DRAFT MEDICARE TRANSACTION FACILITATOR PROGRAM AGREEMENT

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

Between

The Centers for Medicare & Medicaid Services

(hereinafter referred to as "CMS")

And

[FULL NAME OF MANUFACTURER]

(hereinafter referred to as "the Manufacturer")

WHEREAS, pursuant to one or more Medicare Drug Price Negotiation Program Agreements between CMS and the Manufacturer (hereinafter referred to as the "Negotiation Program Agreement(s)," as defined in section I(l) of this Agreement), the Manufacturer is the Primary Manufacturer, as defined in applicable guidance or regulations, of the selected drug(s) identified on Addendum 1 to this Agreement (hereafter referred to as the "selected drug(s)" or each "selected drug") and has agreed to provide access to the maximum fair price ("MFP") for such selected drug(s) to pharmacies, mail order services, and other dispensing entities with respect to MFP-eligible individuals who are dispensed such drug(s);

WHEREAS, CMS determined it will engage a Medicare Transaction Facilitator (MTF) for the Medicare Drug Price Negotiation Program (hereinafter referred to as the "Negotiation Program") to, among other things, facilitate the effectuation of MFP between manufacturers and dispensing entities, including through the exchange of data;

WHEREAS, CMS determined it will engage an MTF for the Negotiation Program to offer a voluntary payment facilitation function for participating manufacturers to pass through MFP refund payments to dispensing entities in a reliable, predicable and consistent manner;

WHEREAS, one or more government contractors will administer the MTF's data exchange functionality (hereinafter the "MTF Data Module" or "MTF DM," as defined in section I(f) of this Agreement) and voluntary payment facilitation functionality (hereinafter the "MTF Payment Module" or "MTF PM," as defined in section I(i) of this Agreement);

WHEREAS, in accordance with sections 1193(a)(5) and 1196 of the Social Security Act ("the Act"), for the purposes of administering and monitoring compliance with the Negotiation Program, participation by manufacturers in the MTF DM shall be mandatory;

WHEREAS, the purpose of a voluntary MTF PM is to facilitate transmission of an MFP retrospective refund on MFP-eligible claims of the selected drug(s) from a participating manufacturer to dispensing entities in accordance with section 1193(a)(3) of the Act, as authorized by the manufacturer's transmission of the necessary payment elements to the MTF DM within the 14-day prompt MFP payment window;

NOW, THEREFORE, 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 1191 through 1198 of the

Act, and for purposes of implementing section II of the Negotiation Program Agreement(s) between CMS and the Manufacturer, hereby agree to the following:

I. DEFINITIONS

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

(a) **"Breach"** is defined in Office of Management and Budget (OMB) Memorandum M-17-12, *Preparing for and Responding to a Breach of Personally Identifiable Information* (January 3, 2017), as the loss of control, compromise, unauthorized disclosure, unauthorized acquisition or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information (PII); or (2) an authorized user accesses or potentially accesses PII for an other than authorized purpose.

(b) **"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.

(c) **"Claim-level payment elements"** means the data, as described in applicable guidance, regulations and technical instruction, 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.

(d) **"Ledger System"** means the system within the MTF PM as described in applicable guidance, regulations, and technical instruction 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.

(e) **"Manufacturer MTF Enrollment Information"** means the Manufacturer's identifying and, if applicable, financial information as described in CMS' instruction for MTF enrollment within the Primary Manufacturer MFP Effectuation Plan. 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.

(f) "**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.

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

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

(i) "**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 this MTF Program Agreement.

(j) **"MTF Payment Module Contractor"** means a contractor to CMS retained to establish and maintain the MTF PM.

(k) **"MTF PM Agreement"** means the agreement between the MTF Payment Module Contractor and the Manufacturer if the Manufacturer elects to utilize the MTF Payment Module.

(l) **"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).

(m) **"Security Incident" or "Incident"** means a security incident as defined in OMB Memorandum M-17-12, *Preparing for and Responding to a Breach of Personally Identifiable Information* (January 3, 2017), as an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality or availability of information or an information system; or (2) constitutes a violation or imminent threat or violation of law, security policies, security procedures or acceptable use policies.

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 1191 through 1198 of the Act and any applicable guidance and regulations implementing those provisions.

II. MANUFACTURER'S RESPONSIBILITIES

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

(a) Manufacturer shall utilize the MTF DM to provide access to the maximum fair price (MFP) for the selected drug(s) to pharmacies, mail order services, and other dispensing entities with respect to MFP-eligible individuals who are dispensed such drug(s);

(b) When utilizing the MTF DM, Manufacturer shall comply with all requirements and conditions for MFP effectuation and CMS monitoring thereof, including, without limitation, all applicable CMS guidance, regulations, and technical instructions.

(c) Manufacturer shall enter into and have in effect, under terms and conditions approved by CMS, an agreement with the MTF Data Module Contractor and, as applicable, the MTF Payment Module Contractor.

(d) Manufacturer shall comply with the MTF Data Module Contractor's and, as applicable, the MTF Payment Module Contractor's, instructions, processes, and requirements.

(e) Manufacturer shall ensure any Secondary Manufacturer(s) of the selected drug(s) for which MFP will be effectuated pursuant to this Agreement complies with the terms of this Agreement, including but not limited to the obligations related to confidentiality and data use established in sections VI, VII and Exhibit A of this Agreement.

(f) Manufacturer shall maintain all records that the Manufacturer may create or receive in connection with the MTF, and any audits and investigations described in section V of this Agreement, for at least ten (10) years from the date of the sale of the selected drug(s) to which the record relates. This includes a requirement that the Manufacturer maintain documentation on all claims for the selected drug(s) that were dispensed to an MFP-eligible individual, whether an MFP refund payment was paid via the MTF PM, outside the MTF PM or whether an MFP refund was not paid. Such records shall be made available to CMS and its agents, designees or contractors or any other authorized representatives of the United States Government, or their designees or contractors, at such times,

places, and in such manner as such entities may reasonably request for the purposes of audits, inspections, and examinations.

(g) Manufacturer shall cooperate with all compliance activities in which CMS shall engage to ensure compliance with applicable guidance and regulations, Negotiation Program Agreement(s), and this Agreement, including but not limited to any audits carried out by CMS pursuant to section V of this Agreement.

(h) Manufacturer shall use the MTF DM and, if applicable, the MTF PM, during the entire term of this Agreement, in accordance with all applicable laws, regulations, and guidance, including, without limitation, the Anti-Kickback Statute.

(i) In regard to the Manufacturer's use of the MTF DM, the Manufacturer shall:

1. Access the MTF claim-level data elements via the MTF DM.
2. Transmit complete and accurate claim-level payment elements to the MTF DM within the 14-day prompt MFP payment window. Such transmission shall be in accordance with all applicable regulations and guidance and shall apply without limitation to instances in which: the claim-level payment elements reflect an adjustment (see section II(i)(3) below); the MFP is provided prospectively; and/or the selected drug(s) is initially sold by a Secondary Manufacturer.
3. When claim-level data elements are sent for an adjusted claim, transmit complete and accurate claim-level payment elements to the MTF DM within the 14-day prompt MFP payment window that begins with the date of MTF DM transmission to the Manufacturer of the claim-level data elements for the adjusted claim. The existence of an adjusted claim does not affect the Manufacturer's obligation to respond to the original claim within the 14-day prompt MFP payment window even if the claim-level data elements for the adjusted claim are sent to the Manufacturer during the original claim's 14-day prompt MFP payment window, though the Manufacturer's claim-level payment elements sent in response to the original claim may incorporate information from the adjusted claim and the Manufacturer may provide a response to the adjusted claim that indicates payment was provided on the original claim.
4. Submit revised claim-level payment elements if the Manufacturer knows or has reason to know that previously returned claim-level payment elements do not accurately reflect the amount needed to make the MFP available to dispensing entities.
5. Notify CMS of a change to the Manufacturer MTF Enrollment Information within thirty (30) calendar days of the change taking effect by updating the information in the MTF DM; notwithstanding the foregoing, in the event of a change to bank account information, if applicable, the Manufacturer shall comply with the notice requirements in section II(j)(3).

(j) If the Manufacturer elects to use the MTF PM, in regard to the Manufacturer's use of the MTF PM, the Manufacturer shall:

1. 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 and regulations. If the Manufacturer opts into the MTF PM, the Manufacturer shall typically use the MTF PM for all its selected drug(s); however, the Manufacturer PM remains free to effectuate MFP outside of the MTF PM with respect to dispensing entities that have mutually agreed upon an alternative process.
2. Provide the MTF Data Module Contractor with the Manufacturer's banking account information

for the MTF Data Module Contractor to share with the MTF Payment Module Contractor in order to execute MFP refund payments, in accordance with applicable guidance, regulations and technical instructions.

3. Notify CMS of a change to the Manufacturer's bank account information thirty (30) calendar days in advance of the change taking effect by updating the information in the MTF Data Module.
4. Authorize the MTF PM to send to dispensing entities a payment equal to the total refunds to be paid as indicated in the Manufacturer's reported claim-level payment elements, regardless of any credits which may be applied under the Ledger System. Manufacturer's return of the claim-level payment elements shall constitute the authorization for the MTF PM to transmit the MFP refund payments from the bank account the Manufacturer has on file with the MTF DM to the dispensing entities identified in the claim-level payment elements.
5. Provide CMS at least ninety (90) calendar day notice of a decision to no longer utilize the MTF PM, either in its entirety or as to a specific selected drug(s).
6. Comply with the terms of the Ledger System described in applicable regulations, guidance, and technical instructions, including but not limited to the following:
    i. Manufacturer shall review all credits and debits to confirm accuracy.
    ii. Manufacturer acknowledges that accrued credits will be applied by the MTF PM to the next MTF refund transaction between the Manufacturer and the specific dispensing entity NPI for the selected drug for which the credit was originally granted.
    iii. Manufacturer acknowledges that, if Manufacturer terminates participation in the Negotiation Program, either in its entirety or as to a specific selected drug(s), therefore terminating this Agreement following the process described in section VIII(d) of this Agreement, or has terminated participation in the MTF PM either in its entirety or as to a specific selected drug(s), CMS will provide the Manufacturer with an accounting of any outstanding credits in the Ledger System. It is the responsibility of the Manufacturer to work with dispensing entities if a Manufacturer believes funds are owed for the credits and to make payment to the dispensing entities if necessary to effectuate MFP. Such outstanding credits shall not be treated as unclaimed funds under applicable guidance, regulations, and technical instructions, and claims by the Manufacturer to any outstanding credits are not within the scope of the dispute or complaint process established in applicable guidance and regulations and must be taken up directly with the applicable dispensing entities.
    iv. Manufacturer acknowledges that if a selected drug(s) transfers ownership, as described in section VIII(e), credits and debits will remain in the Ledger System and be transferred from the Transferring Manufacturer (as defined in section VIII(e)(2)) to the Acquiring Manufacturer (as defined in section VIII(e)(2)). Any agreement between the Transferring Manufacturer and the Acquiring Manufacturer regarding the value of the credits are beyond the scope of this Agreement.

(k) If the Manufacturer is assuming ownership and control of the selected drug(s) as a result of a transfer of all NDAs or BLAs of the selected drug(s), as described in section VIII(e) of this Agreement, the Manufacturer shall assume responsibility to provide access to the MFP with respect to all MFP-eligible claims for the selected drug(s) for which MFP has not been effectuated as of the

date of transfer, including without limitation any adjustments for previous MFP-eligible claims that are received on or after the date of transfer. This provision shall apply notwithstanding that the effective date of such transfer may occur before the effective date of this Agreement. The Manufacturer shall also assume control of any outstanding credits under the Ledger System.

III. CMS' RESPONSIBILITIES

Pursuant to section 1196 of the Act and any applicable guidance and regulations implementing those provisions:

(a) CMS shall engage with an MTF Data Module Contractor and MTF Payment Module Contractor to establish the MTF to facilitate the exchange of data and payment.

(b) CMS shall provide technical instructions and ensure that user inquiries from the Manufacturer are addressed regarding the MTF DM and MTF PM.

(c) CMS shall provide a complaint mechanism through the MTF DM to address concerns raised by the Manufacturer regarding MFP availability and any issues with the MTF, if good faith efforts to address issues with dispensing entities directly are not successful.

(d) CMS shall provide a dispute mechanism within the MTF DM to address technical challenges or issues with a technical aspect of the MTF DM or MTF PM system or process.

(e) CMS shall provide a Ledger System as described in section I(d) of this Agreement.

(f) In accordance with section 1196 of the Act, CMS shall monitor compliance by the Manufacturer with the terms of this Agreement, any applicable guidance and regulations, and the Negotiation Program Agreement(s). Part of CMS' monitoring efforts include the audit process established in section V of this Agreement.

(g) In its sole discretion, CMS may use information related to this Agreement, including, without limitation, information about and generated by the Manufacturer, and, to promote compliance with the statutes, regulations and written directives of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) ("Federal health care program"), CMS may disclose such information to law enforcement and regulatory authorities.

IV. PENALTY PROVISIONS

Pursuant to section 1193(a)(5) of the Act and the terms of Manufacturer's Negotiation Program Agreement(s), compliance with the terms of this Agreement is necessary for the purposes of administering and monitoring compliance with the Negotiation Program. CMS may take enforcement action against Manufacturer for a violation of this Agreement including without limitation, requests for implementation of corrective action plans, referrals to the Office of the Inspector General or other federal law enforcement agencies and assessment of civil monetary penalties (CMPs).

V. AUDIT RIGHTS

(a) The United States Department of Health and Human Services, CMS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any information described in section II(f), including, but not limited to, any books, contracts, and computer or other electronic systems. This right to audit, evaluate, collect, make copies of, and inspect any pertinent information will exist through ten (10) years from the date of sale of the selected drug(s) to which the record relates.

(b) The Manufacturer acknowledges and agrees that, in order to comply with section 1196(b) of the Act, CMS reserves the right to request such information from the Manufacturer as is necessary to monitor compliance by the Manufacturer with the terms of the Negotiation Program Agreement(s), including financial institution and banking information.

VI. CONFIDENTIALITY PROVISIONS

(a) Any information disclosed by the Manufacturer to CMS or its contractors in connection with this Agreement that CMS identifies as proprietary based on applicable guidance and regulations, including but not limited to, the Manufacturer MTF Enrollment Information, banking information, and the claim-level payment elements, will not be disclosed by CMS in a form that identifies the Manufacturer, except as necessary to carry out provisions of sections 1196 of the Act or as otherwise required by law. This restriction does not limit the Health and Human Services Office of Inspector General's authority to fulfill the Inspector General's responsibilities in accordance with applicable Federal law. CMS will disclose contact information for the Manufacturer to dispensing entities for the purposes of resolving issues related to MFP availability or establishing an agreement to make the MFP available.

(b) Except where otherwise specified in the Act, the Negotiation Program Agreement(s), this Agreement, or applicable guidance and regulations, the Manufacturer shall observe applicable confidentiality statutes, regulations and other applicable confidentiality requirements.

(c) The Manufacturer acknowledges that the claim-level payment elements reported by the Manufacturer are retained in compliance with CMS data privacy, security, and storage rules, which align with National Archives and Records Administration ("NARA") records retention and disposition requirements. CMS maintains primary authority over the data's lifecycle, including retention duration and secure disposal requirements per NARA schedules (https://www.archives.gov/about/records-schedule).

(d) 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.

VII. DATA USE PROVISIONS

(a) The Data Use provisions set forth in Exhibit A of this MTF Program Agreement govern the use of data CMS provides to the Manufacturer either directly or through the MTF DM for purposes of administration of the Negotiation Program pursuant to the Negotiation Program Agreement.

(b) Notwithstanding the nonrenewal or termination of this Agreement for any reason, the data use 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.

VIII. EFFECTIVE DATE, TERM AND RENEWAL, APPLICATION TO MULTIPLE SELECTED DRUGS, TERMINATION, AND TRANSFER OF SELECTED DRUG(S)

(a) **Effective Date**: 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) **Term and Renewal**: The initial term of this Agreement will extend through December 31 of the year 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 term for one-year renewal terms starting on January 1 of each following year.

(c) **Application to Multiple Selected Drugs**

1. This Agreement covers all of the Manufacturer's interactions with the MTF DM for all selected drug(s) for which the Manufacturer holds Negotiation Program Agreement(s). Each selected drug for which the Manufacturer holds a Negotiation Program Agreement must be identified on Addendum 1 to this Agreement. If applicable, this Agreement covers all of the Manufacturer's interactions with the MTF PM.
2. Addendum 1 to this Agreement must be updated and executed each time the Manufacturer has entered into a new Negotiation Program Agreement for a selected drug(s) and an MFP is negotiated for that selected drug(s), as evidenced by the execution of Addendum 1 of the Negotiation Program Agreement, or when this Agreement is terminated as to a selected drug(s) but this Agreement remains in effect with respect to another selected drug(s). This Agreement must be executed before the start of the initial price applicability year for the selected drug(s) by the deadline established by CMS in applicable regulations, guidance and technical instructions.
3. Each selected drug covered by this Agreement pursuant to its inclusion in Addendum 1 of 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 this Agreement without affecting this Agreement's continued applicability to the selected drug(s) that remain listed on Addendum 1 to this Agreement.

(d) **Termination**

1. Except as provided in section VIII(e)(2), CMS is the sole party with the authority to terminate this Agreement. CMS may terminate this Agreement if CMS determines it will no longer provide the MTF as a service to manufacturers and dispensing entities. CMS shall provide the Manufacturer with at least one hundred eighty (180) calendar day notice prior to the effective date of termination pursuant to this section VIII(d)(1).
2. Notwithstanding the foregoing and subject to sections VIII(d)(3), VIII(d)(8), and VIII(e), this Agreement shall terminate automatically upon the termination of the Manufacturer's Negotiation Program Agreement with respect to a selected drug(s), in which case the effective date of termination of this Agreement shall be the effective date of termination of the Negotiation Program Agreement with respect to such selected drug(s).
3. Pursuant to section VIII(c)(3) above, termination of this Agreement as to a particular selected drug(s) via removal of that drug from Addendum 1 of this Agreement will not affect other selected drug(s) covered by this Agreement.
4. 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 makes MFP available for all previous time periods in which this Agreement was in effect.
5. The Manufacturer agrees to destroy the claim-level data elements it has received under this Agreement in accordance with Exhibit A of this Agreement and certify the destruction of the data in writing to CMS and the MTF Data Module Contractor.
6. The MTF DM Agreement and, if executed, the MTF PM Agreement, will terminate:
    i. In their entirety if this Agreement is terminated in its entirety, effective as of the termination date of this Agreement; or

ii. As to a specific selected drug(s) as of the date that the particular selected drug(s) is removed from Addendum 1 to this Agreement.

7. 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 under this Agreement before the effective date of its termination, as described in applicable guidance, regulations, and technical instructions , except in cases where the Manufacturer has transferred ownership of the selected drug(s) as described in section VIII(e).
8. If the Manufacturer has executed the MTF PM Agreement for its selected drug(s) and decides to no longer utilize the MTF PM as to its selected drug(s), the Manufacturer must make updates to the MFP Effectuation Plan within the timelines established by applicable guidance and regulations. The Manufacturer must also terminate the agreement between the Manufacturer and the MTF Payment Module Contractor.
9. Notwithstanding the termination of this Agreement, certain requirements and obligations shall continue to apply in accordance with applicable guidance and regulations. The provisions of sections IV, V, VI, VII, VIII, and IX, and other provisions necessary to effectuate the terms herein will survive termination of this Agreement. The other provisions of this Agreement necessary to effectuate the terms herein will survive the termination of this Agreement until all MFP-eligible claims for which the Manufacturer has incurred responsibility for effectuating the MFP prior to the effective date of termination have been addressed by the Manufacturer.

(e) **Transfer of Selected Drug(s)**

1. If the Manufacturer transfers ownership of one or more New Drug Applications ("NDAs") or Biologics License Applications ("BLAs") of the selected drug(s) to another entity, the Manufacturer remains responsible for all requirements of this Agreement associated with the transferred NDAs/BLAs unless and until the Manufacturer transfers all NDAs/BLAs of the selected drug that it holds to an entity and such acquiring entity assumes responsibility as the new Primary Manufacturer of such selected drug(s), in accordance with applicable guidance, regulations, and technical instructions.
2. Notwithstanding any provision herein to the contrary, if the Manufacturer (referred to as the "Transferring Manufacturer" herein) transfers ownership of all NDAs or BLAs of all selected drug(s) covered by this Agreement to another entity (referred to as the "Acquiring Manufacturer" herein), such that no selected drug(s) would remain listed on Addendum 1, this Agreement, the MTF DM Agreement and the MTF PM Agreement, if applicable, shall automatically terminate as of the date of transfer.
3. If the Transferring Manufacturer transfers ownership of all NDAs or BLAs of certain selected drug(s) to the Acquiring Manufacturer but retains ownership and control of additional selected drug(s) covered by this Agreement, and Acquiring Manufacturer does not currently hold a signed MTF Program Agreement

    i. The Transferring Manufacturer's MTF Program Agreement, Addendum 1 shall be updated to remove the transferred selected drug(s).

    ii. The Acquiring Manufacturer must execute an MTF Program Agreement and MTF DM Agreement, and, if it elects to use the MTF PM, an MTF PM Agreement, and must list

the selected drug(s) on Addendum 1 of the Acquiring Manufacturer's MTF Program Agreement.

iii. Updates to the Transferring Manufacturer's MTF Program Agreement and MTF PM Agreement, if applicable, and the Acquiring Manufacturer's MTF Program Agreement, MTF DM Agreement and MTF PM Agreement, if applicable shall have the same effective date.

4. If the Transferring Manufacturer transfers ownership of all NDAs or BLAs of certain selected drug(s) to the Acquiring Manufacturer but retains ownership and control of additional selected drug(s) covered by this Agreement, and Acquiring Manufacturer currently holds a signed MTF Program Agreement:

   i. Addendum 1 to the Transferring Manufacturer's MTF Program Agreement shall be updated to remove the selected drug(s).

   ii. The Acquiring Manufacturer must update Addendum 1 of its existing MTF Program Agreement.

   iii. Updates to the Transferring Manufacturer's Program Agreement and MTF PM Agreement, if applicable, and updates to the Acquiring Manufacturer's Program Agreement shall have the same effective date.

5. Transferring Manufacturer must provide CMS at least thirty (30) calendar day written notice before the effective date of any transfer of ownership covered by this section.

IX. DISCLAIMERS

(a) The MTF DM and MTF PM are provided "as-is" and without any representation or warranty of any kind, either expressed or implied, including but not limited to, the implied warranties of merchantability and fitness for a particular purpose. CMS disclaims responsibility for any consequences or liability attributable to or related to any use, non-use, or interpretation of information contained or not contained in the MTF.

(b) The Manufacturer shall release CMS from all claims, demands, and damages arising out of or connected with the MTF. In no event shall CMS be liable for direct, indirect, special, incidental, or consequential damages arising out of the Manufacturer's use of the MTF.

(c) The Manufacturer shall indemnify and hold harmless CMS and the federal government from and against any and all liability, loss, damage, costs, or expenses, arising out of or in connection with any negligent action, inaction, or willful misconduct of the MTF Data Module Contractor, MTF Payment Module Contractor, the Manufacturer, or dispensing entities.

(d) CMS shall not assume and shall bear no liability with respect to any losses incurred by the Manufacturer as a result of the Manufacturer's use of the MTF DM and, as applicable, the MTF PM.

(e) Under no circumstances and under no legal theory, whether tort (including negligence), contract, or otherwise, shall CMS be liable to the Manufacturer or any other person for any indirect, special, incidental, or consequential damages of any character including, without limitation, damages for loss of goodwill, work stoppage, computer failure or malfunction, or any and all other commercial damages or losses, even if such party shall have been informed of the possibility of such damages. CMS shall not be liable or obligated to the Manufacturer for any losses incurred or sustained by the Manufacturer and arising in whole or in part, directly or

indirectly, from any fault of the Manufacturer, or fault, delay, omission, inaccuracy by or termination of the MTF DM or MTF PM. CMS shall not be liable for any claims attributable to any errors, omissions, or other inaccuracies made by the MTF DM, MTF PM, the Manufacturer, or dispensing entities.

(f) The MTF Payment Module offers a voluntary payment facilitation functionality that will be made available for participating manufacturers to facilitate the transfer of MFP refund payments to dispensing entities for purposes of effectuating access to the MFP for their selected drug(s). The MTF PM connects the Manufacturer, if the Manufacturer elects to participate in the MTF PM, to dispensing entities to facilitate transmission of an MFP retrospective refund on MFP-eligible claims of selected drug(s) from the Manufacturer to dispensing entities in accordance with section 1193(a)(3) of the Act. If applicable, the MTF PM: (1) provides the Manufacturer with a mechanism for electronic transfer of funds or payment by paper check to facilitate MFP refund payments to dispensing entities; and (2) provides the Manufacturer with the Ledger System described in section II(j)(6) of this Agreement to track the flow of MFP refunds and to handle reversals, adjustments, and other claim revisions inevitable in a dynamic claim payment system. However, the MTF PM's receipt and use of payment-related data (originating from the participating Manufacturer, transmitted to the MTF DM, and then provided to the MTF PM) or any other role of the MTF PM in facilitating the transfer of the participating Manufacturer's authorized payments to dispensing entities shall not in any way indicate or imply that CMS had determined payment was required, or that CMS agrees that the amount paid by the participating Manufacturer is necessary and sufficient to make the MFP available to dispensing entities in accordance with the participating Manufacturer's statutory obligations under section 1193(a)(3)(A) of the Act. CMS does not have any interest in, or control over, any interest that might accrue on funds held by the MTF during the period before the funds are transferred to the dispensing entities.

(g) That dispensing entities' contact and payment information is available in the MTF does not in any way indicate or imply a certification from CMS that dispensing entities' contact and payment information is correct and accurate.

(h) The existence of, and the Manufacturer's voluntary participation in, if applicable, the MTF PM does not supersede or alter the Manufacturer's statutory obligation to effectuate the MFP. Neither CMS nor the MTF Data Module Contractor or MTF Payment Module Contractor are responsible for funding or paying the refund amount owed by the Manufacturer in instances where the Manufacturer does not pay an MFP refund owed to dispensing entities, including in cases where the Manufacturer may be unable to pay (e.g., bankruptcy, insolvency).

(i) Under no circumstances will federal funds be used with respect to transactions made through the MTF PM or to resolve or make payment related to disputes that may arise when the MTF PM is utilized, including with respect to nonpayment or insufficient payment by the Manufacturer.

(j) If the Manufacturer elects to participate in the MTF PM, the MTF PM serves only as a mechanism to pass through funds of the Manufacturer to dispensing entities in order to provide access to the MFP as directed by the Manufacturer in the amounts authorized by the Manufacturer and is not for any other use.

(k) Funds collected through the MTF PM are for the sole benefit of dispensing entities who receive those funds and are not collected for any other use.

(l) This Agreement's terms are not enforceable by any third-party beneficiaries.

(m) If the Manufacturer elects to participate in the MTF PM, neither CMS nor its MTF Contractors will assert independent control over the disposition of deposited payment amounts or direct payment transfers; instead, the MTF Contractors will perform a ministerial function at the behest and direction of the Manufacturer with respect to the pass through of the Manufacturer's funds in the amounts and to the dispensing entities identified by the Manufacturer in its claim-level payment elements.

X. GENERAL PROVISIONS

(a) **Authority to Amend**. CMS may unilaterally amend this MTF Program Agreement, including to reflect changes in law, regulation, or guidance. As feasible, CMS will endeavor to provide the Manufacturer at least sixty (60) calendar day notice of any amendment to this Agreement.

(b) **Notice**. Any notice required to be given to CMS pursuant to the terms of this MTF Program Agreement shall be sent in writing via email to IRARebateandNegotiation@cms.hhs.gov. Any notice required to be given to the Manufacturer pursuant to the terms of this MTF Program Agreement shall be sent in writing via email to the Manufacturer's points of contact as identified in the MTF DM.

(c) **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 on any other provision.

(d) **Waiver**. 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.

(e) **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.

(f) **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 and the Negotiation Program Agreement(s), the Negotiation Program Agreement(s) will take precedence.

(g) **Coverage of Third Parties**. 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 to this Agreement 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.

(h) **Force Majeure**. Neither party shall be liable for failure to perform its obligations under this Agreement is 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.

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

(j) **Failure to Insist on Strict Performance**. No failure by any party to this Agreement 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.

(k) **Non-Endorsement of CMS Views**. In signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS'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.

(l) **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.

XI. SIGNATURES

FOR THE MANUFACTURER

(a) By signing this MTF Program Agreement, the Manufacturer agrees to abide by all provisions set forth in this MTF Program Agreement and acknowledges having received notice of potential penalties for violation of the terms of the MTF Program Agreement.

(b) By signing this Agreement, the Manufacturer also attests that:

1. All information the Manufacturer provides to the MTF DM is and will be true, complete, and accurate; and
2. 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 MTF Program Agreement and to legally bind the Manufacturer on whose behalf he or she is executing the MTF Program Agreement to all terms and conditions specified herein. The undersigned individual further attests that he or she has obtained access in the MTF DM as an authorized representative to be signatory for the Manufacturer and that the individual's MTF DM 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 MTF Program Agreement.

By: _____(print name)

_____(signature)

Title: _____

P# _____

Name of Manufacturer_____

Manufacturer's Mailing Address: _____

Date: _____

FOR CMS

By: _____ (print name)

_____(signature)

Title: _____

Date: _____

EXHIBIT A

DATA USE PROVISIONS

(a) PURPOSE

The following provisions address the conditions under which CMS will disclose and the Manufacturer will obtain and use data that 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 (09-70-0553). The CMS data files covered under this Agreement shall include the claim-level data elements, including any derivative data, any data that can be used in concert with other available information to identify Medicare beneficiaries, and any data provided to the Manufacturer in support of the resolution of audits pursuant to section V of this Agreement (hereinafter referred to as "CMS Data"). These provisions govern the use and disclosure of data CMS provides to the Manufacturer either directly or through the MTF Data Module Contractor or MTF Payment Module Contractor for purposes of administration of the Negotiation Program pursuant to section 1196 of the Act and supplement any and all agreements between the parties to this Agreement with respect to the use of MTF DM.

(b) RESPONSIBILITIES CONCERNING AND LIMITATIONS ON USE AND DISCLOSURE OF CMS DATA

1. CMS's RESPONSIBILITIES

   i. CMS and the MTF Data Module Contractor will not disclose to other parties any proprietary 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 sections 1191 through 1198 of the Social Security Act (the Act) as set forth or amended in the Inflation Reduction Act of 2022, Pub. L. 117-169 (IRA) or as otherwise required by law.

   ii. CMS or the MTF Data Module Contractor will disclose to the Manufacturer only the minimum data necessary for the Manufacturer to fulfill its obligations under the Negotiation Program Agreement(s), other applicable guidance, regulations and technical instructions, and this Agreement.

   iii. CMS and the MTF Contractors shall not disclose any direct beneficiary identifiers to the Manufacturer under the Negotiation Program except as may be required by law.

2. MANUFACTURER'S RESPONSIBILITIES

   i. The Manufacturer agrees: (1) to ensure the integrity, security, and confidentiality of CMS Data by complying with the terms of this Agreement and applicable law, including the Privacy Act of 1974 (Privacy Act) and the Health Insurance Portability and Accountability Act of 1996, and its implementing regulations; and (2) to use CMS Data only for purposes of:

      a. Making the MFP available to MFP-eligible individuals who are dispensed selected drug(s) and to pharmacies, mail order services, and other dispensers with respect to such MFP-eligible individuals who are dispensed selected drug(s);

      b. Determining the applicability of the exception to the responsibility to make MFP available established in section 1193(d)(1) of the Act;

      c. Verifying that the MFP for the selected drug(s) was made available to MFP-eligible

individuals who are dispensed such drug(s) and to pharmacies, mail order services, and other dispensers with respect to such MFP-eligible individuals who are dispensed such drug(s); and

d. Addressing disputes and complaints, including complaints regarding the Manufacturer's obligations to make the MFP available as described in applicable statutes, regulations, guidance, the Negotiation Program Agreement(s) and this Agreement.

e. Responding to audits and other compliance monitoring activities undertaken by CMS.

ii. CMS retains all ownership rights to CMS Data referred to in this Agreement. The Manufacturer does not obtain any right, title, or interest in any of CMS Data furnished by CMS through its third-party contractors administering functionalities of the MTF.

iii. The Manufacturer may not use CMS Data to perform any functions not governed by this Agreement. 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.

iv. The Manufacturer agrees not to disclose, use, or reuse CMS Data 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 Negotiation Program or as otherwise required by law. The Manufacturer further agrees not to sell, rent, lease, loan, or otherwise grant access to CMS Data covered by this Agreement, with the exception that the Manufacturer may grant access to CMS Data to contracted third parties for purposes of assisting the Manufacturer in evaluating the accuracy of whether a selected drug(s) was dispensed to an MFP-eligible individual, resolving disputes, and otherwise exercising its rights and responsibilities under this Agreement, so long as such contracted third parties are subject to the same confidentiality and data use requirements set forth in this Agreement and the Manufacturer maintains responsibility for ensuring compliance by these third parties with the confidentiality and data use requirements of this Agreement.

v. The Manufacturer agrees that, within the Manufacturer's organization and the organizations of its agents, access to CMS Data covered by this Agreement shall be limited to the minimum amount of data necessary and minimum number of individuals who need access to CMS Data for permitted activities (i.e., individual's access to CMS Data will be on a need-to-know basis).

vi. The parties to this Agreement mutually agree that CMS Data shall be retained by the Manufacturer for a period of up to ten (10) years from the date of sale of the selected drug(s) to which the record relates. The Manufacturer agrees to destroy CMS Data 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 CMS Data 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 CMS Data once the pending matter is resolved.

vii. The Manufacturer must implement administrative, technical, and physical safeguards that comply with the HIPAA Security Rule (45 CFR Part 164, Subpart C) and align with

CMS's information security policies. Further, the Manufacturer (or a contracted third party) agrees that CMS Data 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 law Any retention of data beyond the ten (10) years from the date of sale of the selected drug(s) to which the record relates requires CMS's prior written approval, and data must be securely destroyed following approved methods, as outlined in the Nara Records Schedule (https://www.archives.gov/about/records-schedule).

viii. The Manufacturer agrees that CMS data, including any data containing or derived from Personally Identifiable Information (PII) or Protected Health Information (PHI) must not be transmitted, stored, processed, or accessed outside the United States without advance written approval of CMS. If CMS approves offshore data handling, the Manufacturer must implement additional safeguards to ensure compliance with all applicable CMS data privacy and security standards, including but not limited to:

a. Maintaining compliance with the HIPAA Privacy and Security Rules, the Privacy Act of 1974, and CMS policies.

b. Ensuring the offshore entity adheres to U.S. federal data protection standards through binding contractual obligations, including audit rights for CMS or its authorized representatives.

c. Establishing encryption standards for data in transit and at rest.

d. Requiring real-time access logging and monitoring to detect unauthorized access.

e. Restricting offshore access to the minimum necessary personnel required to perform approved activities.

f. Ensuring prompt notification to CMS of any data Breach or unauthorized access involving offshore entities, in compliance with Incident reporting requirements in this Agreement.

ix. The Manufacturer further agrees to provide CMS with detailed documentation of the offshore data handling arrangements, including the identity of any subcontractors, security control in place, and measures ensuring compliance with CMS standards.

x. The Manufacturer agrees to grant access to CMS Data 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.

xi. The Manufacturer agrees that it shall not attempt to link records included in CMS Data to any individually identifiable source of information or for the purpose of creating any individually identifiable source of information, except for the purpose of identifying claims that may qualify for the exception under section 1193(d)(1) of the Act (i.e., determining whether the claim was 340B eligible). This includes but is not limited to attempts to link CMS Data to CMS data file(s) obtained pursuant to activities outside of this Agreement. The Manufacturer may link records within CMS Data 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 exceptions to this prohibition that may be necessary for purposes of the administration of the Negotiation Program.

xii. 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 CMS Data 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 CMS Data to CMS or destroy CMS Data it received from CMS under this Agreement.

xiii. In the event that the Manufacturer inadvertently receives any direct beneficiary identifiers, or discovers any other Breach or Incident involving CMS Data, loss of CMS Data or disclosure of CMS Data to any unauthorized persons, the Manufacturer agrees to report the occurrence to the CMS Action Desk by telephone at (410) 786-2580 or by e-mail notification at cms_it_service_desk@cms.hhs.gov within one hour of the Manufacturer's discovery of the occurrence and to cooperate fully in the Federal security incident process. The Manufacturer acknowledges that the use of unsecured telecommunications, including the Internet, to transmit any individually identifiable or deducible information derived from CMS Data is prohibited. While CMS retains all ownership rights to CMS Data, as outlined above, the Manufacturer shall bear all cost and liability for any Breaches or Incidents involving CMS Data while they are in the possession of, or under the control of, the Manufacturer or any of its agent or subcontractors.

3. PENALTIES

The Manufacturer hereby acknowledges that criminal penalties under section 1106(a) of the 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 CMS Data that are covered by section 1106 of the Act 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 any individual employed or affiliated with the Manufacturer knowingly and willfully obtained CMS Data 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 CMS Data, or received CMS Data 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.

ADDENDUM 1: SELECTED DRUGS COVERED BY THIS AGREEMENT ("ADDENDUM 1")

WHEREAS, the Manufacturer has in effect an MTF Program Agreement ("this Agreement"), which Manufacturer entered into with CMS on [DATE];

WHEREAS, over the course of the term of this Agreement, additional selected drug(s) may be covered by this Agreement or certain selected drug(s) may be terminated from this Agreement, following the provisions outlined in section VIII of this Agreement, and the selected drug(s) may be added to or removed from Addendum 1;

WHEREAS, over the course of the term of this Agreement, the Manufacturer may transfer ownership of all New Drug Application(s) (NDAs) or Biologics License Applications (BLAs) of the selected drug(s) to another entity and the Acquiring Manufacturer may assume responsibility for the selected drug(s) as the new Primary Manufacturer as evidenced by a novation to the Transferring Manufacturer's original Negotiation Program Agreement, in which case this Agreement may be terminated with respect to such selected drug(s) as outlined in section VIII(e) of this Agreement and removed from Addendum 1, while this Agreement and Addendum 1 remain in effect for the remaining selected drug(s) listed on Addendum 1;

NOW THEREFORE, Manufacturer and CMS agree to this Addendum 1, such that the below table is a list of the selected drug(s) for which the Manufacturer is the Primary Manufacturer and holds the Negotiation Program Agreement(s) and the status of such selected drug(s) as to this Agreement:

Selected Drug	Date Added to this Agreement	Date Terminated from this Agreement

SIGNATURES

For the Manufacturer

(a) By signing below, the Manufacturer agrees to this Addendum 1 to the Agreement.

(b) The undersigned individual hereby attests that he or she is authorized by the Manufacturer to execute this MTF Program Agreement Addendum 1 and to legally bind the Manufacturer on whose behalf he or she is executing the MTF Program Agreement Addendum 1 to all terms and conditions specified herein. The undersigned individual further attests that he or she has obtained access in the MTF DM as an authorized representative to be signatory for the Manufacturer and that the

individual's MTF DM access credentials contain the same information regarding the undersigned individual as the information set forth below.

By: _____(print name)

_____(signature)

Title: _____

P#: _____

Name of Manufacturer_____

Manufacturer's Mailing Address: _____

Date: _____

For CMS

By:_____(print name)

_____(signature)

Title: _____

Date: _____