

Consistent with the terms of the MTF Program Agreement, and other applicable guidance, regulations, agreements, and technical instructions:

(a) MTF Payment Module Contractor shall provide customer support to the Manufacturer or a third-party contractor supporting the Manufacturer's activity in the MTF when requested by CMS or a contractor engaged by CMS to intake customer service inquiries.

(b) MTF Payment Module Contractor shall facilitate accurate and timely Automated Clearing House (ACH) payment transactions, either via ACH or paper check payments sent to dispensing entities and communicate completion of those transactions to the MTF DM so that the ERA or remittance advice can be generated.

(c) MTF Payment Module Contractor shall support implementation of the Ledger System established in applicable guidance, regulations, and technical instructions.

(d) MTF Payment Module Contractor shall comply with processes related to unclaimed funds as outlined by CMS in applicable guidance, regulations, and technical instructions.

(e) MTF Payment Module Contractor shall facilitate any audit requests from CMS.

IV   MUTUAL OBLIGATIONS

The Manufacturer and the MTF Payment Module Contractor agree that prior to the initial transmission of claim-level data elements, the Manufacturer and the MTF Payment Module Contractor will coordinate with the MTF Data Module Contractor to establish which of the Manufacturer's bank account(s) are to be used to transfer funds of the Manufacturer to dispensing entities, as authorized and directed by the Manufacturer. This process must be completed in accordance with the MTF Data Module Contractor's instructions prior to the first transmission of claim-level data elements in order to allow for validating bank account information.

V   CONFIDENTIALITY PROVISIONS

(a) The Manufacturer shall comply with the confidentiality and data use provisions outlined in sections VI, VII, and Exhibit A of the MTF Program Agreement for all information disclosed to the Manufacturer in connection with or related to this Agreement. The MTF

Payment Module Contractor shall comply with the requirements regarding confidentiality and data security contained in the federal procurement contract between CMS and the MTF Payment Module Contractor.

(b) Any information disclosed by the Manufacturer to the MTF Payment Module Contractor in connection with this Agreement that is identified by the MTF Payment Module Contractor as proprietary based on applicable guidance, regulations, and technical instructions, including but not limited to, the Manufacturer MTF Enrollment Information, banking information, and the claim-level payment elements, will not be disclosed by the MTF Payment Module Contractor in a form that identifies the Manufacturer, except as necessary to carry out provisions of section 1196 of the Act or as otherwise required by law.

(c) Notwithstanding the nonrenewal or termination of this Agreement for any reason, the confidentiality provisions of this Agreement will remain in full force and effect with respect to information disclosed under this Agreement prior to the effective date of such termination.

VI   ORDER OF PRECEDENCE

In the event of any inconsistencies between this Agreement and any applicable statute, regulations, and guidance implementing the Negotiation Program, the applicable statute, regulations, and guidance will take precedence. As related to the Manufacturer, in the event of any inconsistencies between this Agreement, the MTF Program Agreement and the Negotiation Program Agreement(s), first the Negotiation Program Agreement(s) will take precedence, then the MTF Program Agreement will take precedence.

VII   EFFECTIVE DATE, TERM, RENEWAL AND TERMINATION

(a) This Agreement shall have an effective date of the date when it is signed by the last party to sign it (as indicated by the date associated with the party's signature).

(b) The initial term of this Agreement will extend through December 31 following the calendar year in which this Agreement takes effect. This Agreement thereafter shall automatically renew after the initial term and after each subsequent renewal year for one year renewal terms starting on January 1 of each following year.

(c) Subject to the limitations on the scope of termination in sections VII(d), (e), (f), (g), (h) and (j) of this Agreement, this Agreement will terminate:

   (1) Upon the termination of the MTF Program Agreement. As stated in section VIII of the MTF Program Agreement, the termination of the MTF Program Agreement will automatically and simultaneously terminate this MTF PM Agreement and such termination shall be effective as of the termination date of the MTF Program Agreement; or

   (2) Upon the effective date of a decision by the Manufacturer to no longer utilize the MTF PM, following the notice requirements established in section II(h) of this Agreement and in the applicable guidance, regulations and technical instructions.

(d) If the MTF Program Agreement is terminated only as to a specific selected drug(s) as set forth in section VIII of the MTF Program Agreement then this Agreement is terminated

only as to the specific selected drug(s), but otherwise remains in effect with respect to the remaining selected drug(s) listed on Addendum 1 of the MTF Program Agreement.

(e) Each selected drug covered by this Agreement is considered a separate and severable obligation, allowing for independent termination of this Agreement as to a particular selected drug by its removal from Addendum 1 of the MTF Program Agreement without affecting this Agreement's continued applicability to the selected drug(s) that remain listed on Addendum 1 to the MTF Program Agreement.

(f) Any termination of this Agreement will not affect the Manufacturer's responsibility for effectuating the MFP for dispenses of each selected drug to MFP-eligible individuals that were incurred by the Manufacturer before the effective date of this Agreement's termination, as described in applicable guidance, regulations, and technical instructions.

(g) If the Manufacturer transfers ownership of all New Drug Applications ("NDAs") or Biologics License Applications ("BLAs") of certain selected drug(s) to another entity, this Agreement will terminate as to the transferred selected drug(s). This Agreement will stay in effect for the other selected drug(s) of the Manufacturer listed on Addendum 1 of the MTF Program Agreement. If the Acquiring Manufacturer elects to utilize the MTF PM, the new Primary Manufacturer must sign a new agreement with the MTF Payment Module Contractor to utilize the MTF PM for the transferred selected drug(s); or if the Acquiring Manufacturer has already signed this Agreement for its selected drug(s), the selected drug(s) is covered by this Agreement as soon as it is added to Addendum 1 of the Acquiring Manufacturer's MTF Program Agreement.

(h) Notwithstanding the termination of this Agreement, certain requirements and obligations shall continue to apply in accordance with applicable guidance, regulations and technical instructions. The provisions of section V and other provisions of this Agreement necessary to effectuate the terms herein and the terms of the MTF Program Agreement will survive termination of this Agreement.

VIII   GENERAL PROVISIONS

(a) **Force Majeure**. Neither party shall 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 this Agreement promptly upon the cessation of the Force Majeure Event.

(b) **Failure to Insist on Strict Performance**. No failure by any party to insist upon the strict performance of any requirement, obligation or condition of this MTF PM Agreement shall constitute a waiver of any such requirement, obligation or condition.

(c) **Coverage of Third Parties**. The terms "MTF Payment Module Contractor" and "Manufacturer" incorporate any contractors that fulfill responsibilities pursuant to this MTF PM Agreement on behalf of such party unless specifically stated otherwise in this MTF PM Agreement. Each party shall ensure that any contractor fulfilling any of such party's

responsibilities under this MTF PM Agreement on behalf of such party complies with the terms of this MTF PM Agreement.

(d) **Entire Agreement**. This MTF PM Agreement and the addendum attached hereto contains the entire agreement of the parties to this Agreement with respect to the subject matter of this Agreement, and supersedes all prior oral and written representations, agreements and understandings with respect thereto.

(e) **Additional Provisions and Amendments.** The MTF Payment Module Contractor reserves the right to include additional provisions, requirements, or terms and the right to amend this Agreement as it deems necessary or appropriate for the administration of the MTF PM, on its own or at the direction of CMS, subject to applicable laws, guidance, or regulations and the prior approval of CMS. Any such provisions, once approved by CMS, shall be communicated in writing to the Manufacturer and incorporated into this MTF PM Agreement. As feasible, the MTF Payment Module Contractor will endeavor to provide the Manufacturer at least sixty (60) calendar day notice of any amendment to this Agreement.

(f) **Notice**. Any notice required to be given to the MTF Payment Module Contractor pursuant to the terms of this MTF PM Agreement shall be sent in writing to [XX]. Any notice required to be given to the Manufacturer pursuant to the terms of the MTF Program Agreement shall be sent in writing via email to the email address provided as part of the Manufacturer MTF Enrollment Information.

(g) **No Authorization for Acts Contrary to Law; Severability.** Nothing in this Agreement shall 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 shall be construed in all respects as if any invalid or unenforceable provision were eliminated, and without any effect of any other provision.

(h) **Waiver**. Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the MTF Payment Module Contractor under any applicable law.

(i) **Choice of Law and Forum**. 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.

(j) **Non-Endorsement of CMS Views**. In signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS's or the MTF Payment Module Contractor's views and makes no representation or promise beyond its intention to comply with its obligations under the terms of this Agreement with respect to the selected drug(s). Use of the term "maximum fair price" and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms.

(k) **Headings**. The headings of sections and provisions contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

IX   SIGNATURES

FOR THE MANUFACTURER

A. By signing this MTF PM Agreement, the Manufacturer understands that violations of this MTF PM Agreement may result in the penalties as provided in the MTF Program Agreement.

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

C. 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 MTF PM Agreement and agrees to all the terms specified herein.

I certify that I have made no alterations, amendments or other changes to this MTF PM Agreement.

By: _____ (print name)

_____ (signature)

Title: _____

Name of Manufacturer: _____

Manufacturer Mailing Address: _____

Date: _____

FOR THE MTF PAYMENT MODULE CONTRACTOR

By: _____ (print name)

_____ (signature)

Title: _____

Date: _____