

DRAFT MEDICARE TRANSACTION FACILITATOR PROGRAM AGREEMENT
(hereinafter referred to as the “MTF Program Agreement” or “this Agreement”)

Between

The Centers for Medicare & Medicaid Services
(hereinafter referred to as “CMS”)

And

The Dispensing Entity Identified in Section XI of this MTF Program Agreement
(hereinafter referred to as “the Dispensing Entity”)

WHEREAS, pursuant to sections 1191 through 1198 of the Social Security Act (“the Act”), as set forth in the Inflation Reduction Act (“IRA”), P.L. 117-169, CMS is responsible for the administration of the Medicare Drug Price Negotiation Program (hereinafter referred to as the “Negotiation Program”), which sets forth a framework under which participating manufacturers and CMS may negotiate to determine a price (referred to as “maximum fair price” in the Act and hereinafter “MFP”) for each selected drug in order for manufacturers to provide access to such MFP to MFP-eligible individuals and to pharmacies, mail order services, and other dispensing entities; and

WHEREAS, CMS will engage the Medicare Transaction Facilitator (“MTF”) for the Negotiation Program to facilitate the exchange of data and pass through payment between pharmaceutical supply chain entities using two distinct modules—the MTF Data Module (“MTF DM”) to, among other things, support the verification that the selected drug was dispensed to an MFP-eligible individual and the MTF Payment Module (“MTF PM”), a voluntary option for manufacturers to pass through payment to dispensing entities to effectuate MFP; 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, CMS, on behalf of the Secretary of the United States Department of Health and Human Services, and the Dispensing Entity in accordance with sections 1191 through 1198 of the Act, and all applicable guidance and regulations, hereby agree to the following:

I. DEFINITIONS

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

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

accesses or potentially accesses PII for an other than authorized purpose.

- (b) **“Claim-level data elements”** means 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.
- (c) **“Claim-level payment elements”** means data, as described in applicable guidance, regulations, and technical instruction, that manufacturers 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.
- (d) **“Confidential Information”** includes any proprietary, sensitive, or identifying information, such as PII, Protected Health Information (“PHI”) where applicable, financial and banking details, and any other information designated in good faith as confidential, which is taken from or disclosed by one party (the “Disclosing Party”) to the other (the “Receiving Party”).
- (e) **“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.
- (f) **“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.
- (g) **“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.
- (h) **“MTF Data Module Contractor”** means a contractor to CMS retained to establish and maintain the MTF Data Module and to execute on the data exchange, user interface functionality, and issuance of remittance or ERA for dispensing entities.
- (i) **“MTF DM Agreement”** means the agreement between the Dispensing Entity and the MTF Data Module Contractor.
- (j) **“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.
- (k) **“MTF Payment Module Contractor”** means a contractor to CMS retained to establish and maintain the MTF PM.

- (l) **“Security Incident” or “Incident”** is 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.
- (m) **“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.

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. DISPENSING ENTITY’S RESPONSIBILITIES

Pursuant to any applicable guidance and regulations:

- (a) Dispensing Entity shall enter into and have in effect, under terms and conditions approved by CMS, an agreement with the MTF Data Module Contractor.
- (b) Dispensing Entity shall comply with instructions, processes, and requirements of the MTF Data Module Contractor.
- (c) Dispensing Entity shall enroll in the MTF DM by providing complete and accurate Dispensing Entity MTF Enrollment Information in the MTF DM and shall maintain complete and accurate Dispensing Entity MTF Enrollment Information, including information regarding any Third-Party Support Entity. The Dispensing Entity shall be solely responsible for ensuring the accuracy, completeness, reliability, and timeliness of the Dispensing Entity MTF Enrollment Information, including without limitation the information regarding any Third-Party Support Entity.
- (d) Dispensing Entity shall keep Dispensing Entity MTF Enrollment Information current by utilizing the MTF DM to update, correct, or modify Dispensing Entity MTF Enrollment Information within thirty (30) calendar days after becoming aware of a change in the Dispensing Entity MTF Enrollment Information.

(1) Special Carve-Outs for Notification Requirements.

- (A) Changes in Ownership. Notwithstanding the foregoing, the Dispensing Entity shall notify CMS of a change in ownership within thirty (30) calendar days after the Dispensing Entity executes a legal obligation for such an arrangement and no later

than forty-five (45) calendar days prior to the change in ownership taking effect.

- (B) Changes in Financial Information. Notwithstanding the foregoing, the Dispensing Entity shall notify CMS no less than thirty (30) calendar days prior to the effective date of a change to financial information, including but not limited to a change to bank account and routing numbers and/or any Third-Party Support Entity providing payment related services.
 - (C) Bankruptcy. Notwithstanding the foregoing, the Dispensing Entity shall notify CMS within thirty (30) calendar days of filing for bankruptcy, initiating any insolvency proceedings, or becoming aware of any circumstances that may result in such filings.
 - (D) Business Opening and Closure. Notwithstanding the foregoing, the Dispensing Entity shall notify CMS no less than thirty (30) calendar days in advance of any new business line (e.g., long-term care pharmacy) and business closure affecting the Dispensing Entity's operations.
- (e) Dispensing Entity shall maintain all records that the Dispensing Entity may create or receive in connection with the MTF, including with respect to MFP refund payments claimed by the Dispensing Entity or paid by a manufacturer through the MTF PM or outside the MTF PM, and any audits and investigations described in section V of this Agreement for at least ten (10) years after the dispense of the selected drug(s).
 - (f) Dispensing Entity shall make records available upon request 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, verifications, inspections, and examinations upon request.
 - (g) Dispensing Entity shall cooperate with all compliance activities in which CMS shall engage pursuant to applicable guidance and regulations and this Agreement, including but not limited to any audits carried out by CMS pursuant to section V of this Agreement.
 - (h) Dispensing Entity shall use the MTF DM solely in accordance with all applicable laws, regulations, and guidance, including, without limitation, the Anti-Kickback Statute.
 - (i) Dispensing Entity shall ensure its agents, including, as applicable, any Third-Party Support Entity, comply with the terms of this Agreement, including Exhibit A of this Agreement, and applicable guidance, regulations, and technical instruction. 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. CMS' RESPONSIBILITIES

Pursuant to any applicable guidance and regulations:

- (a) CMS shall engage with a contractor to support processes for enrollment of the Dispensing Entity and any Third-Party Support Entity in the MTF DM.
- (b) CMS shall engage 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.
- (c) CMS shall provide technical instruction and address user inquiries from the Dispensing Entity regarding the functionality of MTF DM and MTF PM.
- (d) CMS shall provide a complaint mechanism through the MTF DM to address concerns raised by the Dispensing Entity regarding MFP availability and any issues with the MTF, if good faith efforts to address issues with manufacturers directly are not successful.
- (e) CMS shall provide a dispute mechanism within the MTF DM to address technical challenges or issues with a technical aspect of the MTF DM or MTF PM system or process.
- (f) CMS shall provide a Ledger System via the MTF, for payments passed through the MTF PM, in accordance with applicable guidance, regulations, and technical instruction.
- (g) CMS shall permit the Dispensing Entity's Third-Party Support Entity to perform operations on behalf of the Dispensing Entity as authorized in the Dispensing Entity MTF Enrollment Information in connection with the MTF DM.
- (h) CMS shall perform oversight activities and monitor compliance by the Dispensing Entity with the terms of this MTF Program Agreement and any applicable guidance, regulations, and technical instruction.
- (i) In its sole discretion, CMS may use information related to this Agreement, including without limitation information about and generated by the Dispensing Entity, to promote compliance with the statutes, regulations and written directives of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) ("Federal health care program requirements"). CMS may disclose such information to law enforcement and regulatory authorities to promote compliance with law, regulations, and applicable guidance.

IV. PENALTY PROVISIONS

Violations of this MTF Program Agreement or credible allegations of fraud or similar fault in connection with the MTF DM or MTF PM may result in delayed processing of MFP refund payments; request for implementation of a corrective action plan; increased oversight; temporarily or permanently suspending, modifying, or conditioning access for the Dispensing Entity or any Third-Party Support Entity to one or more features of the MTF DM. Violations of this MTF Program Agreement or credible allegations of fraud or similar fault in connection with

the MTF DM may result in referral to the United States Department of Health and Human Services Office of the Inspector General (“OIG”) and other law enforcement agencies.

V. AUDIT RIGHTS

The United States Department of Health and Human Services, CMS, the Comptroller General, and their designees have the right to audit, evaluate, and inspect any pertinent information, 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 the dispense of the selected drug(s) or otherwise as required by CMS.

VI. CONFIDENTIALITY PROVISIONS

- (a) The Receiving Party agrees (1) to observe applicable confidentiality statutes, regulations, guidance, and other applicable confidentiality requirements; (2) to hold the Disclosing Party’s Confidential Information in strict confidence and to take reasonable precautions to protect such Confidential Information and to prevent unauthorized use or access to it; and (3) not to divulge Confidential Information or information derived therefrom to any third party unless such disclosure is required in the performance of the Receiving Party’s duties under this Agreement, including but not limited to sharing with manufacturers identifying and financial data from the MTF DM as provided by the Dispensing Entity (i.e., Dispensing Entity MTF Enrollment Information).
- (b) Notwithstanding the termination of this MTF Program Agreement for any reason, the confidentiality provisions of this MTF Program Agreement will remain in full force and effect with respect to information disclosed under this Agreement prior to the effective date of such termination.
- (c) Nothing in this Agreement is intended to conflict with, modify, or supersede any existing obligations of the Dispensing Entity under applicable federal or state privacy and security laws, and the Dispensing Entity shall remain responsible for compliance with all such obligations.

VII. DATA USE PROVISIONS

The data use provisions set forth in Exhibit A of this MTF Program Agreement govern the use and disclosure of data CMS provides to the Dispensing Entity either directly or through the MTF DM for purposes of administration of the Negotiation Program pursuant to sections 1193(a)(3), 1193(a)(5), and 1196 of the Act. Notwithstanding the termination of this MTF Program Agreement for any reason, the data use provisions of this MTF Program Agreement will remain in full force and effect with respect to information disclosed under this Agreement prior to the effective date of such termination.

VIII. EFFECTIVE DATE, TERM, RENEWAL, AND TERMINATION

- (a) Effective date. This MTF Program 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 that party's signature).

(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.

(1) Termination by CMS. CMS may at any time terminate this Agreement if CMS determines it will no longer offer the MTF as a service or if CMS determines that the Dispensing Entity has engaged in conduct that is inconsistent with the efficient and effective administration of the Negotiation Program or to safeguard against fraud or similar fault.

A. Notice and opportunity for corrective action, as applicable.

- i. Termination due to cessation of the MTF. If CMS intends to terminate this Agreement because CMS determines it will no longer offer the MTF as a service, CMS shall notify the Dispensing Entity, in writing at least 180 calendar days prior to the effective date of termination.
- ii. Termination for cause. If CMS intends to terminate this Agreement because CMS determines that the Dispensing Entity has engaged in conduct that is inconsistent with the efficient and effective administration of the Negotiation Program, CMS shall notify the Dispensing Entity, any applicable Part D plan sponsor(s), and participating manufacturers of its intent to terminate this Agreement in writing at least 30 calendar days prior to the effective date of termination. CMS shall also provide the Dispensing Entity with a concise description of the Dispensing Entity's deficiencies prior to CMS sending the notice of intent to terminate this Agreement. In its sole discretion, CMS may provide a reasonable opportunity for corrective action by the Dispensing Entity. Thereafter, CMS shall have sole discretion as to whether to proceed with termination.

B. Exceptions. Notwithstanding any other provision herein to the contrary, the procedures specified in paragraph (d)(1)(A) of this section shall not apply if this Agreement is being terminated based on grounds of fraud or similar fault, or if a delay in termination would pose an imminent and serious risk to the administration of the Negotiation Program. In such circumstances, the notice provisions described in paragraph (d)(1)(A) of this section shall not apply, and CMS has sole discretion to determine the effective date of termination. If feasible, CMS will endeavor to provide notice to the Dispensing Entity, any applicable Part D plan sponsor(s), and participating manufacturers of CMS'

termination decision at least thirty (30) calendar days prior to the effective date of termination.

- (2) Termination by the Dispensing Entity. Dispensing Entity may terminate this Agreement subject to the requirements set forth in subparagraphs (i)-(ii). The Dispensing Entity acknowledges that termination of this Agreement by the Dispensing Entity may result in non-compliance with applicable contractual obligation(s) with any applicable Part D plan sponsor(s) requiring the Dispensing Entity to be enrolled in the MTF DM.
- A. Notice. If the Dispensing Entity decides to terminate this Agreement, the Dispensing Entity shall notify CMS of its intent to terminate this Agreement and specify the reasons for termination in the notice. Within thirty (30) calendar days of receiving the Dispensing Entity's notice, CMS shall send an acknowledgment of receipt to the Dispensing Entity of its notice and notify any applicable Part D plan sponsor(s) and participating manufacturers in writing. Unless otherwise expressly provided in writing by CMS in response to the Dispensing Entity's termination notice, the effective date of termination shall be 180 calendar days following CMS' acknowledgment of receipt.
- B. Attestation. In order to terminate this Agreement, the Dispensing Entity shall attest, in a form and manner determined by CMS, that the Dispensing Entity does not participate or no longer participates in any Part D plan sponsor network or will no longer be participating in any Part D plan sponsor network as of the effective date of termination of this Agreement. As part of the attestation, the Dispensing Entity shall agree that it will re-enroll in the MTF DM if the Dispensing Entity contracts with a Part D plan sponsor to be a network pharmacy in the future by executing a new MTF Program Agreement and MTF Data Module Contractor Agreement and by providing all necessary information required for re-enrollment in the MTF DM.
- (3) Effect of termination.
- A. The termination of this MTF Program Agreement will automatically and simultaneously terminate the Dispensing Entity's MTF DM Agreement.
- B. Notwithstanding the termination of this Agreement, certain requirements and obligations shall continue to apply in accordance with applicable guidance and regulations. The provisions of sections IV, V, VI, VII, VIII, and IX will survive termination of this Agreement. The other provisions of this Agreement necessary to effectuate the terms herein will survive the termination of this Agreement until all MFP-eligible claims for which manufacturers have incurred responsibility for effectuating the MFP prior to the effective date of termination have been addressed by manufacturers, as described in applicable guidance, regulations, and technical instructions.
- C. Any termination of this Agreement will not affect manufacturers' responsibility

for effectuating the MFP for dispenses of selected drug(s) to MFP-eligible individuals for all claims with a date of service during a price applicability period.

IX. DISCLAIMERS

- (a) The MTF DM and MTF PM are provided “as-is” and without any representation or warranty of any kind, either expressed or implied, including but not limited to, the implied warranties of merchantability and fitness for a particular purpose. CMS disclaims responsibility for any consequences or liability attributable to or related to any use, non-use, or interpretation of information contained or not contained in the MTF.
- (b) The Dispensing Entity and, as applicable, any Third-Party Entity, shall release CMS from all claims, demands, and damages arising out of or connected with the MTF. In no event shall CMS be liable for direct, indirect, special, incidental, or consequential damages arising out of the Dispensing Entity’s and, as applicable, any Third-Party Entity’s, use of the MTF.
- (c) The Dispensing Entity and, as applicable, any Third-Party Entity, shall indemnify and hold harmless CMS and the federal government from and against any and all liability, loss, damage, costs, or expenses, arising out of or in connection with any negligent action, inaction, or willful misconduct of the MTF Data Module Contractor, MTF Payment Module Contractor, or the manufacturers.
- (d) CMS shall not assume and shall bear no liability with respect to any losses incurred by the Dispensing Entity or, as applicable, any Third-Party Support Entity as a result of the manufacturers’ use of the MTF DM and, as applicable, the MTF PM.
- (e) Under no circumstances and under no legal theory, whether tort (including negligence), contract, or otherwise, shall CMS be liable to the Dispensing Entity, any Third-Party Support Entity, or any other person for any indirect, special, incidental, or consequential damages of any character including, without limitation, damages for loss of goodwill, work stoppage, computer failure or malfunction, or any and all other commercial damages or losses, even if such party shall have been informed of the possibility of such damages. CMS shall not be liable or obligated to the Dispensing Entity and, as applicable, any Third-Party Entity, for any losses incurred or sustained by the Dispensing Entity and, as applicable, any Third-Party Entity, and arising in whole or in part, directly or indirectly, from any fault of the Dispensing Entity and, as applicable, any Third-Party Entity, or fault, delay, omission, inaccuracy by or termination of the MTF DM or MTF PM. CMS shall not be liable for any claims attributable to any errors, omissions, or other inaccuracies made by the MTF DM, MTF PM, manufacturers, or dispensing entities.
- (f) The MTF Payment Module offers a voluntary payment facilitation functionality that will be made available for participating manufacturers to facilitate the transfer of MFP refund payments to dispensing entities for purposes of effectuating access to the MFP for their selected drug(s). The MTF PM connects participating manufacturers to dispensing entities to facilitate transmission of an MFP retrospective refund on MFP-eligible claims of selected drug(s) from manufacturers to dispensing entities in accordance with section 1193(a)(3) of the

Act. The MTF PM (1) provides manufacturers with a mechanism for electronic transfer of funds or payment by paper check to facilitate MFP refund payments to dispensing entities; and (2) provides manufacturers with the Ledger System as established in applicable guidance, regulations, and technical instructions to track the flow of MFP refunds and to handle reversals, adjustments, and other claim revisions inevitable in a dynamic claim payment system. However, the MTF PM's receipt and use of payment-related data (originating from the participating manufacturer, transmitted to the MTF DM, and then provided to the MTF PM) or any other role of the MTF PM in facilitating the transfer of the participating manufacturer's authorized payments to dispensing entities shall not in any way indicate or imply that CMS had determined payment was required, or that CMS agrees that the amount paid by the participating manufacturer is necessary and sufficient to make the MFP available to dispensing entities in accordance with the participating manufacturer's statutory obligations under section 1193(a)(3)(A) of the Act. CMS does not have any interest in, or control over, any interest that might accrue on funds held by the MTF during the period before the funds are transferred to the dispensing entities.

- (g) That the Dispensing Entity's payment information is available in the MTF does not in any way indicate or imply a certification from CMS that the Dispensing Entity's payment information is correct and accurate.
- (h) Neither CMS nor the MTF Data Module Contractor or MTF Payment Module Contractor are responsible for funding or paying the refund amount owed by manufacturers including without limitation in instances where a manufacturer does not pay an MFP refund owed to the Dispensing Entity, including in cases where a manufacturer may be unable to pay (e.g., bankruptcy, insolvency).
- (i) Under no circumstances will federal funds be used with respect to transactions made through the MTF PM or to resolve or make payment related to disputes that may arise when the MTF PM is utilized, including with respect to nonpayment or insufficient payment by the manufacturer.
- (j) The MTF PM serves only as a mechanism to pass through funds of the manufacturer to dispensing entities in order to provide access to the MFP as directed by the manufacturer in the amounts authorized by the manufacturer and is not for any other use.
- (k) Funds collected through the MTF PM are for the sole benefit of dispensing entities who receive those funds and are not collected for the benefit of the federal government.
- (l) This Agreement's terms are not enforceable by any third-party beneficiaries.
- (m) Neither CMS nor its contractors will assert independent control over the disposition of deposited payment amounts or direct payment transfers; instead, CMS' contractors will perform a ministerial function at the behest and direction of manufacturers with respect to the pass through of manufacturers' funds in the amounts and to the dispensing entities identified by the manufacturer in its claim-level payment elements.

X. GENERAL PROVISIONS

- (a) Authority to amend. CMS may unilaterally amend this MTF Program Agreement, including to reflect changes in law, regulation, or guidance. As feasible, CMS will endeavor to provide the Dispensing Entity at least sixty (60) calendar days' notice of any amendment to this Agreement.
- (b) Notice. Any notice required to be given by the Dispensing Entity to CMS pursuant to the terms of this MTF Program Agreement shall be sent in writing via email to IRAREbateandNegotiation@cms.hhs.gov. Any notice required to be given to the Dispensing Entity pursuant to the terms of this Agreement shall be sent in writing via email to the Dispensing Entity's points of contact as identified in the MTF DM.
- (c) No Authorization for Acts Contrary to Law; Severability. Nothing in this MTF Program Agreement shall be construed to require or authorize the commission of any act contrary to law. If any provision of this MTF Program Agreement is found to be invalid by a court of law with competent jurisdiction, this MTF Program 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 Dispensing Entity or CMS under any applicable law.
- (e) Choice of Law and Forum. This MTF Program 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) Construction.
 - (1) For purposes of this Agreement, the term "CMS" incorporates any contractors that fulfill responsibilities pursuant to this Agreement on behalf of such party unless specifically stated otherwise in this Agreement.
 - (2) 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.
 - (3) 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.
 - (4) 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.

- (g) 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.
- (h) Entire Agreement. This Agreement and the exhibit attached 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.
- (i) 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 MTF Program Agreement shall constitute a waiver of any such requirement, obligation or condition.
- (j) Successors and Assigns. In the event of a change of control or change in ownership of the Dispensing Entity, the rights, interests, or obligations under this Agreement and the MTF DM 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' 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.

XI. SIGNATURES

FOR THE DISPENSING ENTITY

- A. By signing this Agreement, the Dispensing Entity 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 MTF Program Agreement.
- B. 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 this 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.

- C. 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 will 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.
- D. 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.
- E. The undersigned individual certifies that he or she has made no alterations, amendments or other changes to this Agreement.
- F. 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 CMS

By: _____ (print name)
_____ (signature)

Title: _____

Date: _____

Exhibit A

DATA USE PROVISIONS

(a) PURPOSE

These provisions address the conditions under which CMS will disclose and the Dispensing Entity will obtain and use certain Medicare Transaction Facilitator (MTF) data specified in paragraph (b)(1). CMS agrees to provide the Dispensing Entity with certain MTF data as described in paragraph (b)(1) that are made available through the MTF DM. In exchange, the Dispensing Entity agrees (1) to ensure the integrity, security, and confidentiality of the MTF data by complying with the terms of this Agreement and applicable law, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations; and (2) to use the data specified in paragraph (b)(1) only for evaluating MFP availability; resolving any complaints and disputes concerning the manufacturer's obligations to make the MFP available as described in the applicable statutes, regulations, guidance, and this MTF Program Agreement; and ensuring accurate Part D claims information and payment.

These provisions supplement any and all agreements between the parties to this Agreement with respect to the use of data specified in paragraph (b)(1). The following provisions are not intended to conflict with, modify, or supersede any existing obligations of the Dispensing Entity under applicable federal or state privacy and security laws, and the Dispensing Entity shall remain responsible for compliance with all such obligations.

(b) DISPENSING ENTITY'S RESPONSIBILITIES CONCERNING AND LIMITATIONS ON USE AND DISCLOSURE OF MTF DATA

- (1) The CMS data files covered under this MTF Program Agreement shall include the Dispensing Entity's and, as applicable, any Third-Party Support Entity's identifying and financial information in the MTF DM (i.e., Dispensing Entity MTF DM Enrollment Information); remittance advice or ERA files; any other data provided by CMS, the MTF contractors, the manufacturers, or the Dispensing Entity (or any Third-Party Support Entity), including any derivative data, for purposes of MTF data exchange and making an ERA or remittance available; any CMS or MTF contractor data that can be used in concert with other available information to identify Medicare beneficiaries; and any data provided in support of the resolution of complaints, disputes, and audits pursuant to this MTF Program Agreement (hereinafter "MTF data").
- (2) The Dispensing Entity agrees to limit the use of the MTF data to those uses necessary to evaluate MFP availability, resolve complaints and disputes, and ensure accurate Part D claims information and payment, and may not use the MTF data to perform any functions not governed by this MTF Program Agreement unless such uses are required by law. 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.

- (3) The parties to this Agreement mutually agree that the Dispensing Entity does not obtain any right, title, or interest in any of the MTF data furnished by CMS through its MTF contractors.
- (4) The Dispensing Entity agrees not to disclose, use, or reuse MTF 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 Medicare Drug Price Negotiation Program or as otherwise required by law. The Dispensing Entity further agrees not to sell, rent, lease, loan, or otherwise grant access to the MTF data covered by this Agreement, with the exception that the Dispensing Entity may grant access to MTF data to the Dispensing Entity's Third-Party Support Entity for purposes of assisting the Dispensing Entity in evaluating MFP availability, resolving complaints and disputes, ensuring accurate Part D claims information and payment, and otherwise exercising its rights and responsibilities under the MTF Program Agreement, so long as such Third-Party Support Entity is subject to the same confidentiality and data use requirements set forth in this MTF Program Agreement and the Dispensing Entity maintains responsibility for ensuring compliance by these third parties with such requirements.
- (5) The Dispensing Entity agrees that, within the Dispensing Entity's organization and the organizations of any Third-Party Support Entity, access to the MTF data covered by the MTF Program Agreement shall be limited to the minimum amount of data necessary and minimum number of individuals who need access to the MTF data for permitted activities.
- (6) The parties to this Agreement mutually agree that the MTF data shall be retained by the Dispensing Entity for a period of up to ten (10) years from the date of dispense of the selected drug(s), hereinafter known as the "Retention Period." The Dispensing Entity agrees to destroy the MTF data as soon as no longer needed after the Retention Period, and to maintain, and provide upon request to CMS, written documentation of the regular destruction of the files within the required timeframe. The Dispensing Entity may retain the data beyond the ten (10) year timeframe if the MTF data are the subject of an unresolved audit, government investigation, or litigation, or if required by another applicable law. Such extension must be approved in advance by CMS in writing and the Dispensing Entity must agree to promptly destroy the MTF data once the pending matter is resolved.
- (7) The Dispensing Entity agrees to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the MTF data and to prevent unauthorized use or access to it. Further, the Dispensing Entity (or any Third-Party Support Entity) agrees that the MTF 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 Dispensing Entity or any Third-Party Support Entity to any sites outside of the control of the Dispensing Entity or any Third-Party Support Entity without advance written approval from CMS unless such movement, transmission, or disclosure is required by a law.

- (8) The Dispensing Entity agrees to grant access to the MTF data to authorized representatives of CMS or the U.S. Department of Health and Human Services Office of the Inspector General for the purpose of inspecting to confirm compliance with the terms of this Agreement upon reasonable notice and during normal business hours.
- (9) In the event that the Dispensing Entity inadvertently receives Personally Identifiable Information or Protected Health Information not authorized by this Agreement, or discovers any other actual or suspected Breach or Incident involving MTF data, loss of MTF data or disclosure of MTF data to any unauthorized persons, the Dispensing Entity agrees to report the occurrence to the CMS Help Desk by telephone at (410) 786-2580 or by e-mail notification at cms_it_service_desk@cms.hhs.gov within one hour of the Dispensing Entity's discovery of the occurrence and to cooperate fully in the Federal Security Incident process. The Dispensing Entity acknowledges that the use of unsecured telecommunications, including the Internet, to transmit any individually identifiable or deducible information derived from the MTF data is prohibited. The Dispensing Entity shall bear all cost and liability for any Breaches or Incidents involving the MTF data while they are in the possession of, or under the control of, the Dispensing Entity or any of its agent or subcontractors.
- (10) The Dispensing Entity agrees that in the event CMS determines or has a reasonable belief that the Dispensing Entity has made or may have made a use, reuse, or disclosure of the MTF data that is not authorized by this Agreement, CMS, at its sole discretion, may require the Dispensing Entity to: (a) promptly investigate and report to CMS the Dispensing Entity'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 MTF data to CMS or destroy the MTF data it received from CMS under this Agreement. The Dispensing Entity understands that as a result of CMS' determination or reasonable belief that unauthorized uses, reuses or disclosures have taken place, CMS may refuse to release certain further MTF data, such as remittance advice or ERA files, to the Dispensing Entity for a period of time to be determined by CMS.
- (11) The Dispensing Entity and, as applicable, the Dispensing Entity's Third-Party Support Entity, acknowledges that MTF data in the MTF DM is retained in compliance with CMS data privacy, security, and storage rules, which align with the 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. The Dispensing Entity and any Third-Party Support Entity must implement administrative, technical, and physical safeguards that comply with the HIPAA Security Rule (45 CFR Part 164, Subpart C) and align with CMS' information security policies. Any retention of MTF data beyond ten (10) years requires CMS' prior written approval and must be destroyed following NARA-

approved methods, as outlined in the NARA Records Schedule (<https://www.archives.gov/about/records-schedule>).

- (12) The Dispensing Entity and any Third-Party Support Entity agree that MTF data, including any data containing or derived from Personally Identifiable Information (PII) or Protected Health Information (PHI), must not be transmitted, stored, processed, or accessed outside the United States without the advance written approval of CMS. If CMS approves offshore data handling, the Dispensing Entity and any Third-Party Support Entity must implement additional safeguards to ensure compliance with all applicable CMS data privacy and security standards, including but not limited to:
- i. Maintaining compliance with the HIPAA Privacy and Security Rules and CMS policies.
 - ii. Ensuring the offshore entity adheres to U.S. federal data protection standards through binding contractual obligations, including audit rights for CMS or its authorized representatives.
 - iii. Establishing encryption standards for data in transit and at rest.
 - iv. Requiring real-time access logging and monitoring to detect unauthorized access.
 - v. Restricting offshore access to the minimum necessary personnel required to perform approved activities.
 - vi. Ensuring prompt notification to CMS of any data breach or unauthorized access involving offshore entities, in compliance with incident reporting requirements in this Agreement.
 - vii. The Dispensing Entity further agrees to provide CMS with detailed documentation of the offshore data handling arrangements, including the identity of any subcontractors, security controls in place, and measures ensuring compliance with CMS standards.