MEDICARE TRANSACTION FACILITATOR DATA MODULE USER AGREEMENT

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

Between

The Centers for Medicare & Medicaid Services

(hereinafter referred to as "CMS")

And

The Manufacturer Identified in Section XII of this Agreement

(hereinafter referred to as "the Manufacturer")

WHEREAS, pursuant to one or more Medicare Drug Price Negotiation Program Agreement(s) between CMS and the Manufacturer ("Negotiation Program Agreement(s)," as defined in section I(k) 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 ("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 (hereinafter "dispensing entities") with respect to MFP-eligible individuals who are dispensed such drug(s);

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

WHEREAS, CMS determined it will engage the 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, predictable, and consistent manner;

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

WHEREAS, the MTF Data Module is intended to accomplish the following tasks in the administration of the Negotiation Program:

(1) Act as the user interface with CMS for the MTF to allow the Manufacturer to enroll in the MTF Data Module and, if applicable, MTF Payment Module;

(2) Support verification that the selected drug(s) identified on Addendum 1 of this Agreement was dispensed to an MFP-eligible individual, furnish the Manufacturer with certain claim-level data elements confirming that the selected drug(s) was dispensed to an MFP-eligible individual, and identify which dispensing entities dispensed the selected drug(s) to the MFP-eligible individual;

(3) Initiate the 14-day prompt MFP payment window for the Manufacturer to transmit certain claim-level payment elements and, if applicable, the MFP refund for each claim for the selected drug(s);

(4) Support the implementation by CMS of a dispute and complaint process including collecting disputes and complaints submitted via the MTF DM;

WHEREAS, if the Manufacturer elects not to use the voluntary MTF PM, the MTF Data Module Contractor will collect the claim-level payment elements for each claim for a selected drug(s) indicating whether a refund was paid and the amount of the refund paid to make the MFP available;

WHEREAS, if the Manufacturer elects to use the voluntary MTF PM, the MTF Data Module Contractor shall:

(1) Collect and communicate to the MTF PM the claim-level payment elements for each claim for the selected drug(s) received from the Manufacturer so that authorized funds can be transferred from the Manufacturer's bank accounts and passed through to the applicable dispensing entities;

(2) Support implementation of the Ledger System as defined in section I(d) of this Agreement;

(3) Make available Electronic Remittance Advice ("ERA") that use the X12 835 standard adopted under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") or remittance advice to dispensing entities;

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;

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 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 and regulations, 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 and regulations, 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 individual.

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

(e) **"Manufacturer MTF Enrollment Information"** means the Manufacturer's identifying and, if applicable, financial information within Section 1 of 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 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 Agreement.

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

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

(k) **"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).

(l) **"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 in connection with providing access to the MFP for the selected drug(s) to 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 and regulations.

(c) If the Manufacturer elects to use the MTF PM, the Manufacturer shall enter into and have in effect, under terms and conditions approved by CMS, an MTF PM User Agreement with the MTF Payment Module Contractor.

(d) Manufacturer shall comply with reasonable instructions, processes, and requirements of the MTF Data Module Contractor and, as applicable, the MTF Payment Module Contractor that are associated with use and operations of the MTF DM and, as applicable, the MTF PM.

(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 obligations related to record retention described in section II(f) and section VI of this Agreement and the confidentiality and data use obligations established in sections VII, VIII 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 VI 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, investigations, verifications, 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 VI 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. Establish, identify, and maintain a primary and secondary Point-of-Contact responsible for establishing and maintaining connectivity between the Manufacturer's application programming interface ("API") and the CMS cloud-based software hosting the MTF DM for the purpose of timely receipt of claim-level data elements, timely transmission of claim-level payment elements, and transmission of other information required by CMS, including but not limited to, audit, complaint and dispute information. The primary or secondary Point-of-Contact shall notify the MTF Data Module Contractor in advance of changes that may impact connectivity between the systems.
2. Enroll with the MTF DM and provide complete and accurate Manufacturer MTF Enrollment Information.
3. Notify CMS of a change to the Manufacturer MTF Enrollment Information no later than thirty (30) calendar days following the change taking effect by updating the information in the MTF DM.
4. Utilize the MTF DM to update, correct, maintain, and re-certify the completeness and accuracy of the Manufacturer MTF Enrollment Information.
5. Access the MTF claim-level data elements via the MTF DM and maintain functionality necessary to receive claim-level data elements and return claim-level payment elements via the MTF DM.
6. 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)(7) below); the MFP is provided prospectively; and/or the selected drug(s) is initially sold by a Secondary Manufacturer.
7. 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 triggered by the 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 triggered by transmission of the claim-level data elements for the original claim 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. However, 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.
8. 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.

(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 use the MTF PM for all its selected drug(s); provided, however, that the Manufacturer remains free to effectuate the MFP outside of the MTF PM with respect to transactions with dispensing entities for which the Manufacturer and the dispensing entity have mutually agreed upon an alternative process.
2. Provide the MTF Data Module Contractor with the Manufacturer's banking account information, in accordance with applicable guidance and regulations, for the MTF Data Module Contractor to share with the MTF Payment Module Contractor in order to execute MFP refund payments.
3. 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.
4. Provide CMS at least ninety (90) calendar day notice of a decision to no longer utilize the MTF PM.
5. Comply with the terms of the Ledger System described in applicable regulations and guidance including but not limited to the following:
    i. Manufacturer is responsible for reviewing credits and debits using data provided by the MTF DM 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 IX(d) of this Agreement, or has terminated participation in the MTF PM, CMS will provide the Manufacturer, in a time and manner to be determined by CMS, with an accounting of any outstanding credits and debits in the Ledger System. It is the responsibility of the Manufacturer to work with dispensing entities if a Manufacturer believes funds are owed to the Manufacturer 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 and regulations, 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 by the Manufacturer with the applicable dispensing entities.

iv. Manufacturer acknowledges that if a selected drug(s) transfers ownership, as described in section IX(e), credits and debits will remain in the Ledger System and be transferred from the Transferring Manufacturer (as defined in section IX(e)(2)) to the Acquiring Manufacturer (as defined in section IX(e)(2)). Any arrangement between the Transferring Manufacturer and the Acquiring Manufacturer regarding the value of the credits is beyond the scope of this Agreement.

(k) If the Manufacturer is assuming responsibility as the new Primary Manufacturer of the selected drug(s) as a result of a transfer of all NDA(s) or BLA(s) of the selected drug(s) to the Manufacturer, as described in section IX(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 effective 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 for such selected drug(s) under the Ledger System.

III. CMS' RESPONSIBILITIES

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

(a) Engage with an MTF Data Module Contractor and MTF Payment Module Contractor to establish the MTF to facilitate the exchange of data and payment in connection with MFP effectuation.

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

(c) 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) 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) Provide for 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 VI of this Agreement.

(g) In its sole discretion and to the extent permitted by applicable law, including section 1193(c) of the Act, to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)), CMS may use and disclose to other law enforcement and regulatory authorities, information related to this Agreement, including, without limitation, information about and generated by the Manufacturer.

IV. MTF DATA MODULE CONTRACTOR'S RESPONSIBILITIES

Pursuant to any applicable guidance and regulations, and consistent with the requirements of applicable procurement contract(s) with CMS, the MTF Data Module Contractor shall:

(a) Maintain the MTF DM user interface and a database of enrolled dispensing entities and manufacturers, including making available certain Manufacturer MTF Enrollment Information and dispensing entity MTF enrollment information, including, for example, contact information for dispensing entities in case the Manufacturer needs to connect with dispensing entities directly.

(b) Provide technical instructions to the Manufacturer to onboard the Manufacturer to the MTF DM and, where elected by the Manufacturer, the MTF PM.

(c) Process Prescription Drug Event ("PDE") records received from CMS' Drug Data Processing System ("DDPS") to support verification that a selected drug was dispensed to an MFP-eligible individual and transmit claim-level data elements to the Manufacturer or its designated third-party contractor.

(d) Acknowledge receipt of the claim-level payment elements submitted by the Manufacturer.

(e) If the Manufacturer elects to use the MTF PM, the MTF Data Module Contractor shall:

(1) Prior to the initial transmission of claim-level data elements, communicate instructions to the Manufacturer on the process for the Manufacturer to establish the bank account(s) that are to be used to transfer funds of the Manufacturer, as authorized and directed by the Manufacturer, to allow for the validation of the bank account information prior to funds transfer.

(2) Timely communicate the claim-level payment elements to the MTF PM so that the MTF PM can initiate a transfer of authorized payment amounts out of the bank account the Manufacturer has on file with the MTF to pass through the MFP refund payments to dispensing entities.

(3) Calculate the Standard Default Refund Amount using the selected drug(s)'s Wholesale Acquisition Cost ("WAC"), as published in pharmaceutical pricing database compendia on the date of service of the Part D claim.

(4) Maintain functionality for the Manufacturer to view the status of MFP refund payments.

(5) Make available an ERA that uses the X12 835 standard adopted under HIPAA (for electronic payments) or remittance advice (for payment made by paper check) to dispensing entities for all payments that the Manufacturer chooses to pass through the MTF PM.

(6) Support implementation of the Ledger System established in applicable guidance and regulations.

(f) Support CMS' implementation of the dispute and complaint process, including collecting disputes and complaints and any related documentation submitted via the MTF DM, and assisting CMS in the triage, investigation, and resolution of disputes and complaints, as appropriate.

(g) Provide customer support to the Manufacturer or a third-party contractor supporting the

Manufacturer's activity in the MTF DM when requested by CMS or a contractor engaged by CMS to intake customer service inquiries.

(h) Facilitate any requests from CMS in accordance with any applicable procurement contract(s) between CMS and the MTF Data Module Contractor, and collaborate with other CMS contractors supporting the MTF program requirements and oversight.

(i) Comply with the requirements regarding confidentiality and data security contained in any applicable procurement contract(s) between CMS and the MTF Data Module Contractor.

(j) Limit the use and disclosure of Manufacturer MTF Enrollment Information to such uses and disclosures necessary to facilitate manufacturer effectuation of MFPs of selected drugs and to aid CMS in performance of its administrative duties and compliance monitoring related to the Negotiation Program pursuant to section 1196 of the Act.

(k) Employ security measures necessary to protect claim-level data elements and claim-level payment elements transmitted to and received from the Manufacturer, including authentication, encryption, password use, or other security measures in compliance with the section 1173(d) of the Act and any U.S. Department of Health and Human Services implementing regulations or guidelines and as set forth in section VII, section VIII, and Exhibit A of this Agreement.

V. 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 the 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").

VI. AUDIT RIGHTS

(a) The United States Department of Health and Human Services, CMS, and 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 any additional 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.

VII. 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 section

1196 of the Act or as otherwise required by 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, or where such disclosure is 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, including section 1193(c) of the Act.

(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.

VIII. DATA USE PROVISIONS

(a) The Data Use provisions set forth in Exhibit A of this 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.

IX. 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 and for which an MFP has been established 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). When a new selected drug(s) must be added to Addendum 1 of this Agreement as a result of an MFP having been negotiated with CMS, Addendum 1 to this Agreement must be updated and executed before the start of the price applicability period for the added selected drug(s) and by the deadline established by CMS. When a selected drug(s) must be added to Addendum 1 of this Agreement due to the transfer of the selected drug(s), see section IX(e) of this Agreement for information about applicable timeframes.
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 IX(d)(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 provision.
2. Notwithstanding the foregoing and subject to section IX(d)(3) and (e) of this Agreement, 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 IX(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 data covering new and adjusted claims with dates of service during all previous time periods in which this Agreement was in effect.
5. The Manufacturer agrees to retain and later destroy the claim-level data elements it has received under this Agreement, and maintain documentation of the data destruction, in accordance with Exhibit A of this Agreement.
6. The MTF PM User Agreement, if executed, will terminate:
    i. In its 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 with a date of service before the effective date of the termination of this Agreement with respect to such selected drug(s), as described in applicable guidance and regulations, except in cases where the Manufacturer has transferred ownership of the selected drug(s) as described in section IX(e).

8. If the Manufacturer has executed the MTF PM User 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.

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 V, VI, VII, VIII, IX, and X, 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 the selected drug(s) that were dispensed 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 and regulations.

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 and the MTF PM User 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 remains the Primary Manufacturer of other selected drug(s) covered by this Agreement, and the Acquiring Manufacturer does not currently hold a signed MTF DM User Agreement:

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

   ii. The Acquiring Manufacturer must execute an MTF DM User Agreement and, if it

elects to use the MTF PM, an MTF PM User Agreement, and must list the transferred selected drug(s) on Addendum 1 of the Acquiring Manufacturer's MTF DM User Agreement.

iii. Updates to the Transferring Manufacturer's MTF DM User Agreement and the Acquiring Manufacturer's MTF DM User Agreement 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 remains the Primary Manufacturer of other selected drug(s) covered by this Agreement, and the Acquiring Manufacturer currently holds a signed MTF DM User Agreement:

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

   ii. The Acquiring Manufacturer must update Addendum 1 of its existing MTF DM User Agreement by adding the name of the transferred selected drug(s) to Addendum 1 and the date on which the selected drug(s) was added to Addendum 1.

   iii. Updates to the Transferring Manufacturer's MTF DM User Agreement and updates to the Acquiring Manufacturer's MTF DM User Agreement shall have the same effective date.

5. The 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.

X. DISCLAIMERS

The following provisions set forth limitations on CMS' liability and the expectation that the MTF Data Module Contractor and MTF Payment Module Contractor will carry out their responsibilities as prescribed in this Agreement and pursuant to their contractual undertakings with CMS.

(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 directly stemming from operation of 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 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)(5) 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.

(d) 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.

(e) 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).

(f) 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.

(g) 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.

(h) 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.

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

(j) If the Manufacturer elects to participate in the MTF PM, neither CMS nor the MTF Data Module Contractor or MTF Payment Module Contractor 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.

XI. GENERAL PROVISIONS

(a) **Authority to Amend**. CMS may unilaterally amend this 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 Agreement shall be sent in writing via email to MFPMedicareTransactionFacilitator@cms.hhs.gov. Any notice required to be given to the Manufacturer pursuant to the terms of this 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 term "Manufacturer" incorporates any third parties that perform required operations on behalf of the Manufacturer pursuant to this Agreement. The Manufacturer shall ensure that any third party fulfilling responsibilities under this Agreement on behalf of the Manufacturer complies with the terms of this Agreement. The Manufacturer remains responsible for compliance with all requirements under this Agreement notwithstanding any actions that third parties may perform on the Manufacturer's behalf.

(h) **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.

(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' 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.

XII. SIGNATURES

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. All information the Manufacturer provides to the MTF DM is and will be, to the best of the Manufacturer's knowledge, true, complete, and accurate and prepared in good faith after reasonable efforts; 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 Agreement 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 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 Agreement.

By: _____(e-signature)

Title: _____

P# _____

Name of Manufacturer:_____

Manufacturer's Mailing Address: _____

Date: _____

FOR CMS

By: _____ (e-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 from 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 VI of this Agreement (hereinafter referred to as "CMS Data"). These provisions govern the use and disclosure of CMS Data that 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. These provisions 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' RESPONSIBILITIES

   i. 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 and regulations and this Agreement.

   ii. 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 privacy and security laws, 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 dispensing entities (hereinafter "dispensing entities") 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 dispensing entities with respect to such MFP-eligible individuals who are dispensed such drug(s);

      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; and

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 the 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., an 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 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 after the ten (10) year period has passed, and to maintain, and provide upon request to CMS, written documentation of the destruction of the files. The Manufacturer may retain the data beyond the ten (10) year timeframe if CMS Data are relevant to 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. 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).

vii. The Manufacturer must implement appropriate administrative, technical, and physical safeguards that align with CMS's information security policies found at https://security.cms.gov/policy-guidance/cms-privacy-program-plan.to protect the confidentiality of CMS Data and to prevent unauthorized use or access to the CMS Data. 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.

viii. The Manufacturer agrees to grant access to CMS Data in their system(s) 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.

ix. 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.

x. 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.

xi. In the event that the Manufacturer inadvertently receives any direct beneficiary identifiers, or discovers any other actual or suspected 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 (1) 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 Data Module User 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 IX of this Agreement, and the selected drug(s) may be added to or removed from 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 Agreement Addendum 1 and to legally bind the Manufacturer on whose behalf he or she is executing 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: _____(e-signature)
Title: _____

P#: _____

Name of Manufacturer_____

Manufacturer's Mailing Address: _____

Date: _____

For CMS

By:_____(e-signature)

Title: _____

Date: _____