

**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

**The Dispensing Entity Identified in Section IX of this MTF DM Agreement
(hereinafter referred to as “the Dispensing Entity”)**

WHEREAS, the MTF Data Module (“MTF DM”) 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) support verification that the selected drug was dispensed to a maximum fair price (“MFP”)-eligible individual and to furnish manufacturers with certain claim-level data elements confirming that a selected drug was dispensed to an MFP-eligible individual and identifying which dispensing entity dispensed the selected drug to the MFP-eligible individual; (2) initiate the 14-day prompt MFP payment window for transmitting the MFP refund for each claim for a selected drug; (3) collect claim-level payment elements for each claim for a selected drug from manufacturers indicating whether a refund is being paid and the amount of the refund being paid to make the MFP available, if applicable; (4) make available electronic remittance advice (“ERA”) for electronic payments or a remittance for payment made by paper check to dispensing entities for payments manufacturers pass through the MTF Payment Module (“MTF PM”); and (5) establish a centralized intake system for receiving reports related to access to the MFP with respect to MFP-eligible individuals and dispensing entities; and

WHEREAS, the MTF Data Module Contractor supports the Centers for Medicare & Medicaid Services (“CMS”) in the operationalization of the MTF DM; and

WHEREAS, the Dispensing Entity is or will be a pharmacy for a Medicare Part D plan sponsor or otherwise anticipates it will dispense a selected drug to MFP-eligible individuals;

NOW, THEREFORE, the MTF Data Module Contractor, as a contractor to CMS, and the Dispensing Entity and in accordance with the Medicare Transaction Facilitator Program Agreement (“MTF Program Agreement”) between the Dispensing Entity and CMS, 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 data, as described in applicable guidance, regulations, and technical instruction, that CMS transmits to manufacturers 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 data, as described in applicable guidance, regulations, and technical instruction, that manufacturers will transmit to CMS via the MTF Data Module indicating manufacturers’ responses to the claim-level data elements for a selected drug dispensed to MFP-eligible individuals.
- (c) **“Dispensing Entity MTF Enrollment Information”** means the Dispensing Entity’s identifying and financial information as requested in the Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Entity Enrollment Form.
- (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 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 Payment Module” or “MTF PM”** means the voluntary system, operated by the MTF Payment Module Contractor 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.
- (h) **“MTF Payment Module Contractor”** means a contractor to CMS retained to establish and maintain the MTF PM.
- (i) **“MTF Program Agreement”** means the Agreement between the Dispensing Entity 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) **“Third-Party Support Entity”** means an entity, such as a pharmacy services administrative organization or reconciliation vendor, identified by the Dispensing Entity on its Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Entity Enrollment Form as having a contract to provide services to that Dispensing Entity in connection with the MTF, such as receive MFP refunds, receive

ERAs or remittance advice, submit complaints/disputes, and assist in producing records during an investigation or audit for the Dispensing Entity.

II. DISPENSING ENTITY'S RESPONSIBILITIES

Pursuant to any applicable guidance and regulations, as well as the MTF Program Agreement:

- (a) Dispensing Entity shall enroll with the MTF DM and provide and certify the completeness and accuracy of the Dispensing Entity MTF Enrollment Information in the MTF DM.
- (b) Dispensing Entity shall keep the Dispensing Entity MTF Enrollment Information current in accordance with the requirements provided in section II, paragraphs (c) and (d) of the MTF Program Agreement.
- (c) Dispensing Entity shall comply with any instructions, processes, and requirements as directed by the MTF Data Module Contractor.
- (d) Dispensing Entity 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.
- (e) Dispensing Entity shall ensure its agents, including, as applicable, any Third-Party Support Entity contracted comply with the terms of this Agreement, including Exhibit A of this Agreement, and applicable guidance, regulations, and technical instructions. The Dispensing Entity shall retain sole responsibility for compliance with the terms of this Agreement and applicable guidance, regulations, and technical instructions notwithstanding any actions that any Third-Party Support Entity may perform on the Dispensing Entity's behalf.

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 manufacturers need to connect with the Dispensing Entity directly, and with respect to 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 Dispensing Entity so that the Dispensing Entity may access and use the MTF DM.
- (c) MTF Data Module Contractor shall receive and process the Dispensing Entity MTF Enrollment Information submitted by the Dispensing Entity and/or any Third-Party Support Entity.

- (d) MTF Data Module Contractor shall provide look-up access to manufacturers that establish their own MFP refund payment methods outside of the MTF PM and share with those manufacturers the Dispensing Entity's and/or, as applicable, Third-Party Support Entity's identifying and financial information, including bank account information, in a secure and confidential manner.
- (e) MTF Data Module Contractor shall use databases managed by the National Council for Prescription Drug Programs ("NCPDP") as a source of demographic pharmacy information in creating efficiencies for the enrollment process.
- (f) 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.
- (g) MTF Data Module Contractor shall collect claim-level payment elements for each claim for a selected drug from manufacturers indicating whether an MFP refund is being paid and the amount of the refund being paid to make the MFP available.
- (h) MTF Data Module Contractor shall, with respect to manufacturers participating in the MTF PM,
 - (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.
- (i) MTF Data Module Contractor shall maintain functionality for the Dispensing Entity to view the status of MFP refund payments for manufacturers that opt to pay through the MTF PM.
- (j) MTF Data Module Contractor shall make available an ERA that uses the X12 835 standard adopted under HIPAA (for electronic payments) or a remittance (for payment made by paper check) for all payments that a manufacturer chooses to pass through the MTF PM.
- (k) MTF Data Module Contractor shall facilitate any requests from CMS and collaborate with other CMS contractors supporting MTF program requirements and oversight.
- (l) MTF Data Module Contractor shall, as applicable, support implementation of the Ledger System established in applicable guidance, regulations, and technical instructions.

- (m) MTF Data Module Contractor shall 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.
- (n) MTF Data Module Contractor shall provide customer support to the Dispensing Entity or the Dispensing Entity's Third-Party Support Entity relating to activity in the MTF DM when requested by CMS or a contractor engaged by CMS to intake customer service inquiries.
- (o) MTF Data Module Contractor shall facilitate any audit requests from CMS.

IV. MUTUAL OBLIGATIONS

The Dispensing Entity and the MTF Data Module Contractor agree to the following:

- (a) The MTF DM shall issue security access code(s) to the Dispensing Entity and an initial login test shall be executed by the Dispensing Entity to test successful access for purposes of enrollment. The MTF Data Module Contractor and the Dispensing Entity further agree that the security access code(s) that the MTF Data Module Contractor issues to the Dispensing Entity shall be legally sufficient to verify the identity of the Dispensing Entity and to authenticate actions taken by the Dispensing Entity.
- (b) The MTF Data Module Contractor shall validate with the Dispensing Entity and the MTF PM the Dispensing Entity's banking information, which shall be subject to a pre-certification period in which all bank accounts are verified by the qualifying financial institution before any electronic transfers of funds are made.
- (c) The MTF Data Module Contractor and the Dispensing Entity shall employ security measures necessary to protect any data exchanged between them, including authentication, encryption, password use, or other security measures in compliance with 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.

V. CONFIDENTIALITY AND DATA USE

The Dispensing Entity shall comply with the confidentiality and data use provisions outlined in the MTF Program Agreement and Exhibit A of the MTF Program Agreement. The MTF Data Module Contractor shall comply with the requirements regarding confidentiality, privacy, and data security contained in the federal procurement contract between CMS and the MTF Data Module Contractor.

VI. ORDER OF PRECEDENCE

In the event of any inconsistencies between this MTF DM Agreement and any applicable statute, regulations, and guidance implementing the Negotiation Program, the applicable statute,

regulations, and guidance shall take precedence. As related to the Dispensing Entity, in the event of any inconsistencies between this MTF DM Agreement and the MTF Program Agreement, the MTF Program Agreement shall take precedence.

VII. EFFECTIVE DATE, TERM, RENEWAL, AND TERMINATION

- (a) Effective Date. This MTF DM Agreement shall be effective on the date this MTF DM Agreement is signed by the Dispensing Entity.
- (b) Term. The initial term for this Agreement will extend through December 31 of the calendar year immediately following the calendar year in which the effective date occurs.
- (c) Renewal. Subject to paragraph (d) of this section, this Agreement shall automatically renew after the initial term and after each subsequent renewal term for a period of twelve (12) months from January 1.
- (d) Termination. This Agreement will terminate only upon the termination of the MTF Program Agreement. As stated in the MTF Program Agreement, the termination of the MTF Program Agreement will automatically and simultaneously terminate this MTF DM Agreement and such termination shall be effective as of the termination date of the MTF Program Agreement. Any termination will not affect a manufacturer's responsibility for effectuating the MFP for dispenses of a selected drug to MFP-eligible individuals for all claims with a date of service during a price applicability period.

VIII. GENERAL PROVISIONS

- (a) Force Majeure. Neither party shall be liable for failure to perform its obligations under this MTF DM Agreement if such failure is occasioned by a contingency beyond such party's reasonable control, including, but not limited to, lockouts, riots, wars, fires, floods or storms (a "Force Majeure Event"). A party claiming a right to excused performance under this section shall promptly notify the other party in writing of the extent of its inability to perform, which notice shall specify the Force Majeure Event that prevents such performance and include a timeline for remediation. The party failing to perform shall use reasonable efforts to avoid or remove the cause of the Force Majeure Event and shall resume performance under the MTF DM Agreement promptly upon the cessation of the Force Majeure Event.
- (b) 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.
- (c) Entire Agreement. This Agreement contains 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.
- (d) 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 Dispensing Entity and incorporated into this MTF DM Agreement. As feasible, the MTF Data Module Contractor will endeavor to provide the Dispensing Entity at least sixty (60) calendar day notice of any amendment to this Agreement.

- (e) Notice. Any notice required to be given to the MTF Data Module Contractor pursuant to the terms of this Agreement shall be sent in writing via email to [XX].
- (f) 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.
- (g) Waiver. Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Dispensing Entity or the MTF Data Module Contractor under any applicable law.
- (h) 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.
- (i) Construction.
 - (1) For purposes of this Agreement, the term “Dispensing Entity” incorporates, as applicable, any associated dispensing entities such as chain drug stores of the parent company or corporate parent under its common ownership and control.
 - (2) Each party to this Agreement shall ensure that any contractor or Third-Party Support Entity fulfilling any of such party’s responsibilities under this Agreement on behalf of such party complies with the terms of this Agreement.
- (j) Successor and Assigns. In the event of a change of control or ownership of the Dispensing Entity, the rights, interests, or obligations under this Agreement and the MTF Program Agreement are automatically assigned to the new owner and all terms and conditions of the agreements remain in effect and binding upon the new owner.
- (k) Non-Endorsement of CMS Views. In signing this Agreement, the Dispensing Entity does not make any statement regarding or endorsement of CMS’ or the MTF Data Module Contractor’s views. 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.

IX. SIGNATURES

FOR THE DISPENSING ENTITY

- A. By signing this MTF DM Agreement, the Dispensing Entity understands that violations of this MTF DM Agreement, including credible allegations of fraud or similar fault may result in the penalties as provided in section IV of the MTF Program Agreement.
- B. By signing this MTF DM Agreement, the Dispensing Entity agrees to abide by all provisions set forth in this MTF DM Agreement and acknowledges having received notice of potential penalties for violation of the terms of the MTF DM Agreement.
- C. The undersigned individual hereby attests that he or she is authorized by the Dispensing Entity to execute this MTF Program Agreement and to legally bind the Dispensing Entity, and, as applicable, all associated dispensing entities under the Dispensing Entity's ownership and control, that shall be bound by the terms herein, on whose behalf he or she is executing the MTF Program Agreement to all terms and conditions specified herein. As applicable, the undersigned individual hereby acknowledges that enrollment in the MTF DM is being conducted solely through the Dispensing Entity and certifies, represents, and warrants that none of the Dispensing Entity's associated dispensing entities have independently enrolled in the MTF DM as of the Effective Date and agrees that the Dispensing Entity will ensure no such associated dispensing entity will independently enroll in the MTF DM during the term of this Agreement, unless otherwise expressly permitted in writing by CMS.
- D. The undersigned individual further attests that he or she shall ensure that any Third-Party Support Entity engaged to perform services or fulfill obligations under this Agreement for the Dispensing Entity comply with all applicable terms, conditions, and requirements of this Agreement. The Dispensing Entity shall remain fully responsible for the conduct of its Third-Party Support Entity as if such performance were conducted by the Dispensing Entity itself. The Dispensing Entity acknowledges and agrees that the engagement of a Third-Party Support Entity shall not relieve the Dispensing Entity of any obligations or liabilities under this Agreement.
- E. The undersigned individual further attests that he or she has obtained access in the MTF DM as an Authorized Signatory Official to be a signatory for the Dispensing Entity and that the individual's access credentials contain the same information regarding the undersigned individual as the information set forth below.
- F. The undersigned individual certifies that he or she has made no alterations, amendments or other changes to this MTF DM Agreement.
- G. The undersigned individual certifies that the Dispensing Entity and any associated

individuals and entities involved in the dispensing, billing, or administration of services to Medicare beneficiaries under the Dispensing Entity are not currently on the CMS Preclusion List and OIG List of Excluded Individuals/Entities (LEIE).

By: _____ (print name)
_____ (signature)
Title: _____
Name of Dispensing Entity: _____
Dispensing Entity Mailing Address: _____
Date: _____

FOR THE MTF DATA MODULE CONTRACTOR

By: _____ (print name)
_____ (signature)
Title: _____
Date: _____

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