Submitted electronically to: IRARebateandNegotiation@cms.hhs.gov

January 29, 2025

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: MTF Agreements Feedback

Dear CMS Staff,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) to its Dispensing Entity-CMS Agreement and Dispensing Entity-MTF Data Module Contractor Agreement (collectively, "the Agreements").

NCPA represents America's community pharmacists, including 18,900 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members employ 205,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers. NCPA submits these comments on behalf of both community and LTC independent pharmacies.

NCPA's General Comments to MTF Agreements

NCPA believes that the proposed Agreements would be detrimental to its members. While NCPA will indicate to each of its members that it is free to participate in these Agreements and the Medicare Drug Price Negotiation Program (MDPN), NCPA will be advising them not to sign either agreement in current form. Further, the purpose of our alarm is not to disadvantage competitors, but to facilitate competition and help keep markets competitive and provide choice to Americans.

NCPA believes that the only way to get CMS to listen to the concerns of America's community pharmacists is for independent pharmacists to reject these Agreements as well as the MDPN program. NCPA and its members are in favor of competition, which runs counter to the anti-competitive nature of these Agreements and the MDPN program. The Agreements and the MDPN program would destroy competition and further the steps toward pharmacy monopolies, further vertical consolidation, lessen competition and increase harm to consumers.

Our specific comments to the Agreements are as follows:

NCPA Comments on the Dispensing Entity-CMS Agreement

Page 1
NCPA advises CMS to insert new third paragraph to read:

> "WHEREAS, Dispensing Entity may be forced by Medicare Part D plan sponsor or their downstream entities to participate in the Negotiation Program to get access to other commercial or Medicare Part D networks (hereinafter referred to as "tie or tying");"

NCPA has brought the issue of PBMs and plans of "tying" participation in commercial and/or other networks to their participation in Part D networks to CMS, and is requesting CMS to provide clarity on this being an unacceptable practice.

NCPA suggests the following edit:

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

NCPA opposes this Agreement as it is a contract of adhesion and unconscionable, mandating that pharmacies dispense selected drugs to MFP-eligible individuals. NCPA proposes that the language be changed to reflect pharmacies having a choice to enter this program.

Section II: DISPENSING ENTITY'S RESPONSIBILITIES

Page 3
NCPA requests the following edits:

Pursuant to any applicable guidance and regulations:

(a) Dispensing Entity shall enter into and have in effect, under commercially reasonable terms and conditions approved by CMS, an agreement with the MTF Data Module Contractor.

(b) Dispensing Entity shall comply with relevant and commercially reasonable instructions, processes, and requirements of the MTF Data Module Contractor.

Similar to above, NCPA opposes requiring pharmacies to enter into an agreement with the MTF Data Module Contractor, as this is part of the boarder Agreement that is a contract of adhesion and unconscionable, mandating that pharmacies dispense selected drugs to MFP-eligible individuals.

Page 3

On page 3, the draft agreement states the following:

> 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. [NCPA emphasis]

NCPA opposes the above requirements on dispensers, and asks that CMS strike these requirements as being overly burdensome. Alternatively, for the above notifications in this section, NCPA believes that the notice should go to the MTF Data Module Contractor and not CMS. If the MTF Data Module Contractor is tasked with "execut[ing] on the data exchange, user interface functionality, and issuance of remittance or ERA for dispensing entities," NCPA believes that it makes more sense to provide the notice to the MTF Data Module Contractor. NCPA seeks clarification on this.

Page 4

On page 4, the draft agreement states the following:

> 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).

NCPA finds the 10-year period to be overly burdensome. Both Medicare[1] and Medicaid[2] recovery audit contractors (RACs), for example, have at most three years to look back from the date of a claim, and NCPA similarly requests at most a three-year look back period in these agreements.

Section III: CMS' RESPONSIBILITIES

Page 5

After (a), NCPA advises CMS to add a new (b) and re-number accordingly:

> (b) CMS shall ensure, regularly monitor, and require corrections (when issues arise regarding) whether the MTF Data Module Contractor's instructions, processes, and requirements are relevant and commercially reasonable and not overly burdensome to the Dispensing Entities.

NCPA believes that this clause is necessary to ensure proper program integrity, and that dispensers are not overly burdened by this program.

Section IV: PENALTY PROVISIONS and Section VIII: EFFECTIVE DATE, TERM, RENEWAL, AND TERMINATION

Pages 5 and 8

NCPA notices a total of four (4) mentions of fraud in this document, and that CMS seems to have a significant concern related to the dispensing entity committing fraud. Given that dispensing entities are likely not wanting to participate in this program at all due to the financial impact it will have on them due to the prospect of floating costs, and under reimbursement from PBMs, can CMS clarify what is the actual fraud concern?

Section V: AUDIT RIGHTS

Page 6
CMS currently proposes the following text:

> 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

[1] See The-Recovery-Audit-Program-and-Medicare-Slides-051313.pdf.
[2] See 42 CFR 455.508(f).

ten (10) years, from the date of the dispense of the selected drug(s) or otherwise as required by CMS.

NCPA finds the 10-year period to be overly burdensome. Both Medicare[3] and Medicaid[4] recovery audit contractors (RACs), for example, have at most three years to look back from the date of a claim, and NCPA similarly requests at most a three-year look back period in these agreements.

Section VIII: EFFECTIVE DATE, TERM, RENEWAL, AND TERMINATION

Page 8
NCPA requests the following edit:

> Termination by the Dispensing Entity. Dispensing Entity may terminate this Agreement subject to the requirements set forth in subparagraphs ~~(i)-(ii)~~ (A)-(B). The Dispensing Entity acknowledges that termination of this Agreement by the Dispensing Entity ~~may~~ shall not 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 because CMS shall not allow Part D plan sponsor(s) to tie Part D network participation with the Negotiation Program.

NCPA does not believe that CMS has the authority to tie participation in Part D as a whole with participation in the MDPN Program. NCPA requests formal explanation as to why it believes it has such authority.

> "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."

NCPA requests clarity if the dispensing entity must notify CMS, or the contractor in this instance?

> 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.

[3] See The-Recovery-Audit-Program-and-Medicare-Slides-051313.pdf.
[4] See 42 CFR 455.508(f).

NCPA strongly opposes the 180-calendar day requirement, as such a long period favors PBMs. If a dispensing entity is getting under-reimbursed by a PBM, it should be able to terminate its participation, effective immediately.

> 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.

NCPA proposes that CMS strike this language. NCPA believes that this provision is egregious, given that it gives PBMs even greater market power over their competitors. Pharmacies are being required to participate in the Negotiation Program without protections against under reimbursement or clawbacks by PBMs and plans.

Section IX: Disclaimers

Page 9

CMS' proposed text states the following:

> (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.

NCPA proposes that CMS strike the above language. NCPA finds it unconscionable that CMS is mandating pharmacies participation in the Medicare Drug Price Negotiation (MDPN) program as well as the MTF DM, while disclaiming all warranties that the MTF PM and MTF DM will work, and that also CMS cannot ensure that pharmacies will be paid reasonably and timely within the MDPN program. How can CMS protect pharmacies against the vendors or the program itself being a total failure?

(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.

NCPA proposes that CMS strike the above language. NCPA finds it unconscionable that CMS would require the Dispensing Entity to indemnify CMS for actions of CMS' own vendors, the MTF Data Module Contractor, MTF Payment Module or manufacturers. Dispensing entities have no control over any of these entities. Additionally, indemnification and broad disclaimers were not required for pharmacies for the COVID-19 vaccine agreements. Moreover, we find the disclaimers to be problematic as written. CMS disclaims any and all damages for anything arising out of or connected with the MTF, which is incredibly and unreasonably broad. CMS also disclaims any damages resulting from any use of either the MTF DM or MTF Payment Module (PM). Our understanding of the Negotiation Program is that CMS is selecting the MTF DM and MTF PM and mandating as part of the Medicare program that dispensers must participate in the Negotiation Program, however CMS would take no responsibility for any damages arising from the Program. There should at least be a mechanism to hold the MTF DM and MTF PM accountable if CMS is disclaiming any and all liability. For instance, CMS should provide language that their contract with MTF DM and MTF PM will include indemnification of the dispensing entities.

CMS' proposed text states the following:

(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.

NCPA proposes that CMS strike the above language. NCPA finds this provision unconscionable as well. If CMS is requiring dispensing entities' participation in the MDPN Program, then CMS should take responsibility for its contractors' failures.

CMS' proposed text states the following:

(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.

NCPA finds this clause unconscionable. CMS controls its contractors, so CMS should be liable for errors, omissions, or other inaccuracies by the DM and PM. NCPA proposes that CMS strike the above language.

CMS' proposed text states the following:

> (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).

NCPA proposes that CMS strike the above language. NCPA finds it unconscionable that the MTF Payment module is voluntary to manufacturers, but the MTF DM program is not voluntary to pharmacies, and CMS is requiring pharmacies to participate in the MDPN in order to participate in Medicare Part D. Approximately one third of a dispensing entities' business is in Medicare Part D, and dispensing entities cannot give up one third of its business.

<u>Page 10</u>

CMS' proposed text states the following:

> (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).

NCPA finds it unconscionable that while dispensing entities are required to participate in this program, CMS is disclaiming all responsibility for it. NCPA proposes that CMS strike the above language.

CMS' proposed text states the following:

> (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.

[…]

(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.

NCPA's analysis of 5,200 community pharmacies to determine the effect of the MDPN Program found that the average pharmacy will have to float over $27,000 every month waiting to be made whole for the MFP refunds from manufacturers. The impact on the cash flow on the roughly 20,000 independent pharmacies in the country will be a collective half a billion dollars every month. This huge number is only for year one of the MDPN Program and will grow larger and larger as more drugs are added each year, resulting in devastating, irreparable impact on pharmacies serving most vulnerable and at-risk patients, especially those serving long-term care facilities. NCPA will be releasing a study showing updated IRA MDPN Program impacts on community pharmacy in the near future and will share that study with CMS once available. In addition, a recent NCPA member survey, conducted in January 2025, indicated that approximately 61 percent of independent pharmacists are strongly not considering stocking one or more drugs with prices negotiated under Medicare Part D, while an additional approximately 33 percent have already decided not to stock one or more of the drugs, which would all but guarantee that CMS' attempt to reduce prescription drug prices will fail.[5] Independent pharmacies cannot and should not, nor was it the intent of Congress for pharmacy to pre-fund the MDPN program. **Without CMS making the necessary changes outlined above, including CMS pre-funding the program, pharmacies will not be able to afford to dispense these drugs and the MDPN program will fail.**

(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.

Again, NCPA opposes CMS and its contractors from relinquishing responsibility of this program as stated in this section. Further, NCPA questions CMS' desire to audit the dispensing entities for 10 years, given the language in section (m) above stating that CMS relinquishes control over this program.

Section X: General Provisions

[5] See 1.27.2025-FinalExecSummary.NCPA .MemberSurvey.pdf.

Page 11

NCPA proposes the following edit:

(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~~ shall provide the Dispensing Entity at least sixty (60) calendar days' notice of any amendment to this Agreement, and any amendments should be in effect at the beginning of the plan year (like PDPs and MAPDs).

NCPA believes that the first sentence is unconscionable and echoes arbitrary contracting procedures of PBMs. NCPA argues that in the second sentence, to protect the dispensing entities, CMS shall provide the dispensing entity with 60 days notice, as the language "endeavor to provide" does not provide adequate protections. NCPA also believes that to avoid great administrative burden to pharmacies, amendments should be in effect at the beginning of the plan year.

Page 12

NCPA proposes the following edit:

(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.~~

NCPA believes CMS must provide greater clarity as to what is included in the definition of MFP because it appears MFP is susceptible to post adjudication claw backs like DIR. In its final guidance, CMS did not regulate PBM payment to pharmacies for MFP drugs – neither fair reimbursement nor dispensing fees. Furthermore, while NCPA has advocated for WAC – MFP as the manufacturer refund amount to pharmacies, CMS states in the final guidance that this standard default refund may not be universally appropriate or sufficient to effectuate the MFP, and manufacturers can use another metric such as pharmacy acquisition cost. Furthermore, CMS stated that "dispensing entities are reimbursed at or below the MFP plus dispensing fee by Part D plans."[6] So PBMs can reimburse pharmacies less than MFP for selected drugs and are not obligated to pay any dispensing fees. **NCPA continues to ask that pharmacy reimbursement will incorporate a negotiated price that is no lower than the maximum fair price and; 2) cover acquisition cost plus commensurate professional dispensing fee in line with Medicaid fee-for-service and should be paid within Medicare prompt pay requirements.**

[6] See Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027, page 48.

Exhibit A: DATA USE PROVISIONS

Page 14

CMS' proposed text states the following:

> (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.

NCPA advises CMS to strike this text, as dispensing entities will have other reasons to "use" this data. For example, the data will be uploaded to dispensing entity's pharmacy management system (PMS), switches, and PBMs.

Page 15 and 16

In the draft agreement, there are multiple mentions obligating dispensers to either "destroy" MTF data or "return" it to CMS. NCPA asks CMS to strike these provisions, as they are overly burdensome on pharmacies. It is unclear why Dispensing Entities should not be allowed to keep this data.

Page 16

CMS' proposed text states the following:

> (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.

NCPA advises striking the above language (Section (9)). NCPA asserts that having to notify CMS about a breach or security incident involving MTF data within one hour of discovery is unreasonable and overly burdensome. Breach notification should follow current OCR protocols and guidelines for timing.

CMS' proposed text states the following:

> *(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)

NCPA advises striking the above language (Section (11)). NCPA is concerned about these provisions, which require that pharmacies comply with additional information security policies. Following HIPAA privacy and security rules and complying with confidentiality requirements of the agreement should be sufficient.

Page 17

CMS' proposed text states the following:

> (b)(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.

NCPA urges CMS to delete the above language. The draft language would prohibit Dispensing Entities from transmitting, storing, processing, or accessing MTF data outside the United States without advance written approval of CMS, and also provides that if CMS provides such approval, the Dispensing Entity must implement additional safeguards. NCPA urges CMS to reconsider the requirement for prior approval from CMS and for additional safeguards. First, CMS approval should not be necessary so long as the required safeguards are implemented. Second, while we believe subclause (i) is reasonable, we are concerned that not all of our vendors can agree to the other provisions that go far beyond what is required under HIPAA. Implementing requirements above and beyond the requirements of HIPAA is unnecessarily burdensome and unnecessary to protect the privacy and security of MTF data.

NCPA Comments on the Dispensing Entity-MTF Data Module Contractor Agreement

Page 1

CMS' proposed text states the following:

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 **[NCPA emphasis]**

NCPA presumes that this "refund [that] is being paid" refers to the manufacturer refund. NCPA continues to oppose the arbitrariness of this refund. NCPA continues to strongly urge CMS to require the use of WAC as the standardized metric and that any difference between WAC and MFP is the Standard Default Refund Amount (SDRA).

However, CMS acknowledged in its final guidance that the SDRA may not be universally appropriate or sufficient to effectuate the MFP. Under the statute, the obligation to calculate and pay an MFP refund amount that ensures the dispensing entity has access to the MFP rests with the Primary Manufacturer. A Primary Manufacturer can choose to refund an amount different than the SDRA if the Primary Manufacturer determines and can document some other amount is appropriate to make the MFP available (e.g., the dispensing entity purchased the selected drug at a cost above WAC). CMS encouraged Primary Manufacturers and dispensing entities to work together to establish an MFP refund amount using the SDRA or the dispensing entity's actual acquisition cost or an adjusted standardized pricing metric that ensures the MFP has been made available prior to the issuance of MFP refund payments between the interested parties. CMS recommended Primary Manufacturers and dispensing entities remediate MFP refund payment issues with each other directly. If remediation between the parties cannot be reached, Primary Manufacturers and dispensing entities may utilize the complaints process within the complaint and dispute system provided in the guidance to report that the MFP was not made available.

CMS' proposed text states the following:

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;

NCPA does not believe that CMS has the authority to tie participation in Part D as a whole with participation in the Negotiation program. NCPA requests formal acknowledgement of that here in this Agreement.

Definitions

Page 2

NCPA requests the following edit:

(i) "**MTF Program Agreement**" means the compulsory, non-negotiable, take-it-or-leave-it 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.

As discussed above, NCPA believes that the proposed Agreement between the Dispensing Entity and CMS is unconscionable.

Section II: Dispensing Entity's Responsibilities

Page 3

CMS' proposed text states the following:

> 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.

NCPA argues that the "shall enroll" language makes this program compulsory for any pharmacy that wants to participate in any part of Part D. NCPA would like CMS to cite its authority to tie participation in Part D as a whole with participation in the Negotiation program. NCPA requests formal acknowledgement of that here in this Agreement.

NCPA proposes the following edits:

> (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 commercially reasonable instructions, processes, and requirements as directed by the MTF Data Module Contractor.
> (d) Dispensing Entity shall assist in audits and investigations by timely submitting commercially reasonable 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 commercially reasonable guidance, regulations, and technical instructions. The Dispensing Entity shall retain sole responsibility for compliance with the terms of this Agreement and commercially reasonable guidance, regulations, and technical instructions notwithstanding any actions that any Third-Party Support Entity may perform on the Dispensing Entity's behalf.

In the interest of reducing administrative burden, NCPA advises CMS to add "commercially reasonable" to these responsibilities.

Section III. MTF Data Module Contractor's Responsibilities

Page 3

CMS' proposed text states the following:

> (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.

CMS must require the MTF Data Module Contractor to agree to additional provisions regarding data security. The range of topics, given the information being exchanged shall include the scope and definition of the data subject to protection, the purpose and duration of the data processing and storage, the rights and obligations of the data owner, processor, and sub-processor, security policies and procedures, notification and reporting requirements in case of a data breach, audit and verification rights of the data owner, and remedies and penalties for non-compliance or breach of contract. Additional paragraphs should be added after (c) to accommodate those provisions.

Page 5

To best protect dispensers in this program, NCPA advocates for the following edit:

(n) MTF Data Module Contractor shall provide twenty-four-hour customer support 365 days a year 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.

CMS also needs to provide a means by which Dispensing Entities can dispute issues arising under this Agreement and the Service Legal Agreement (SLA). To that end, NCPA proposes that CMS add a new section (p):

(o) MTF Data Module Contractor shall facilitate any audit requests from CMS.

(p) MTF Data Module Contractor shall enter into a Service Level Agreement with Dispensing Entities and manufacturers which specifies key performance indicators and benchmarks regarding the performance, uptime, and maintenance of the MTF DM. MTF Data Module Contractor shall use all reasonable efforts to provide the MTF DM error free and in accordance with the SLA. MTF Data Module Contractor shall be responsible for and cause any third party it uses in the creation or implementation of, or ongoing maintenance of, the MTF to abide by the SLA. MTF Data Module Contractor shall be liable for any loss, liability, claim, cost, or expense to the extent resulting from or caused by the failure of it to meet any obligations under the SLA, or for the failure of any aspect of the MTF DM, any audits, or other obligations it has arising under this Agreement. It shall be the

obligation of MTF Data Module Contractor to develop and oversee the implementation of the procedural or operational changes set by CMS while also enabling the SLA to be met.

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Section IV: Mutual Obligations

CMS' proposed text states the following:

> (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.

It is not appropriate for CMS to place such security measures obligations on Dispensing Entities. The MTF DM should be a secure portal and the only obligation of the Dispensing Entity should be to securely sign on and submit the data through the secure portal. The above paragraph (c) should apply to the MTF Data Module Contractor only.

Section V: CONFIDENTIALITY AND DATA USE

CMS' proposed text states the following:

> 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.

NCPA urges CMS to include by reference the confidentiality and data use provisions outlined in the MTF Program Agreement **into this agreement -- and be made part of this Agreement because if the MTF Data Module Contractor suffers a cyber security attack or does not maintain confidentiality of the data provided by the Dispensing Entities, it could cause a lot of damage to the Dispensing Entities, and they would have no contractual recourse.**

As we have indicated above, pharmacies should not be required to comply with confidentiality and data use provisions that are beyond the requirements of the HIPAA privacy and security rules and the confidentiality provisions of MTF Program Agreement. In other words, the confidentiality, privacy, and data security contained in the federal procurement contract between CMS and the MTF Data Module Contractor should not flow to, or affect pharmacies.

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NCPA asks CMS for the following edit:

Section VII: EFFECTIVE DATE, TERM, RENEWAL, AND TERMINATION

[…]

> (d) Termination. Dispensing Entity may terminate this Agreement without cause by providing the MTF Data Module Contractor thirty (30) days written notice. ~~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.

NCPA believes that dispensing entities need only provide 30 days notice to terminate the agreement. NCPA also believes that the requirement in the draft that the agreement can only terminate with the termination of the MTF program is unconscionable, and unacceptable: pharmacies should be able to terminate the agreement whenever they would like. The language as written sounds like an adhesion contract and PBM-like bullying of pharmacies. NCPA argues that these requirements should be pulled into this agreement and be made part of this Agreement because if the MTF Data Module Contractor breaches, it could cause a lot of damage to the dispensing entities and they would have no contractual recourse.

NCPA proposes the following edits:

> (d) Additional Provisions and Amendments. The MTF Data Module Contractor ~~reserves the right to~~ may include additional provisions, requirements, or terms, ~~and the right to amend this Agreement~~ as ~~it~~ CMS deems necessary or appropriate for the administration of the MTF DM, ~~on its own or~~ but only 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. CMS, by way of ~~As feasible,~~ the MTF Data Module Contractor ~~will endeavor to~~ shall provide the Dispensing Entity at least sixty (60) calendar days notice of any amendment to this Agreement, and any amendments should be in effect at the beginning of the plan year (like PDPs and MAPDs).

NCPA requests these edits as it emphasizes that the entity deciding additional provisions and amendments should be CMS, not the MTF Data Module Contractor. Additionally, as stated above, "will endeavor to" is language that does not protect pharmacies sufficiently, hence the edit to "shall." NCPA also believes that to avoid great administrative burden to pharmacies, amendments should be in effect at the beginning of the plan year.

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CMS' proposed text states the following:

> (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.

NCPA advises CMS to consider ways to address disputes around improper payments and cybersecurity incidents that may require mediation or arbitration to correct errors without full litigation.

CMS' proposed text states the following:

> (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.** [NCPA emphasis]

NCPA disputes the contention that Maximum Fair Price is clearly defined in the statute. Our position is that it does not include DIR or like fees (retroactive or otherwise), but CMS has yet to provide clarity if it agrees with that position or not. As stated above, NCPA believes CMS must provide greater clarity as to what is included in the definition of MFP because it appears MFP is susceptible to post adjudication claw backs like DIR. In its final guidance, CMS did not regulate PBM payment to pharmacies for MFP drugs – neither fair reimbursement nor dispensing fees. Furthermore, while NCPA has advocated for WAC – MFP as the manufacturer refund amount to pharmacies, CMS states in the final guidance that this standard default refund may not be universally appropriate or sufficient to effectuate the MFP, and manufacturers can use another metric such as pharmacy acquisition cost. Furthermore, CMS stated that dispensing entities will be reimbursed at or below the MFP plus dispensing fee. So PBMs can reimburse pharmacies less than MFP for selected drugs and are not obligated to pay any dispensing fees. **NCPA continues to ask that pharmacy reimbursement will incorporate a negotiated price that is no lower than the maximum fair price and; 2) cover acquisition cost plus commensurate professional**

dispensing fee in line with Medicaid fee-for-service and should be paid within Medicare prompt pay requirements.

CMS Must Address Part D Plan Sponsor/PBM Payments to Pharmacies for MFP Drugs to Ensure Beneficiary Access to MFP Drugs

NCPA is concerned that the CMS continues to not address Part D plan sponsor/PBM payment for MFP drugs. NCPA requests confirmation from CMS that the MFP is the ingredient cost for a selected MFP drug, and that CMS has the authority to ensure that pharmacies are paid at that specific price.

Under the Inflation Reduction Act, there is a process by which the Secretary selects MFP drugs. Once a drug is selected, the Secretary is required to enter into agreements with manufacturers to set the MFP for particular drugs. The manufacturer is then required to "provide access to such price . . . to maximum fair price eligible individuals who . . . are dispensed such drug (and to pharmacies, mail order serves, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs)."[7] In addition, the basic definition of "maximum fair price" means the amount negotiated between the Secretary and a manufacturer for a selected drug—that is, for the ingredient cost of that drug.[8] **Given the above, NCPA believes that the IRA equates MFP with ingredient cost, because manufacturers have to make selected drugs available for purchase by pharmacies at MFP.**

NCPA submits that the Inflation Reduction Act means that pharmacies are to be reimbursed by PDP sponsors at MFP for their ingredient costs, plus a dispensing fee, with no extraction of further concessions. There are a few reasons that CMS should arrive at this conclusion. First, as discussed above, the IRA is constructed around treating MFP as the ingredient cost, and it uses a single definition for MFP throughout. Second, the amended definition of "negotiated prices" supports this conclusion. For non-MFP drugs, the total amount of the negotiated price for a non-MFP drug includes (1) the ingredient cost, (2) any "price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs," and (3) "any dispensing fees for such drug[ ]."[9] *In contrast, for MFP drugs* [emphasis added], the "negotiated price" is simply a payment (1) "no greater than the maximum fair price" for the drug and (2) "any dispending fees."[10] Thus, unlike non-MFP drugs, where Congress acknowledged the existence of "concessions" in addition to ingredient costs, Congress did not provide PDP sponsors explicit authorization to extract "concessions" for MFP drugs. Therefore, PDP sponsors should reimburse pharmacies at ingredient cost plus a dispensing fee.

To be sure, Congress provided that the PDP sponsors should make payments to pharmacies at an amount "no greater than the maximum fair price,"[11] which implies that PDP sponsors could

[7] 42 U.S.C. § 1320f-2(a)(1) (NCPA emphasis added); *accord id.* § 1320f-2(a)(2), (a)(3).
[8] *Id.* § 1320f(c)(3); *see also id.* § 1320f-3 (describing the negotiating process for the "maximum fair price").
[9] *Id.* § 1320w-102(d)(1)(B).
[10] *Id.* § 1320w-102(d)(1)(D).
[11] *Id.* § 1320w-102(d)(1)(D).

reimburse less than MFP, but that is not the best reading of the statute. For one thing, the IRA consistently treats MFP at the ingredient cost, and the fact that manufacturers must provide pharmacies with access to MFP when those pharmacies dispense to an MFP eligible individual strongly implies that the pharmacies will then be reimbursed by PDP sponsors at MFP plus any dispensing fee. For another, as noted above, if Congress had wished to allow PDP sponsors to extract additional concessions, it could have said so when it came to defining "negotiated prices" for MFP drugs. But it deliberately excluded concessions from that definition.

This is also consistent with the reality of the IRA. For MFP drugs, manufacturers are being forced to provide access to certain drugs at below their customary price for eligible individuals and the pharmacies that dispense those drugs. It makes sense that Congress would have wanted to reimburse pharmacies no greater than MFP—to ensure that taxpayers are maximizing their savings—while at the same time ensuring that pharmacies at least break even on their ingredient costs while providing for a dispensing fee. Further, the IRA intended to only extract price concessions from the manufacturers, not the providers; therefore, any attempt to pay pharmacies less that MFP would be against the legislative intent of the IRA.

NCPA anticipates that PDP sponsors and their PBMs may argue that depriving them of the ability to reimburse at less than MFP would read "no greater than" out of the statute. However, such an argument is not persuasive, because the statute does not expressly prohibit the Secretary from ensuring that pharmacies are reimbursed at not *less* than MFP. It simply says pharmacies may not be reimbursed greater than MFP. The "not greater than" language also continues to serve a purpose, because ultimately, a PDP sponsor's costs factor into how much CMS pays it under the Part D program. So, it was necessary for Congress to clarify both that manufacturers would sell MFP drugs at a maximum fair price and PDP sponsors would reimburse pharmacies no more than that same price plus a dispensing fee.

14 days prompt pay. **NCPA stresses that pharmacies need to be paid timely, within 14 days of adjudicating the claim.** As CMS acknowledges, under 42 C.F.R. § 423.520 (Prompt Payment by Part D Sponsors), Part D sponsors are required to pay pharmacies within 14 days after receiving an electronic Part D claim that is a clean claim.[12] **At the outset of the Part D program and before this provision was put in place, independent pharmacies were closing rapidly due to delays in payment that caused significant impacts on cashflow. Independent pharmacies operate on small margins and are presently closing at the rate of approximately 1 per day, decreasing beneficiary access to care in their local communities. While NCPA appreciates CMS's effort to incorporate a 14-day prompt payment requirement for Primary Manufacturers, the proposed trigger for that window can vary widely depending on when data is transmitted to the Primary Manufacturer. NCPA stresses that pharmacies need to be paid amounts owed for the MFP within 14 days of adjudicating the claim.**

[12]See 42 C.F.R. § 423.520, available at: https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423/subpart-K/section-423.520.

Part D plan sponsors have 30 days to submit complete PDE records to DDPS. Once those records are sent, the MTF would then need to send the data to the Primary Manufacturers. Depending on the frequency of the transmission, this could result in pharmacies waiting more than several days to receive the amounts owed to them. CMS states that it is evaluating whether the current 30-day window for plans to submit PDE records should be shortened to seven days to ensure dispensing entities receive timely payment of MTF refunds. **CMS must shorten the current 30-day window to 7 days, to ensure pharmacies receive prompt payment. However, in the alternative, should CMS not agree with us that it has the authority to pre-fund the Negotiation Program or to require manufacturers to pre-fund the Program (see below), then we urge CMS to shorten the PDE reporting period from 30 days to 1 day, and to require MTFs to provide the requisite data to the Primary Manufacturers on a daily basis.**

Even if the 7-day window for submitting PDE records is implemented, pharmacies will still be waiting longer than 14-days to receive MFP related payments. In its final guidance, CMS stated that the 14-day prompt MFP payment window begins when the MTF DM sends the claim-level data elements to the Primary Manufacturer, and that it may result in MFP refund payments in excess of 14 days from time of claim submission by the dispensing entity.[13]

Given the 7-day window that NCPA recommends that CMS should implement to submit PDE records, plus the 14-day manufacturer prompt pay window, this means pharmacies will be waiting at a minimum of 21 days for payment. This is unsustainable for independent pharmacies. Pharmacies need to be made whole within 14 days of adjudicating the claim at the pharmacy, period. Pharmacies must pay their wholesalers on an approximate two-week payment cycle, and cannot float the MFP program. Payment to pharmacies should in no circumstances exceed the 14-day prompt pay requirement under Medicare Part D.

Additionally, without action on reforming the MDPN Program, patients, especially seniors and those with disabilities could go without their medication. Given the rapid rate at which the IRA implementation is occurring, we wanted to reach out and share our concerns. We urge CMS to freeze the MDPN Program until we can meet and share our concerns in depth and work collaboratively to identify a method that will ensure the program is workable for pharmacists and patients.

[13] Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027, page 50.

NCPA thanks CMS for the opportunity to provide feedback, and we stand ready to work with the agency to offer possible solutions and ideas. Please let us know how we can assist further, and should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

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