

**MEDICARE TRANSACTION FACILITATOR PAYMENT MODULE
CONTRACTOR AGREEMENT**

(hereinafter referred to as the “MTF PM Agreement” or “this Agreement”)

between

**National Government Services, Inc.,
in its capacity as the Medicare Transaction Facilitator Payment Module Contractor
(hereinafter referred to as “MTF PM Contractor”)**

and

**The Manufacturer Identified in Section VIII of this Agreement
(hereinafter referred to as “Manufacturer”)**

This Agreement is by and between MTF PM Contractor and Manufacturer (collectively, “the Parties”). The Centers for Medicare & Medicaid Services (“CMS”) has required, reviewed, and approved this Agreement. The purpose of this Agreement is to set forth the Parties’ expectations regarding their respective roles under the Medicare Drug Price Negotiation Program (“Negotiation Program”).

I DEFINITIONS

These terms have the meanings specified as follows when used in this Agreement:

- (a) **“Claim-level data elements”** means the data, as described in applicable guidance and regulations, that CMS transmits to Manufacturer via the MTF Data Module for each claim for a selected drug that is dispensed to a maximum fair price (“MFP”)-eligible individual.
- (b) **“Claim-level payment elements”** means the data, as described in applicable guidance and regulations, that Manufacturer transmits to CMS via the MTF Data Module indicating 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 and regulations, to track credits and debits for MFP refund payments for each of the selected drug(s) at the dispensing entity National Provider Identifier (“NPI”)-level.
- (d) **“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.
- (e) **“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 the remittance or ERA for manufacturers and 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 Manufacturer’s direction in the transmitted claim-level payment elements received from the MTF Data

Module Contractor to effectuate MFP in connection with this Agreement.

- (g) **“MTF Data Module User Agreement” or “MTF DM User Agreement”** means the agreement between 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.
- (h) **“Negotiation Program Agreement” or “Negotiation Program Agreement(s)”** means the agreement(s) between CMS and Manufacturer as established under section 1193 of the Social Security Act (“the Act”) with respect to 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 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 MTF PAYMENT MODULE

- (a) The MTF PM, as defined in section I(f) of this Agreement, is intended to accomplish the following tasks in the administration of the Negotiation Program in a ministerial role:
 - (1) Facilitate MFP refund payments from Manufacturer to dispensing entities, or parties authorized by dispensing entities to receive payment on their behalf, by passing through payment of such MFP retrospective refunds on MFP-eligible claims of selected drug(s) for which Manufacturer is the Primary Manufacturer (hereafter referred to as the “selected drug(s)” or each “selected drug”). If the Manufacturer opts into the MTF PM, the Manufacturer shall use the MTF PM for all selected drug(s); provided, however, that the Manufacturer remains free to effectuate the MFP outside of the MTF PM with respect to transactions with dispensing entities for which the Manufacturer and the dispensing entity have mutually agreed upon an alternative process.
 - (2) Provide an efficient and unified payment flow.
 - (3) Support implementation of the Ledger System as defined in section I(c) of this Agreement.
- (b) The MTF PM shall not supersede or alter Manufacturer’s statutory obligation to effectuate the MFP.

III MTF PAYMENT MODULE CONTRACTOR

- (a) Consistent with the terms of the MTF PM Contractor’s procurement contract with CMS (“MTF PM Contract”), MTF PM Contractor is intended to accomplish the following tasks in a ministerial role:
 - (1) Administer the MTF PM and facilitate transactions between Manufacturer and dispensing entities based upon Manufacturer’s claim-level payment elements provided to the MTF Data Module Contractor by debiting Manufacturer’s account.
 - (2) Comply with all requirements regarding confidentiality, privacy, data use, and data security contained in its MTF PM Contract with CMS.
- (b) Consistent with the terms of the MTF PM Contract, the MTF PM Contractor shall not:
 - (1) Determine any MFP refund payment amounts or collect funds for any other use.

- (2) Perform duties or actions that are beyond the scope of its contract with CMS, which, in relation to the Negotiation Program, is predicated on the existence and continued, sufficient funding of its MTF PM Contract with CMS.
- (3) Accrue any interest on funds held by the MTF PM during the period before the funds are transferred to dispensing entities (or returned to Manufacturer in the event of unclaimed funds).

IV MANUFACTURER

Pursuant to the Negotiation Program Agreement(s), including any applicable guidance and regulations describing the obligations thereunder, and the MTF DM User Agreement, Manufacturer shall:

- (a) Within the 14-day prompt MFP payment window, authorize MTF PM Contractor to initiate a paper check or an Automated Clearing House (ACH) debit entry to Manufacturer's financial institution account indicated for MFP refund payments, and authorize the MTF PM Contractor's financial institution to debit the entry to the Manufacturer's bank account on file in the MTF DM in the amount specified by the Manufacturer in the claim-level payment elements. Manufacturer's return of the claim-level payment elements to the MTF Data Module Contractor is Manufacturer's authorization for MTF PM Contractor to debit the funds from Manufacturer.
- (b) Ensure that sufficient funds are maintained in the Manufacturer's identified bank account in the MTF DM to complete the transfer of the amounts authorized by the Manufacturer's claim-level payment elements.
- (c) Update the Manufacturer's financial information in the MTF DM if the Manufacturer's financial institution or bank account information changes in accordance with the MTF DM User Agreement and applicable guidance and regulations.
- (d) Manufacturer acknowledges that Manufacturer alone is responsible for determining refund amounts owed to dispensing entities.

V 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 takes precedence. As related to the MTF PM Contractor, in the event of any inconsistencies between this Agreement and the MTF PM Contract, the MTF PM Contract takes precedence. As related to Manufacturer, in the event of any inconsistencies between this Agreement, the MTF DM User Agreement, and the Negotiation Program Agreement(s), first the Negotiation Program Agreement(s) will take precedence, then the MTF DM User Agreement will take precedence.

VI 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 this Agreement takes effect. Thereafter, this Agreement shall automatically renew each subsequent year for one-year renewal terms starting on January

1 each year.

- (c) Subject to the limitations on the scope of termination in subparagraphs (d), (e), (f), (g), and (h) of this section in this Agreement, this Agreement will terminate:
 - (1) Upon the termination of the MTF DM User Agreement. As stated in section VIII of the MTF DM User Agreement, the termination of the MTF DM User Agreement will automatically and simultaneously terminate this MTF PM Agreement and such termination shall be effective as of the termination date of the MTF DM User Agreement;
 - (2) Upon the effective date of a decision by the Manufacturer to no longer utilize the MTF PM, following the notice requirements established in the MTF DM User Agreement and in the applicable guidance and regulations; or
 - (3) Upon the end of CMS' procurement agreement with the MTF Payment Module Contractor.
- (d) If the MTF DM User Agreement is terminated only as to a specific selected drug(s) as set forth in section IX of the MTF DM User 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 DM User Agreement.
- (e) Each selected drug covered by this Agreement is considered a separate and severable obligation, allowing for independent termination of this Agreement as to a particular selected drug by its removal from Addendum 1 of the MTF DM User Agreement without affecting this Agreement's continued applicability to the selected drug(s) that remain listed on Addendum 1 to the MTF DM User Agreement.
- (f) If a Primary Manufacturer decides to terminate participation in the MTF PM, the Primary Manufacturer remains responsible for making the MFP available through the transmission of payment via the MTF PM for any claims for which the claim-level payment elements have been transmitted to the MTF PM prior to the effective date of termination, unless the Primary Manufacturer has in place an alternative arrangement for making the MFP available, as documented in the MFP Effectuation Plan.
- (g) If the Manufacturer transfers ownership of all New Drug Applications ("NDAs") or Biologics License Applications ("BLAs") of certain selected drug(s) to another entity (referred to as the "Acquiring Manufacturer" herein), this Agreement will terminate as to the transferred selected drug(s). This Agreement will stay in effect for the other selected drug(s) of the Manufacturer listed on Addendum 1 of the MTF DM User Agreement. If the Acquiring Manufacturer elects to utilize the MTF PM, the Acquiring Manufacturer must sign a new agreement with the MTF Payment Module Contractor to utilize the MTF PM for the transferred selected drug(s); or if the Acquiring Manufacturer has already signed an agreement with the MTF Payment Module Contractor, the transferred selected drug(s) will be covered by such agreement upon being added to Addendum 1 of the Acquiring Manufacturer's MTF DM User Agreement.
- (h) Notwithstanding the termination of this Agreement, certain requirements and obligations shall continue to apply in accordance with applicable guidance and regulations. For clarity, the termination of this Agreement shall have no legal effect on Manufacturer's confidentiality, privacy, data use, and data security obligations under its MTF DM User

Agreement with CMS, nor on MTF PM Contractor's obligations regarding confidentiality, privacy, data use, and data security under the MTF PM Contract with CMS.

VII CONFLICT RESOLUTION, WAIVER, LIMITATION OF LIABILITY, AND JURISDICTION

- (a) MTF PM Contractor's obligations under this Agreement are identified in their entirety in Section III of this Agreement. The Parties further agree to enter into negotiations to resolve any conflicts arising out of MTF PM Contractor's performance of its obligations as identified in this Agreement. The Parties will negotiate in good faith to attempt to reach a mutually agreeable solution or settlement within a reasonable amount of time, to ensure the Parties meet their obligations to CMS.
- (b) In the event negotiations are unsuccessful, the Parties agree that the sole venue for any legal proceeding arising out of or relating to MTF PM Contractor's performance of its obligations as identified in Section III of this Agreement shall be in the state or federal courts of Virginia. The Parties expressly submit to the jurisdiction of the commonwealth and federal courts of Virginia and agree that Virginia law shall govern any dispute.
- (c) The Parties agree that any claim or action brought arising out of the MTF PM Contractor's performance of its obligations as identified in Section III of this Agreement shall be limited to an individual transaction. Claims may not be consolidated or pursued in aggregate for purposes of litigation. The Parties waive any right to a jury trial.
- (d) Neither Party shall be liable to the other for any amounts representing special, incidental, indirect, and/or consequential damage, including, but not limited to: loss of profits; loss of business; exemplary damages; punitive damages; and/or civil monetary penalties, regardless of whether such damages were foreseeable or whether a party has been advised of the possibility of such damages. Neither the MTF PM contract with CMS nor this Agreement have third-party beneficiaries.
- (e) In accordance with the requirements of the Antideficiency Act, 31 U.S.C. § 1341 and the Adequacy of Appropriations Act, 41 U.S.C. § 11, no indemnification by the Government or its agents is available for any action or omission by the MTF, and the MTF PM Contract's terms are not enforceable by any third-party beneficiaries.

VIII SIGNATURES

In signing this Agreement, the Parties do not make any statement regarding or endorsement of CMS' views. Use of the term "maximum fair price" or 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.

FOR MANUFACTURER

By: _____ (e-signature)

Title: _____

Name of Manufacturer: _____

Manufacturer Mailing Address: _____

Date: _____

FOR MTF PM CONTRACTOR

By: _____ (e-signature)

Title: _____

Date: _____