

**DRAFT MEDICARE TRANSACTION FACILITATOR DATA MODULE
CONTRACTOR AGREEMENT
(hereinafter referred to as the “MTF DM Agreement” or “this Agreement”)**

Between

**The Medicare Transaction Facilitator Data Module Contractor
(hereinafter referred to as the “MTF Data Module Contractor”)**

And

**[FULL NAME OF MANUFACTURER]
(hereinafter referred to as “the Manufacturer”)**

WHEREAS, the MTF Data Module is intended to accomplish the following tasks in the administration of the Medicare Drug Price Negotiation Program (hereinafter referred to as the “Negotiation Program”):

- (1) Act as the user interface with the Centers for Medicare & Medicaid Services (“CMS”) for the Medicare Transaction Facilitator (“MTF”) to allow the Manufacturer to enroll in the MTF Data Module (hereinafter the “MTF Data Module” or “MTF DM,” as defined in section I(e) of this Agreement) and MTF Payment Module (hereinafter the “MTF Payment Module” or “MTF PM,” as defined in section I(f) of this Agreement), if applicable.
- (2) Support verification that the selected drug(s) identified on Addendum 1 of the MTF Program Agreement as defined in section I(i) of this Agreement (hereinafter referred to as the “selected drug(s)” or each “selected drug”) was dispensed to a maximum fair price (“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 transmitting 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 will:

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

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

I DEFINITIONS

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

- (a) "**Claim-level data elements**" means the data, as described in applicable guidance, regulations, and technical instruction, that CMS transmits to the Manufacturer via the MTF Data Module for each claim for a selected drug that is dispensed to an MFP-eligible individual.
- (b) "**Claim-level payment elements**" means the data, as described in applicable guidance, regulations, and technical instructions, that the Manufacturer transmits to CMS via the MTF Data Module indicating the Manufacturer's response to the claim-level data elements for each claim for a selected drug dispensed to an MFP-eligible individual.
- (c) "**Ledger System**" means the system within the MTF PM as described in applicable guidance, regulations, and technical instructions to track credits and debits for MFP refund payments for each of the selected drug(s) at the dispensing entity National Provider Identifier ("NPI")-level on behalf of participating manufacturers.
- (d) "**Manufacturer MTF Enrollment Information**" means the Manufacturer's identifying, and, if applicable, financial information as described in CMS' instruction for MTF enrollment 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.
- (e) "**MTF Data Module**" or "**MTF DM**" means the system that provides MTF claim-level data elements to manufacturers, receives claim-level payment elements from manufacturers, operates the user interface for dispensing entities and manufacturers, and provides an Electronic Remittance Advice ("ERA") that uses the X12 835 standard adopted under HIPAA for electronic transfer of funds or remittances for paper checks to dispensing entities.
- (f) "**MTF Payment Module**" or "**MTF PM**" means the voluntary system, to pass through MFP

refund payments from a participating Manufacturer to dispensing entities per the Manufacturer's direction in the transmitted claim-level payment elements received from the MTF Data Module Contractor to effectuate MFP in connection with the MTF Program Agreement.

- (g) **"MTF Payment Module Contractor"** means a contractor to CMS retained to establish and maintain the MTF PM.
- (h) **"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.
- (i) **"MTF Program Agreement"** means the agreement between the Manufacturer and CMS, on behalf of the Secretary of the United States Department of Health and Human Services, with respect to the respective parties' obligations in connection with the MTF.
- (j) **"Negotiation Program Agreement" or "Negotiation Program Agreement(s)"** means the agreement(s) between CMS and the Manufacturer as established under section 1193 of the Act with respect to the Manufacturer's participation in the Negotiation Program for a selected drug(s).

Except where such terms are expressly defined in this Agreement, all other terms used in this Agreement will have the meanings given to them under the provisions of sections 1191 through 1198 of the Act, any applicable regulations and guidance implementing those provisions, and section I of the MTF Program Agreement.

II MANUFACTURER'S RESPONSIBILITIES

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

- (a) Manufacturer shall 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 Point-of-Contact shall notify the MTF Data Module Contractor in advance of changes that may impact connectivity between the systems.
- (b) Manufacturer shall enroll with the MTF DM and provide complete and accurate Manufacturer MTF Enrollment Information.
- (c) Manufacturer shall certify that the Manufacturer MTF Enrollment Information is complete and accurate upon enrollment.
- (d) Manufacturer shall utilize the MTF DM to update, correct, maintain, and re-certify the completeness and accuracy of the Manufacturer MTF Enrollment Information.
- (e) Manufacturer shall provide updated Manufacturer MTF Enrollment Information within thirty (30) calendar days of any changes to the Manufacturer MTF Enrollment Information;

notwithstanding the foregoing, in the event of a change to bank account information, if applicable, the Manufacturer shall provide updated information no less than thirty (30) calendar days prior to the effective date of such changes to banking information.

- (f) Manufacturer shall maintain functionality necessary to receive claim-level data elements and return claim-level payment elements via the MTF DM.
- (g) Manufacturer shall return claim-level payment elements for each claim within the 14-day prompt MFP payment window and ensure that the claim-level payment elements returned are timely, complete and accurate to the best of their knowledge.
- (h) Manufacturer shall ensure that any third party the Manufacturer contracts with to support the Manufacturer's activities related to the MTF DM complies with all requirements of this Agreement, the MTF Program Agreement, and the Negotiation Program Agreement(s).
- (i) Manufacturer shall comply with any instructions, processes, and requirements as directed by the MTF Data Module Contractor.
- (j) Manufacturer shall assist in audits and investigations by timely submitting the requested documentation to the MTF Data Module Contractor or through other mechanisms CMS determines are appropriate.

III MTF DATA MODULE CONTRACTOR'S RESPONSIBILITIES

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

- (a) MTF Data Module Contractor shall 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, and for manufacturers utilizing the MTF PM, status reporting for MTF payments made by manufacturers utilizing the MTF PM.
- (b) MTF Data Module Contractor shall provide technical instructions to the Manufacturer to onboard the Manufacturer to the MTF DM and, where elected by the Manufacturer, the MTF PM.
- (c) MTF Data Module Contractor shall 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 manufacturers or its designated third-party contractor. Facilitate any requests from CMS and collaborate with other CMS contractors supporting the MTF program requirements and oversight.
- (d) MTF Data Module Contractor shall 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, which allows 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 payment 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 data base 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, regulations, and technical instructions.
- (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 audit requests from CMS.

IV MUTUAL OBLIGATIONS

The Manufacturer and the MTF Data Module Contractor agree to the following:

- (a) Prior to the initial transmission of claim-level data elements, the Manufacturer and the MTF Data Module Contractor will confirm the connectivity between the Manufacturer and the MTF DM. Access codes for the MTF DM will be subsequently issued and a login test should be executed to test successful access. This process must be completed prior to the first transmission in accordance with instructions from the MTF Data Module Contractor. For the Manufacturer, the duties of the point(s) of contact required in Section II of this Agreement include relaying general information regarding the MTF DM, receiving all MTF DM related notifications distributed by the MTF Data Module Contractor, and communicating with the MTF Data Module Contractor to address payment matters.
- (b) The MTF Data Module Contractor will issue security access codes to the Manufacturer. The Manufacturer and the MTF Data Module Contractor will employ security measures necessary to protect claim-level data elements and claim-level payment elements transmitted between them, 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 V of this Agreement and Section VII and Exhibit A of the MTF Program Agreement.

- (c) The Manufacturer and the MTF Data Module Contractor agree that the security access codes that the MTF DM issues to the Manufacturer will, when affixed to transmission of claim-level data elements and claim-level payment elements be legally sufficient to verify the identity of the transmitter and to authenticate the transmission and therefore establish the transmission's validity.
- (d) Where applicable, prior to the initial transmission of the claim-level data elements, the Manufacturer and the MTF Data Module Contractor will coordinate with each other and the MTF Payment Module Contractor to establish which of the Manufacturer's bank account(s) are to be used to transfer funds of the Manufacturer to dispensing entities, as authorized and directed by the Manufacturer.

V CONFIDENTIALITY AND DATA USE

- (a) The Manufacturer shall comply with the confidentiality and data use provisions outlined in sections VI, VII, and Exhibit A of the MTF Program Agreement for all information disclosed to the Manufacturer pursuant to this Agreement. The MTF Data Module Contractor shall comply with the requirements regarding confidentiality and data security contained in the federal procurement contract between CMS and the MTF Data Module Contractor.
- (b) Any information disclosed by the Manufacturer to the MTF Data Module Contractor in connection with this Agreement that is identified by the MTF Data Module Contractor as proprietary based on applicable guidance, regulations and technical instructions, including but not limited to, the Manufacturer MTF Enrollment Information, banking information and the claim-level payment elements, will not be disclosed by the MTF Data Module Contractor in a form that identifies the Manufacturer, except as necessary to carry out provisions of section 1196 of the Act or as otherwise required by law. 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. The MTF Data Module Contractor 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.
- (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 MTF data's lifecycle, including retention duration and secure disposal requirements per NARA schedules.
- (d) Notwithstanding the nonrenewal or termination of this Agreement for any reason, the confidentiality and 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.

VI ORDER OF PRECEDENCE

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

VII EFFECTIVE DATE, TERM, RENEWAL AND TERMINATION

- (a) This Agreement shall have an effective date of the date when it is signed by the last party to sign it (as indicated by the date associated with the party's signature).
- (b) The initial term of this Agreement will extend through December 31 following the calendar year in which the Agreement takes effect. This Agreement thereafter shall automatically renew after the initial term and after each subsequent renewal year for one year renewal terms starting on January 1 of each following year.
- (c) Subject to the limitations on the scope of termination in sections VII(d), (g), (h), and (i) this Agreement will terminate only upon the termination of the MTF Program Agreement. As stated in section VIII(d) of the MTF Program Agreement, the termination of the MTF Program Agreement will automatically and simultaneously terminate this MTF DM Agreement, subject to the limitations on the scope of termination in section VII(d) of this Agreement, and such termination shall be effective as of the termination date of the MTF Program Agreement.
- (d) If the Manufacturer has multiple selected drug(s) covered by the MTF Program Agreement, as identified in Addendum 1 of the MTF Program Agreement, then this Agreement terminates in its entirety only if the MTF Program Agreement is terminated in its entirety. If the MTF Program Agreement is terminated only as to a specific selected drug(s) as set forth in section VIII of the MTF Program Agreement, then this Agreement is terminated only as to the specific selected drug(s) but otherwise remains in effect with respect to the remaining selected drug(s) listed on Addendum 1 of the MTF Program Agreement.
- (e) Upon the effective date of the termination of this Agreement, the MTF DM 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. If any additional data is received regarding MFP-eligible claims covered by this Agreement, CMS will notify the Manufacturer following the notice process established in section VIII(f) of this Agreement and will work with the Manufacturer to ensure that claim-level data elements are received, and claim-level payment elements are communicated.
- (f) Upon termination, the Manufacturer agrees to destroy the claim-level data elements it has received under this Agreement in accordance with Exhibit A of the MTF Program Agreement and certify the destruction of the data in writing to CMS and the MTF Data Module Contractor.
- (g) Any termination of this Agreement will not affect the Manufacturer's responsibility for

effectuating the MFP for dispenses of each selected drug to MFP-eligible individuals that were incurred by the Manufacturer before the effective date of this Agreement's termination, as described in applicable guidance, regulations, and technical instructions.

- (h) If the Manufacturer transfers ownership of all New Drug Applications (“NDAs”) or Biologics License Applications (“BLAs”) of certain selected drug(s) to another entity, this Agreement will terminate as to the transferred selected drug(s). This Agreement will stay in effect for other selected drugs(s) of the Manufacturer listed on Addendum 1 of the MTF Program Agreement. The Acquiring Manufacturer must sign a new Agreement with the MTF Data Module Contractor to utilize the MTF DM for the selected drug(s), if the Acquiring Manufacturer does not already have a signed MTF Data Module Contract in place.
- (i) The provisions of Section V and other provisions necessary to effectuate the terms herein and the terms of the MTF Program Agreement will survive termination of this Agreement.

VIII GENERAL PROVISIONS

- (a) **Force Majeure.** Neither party shall be liable for failure to perform its obligations under this Agreement if such failure is occasioned by a contingency beyond such party's reasonable control, including, but not limited to, lockouts, riots, wars, fires, floods or storms (a “Force Majeure Event”). A party claiming a right to excused performance under this section shall promptly notify the other party in writing of the extent of its inability to perform, which notice shall specify the Force Majeure Event that prevents such performance and include a timeline for remediation. The party failing to perform shall use reasonable efforts to avoid or remove the cause of the Force Majeure Event and shall resume performance under this Agreement promptly upon the cessation of the Force Majeure Event.
- (b) **Failure to Insist on Strict Performance.** No failure by any party to insist upon the strict performance of any requirement, obligation or condition of this MTF DM Agreement shall constitute a waiver of any such requirement, obligation or condition.
- (c) **Coverage of Third Parties.** The terms “MTF Data Module Contractor” and “Manufacturer” incorporate any contractors that fulfill responsibilities pursuant to this MTF DM Agreement on behalf of such party unless specifically stated otherwise in this MTF DM Agreement. Each party shall ensure that any contractor fulfilling any of such party's responsibilities under this MTF DM Agreement on behalf of such party complies with the terms of this MTF DM Agreement.
- (d) **Entire Agreement.** This MTF DM Agreement contains the entire agreement of the parties to this Agreement with respect to the subject matter of this Agreement, and supersedes all prior oral and written representations, agreements and understandings with respect thereto.
- (e) **Additional Provisions and Amendments.** The MTF Data Module Contractor reserves the right to include additional provisions, requirements, or terms and the right to amend this Agreement as it deems necessary or appropriate for the administration of the MTF DM, on its own or at the direction of CMS, subject to applicable laws, guidance, or regulations and the prior approval of CMS. Any such provisions, once approved by CMS, shall be communicated in writing to the Manufacturer and incorporated into this MTF DM Agreement. As feasible, the MTF Data Module Contractor will endeavor to provide the

Manufacturer at least sixty (60) calendar day notice of any amendment to this Agreement.

- (f) **Notice.** Any notice required to be given to the MTF Data Module Contractor pursuant to the terms of this MTF DM Agreement shall be sent in writing to [XX]. Any notice required to be given to the Manufacturer pursuant to the terms of the MTF DM Agreement shall be sent in writing via email to the email address provided as part of the Manufacturer MTF Enrollment Information.
- (g) **No Authorization for Acts Contrary to Law; Severability.** Nothing in this Agreement shall be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is found to be invalid by a court of law with competent jurisdiction, this Agreement shall be construed in all respects as if any invalid or unenforceable provision were eliminated, and without any effect on any other provision.
- (h) **Waiver.** Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the MTF Data Module Contractor under any applicable law.
- (i) **Choice of Law and Forum.** This Agreement shall be construed in accordance with Federal law and ambiguities shall be interpreted in the manner that best effectuates the applicable statute(s). Any litigation arising from or relating to this Agreement, to the extent that jurisdiction and a cause of action would otherwise be available for such litigation, shall be resolved in Federal court.
- (j) **Non-Endorsement of CMS Views.** In signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS's or the MTF Data Module Contractor's views and makes no representation or promise beyond its intention to comply with its obligations under the terms of this Agreement with respect to the selected drug(s). Use of the term "maximum fair price" and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms
- (k) **Headings.** The headings of sections and provisions contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

IX SIGNATURES

FOR THE MANUFACTURER

- A. By signing this MTF DM Agreement, the Manufacturer understands that violations of this MTF DM Agreement may result in the penalties as provided in the MTF Program Agreement.
- B. By signing this MTF DM Agreement, the Manufacturer agrees to abide by all provisions set out in this MTF DM Agreement and acknowledges having received notice of potential penalties for violation of the terms of the MTF DM Agreement.
- C. On behalf of the Manufacturer, the undersigned individual hereby attests that he or she is authorized to legally bind the Manufacturer to the terms of this MTF DM Agreement and agrees to all the terms specified herein.

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

By: _____ (print name)

_____ (signature)

Title: _____

P#: _____

Name of Manufacturer: _____

Manufacturer's Mailing Address: _____

Date: _____

FOR THE MTF Data Module Contractor

By: _____ (print name)

_____ (signature)

Title: _____

Date: _____

