DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

This file includes the 13 timely public submissions that CMS received on the draft Medicare Transaction Facilitator (MTF) agreements during the 45-day feedback period that began on December 17, 2024 and ended on January 31, 2025. CMS thanks all commenters for their feedback.

RxParadigm, an innovative pharmacy solutions and technology firm, formally submits comments to the CMS' Draft Medicare Transaction Facilitator Program Agreement.

The CMS' efforts to provide clarity, transparency, and accountability in the Medicare Program align with RxParadigm's core values and initiatives. Key highlights of our leadership team's expertise include:

1. Extensive Government Experience: Our executives have over four decades of collective experience in working with government agencies, understanding their requirements, and implementing successful pharmacy solutions tailored to their needs.

2. Deep Knowledge of Regulatory Landscape: We have a thorough understanding of the regulatory environment governing pharmacy in the public sector. Our team ensures compliance with all relevant regulations while maximizing cost savings and improving health outcomes for program beneficiaries.

3. Experience in Reimbursement Negotiation and Administration Using Innovative Solutions: RxParadigm team boasts over 25 years of experience in drug reimbursement negotiation and administration for government–funded programs as well as commercial payers. Leveraging innovative technology and data analytics, our company provides actionable insights to inform drug contracting decisions, maximizing resource utilization while optimizing patient outcomes. Specifically, for the 340B program, RxParadigm has integrated unique functionality into its technology platform, Tungsten+ PLUS™. This platform can identify 340B claims, serving as a neutral 340B clearinghouse technology that fulfills all stakeholders' requirements including IRA.

RxParadigm proposes adding language to Draft Medicare Transaction Facilitator Program Agreement Between CMS and the Manufacturer. Page 15, Contract Section – Exhibit A, Data Use Provisions, subsection (b), item #1 CMS's Responsibilities. RxParadigm suggests the following language:

"CMS agrees that manufacturers can require 340B Covered Entities to submit all claims for selected drugs to a neutral third-party 340B clearinghouse that is independent of both drug manufacturers and covered entities. This ensures the prevention of duplication between 340B and Maximum Fair Price (MFP) claims.

Historically, the lack of trust between PBMs, Covered Entities (CEs), and manufacturers has been a significant source of controversy, contributing to current double payment issues. For the success of the program, CEs require a neutral entity they can trust. Whether

the 340B program is managed as a straightforward system with upfront discounts or integrated into a rebate management framework, a neutral clearinghouse is essential."

RxParadigm applauds CMS's actions to strengthen Medicare facilitation, and our comments aim to streamline and increase efficiency for the interaction between MFP and 340B program.

January 31, 2025

[Submitted electronically to IRARebateandNegotiation@cms.hhs.gov]
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8016
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: MTF Agreements Feedback

ASHP (American Society of Health-System Pharmacists) is pleased to submit comments to the Centers for Medicare & Medicaid Services (CMS) regarding draft Medicare Transaction Facilitator (MTF) agreements. ASHP is the largest association of pharmacy professionals in the United States, representing 60,000 pharmacists, student pharmacists, and pharmacy technicians in all patient care settings, including hospitals, ambulatory clinics, and health-system community pharmacies. For over 80 years, ASHP has championed innovation in pharmacy practice, advanced education and professional development, and served as a steadfast advocate for members and patients.

As ASHP has noted in comments to CMS and during meetings with CMS staff, we believe that the proposed Inflation Reduction Act (IRA) drug price negotiation framework is fundamentally flawed. The current retrospective reimbursement framework undermines the IRA's goals by increasing drug purchasing costs for providers. We continue to urge the agency to pause implementation of the IRA's negotiated drug pricing framework and reassess and revise the proposal with additional input from pharmacies and other stakeholders. This will also necessitate revising the proposed MTF agreements.

ASHP strongly supports a robust MTF, but as part of a framework built around a prospective discount on the Medicare Maximum Fair Price for negotiated price drugs. Our comments on the draft agreements highlight areas where the agency needs to strengthen language to ensure that data and pharmacies are adequately protected, but do not imply approval of the underlying framework.

At a high level, the MTF agreements lack sufficient specificity in many sections. It also includes disclaimer and warranty provisions that create significant risk for pharmacies and their patients. Specifically, we have the following concerns with the draft MTF agreements:

- **Requiring MTF Participation as Condition of Network Participation**: Pursuant to the draft CMS-dispensing entity agreement, signing the agreement is a condition of Part D network participation for pharmacies. Conversely, manufacturers' use of the MTF is voluntary. Pharmacy participation should not be conditioned on use of the MTF when manufacturers do not have a corresponding obligation, particularly when CMS has provided no safeguards against plans undercutting pharmacy reimbursement via direct and indirect remuneration (DIR) fees.

- **Unilateral CMS Authority to Modify the Agreements**: The draft agreement provides CMS with unilateral authority to modify the agreements at any time. We recognize that modification of the agreements may be necessary to respond to market conditions or new regulatory requirements, but pharmacies must

have appropriate notice (e.g., a minimum of 90 days). Further, because CMS proposes to condition pharmacy participation in Part D networks on signing this agreement, pharmacies will be forced to accept any changes without reasonable recourse or opportunity to comment. Manufacturers, on the other hand, are free to opt out of the MTF altogether and impose their own effectuation plans, which the agency will not formally approve.

- **Disclaimer:** Pursuant to the agreements, the MTF data and payment modules are provided "as is" with no warranties of any kind. Given that CMS is solely responsible (even through a contractor) for the design, build, and security of the MTF modules, this presents unacceptable risk for pharmacies. As noted above, pharmacies have little choice but to sign the agreement given that the alternative – opting out of Medicare network participation – is unrealistic for most. CMS must take some level of responsibility for MTF operations, particularly the data security elements. Given the recent Change Healthcare cyberattack, no pharmacy or provider should be expected to sign a product use agreement with zero expectation that the product will work as it should and no recourse in the event of a failure or a data breach. This blanket disclaimer, along with the lack of warranty and the indemnification clauses, will likely be similarly unacceptable to manufacturers, increasing the likelihood that manufacturers will opt out of the MTF. This will result in a plethora of bespoke manufacturer effectuation plans, further increasing administrative burden and the cost of IRA implementation for pharmacies.

- **Lack of Clarity around Complaint and Dispute Procedures:** Although the CMS-dispensing entity agreement commits CMS to developing processes for complaint submission and dispute resolution generally, it contains no specifics. Pharmacies are likely to rely heavily on both processes to ensure that they are being reimbursed fairly for negotiated price drugs. CMS must provide additional detail and clarity around complaint and dispute resolution processes to allow pharmacies to assess whether the provisions are workable and sufficiently robust.

- **Robust Data Security Requirements**: Pursuant to the agreements, manufacturers must comply with all CMS data security rules when handling MTF data. However, nothing in the agreements, including the draft agreement for MTF data module usage commits CMS, or any contractor, to any clear security standards. Given the increasing prevalence of cyberattacks on healthcare providers, it is imperative that pharmacies can trust that data provided to the MTF will be adequately safeguarded. The "CMS Responsibilities" section should be amended to clearly enumerate the level of data security that will be provided. Because CMS has also included a blanket disclaimer, the agreement cannot be silent regarding data security standards.

ASHP appreciates the opportunity to offer our input and suggestions on the draft MTF agreements. As CMS moves forward with IRA implementation, please do not hesitate to contact me at 301-664-8698 or jschulte@ashp.org if ASHP can provide any further information or assist the agency in any way.
Sincerely,

Jillanne Schulte Wall, J.D.
Senior Director, Health & Regulatory Policy

Bristol Myers Squibb™

VIA EMAIL SUBMISSION

January 31, 2025

Christina Ritter
Director
Centers for Medicare & Medicaid Services (CMS)
Medicare Drug Rebate and Negotiations Group (MDRNG)

Re: Draft Medicare Transaction Facilitator (MTF) Agreements

Dear Director Ritter:

Bristol Myers Squibb (BMS) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) draft Medicare Transaction Facilitator (MTF) Agreements.[1]

At BMS, we are inspired by a single vision—transforming patients' lives through science. Our talented employees come to work every day dedicated to the mission of discovering, developing, and delivering innovative medicines that help patients prevail over serious diseases. We combine the agility of a biotech with the reach and resources of an established pharmaceutical company to create a global leading biopharma company. In oncology, hematology, immunology, cardiovascular disease, and neuroscience—with one of the most diverse and promising pipelines in the industry—we focus on innovations that drive meaningful change.

BMS supports Medicare policies that promote beneficiary access to new and effective medical treatments and help ensure Medicare patients benefit from the innovation that defines the U.S. health care system. We do not support the so-called Medicare "negotiation" provisions contained in the *Inflation Reduction Act (IRA)*. We are extremely concerned by the impact that these provisions will have on clinical research in addition to current and future innovation for patients.[2]

The IRA will have vast ramifications for patients, providers, manufacturers, and other stakeholders across the country. BMS is concerned that CMS' implementation of the IRA could have sweeping negative repercussions with respect to Medicare beneficiary access to needed medicines, and, indeed, for all patients. It is vital for CMS to give meaningful

[1] CMS, MTF Agreements, *available at* https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation.
[2] For these reasons, BMS has filed a federal lawsuit asking a court to declare the IRA unconstitutional. BMS believes that, in the absence of full repeal of the IRA's drug pricing provisions, significant clarity and reforms are necessary in several critical areas. Although our comments are designed to help CMS in these areas as it implements the process that Congress established in the IRA, nothing we say in this comment letter should be construed as suggesting that CMS can cure the constitutional flaws in the statute that Congress wrote. The IRA takes BMS' property without just compensation and compels manufacturers to express "agreement" that there is a "negotiation," and that the resulting government-mandated price is the "maximum fair price" ("MFP"). But as we have noted in our litigation, there are no true negotiations or agreements involved, and the price is not fair.

consideration of and response to stakeholder feedback on its proposals, particularly as the Agency updates its approach for effectuating the "Maximum Fair Price" (MFP) for selected medicines in Initial Price Applicability Years (IPAYs) 2026 and 2027.

BMS appreciates the opportunity to provide the following comments on the MTF Agreements, and we intend our input to help CMS improve transparency and clarity of IRA implementation. Our recommendations reflect and are driven by our deep expertise in pharmaceutical innovation, delivery and supply chain, and access, as well as our experience with the IRA to date.[3] Pertinent to the draft agreements, BMS has significant experience with transaction processing. For example, Eliquis is prescribed and supplied across thousands of providers and dispensing entities—in 2023 alone, there were over 30 million prescriptions of Eliquis filled as a result of BMS-led inventory and supply chain management. Wholesalers also assist BMS in managing distribution to thousands of dispensing entities, and we recognize the need for support and seamless transition flow in the MTF process. Not only have manufacturers correctly flagged manufacturer and patient concerns early in the IRA engagement process for CMS, but we have also flagged other stakeholder concerns, including dispensing entity financial concerns, that are now being recognized by the Agency. We thank CMS for seeking feedback from manufacturers to improve the MTF process, but we strongly encourage the Agency to weigh this feedback appropriately as manufacturers are experts in data and claims processing in our supply chains. We offer our comments to help mitigate against the negative consequences the IRA would have on innovation and, most importantly, patients.

We continue to note our concerns with CMS' MTF approach due to various operational complexities. These include but are not limited to significant financial and operational burdens on manufacturers, lack of accountability and transparency across the supply chain, and complexity related to CMS' obligation not to require unlawful 340B Program and MFP duplication. We hope to work with the Agency to ensure operational success, but in the absence of additional Agency action to remedy these serious concerns, CMS should provide flexibility for manufacturers to establish the appropriate data sets, timeframes, and processes to support compliance and ensure efficient operationalization of the MFP, particularly in the early IPAYs.

Below, BMS is seeking to share several thematic, but non-exhaustive, concerns with CMS. In general, we support and refer the Agency to the Pharmaceutical Research and Manufacturers of America's (PhRMA's) comments.

Overarching Concerns:

- MTF Agreements Reinforce Coercive, One-Sided Negotiation: BMS continues to reiterate that the MFP process, despite being named the "Drug Price Negotiation Program" (DPNP), does not involve actual "negotiation." If we, as a manufacturer of a selected medicine, do not participate in the DPNP, we would be required to pay impossibly high penalties unless we withdraw all our medicines from Medicare and Medicaid—which is not a real choice for us or for our patients. The MTF Agreements underscore the DPNP's constitutional violations and one-sided nature. Here again, CMS falsely represents that the Agency and the manufacturer "agree" to the contract terms, when, in reality, the manufacturer is compelled to "agree" under the threat of impossibly high penalties. Further compounding this problem, in the MTF Program Agreement's Section IV ("Penalty Provisions"), manufacturers are bound to significant civil monetary penalties (CMPs) for failing to comply with still largely unknown and undecided terms. Meanwhile, Section IX ("Disclaimers") only shields CMS from liability—even when the Agency is at fault—and further imposes liability on manufacturers even when the

[3] In general, we refer CMS to BMS' comments in response to: the "Medicare Drug Price Negotiation Program: Draft 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 (MFP) in 2026 and 2027" Draft Guidance, released on May 3, 2024 (hereinafter referred to as the "IPAY 2027 comments") and other corresponding IRA comment letters.

manufacturer is not at fault. Finally, in almost all circumstances, CMS states that it is the sole party with the authority to terminate these Agreements, again making explicit their one-sided nature. These examples do not reflect a back-and-forth, two-way agreement, but rather, once again, demonstrate a coercive system in which manufacturers are forced to comply.

- MTF Agreements Violate the Law: BMS continues to believe that the IRA violates the First and Fifth Amendments of the Constitution, requiring manufacturers to express "agreement" that there is a "negotiation," and that the resulting government-mandated price is "fair" (i.e., the MFP). We maintain that it is not a true "negotiation" or that this compelled process has resulted in a "fair" price. BMS notes that while the MTF Program Agreement includes Section X ("General Provisions"), subsection (k), "Non-Endorsement of CMS Views in the MTF Program Agreement," such a provision does not cure the First Amendment violation; and the Agreements make clear that CMS interprets providing "access" to the MFP in a way that underscores our Fifth Amendment claims.
- MTF Agreements Contain Open-Ended Language: Across all draft Agreements, CMS uses open-ended and vague language,[4] with the expectation that manufacturers will "agree" to all future terms and conditions, including future policy changes, in the present. BMS strongly disagrees with this approach and asserts this violates basic contracting principles and raises serious due process concerns. Manufacturers cannot be bound to unknown terms or later-adopted provisions. We ask CMS to revise the draft agreements to ensure there are clear terms, in accordance with contracting principles and due process requirements.
- CMS Should Leverage Familiar, Successful Processes: BMS has long held that CMS should adopt an approach similar to the Coverage Gap Discount Program (CGDP) when effectuating the MFP, where the Agency would pass through MFP refund amounts at the time of claim adjudication. This would not only support manufacturers as we review claim-level data from the MTF and make payments more in line with standard business practices but also ensure dispensers receive prompt payment of MFP refunds. Even more, manufacturers and supply chain stakeholders are familiar with CMS' prior agreements like the CGDP and Manufacturer Discount Program (MDP) Agreements that generally have reasonable terms that have been agreed to previously. For consistency and simplicity, we urge CMS to reissue these Agreements, modeling them after the CGDP and MDP Agreements.
- CMS Should Reconsider its View of a 340B Rebate Model: As BMS continues to reiterate, we are concerned with 340B Program integrity under the current chargeback model with replenishment—and we note that the chargeback model is unsustainable and has undermined program intent and requirements. The 340B chargeback model with replenishment does not provide a way to accurately verify if a 340B claim submitted by a covered entity results in appropriate discounts. IRA implementation highlights a major issue with 340B: ensuring that 340B discounts are appropriately applied to the appropriate patient. In order to satisfy both the IRA and the 340B statute, manufacturers must be able to ensure that duplicate discounts are not paid on MFP-eligible units. While we appreciate CMS adding additional claims data requirements in the IPAY 2027 guidance, these elements are not adequate for manufacturers to fully comply with the law. To prevent MFP/340B duplicate discounts, manufacturers must have access to the proper data. Said another way, in order to identify 340B units at the claim-level at this time and ensure the integrity of both the 340B Program and IRA implementation, robust data must be exchanged between covered entities and manufacturers. The current data fields are insufficient and do not allow enough information for manufacturers to de-duplicate the claims, making data sharing between covered entities and manufacturers essential. Ultimately, incomplete data inputs lead to incomplete outcomes, and voluntary processes that allow partial data submissions or rely on inaccurate input data ultimately do not provide the needed transparency. A "data before discount" approach, as allowed under a 340B rebate model, would ensure that manufacturers are not paying multiple discounts for the same units. A 340B rebate model would also provide transparency and benefits to patients and program stakeholders, including CMS. In light of CMS' position that manufacturers must resolve these issues independently but given the challenges if not

[4] BMS refers CMS to PhRMA's comment letter which highlighted a non-exhaustive list of open-ended, vague contract terms.

impossibility of doing so now, BMS urges CMS and the Secretary more broadly to acknowledge that a 340B rebate model is an appropriate and viable solution and would help both manufacturers and CMS implement MFP effectuation.[5]

Agreement between CMS and Manufacturer:

- Manufacturer MTF Enrollment Information: Section I(e) defines "Manufacturer MTF Enrollment Information" as "… the Manufacturer's identifying and, if applicable, financial information as described in CMS' instruction for MTF enrollment within the Primary Manufacturer MFP Effectuation Plan."[6] BMS believes this provision needs to be clearer and more specific on what is included in this definition; additional clarity would be particularly helpful because Section II(i)(5) requires the manufacturer to notify CMS "of a change to the Manufacturer MTF Enrollment Information within thirty (30) calendar days of the change taking effect."[7] A manufacturer needs to understand what CMS' "instruction" might be in order to confirm it can comply with the 30-day advance notice requirement. We note that this comment also applies to the MTF Data Module and MTF Payment Module Agreements.
- Manufacturer's Responsibilities: The Agreement requires manufacturers—on threat of civil penalties—to comply with "the MTF Data Module Contractor's and, as applicable, the MTF Payment Module Contractor's, *instructions, processes, and requirements*" (emphasis added).[8] BMS continues to reiterate our concerns with CMS' MTF approach due to significant, and various, financial and operational complexities and burdens. Manufacturers will need clarity on what those instructions, processes, and requirements are to confirm their ability to comply with them, and we ask CMS and its contractors to work with stakeholders to rectify these issues immediately. In the absence of additional Agency action to remedy these serious operational and financial concerns, CMS must provide flexibility for manufacturers to establish appropriate data sets, timeframes, and processes to support compliance and ensure efficient and compliant MFP operationalization. We note that this comment also applies to the MTF Data Module and MTF Payment Module Agreements.
- 14-Day Prompt Payment Window: The Agreement states the following with respect to the 14-day prompt MFP payment window timeline: "… within the 14-day prompt MFP payment window that begins with the date of MTF DM transmission to the Manufacturer of the claim-level data…."[9] Yet, the IPAY 2027 Final Guidance states that the date of transition of the claim-level data elements from the MTF DM to the Primary Manufacturer is considered day 0 of the 14-day prompt MFP payment window.[10] CMS must make the necessary clarifications to rectify this inconsistency. In general, based on our significant experience with transaction processing, we ask CMS to lengthen the 14-day prompt MFP payment window, or at a minimum, allow manufacturers who do not utilize the MTF payment facilitation process to agree with dispensers on an acceptable and compliant payment timeline. CMS could also consider starting the 14-day prompt payment window only when the manufacturer obtains all of the data necessary to validate MFP eligible eligibility, including whether the unit is a 340B unit.
- Ledger System: The Agreement states that if the manufacturer elects to use the MTF PM, then the manufacturer shall "authorize the MTF PM to send to dispensing entities a payment equal to the total refunds to be paid as indicated in the Manufacturer's reported claim-level payment elements, regardless of any credits which may be

[5] BMS has filed a federal lawsuit in response to HRSA's rejection of the company's statutory right to implement a cash-rebate model under the 340B program, which, as noted in our complaint, is the only way BMS can meet its MFP obligation without also becoming subject to unlawful 340B duplication.
[6] CMS, MTF Program Agreement, p. 2.
[7] *Id*. at p. 4.
[8] *Id*. at p. 3.
[9] *Id*. at p 4.
[10] CMS, IPAY 2027 Final Guidance, p. 206.

applied under the Ledger System."[11] We ask CMS to clarify this statement, particularly how it would be possible for a manufacturer to report a net payment to a dispensing entity if there are credits which may be applied under the Ledger System. This clarification is further warranted given this later statement: "Manufacturer acknowledges that accrued credits will be applied by the MTF PM to the next MTF refund transaction between the Manufacturer and the specific dispensing entity NPI for the selected drug for which the credit was originally granted."[12] BMS takes this statement to imply that accrued credits attributable to a dispensing entity, if any, are to be applied prior to any additional payments being made.

- Credits and Debits: The Agreement states that the "Manufacturer shall review all credits and debits to confirm accuracy."[13] Manufacturers will need to have additional information on how the Ledger System will work and the types of information that will be made available to agree to this provision, and we ask CMS to update the Agreement accordingly.
- Accrued Credits: The Agreement states: "Manufacturer acknowledges that accrued credits will be applied by the MTF PM to the next MTF refund transaction between the Manufacturer and the specific dispensing entity NPI for the selected drug for which the credit was originally granted."[14] BMS is concerned that this approach could potentially result in a scenario in which credits could be outstanding for some time, and we ask CMS that credits be applied at a broader level—e.g., in the event a credit is generated by a dispensing entity NPI that is part of a chain pharmacy such that MFP payments are received by the dispensing entity chain home office ("CHO"), the credit should be applicable to any other MFP refund claims of a different dispensing entity NPI under the same CHO.
- Amendment Authority: This section indicates that CMS may unilaterally amend the MTF Program Agreement and will "endeavor to provide the Manufacturer at least sixty (60) calendar day notice of any amendment to this Agreement."[15] While we object to CMS' ability to unilaterally amend the MTF Program Agreement, we ask that at a minimum, consistent with our comments elsewhere in this document, that CMS provide manufacturers 90 days advance notice of any amendments to the Agreement, just as manufacturers must give CMS 90 days' advance notice before implementing a change to their MFP effectuation plan.
- Manufacturer Attestation: Manufacturers must attest to the following statement: "All information the Manufacturer provides to the MTF DM is and will be *true, complete, and accurate*" (emphasis added).[16] As BMS notes above, the current proposed data fields are insufficient and do not allow enough information for manufacturers to de-duplicate the claims, making data sharing between covered entities and manufacturers essential. In light of CMS' position that manufacturers must resolve these issues independently but given the challenges of doing so, BMS urges CMS and the Secretary more broadly to acknowledge that a 340B rebate model is an appropriate and viable solution and would help both manufacturers and CMS implement MFP effectuation. To the extent CMS remains unwilling to do so and given significant concerns about the insufficiency of the data, CMS must, at a minimum, update the attestation language such that manufacturers are subject to a "best knowledge and belief" qualifier, consistent with the other MTF Agreements.[17]

[11] CMS, MTF Program Agreement, p. 5.
[12] *Id*.
[13] *Id*.
[14] *Id*.
[15] *Id*. at p 12.
[16] *Id*. at p. 13.
[17] *See*: Manufacturer-MTF Data Module Contractor Agreement, which provides at Section II(g) that "Manufacturer shall return claim-level payment elements for each claim within the 14-day prompt MFP payment window and ensure that the claim-level payment elements returned are timely, complete and accurate to the **best of their knowledge**" and Manufacturer-MTF Payment Module Contractor Agreement, which provides the same in Section II(c): "Manufacturer shall ensure that electronic funds transfers or other payments to dispensing entities are timely, complete, and accurate to the **best of their knowledge**…" (emphasis added).

- Data Use Provisions: This section requires the manufacturer to report to CMS within one hour of discovering that it inadvertently received any direct beneficiary identifiers or any other breach or incident involving CMS Data, loss of CMS Data, or disclosure of CMS Data to any unauthorized persons.[18] Operationally speaking, BMS asserts that this will be challenging, if not impossible, to do under the proposed timeline, and we ask CMS to assume good intent on the manufacturers' part and allow manufacturers one full business day to comply with this provision.

Agreement between MTF Data Module Contractor and Manufacturer:

- Additional Provisions and Amendments: The Agreement states that the MTF Data Module Contractor reserves the right to include additional provisions, requirements, or terms and the right to amend this Agreement as it deems necessary or appropriate for the administration of the MTF DM, on its own or at the direction of CMS, subject to applicable laws, guidance, or regulations and the prior approval of CMS, and that the MTF Data Module Contractor will "endeavor to provide the Manufacturer at least sixty (60) calendar day notice of any amendment to this Agreement."[19] For a similar reason made above, BMS objects to such unilateral amendment and urges CMS, at a minimum, to revise the Agreement such that the MTF Data Module Contractor should also provide 90 days advance notice of any amendments to the Agreement. We note that this comment additionally applies to the MTF Payment Module Agreement.

Agreement between MTF Payment Module Contractor and Manufacturer:

- Recitals: The Agreement indicates that the MTF PM shall only facilitate transactions between the "Manufacturer and dispensing entities,"[20] but BMS notes that CMS should expand this to include "or parties authorized by dispensing entities to receive payment on their behalf,"[21] consistent with provision II(b) in the Agreement.
- Manufacturer's Responsibilities: The Agreement states, "Manufacturer shall ensure that electronic funds transfers or other payments to dispensing entities are timely, complete, and accurate to the best of their knowledge, including maintaining sufficient funds in the identified bank account(s) to complete the transfer…."[22] BMS takes issue with this provision because the manufacturer cannot ensure that electronic funds transfers or checks are issued in a timely, complete, and accurate manner, because that part of the process will be managed by the PM Contractor and not the manufacturer itself. At most, the manufacturer can ensure that it maintains sufficient funds in the bank account designated for MFP refunds that are authorized in the manufacturer's claim-level payment elements report. We ask CMS to modify the Agreement to reflect this.
- MTF PM Contractor's Responsibilities: The Agreement states that the MTF PM Contractor "shall comply with processes related to unclaimed funds as outlined by CMS in applicable guidance, regulations, and technical instructions."[23] While the IPAY 2027 Final Guidance states that unclaimed funds will be returned to the Primary Manufacturer,[24] and that as part of the MTF agreement for the MTF PM, CMS will provide additional information in the future to inform the handling of these situations, we note that there needs to be clarity on the process for the return of unclaimed funds, including the timing related to the return of unclaimed funds. CMS must clarify this process before a manufacturer can agree to these terms.

***

[18] CMS, MTF Program Agreement, p. 18.
[19] CMS, MTF DM Agreement, pp. 8-9.
[20] CMS, MTF PM Agreement, p. 1.
[21] *Id*. at p. 3.
[22] *Id.*
[23] *Id*. at 4.
[24] CMS, IPAY 2027 Final Guidance, p. 214.

BMS appreciates the opportunity to comment on the MTF Agreements. We would be pleased to discuss these comments in further detail. Should you have any questions or concerns, please contact Caroline Tucker, Director, Executive Branch Strategy, at caroline.tucker@bms.com.

Sincerely,

/s/

Katie Verb
Senior Director, Federal Policy & Reimbursement
U.S. Policy & Government Affairs and U.S. Policy Communications

1240 N Pitt St, 3rd Floor
Alexandria, VA 22314
703.739.1300

ascp
American Society of Consultant Pharmacists

January 31, 2025

Jeff Wu, J.D., MBA
Acting Administrator

Mehmet Oz, M.D.
Administrator-designee
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244–1850

Re: Draft Medicare Transaction Facilitator (MTF) Agreements Feedback

Dear Acting Administrator Wu and Administrator-designee Oz, M.D.,

The American Society of Consultant Pharmacists (ASCP) appreciates the opportunity to provide comments to the draft Medicare Transaction Facilitator (MTF) agreements proposed by CMS.

ASCP is the only international professional society devoted to optimal medication management and improved health outcomes for older adults, the medically complex and individuals with severe disabilities. Our thousands of member pharmacists manage drug therapies in various settings—including sub-acute and long-term care facilities (LTCFs), skilled nursing facilities (SNFs), assisted living communities, psychiatric hospitals, hospice programs, correctional facilities, and home and community-based care.

Below, ASCP's comments are divided into two sections. The first section addresses Draft Medicare Transaction Facilitator Data Module Contractor Agreement; the second section addresses the Draft Medicare Transaction Facility Program Agreement and associated Exhibit A. Comments are crafted to reflect the denoted section as it appears in the Draft Agreements; bolded language reflects ASCP's recommended additions or changes to the proposed contract language.

Draft Medicare Transaction Facilitator Data Module Contractor Agreement

IIc – Given the broad language in the draft contract line, dispensing entities could be forced to comply with any activity requested by the MTF Data Module Contractor, including potentially illegal or counterproductive activities. ASCP recommends that language be amended to state:

"(c) Dispensing Entity shall comply with any **reasonable and legal** instructions, processes and requirements as directed by the MTF Data Module Contractor."

IIIb – The language should ensure that the MTF Data Module Contractor must also provide support as well as technical instruction to the dispensing entity. We recommend the agreement language be amended to read: "(b) MTF Data Module Contractor shall provide technical instructions **and support** to the Dispensing Entity so that the Dispensing Entity may access and use the MTF DM."

IIIe – ASCP is supportive of this language as constructed. We believe the existing datasets managed by the National Council for Prescription Drug Programs (NCPDP) should serve as the source for demographic pharmacy information.

IIIp – ASCP believes that CMS should add an additional sub-element outlining the requirement of the MTF Data Module Contractor to maintain robust cybersecurity protections for the MTF Data Module (MTF DM.) We recommend this or similar language: "(p) MTF Data Module Contractor shall maintain compliance with all applicable CMS data privacy and security standards, including but not limited to HIPAA Privacy and Security Rules, CMS policies and federal data protection standards, in accordance with industry-standard cybersecurity to prevent breaches."

VIIId – As currently drafted, the language always the MTF Data Module Contractor to unilaterally add or amend, subject solely to CMS' approval. Additionally, the current provision allows for these changes to be made without notice. Such a provision is unfair and unreasonable; as currently constructed, the broad nature of this provision would put dispensing entities at a contractual disadvantage to the other contract parties. ASCP recommends amending this element to require a 60-day notice and allow amendments or additions only if required by U.S. law.

Draft Medicare Transaction Facility Program Agreement

IIb – Given the broad language in the draft contract line, dispensing entities could be forced to comply with any activity requested by the MTF Data Module Contractor, including potentially illegal or counterproductive activities. ASCP recommends that language be amended to state: "(b) Dispensing Entity shall comply with any **reasonable and legal** instructions, processes and requirements as directed by the MTF Data Module Contractor."

IIe – ASCP believes that a ten (10) year "Retention Period" is entirely unreasonable. We believe that three (3) years is more than sufficient to ensure program integrity. Within this Agreement and associated Exhibit A, we recommend that all places denoting a ten year record retention period should be amended to three years. As such, IIe should be amended to "(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 **three (3) years** after the dispense of the selected drug(s).

IIf – As currently constructed, this provision does not reasonably limit the number of audits, verifications, inspections and examinations to which a dispensing entity may be subject. We believe that one audit-like activity per calendar year is fair and reasonable, especially for audit-like activities initiated without cause or specific accusation of waste, fraud or abuse. We recommend the language read: "(f) Dispensing Entity shall**, no more than once per calendar year,** 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."

IIIi – ASCP believes this provision needs to be amended to ensure CMS does not transfer to commercial entities, including insurance plans and/or their third-party contractors. We recommend that following language be added after the proposed text from CMS: "**Under no circumstances shall CMS disclose such information to commercial third parties, including plan sponsors, insurance companies, their associated third parties and/or firms who would leverage this data for commercial purposes.**"

IV – ASCP finds it unconscionable that CMS would suggest that dispensing entities be punished by "temporarily or permanently suspending" access to the MTF DM. ASCP reminds CMS that the agency, through independent rulemaking, is attempting to mandate, as a contract condition, the enrollment of the dispensing entity with the MTF DM. We ask CMS: "why does the agency believe a fair and valid punishment is suspension or conditioning of access when the agency has mandate, through rulemaking, participation in the platform?" Furthermore, the language, as currently proposed by CMS, provides not mechanism of redress or an opportunity for a dispensing entity to "have their day in court." ASCP recommends the removal of all of section IV.

V – As outlined above, ASCP does not believe a ten (10) "Retention Period" is unreasonable. We recommend the section be amended to read: "V. 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 **three (3)** years, from the date of the dispense of the selected drug(s) or otherwise as required by CMS."

VIIId – In this section, CMS empowers itself to unilaterally terminate MTF service, despite, as previously discussed, the agency's intention to require dispensing entities to enroll with the MTF DM. Such a unilateral authority without opportunity for redress is unfair and not part of standard contracting practices. CMS should not have the sole and independent authority to terminate the MTF DM and/or dispensing entity's participation. As such, we believe CMS must amend this section to read:

d) Termination.

(1) Termination by CMS. **With 365-day notice,** 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**, following a third-party investigation, hearing and**

mediation process, 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**, following a third-party investigation, hearing and mediation process,** 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~~ **365** 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.~~

Additionally, we find the provisions of VIIId1B to be unnecessary and recommend their wholesale elimination from the Agreement.

With regards to VIIId2A which provides for termination by the dispensing entity, we believe that 90 days is enough time for CMS or its contractor to terminate the dispensing entity's participation. As such, we recommend the language be amended to read: "A. Notice. If…..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~~ **90** calendar days following CMS' acknowledgment of receipt."

In section VIIId2B, CMS appears to create an attestation related to an unfinalized proposed rule. As the proposed rule has not been finalized, this provision must be removed from the Agreement.

IX - In this section, CMS attempts to issue several disclaimers that ASCP finds unreasonable. As reflected in the Agreement, dispensing entities are responsible for the actions of their third-party contractors; we believe CMS should be responsible for its contractor, namely the MTF DM Contractor and MTF PM Contractor. We believe that subclauses a-e should be deleted from the Agreement. Refusal by CMS to remove these provisions should lead contract parties to understand that CMS does not intend to ensure that the MTF DM or MTF PM will function; we are shocked that agency would attempt to include these provisions.

Xa - As discussed above, attempts by CMS to unilaterally amend these Agreements, with or without notice, is frankly unfair and unreasonable. If the Agreement is subject to amendment, all parties should share the equal right to propose and agree to amendments. CMS' actions are participating disconcerting because of the agency's outright effort through a proposed rulemaking to force dispensing entities to enroll with the MTF DM. ASCP believes this provision should be removed from the Agreement.

Conclusion

Thank you in advance for considering ASCP's comments to these proposed Agreements. If you have questions or require additional information, please contact ASCP's senior director of policy and advocacy, James Lewis, at jlewis@ascp.com.

Sincerely,

Chad Worz, PharmD, BCGP, FASCP
Chief Executive
American Society of Consultant Pharmacists (ASCP)

January 31, 2025

Mr. Jeff Wu
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted Electronically: *IRARebateandNegotiation@cms.hhs.gov*

Re: MTF Agreements Feedback

Dear Mr. Wu:

The National Association of Specialty Pharmacy (NASP) writes in response to the request for pharmacy stakeholder feedback on the draft Medicare Drug Negotiation Program Medicare Transaction Facilitator (MTF) contract agreements released for comment in December 2024 as proposed under the Biden Administration. **NASP urges the Trump Administration to pause any finalization of these MTF agreements and to instead work with the pharmacy/dispensing community to immediately revisit and revise the operational plan for pharmacies/dispensing entities and manufacturers to engage with the new Medicare Transaction Facilitator (MTF) under the Inflation Reduction Act's (IRA) Medicare Drug Negotiation Program. The approach proposed under the Biden Administration to implement in 2026 maximum fair prices (MFPs) and reconcile payments to the pharmacies that dispense the negotiated drugs threatens specialty pharmacies and other pharmacy businesses across the United States. NASP does not believe that the process outlined by CMS accurately interprets the IRA statute and remains extremely concerned the approach proposed will work against any effort to implement the Medicare Drug Negotiation Program. While we are grateful for the CMS career staff's efforts to engage with the pharmacy community, it is paramount that the Trump Administration immediately intervene and work with the pharmacy/dispensing community to reconsider and revise this process.**

As CMS works to implement the IRA, it must first acknowledge and understand the immense amount of financial pressure most pharmacies are already under within the Medicare Part D program. It is paramount that pharmacies' financial and administrative challenges are not further compounded and escalated through implementation of the IRA drug pricing program.

NASP shares the Administration's goal of ensuring beneficiaries have affordable access to the medicines they need. We also believe it is most important that implementation of the IRA law ensures patients will have continued access to the specialty pharmacy of their choice and to the pharmacy-related services that are essential to support beneficiary medication adherence and management, improve health outcomes, and reduce beneficiary, health system, and government costs. This access may be negatively impacted with dire consequences for all if it is not financially feasible for specialty pharmacies to dispense the Medicare negotiated drugs.

Specialty pharmacies provide medications that are typically not dispensed in a community pharmacy but rather by a pharmacy that specializes in and is accredited to manage patients that have chronic diseases and serious medical conditions. The drugs dispensed include biologics, injectables, oncology drugs, and other often high-cost drugs used to treat conditions like cancer, rheumatoid arthritis, organ transplantation, HIV/AIDS, multiple sclerosis, and genetic disorders. These pharmacies manage medications that require special protective packaging, cold chain storage and handling, along with ongoing patient education and 24/7 engagement to support medication management. The complexity of these specialty medications may be due to the drug itself, the way it is administered, the management of its side effect profile and toxicity risk, the disease or condition it is used to treat, and the appropriate way to ensure the drug is not compromised when shipped or sent by courier.

NASP represents the entire spectrum of the specialty pharmacy industry, which includes the nation's leading specialty pharmacies and practicing pharmacists, pharmacy benefit managers (PBMs), pharmaceutical and biotechnology specialty drug manufacturers, group purchasing organizations, wholesalers, distributors, integrated delivery systems, health systems, patient assistance organizations and technology and data management companies, among others. NASP's pharmacy members include specialty pharmacies of all types, including independent (non-affiliated with plan sponsors/PBMs), chain, grocery store, hospital and health system, PBM and health plan owned, and home infusion.

Medicare Transaction Facilitator Requirements for Network Pharmacy Agreements

CMS proposes requiring that Part D Sponsors' include in their network contracts a mandate for pharmacies to enroll in the Medicare Drug Price Negotiation Program's newly designed Medicare Transaction Facilitator Data Module (''MTF DM''). **NASP is alarmed CMS would suggest it intervene in the Part D contracting process to propose such a mandate. NASP finds this effort objectionable and asks that CMS stop pushing this process and engage with pharmacies to establish solutions to the concerns NASP and other pharmacy associations have raised and not proceed with any regulatory mandate on plan sponsor-pharmacy Part D contract agreements or the signing of any MTF DM-pharmacy/dispensing entity contract terms or CMS-pharmacy/dispensing entity contract terms.**

NASP appreciates CMS' effort to establish a neutral third-party entity to help pharmacies and other dispensing entities access "maximum fair prices (MFPs)" from drug manufacturers under the new Medicare Drug Negotiation Program. Additionally, we recognize the goal of streamlining data exchange to ensure accurate payment processing between manufacturers and pharmacies. However, the proposed 2026 implementation timeline, coupled with the absence of system modeling or testing, raises serious concerns about the viability of this approach and the potentially devastating consequences for both patients and pharmacies if it proves ineffective. **NASP remains frustrated that CMS has not prioritized the creation of a single, seamless system to manage both data and transaction payments between manufacturers and pharmacies/dispensing entities. Without this integration, the entire process will likely be unworkable and unsustainable for pharmacies/dispensing entities.**

CMS faces multiple immediate risks it must address before it should be working to finalize any contract terms for dispensing entities and manufacturers with the agency or with the MTF DM:

- Pharmacies/dispensing entities do not have the ability to reconfigure their internal claims systems to support varied and not-yet-understood manufacturer processes for effectuating the maximum fair price to pharmacies/dispensing entities for January 1, 2026 and to also plan for any cash flow concerns when manufacturers are not required by CMS to outline their planned payment processes until September 2025. CMS is requiring manufacturers to establish their own MFP effectuation plans for every Medicare negotiated medication they manufacture, and NASP is concerned that there is no clarity on what these plans will look like, how they will work with specialty pharmacies, or what they will require of specialty pharmacies.
- Under CMS' requirements, pharmacies and their technology providers will only have 122 days to establish systems and processes to work with manufacturer effectuation plans, which is grossly insufficient, especially if the manufacturer plans all require different internal procedures to be in place.
- Manufacturers have the option of whether or not to use the MTF PM to pay pharmacies/dispensing entities the difference between their acquisition cost and the Medicare negotiated drugs' maximum fair prices. If manufacturers opt to set up their own system of payment and their own way of establishing pharmacy acquisition costs that differs from CMS' recommended standard default rate (Wholesale Acquisition Cost), manufacturers will only have three months (September-December 2025) to figure out how to ensure their system of payment works with all of the pharmacies they will need to pay.
- Pharmacies/dispensing entities are not typically paid by manufacturers today. As a result, pharmacies will need to establish new payment reconciliation processes and estimate the "maximum fair price" refund amounts they will receive from manufacturers across different drugs.

- Pharmacies/dispensing entities will need to develop financial tracking and reconciliation processes across all claims for the negotiated price drugs they dispense.
- Pharmacies/dispensing entities will not understand when PDE transmission occurs and Part D claims for negotiated drugs are provided to the DDPS and if there are any PDE rejections that prohibit claims from then going forward to the manufacturer, nor the impact this process and timing will have adding onto the 14-day prompt payment standard required of the manufacturers.

Repeatedly, through numerous meetings and comment letters, NASP, other pharmacy associations and individual pharmacies have tried to impress upon CMS their concerns about CMS' proposed data management and payment systems for negotiated drugs, emphasizing the devastating impact CMS' current plan will have on pharmacy cash flow. The MTF data module alone will take at least 21 days. If a claim is rejected, the MTF data module could take longer. CMS is requiring manufacturers to issue payments within 14 days after receipt of the claim, but by the time this payment is issued, the pharmacy may have waited for nearly 40 days or longer (if there is a claim dispute), given the potential length of the entire process. This will not be sustainable, particularly for a specialty pharmacy that only dispenses limited types of drugs to support patients with certain conditions. As the negotiation program grows each year, for some of these specialty pharmacies, the only drugs they dispense may be negotiated drugs.

Recommendations

- **Require manufacturer participation in the CMS-designed MTF payment module (PM) for negotiated drugs instead of forcing pharmacies to potentially manage a different claims process for engagement with every individual manufacturer of a Medicare negotiated drug and pilot test these systems in advance with different types of pharmacies/dispensing entities (including independent specialty pharmacies) to give manufacturers and pharmacies/dispensing entities assurance that the tested system is viable for broad operation.**
- **Require Plan Sponsors or their PBMs to provide financial or administrative support to pharmacies for administration of the claims process for negotiated drugs and to address the burden and complexity of reconciled claims payments on negotiated drugs.**
- **Leverage existing NCPDP data to automate pharmacy enrollment in the MTF DM and MTF PM as much as possible to lessen burden on pharmacies/dispensing entities and as an alternative to contractual mandates on pharmacies.**

Rather than mandate that specialty and other pharmacies/dispensing entities participate in a system that is destined to fail, we implore the Administration to hear pharmacies' concerns and design a workable payment system for pharmacies/dispensing entities under the Medicare Drug Negotiation Program.

If these efforts are not achievable, another recommended alternative would be for CMS to rely on a model of claims administration and payment that has already existed. The Coverage Gap Discount Process (CGDP) under Medicare Part D could be mirrored to support manufacturer effectuation of the MFP as required under the IRA law. We do not see any legal reason why CMS could not require manufacturers to pre-fund MFP effectuation payments, as the IRA provides no such prohibition. Indeed, NASP understands that Congress sought to model the MFP effectuation statutory requirement after the statute that established the CGDP[1] in an effort to follow past precedent for a discount program under Part D.

CMS effectuates CGDP discounts through contracted third-party entities with the Part D plans serving as payment facilitators. In the CGDP, manufacturers are required to provide CGDP-eligible individuals discounted prices for drugs at the point of sale. Part D plans include the manufacturer-required discount amount as part of the Plan's payment obligation. The pharmacy knows its full compensation amount for related claims in real time and within the claims workflow, and payments are made within a 14-day prompt payment standard. Manufacturers repay Part D plans through the CGDP contractor. CMS, Part D plans, and manufacturers reconcile financial transactions independently without disrupting patient access or pharmacy economics. Such a financing model would allow manufacturers to seamlessly pay MFP refund amounts to pharmacies at the point of sale.

If the CGDP was to serve as the model for MFP effectuation, the MTF DM could potentially serve as the data facilitator to manage access to 340B data and to also ensure trust and protect the competitive interests of pharmacies and manufacturers in relation to acquisition-related data. The CGDP includes a pre-funded account approach to managing reconciled payments to pharmacies to meet statutory payment obligations in a timely manner. Under a CGDP-like approach, CMS should have direct oversight of the MFP effectuation process as well as govern the necessary data and financial flows. CMS should also consider alternative pre-funding pathways that ultimately could reduce a manufacturer's risk and a pharmacy's administrative and financial risk of no MFP retroactive payment or delayed retroactive payments.

Legal Concerns with CMS-Proposed Contract Agreements

NASP is advising that the Administration put a hold on moving forward with its proposed CMS-dispensing entity agreement, CMS-manufacturer agreement, MTF DM-dispensing entity agreement, and MTF-manufacturer agreement until improvements are made to change processes to effectuate the MFP to pharmacies/dispensing entities and address pressing cash flow concerns. It is essential that the Trump Administration engage specialty pharmacy and the broader pharmacy/dispensing entity communities to address these concerns first before proceeding with contract agreements between entities. That said, as plans continue to move

[1] 42 U.S. Code § 1395w–114a.

forward, NASP wants to share some specific legal questions and issues of significant concern regarding the terms of the CMS contracts that were presented for comment, affecting pharmacies/dispensing entities:

CMS and Dispensing Entity and MTF DM and Dispensing Entity Agreements:

II. DISPENSING ENTITY'S RESPONSIBILITIES

(c) Dispensing Entity ***shall*** enroll in the MTF DM… [emphasis added]

NASP Comment: Through this agreement, CMS would require pharmacies to join the MTF DM as a condition for participation in Medicare Part D, which there is no statutory requirement under the IRA for pharmacies to do. Pharmacies do not support a mandate to be under this contract agreement or a mandate to participate in the MTM DM.

II. DISPENSING ENTITY'S RESPONSIBILITIES

(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.

NASP Comment: This audit, inspection and examination requirement on pharmacies is grossly overreaching. It is broad and extensive, requiring that a pharmacy provide any of its records at any time essentially to any entity, including potential competitors in the channel if they are considered as meeting the terms of this section of the agreement.

II. DISPENSING ENTITY'S RESPONSIBILITIES

(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.

NASP Comment: This requirement would allow CMS to establish any new "compliance activities" without promulgating a formal rule for notice and comment. A pharmacy would have no notion of what it would be agreeing to under this requirement.

(1) 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.

NASP Comment: Pharmacies are not required to dispense MFP drugs; therefore, a pharmacy cannot be mandated to enroll with the MTF DM nor would a pharmacy be violating its agreement to participate in Medicare Part D by terminating this MTF DM agreement. The clauses above appear to mandate that the dispenser must furnish all MFP drugs in order to participate in the Medicare Part D program, which is by no means a statutory requirement.

IX. DISCLAIMERS

NASP COMMENT: CMS disclaims too broad of liability with the disclaimers. CMS mandates participation in the MTF DM while simultaneously disclaiming all liability for the MTF DM.

XI. SIGNATURES

NASP COMMENT: The requirements in this section, much like the requirements throughout the agreement incorporate current and future sub-regulatory requirements outside of this document with terms that remain undefined. A pharmacy/dispensing entity would never

truly understand what it is agreeing to in this contract agreement, as CMS could alter the terms at any time. There are associated penalties on a pharmacy/dispensing entity for non-compliance with any term CMS determines to put in place at any time it chooses to do so. Requiring dispensing entities sign an agreement that allows the other party to unilaterally modify the agreement would seem to create an invalid contract promise and no contract formation.

Conclusion

The Trump Administration must stop and revisit efforts to comply with the IRA and effectuate the MFP for pharmacies/dispensing entities under the Medicare Drug Negotiation Program. Pharmacies cannot be placed at any financial risk in order for the law's requirements to be carried out. NASP looks forward to working with the Trump Administration to address these concerns. For further information, please contact me at Sheila.Arquette@naspnet.org.

Sincerely,

Sheila Arquette, RPh.

President and CEO

January 31, 2025

VIA Email Submission

Christina Ritter
Director
Centers for Medicare & Medicaid Services
Medicare Drug Rebate and Negotiations Group (MDRNG)
IRARebateandNegotiation@cms.hhs.gov

Re: Comments Regarding Draft Medicare Transaction Facilitator Agreements

Dear Director Ritter:

Novo Nordisk Inc. ("Novo Nordisk") appreciates the opportunity to provide comments in response to the draft Medicare Transaction Facilitator ("MTF") Agreements issued by the Centers for Medicare & Medicaid Services ("CMS" or the "agency"), including the draft Medicare Transaction Facilitator Program Agreement ("MTF Program Agreement"), Medicare Transaction Facilitator Data Module Contractor Agreement ("MTF DM Agreement"), and Medicare Transaction Facilitator Payment Module Contractor Agreement ("MTF PM Agreement") (collectively, "MTF Draft Agreements").

Novo Nordisk is a global health care company committed to improving the lives of those living with serious chronic conditions, including diabetes, rare bleeding disorders, growth disorders, and obesity. The Novo Nordisk Foundation, our majority stakeholder, is among the top five largest charitable foundations in the world. Accordingly, our company's mission and actions reflect the Foundation's vision to contribute significantly to research and development that improves the lives of people and sustainability of society.

Novo Nordisk is a member of the Pharmaceutical Research and Manufacturers of America ("PhRMA"). We are supportive of PhRMA's comments and incorporate them herein by reference, except where they might otherwise diverge from these comments, as noted below. In addition, we underscore our concerns with the following:

- These agreements should not hold a Primary Manufacturer responsible for the effectuation of maximum fair price ("MFP") by an independent Secondary Manufacturer, nor should CMS be permitted to pursue penalties against a manufacturer that demonstrates good faith attempts to fulfill its 340B Drug Pricing Program and MFP obligations.
- CMS should strike several disclaimers from these agreements because they violate basic contracting principles and improperly seek to insulate CMS and its third-party contractors from liability, while imposing severe penalties on manufacturers that fail to comply with these agreements.
- Manufacturers should not be forced to turn over information that they treat and maintain as proprietary and confidential, and neither CMS nor its third-party contractors should be second-guessing those confidentiality determinations.

- Several provisions within the agreements are vague or seemingly inconsistent; they should be withdrawn or revised.
- CMS should issue these agreements through appropriate notice-and-comment rulemaking.

I. CMS's draft agreements should not hold a Primary Manufacturer responsible for the effectuation of MFP by an independent Secondary Manufacturer, nor should CMS pursue penalties against a manufacturer that demonstrates good faith attempts to fulfill its 340B Drug Pricing Program and MFP obligations.

We are concerned with the agency's flawed attempts to distinguish between "Primary" and "Secondary" Manufacturers. Through these draft agreements, CMS seeks to hold responsible the entity that holds an NDA/BLA for a selected drug (the "Primary Manufacturer") for effectuation of MFP by *other* manufacturers, including re-packers and re-labelers of the selected drug ("Secondary Manufacturers"). Primary Manufacturers would be required to "ensure" that "any Secondary Manufacturer(s) of the selected drug(s) for which MFP will be effectuated pursuant to this Agreement complies with the terms of this Agreement," including provisions related to confidentiality and data use.[1] With regard to the Primary Manufacturer's use of the MTF Data Module ("MTF DM"), CMS also would require that the Primary Manufacturer "transmit complete and accurate claim-level payment elements to the MTF DM within the 14-day prompt MFP payment window" and "shall apply without limitation to instances in which … the selected drug(s) is initially sold by a Secondary Manufacturer."[2]

As we have explained in previous comment letters, this requirement presents significant practical concerns, and it also violates the statute and constitutional requirements.[3] Nothing in the Inflation Reduction Act ("IRA") distinguishes between "Primary Manufacturers" and "Secondary Manufacturers," or authorizes CMS to hold manufacturers responsible for the conduct of third parties. To the contrary, section 1191(c)(1) of the IRA states: "[t]he term 'manufacturer' has the meaning given that term in section 1847A(c)(6)(A) [of the Social Security Act]." That definition cross-references section 1927(k)(5) of the Social Security Act, which also does not distinguish between "primary" and "secondary" manufacturers.[4] There is no indication that Congress intended to impose obligations on certain manufacturers—with a threat of massive penalties—to be responsible for the compliance of other, independent entities, particularly given the enormous public policy and practical concerns that result from CMS's approach. CMS has not provided any mechanism for Primary Manufacturers to control the prices at which Secondary Manufacturers sell their goods. Compliance with such requirements cannot be ensured, placing manufacturers at risk of significant fines and penalties. Moreover, CMS is not permitted to impose these extra-statutory obligations without first complying with proper notice-and-comment rulemaking procedures, which are required whenever an agency attempts to impose binding substantive requirements on regulated parties.

---

[1] Draft MTF Program Agreement, section II(e).
[2] Draft MTF Program Agreement, section II(i)(2).
[3] Novo Nordisk, Inc. (Plainsboro, NJ). Letter to: Meena Seshamani (Center for Medicare, Centers for Medicare & Medicaid Services, Baltimore, MD). 2023 Apr 14.
[4] *See* 42 U.S.C. § 1396r-8(k)(5).

We also remain concerned about CMS's and the Health Resources and Services Administration's ("HRSA's") lack of action to identify MFP claims subject to an agreement under Section 340B of the Public Health Services Act. Manufacturers do not have adequate insight into which prescriptions are designated as 340B-eligible by covered entities and why. The 340B program deficiencies will continue to hinder proper administration of the MFP. Novo Nordisk continues to believe that identifying 340B-eligible units through a clearinghouse and through the use of mandatory 340B and non-340B claim modifiers with accountability for 340B covered entities would be the best approach to identify claims involving 340B-eligible units and efficiently prevent duplicate discounts. Given CMS's current position that it will not "assume responsibility for deduplicating discounts between the 340B ceiling price and MFP" and will not require covered entities to include 340B modifiers on claims, it is critical that CMS and HRSA not interfere with or impede manufacturers exercising their rights to develop and utilize their own processes to comply with this part of the IRA, including, but not limited to, the use of a rebate mechanism to effectuate 340B pricing.[5] In addition, these agreements must be revised to, at a minimum, clarify that a 340B covered entity will forfeit its right to the MFP if it does not participate in a manufacturer's reasonable process to address the intersection of MFP and 340B. CMS should guarantee that manufacturers will be held harmless in such cases. CMS also should amend these draft agreements to expressly allow manufacturers to link records for purposes of claims data to meet manufacturer obligations under the IRA, the 340B program, and other price reporting programs.

Manufacturers should not be subject to enforcement action from CMS or HRSA under the agencies' respective IRA and section 340B authorities if they can demonstrate that they have engaged in reasonable, good faith efforts to fulfill their obligations under section 1193 of the Social Security Act and section 340B(a)(1) of the Public Health Service Act. Indeed, neither CMS nor HRSA should seek to bring any enforcement action against a manufacturer that utilizes a reasonable mechanism to prevent erroneous duplicate MFP and 340B discounts on the same unit and effectuates availability of the appropriate price (whether prospectively or retrospectively). If a manufacturer makes the MFP available for a claim, then it is subsequently determined (outside the 14-day prompt MFP payment window) that the claim is 340B-eligible and the 340B price is lower than the MFP, then the manufacturer should be held harmless if it has utilized reasonable, good faith efforts to provide the difference between the MFP and 340B price.

---

[5] "CMS is not mandating that dispensing entities add a 340B claim indicator to claims at this time. The 340B claim indicator data element passes through information on the 340B status of a claim that the dispensing entity voluntarily provides. Neither CMS nor the MTF DM will verify that a claim was or was not billed as a 340B-eligible drug." *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*, at 54.

II. Several provisions violate basic contract requirements by imposing unknown future terms and obligations on manufacturers and by seeking to insulate CMS and its third-party contractors from any liability, while also imposing severe penalties on manufacturers that fail to comply.

CMS's MTF Draft Agreements include several provisions that are unlawful and violate basic contracting terms. As drafted, these agreements are contracts of adhesion because they permit only one side—CMS or its third-party government contractors, the MTF Data Module ("DM") Contractor and the MTF Payment Module ("PM") Contractor—to modify the terms of the agreements.[6] In contrast, manufacturers must certify that they have made no "alterations, amendments or other changes to this MTF Program Agreement."[7] Similarly, CMS alone has the right to terminate the draft MTF Program Agreement.[8] Under basic contracting principles, both parties should be empowered to withdraw from an agreement on equal terms. CMS should therefore revise its draft agreements to provide that (i) neither party has the authority to unilaterally amend these agreements; and (ii) both parties are authorized to terminate any of these agreements.

These agreements also unlawfully seek to bind manufacturers to unknown future terms and obligations. For example, the draft MTF Program Agreement provides that, "When utilizing the MTF DM, Manufacturer shall comply with all requirements and conditions for MFP effectuation and CMS monitoring thereof, including, without limitation, all applicable CMS guidance, regulations, and technical instructions."[9] Here, CMS attempts to bind manufacturers to "guidance, regulations, and technical instructions" that it has not yet finalized or published.

These provisions are an unlawful attempt to expand the agency's powers beyond those granted by Congress and without complying with required procedures. No party to a properly negotiated contract could reasonably agree to allow the other side to change the terms of a contract unilaterally and at will. As has been well documented, however, the processes established by CMS under the IRA do not allow for an actual negotiation, and CMS is exercising coercive regulatory powers in a way that leaves manufacturers no choice but to sign these agreements and participate in CMS's price-control program. These provisions are thus especially objectionable because they raise the potential that the agency will change program requirements and then claim that manufacturers have consented to the future terms—no matter how objectionable—by being forced to sign this agreement.

Under settled separation-of-powers principles, CMS may not use government agreements to expand its powers to impose obligations on manufacturers without complying with constitutionally adequate procedures to ensure that CMS is acting within the scope of its delegated authority. That constitutional violation is exacerbated here, as CMS seeks to *share* this impermissible and overbroad power with its third-party contractors, the MTF DM Contractor and the MTF PM Contractor. Manufacturers are required to agree to comply with unknown

---

[6] Draft MTF Program Agreement, section X(a); Draft MTF DM Agreement, section VIII(e); Draft MTF PM Agreement, section VIII(e).
[7] Draft MTF Program Agreement, section XI(d).
[8] Draft MTF Program Agreement, section VIII(d).
[9] Draft MTF Program Agreement, section II(b).

"instructions, processes, and requirements" set forth by these contractors.[10] That is an unconstitutional and improper delegation of governmental authority. Further, manufacturers are permitted no avenue to contest these contractors' requirements, no matter how egregious.

CMS proposes that *third-party, commercial contractors* would be authorized to identify which pieces of any information disclosed by the manufacturer are "proprietary."[11] However, only the Department of Health and Human Services ("HHS") is authorized to make that determination under the IRA.[12] Accordingly, CMS's proposed agreements are unlawful because they improperly seek to assign responsibility of HHS to a third-party contractor as it relates to highly sensitive data from manufacturers. Third-party contractors are not likely to be familiar with such data or be otherwise equipped to appropriately identify such data. This is yet another example of agency overreach where CMS has exceeded its statutory authority. Given the sensitive nature of the information at issue, CMS must ensure that manufacturers—not CMS's third-party commercial contractors—are authorized to identify proprietary information and coordinate any negotiations with CMS on the potential release of their own proprietary information prior to disclosure.

CMS further showcases the unbalanced nature of these draft agreements by attempting to shield itself from all responsibility and accountability, while subjecting manufacturers to liability and penalties through heavy-handed disclaimers. For example, 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."[13] CMS also boldly proposes that "[u]nder no circumstances and under no legal theory, whether tort (including negligence), contract, or otherwise" shall CMS be liable to the manufacturer or any other person.[14] While the agency attempts to absolve itself from all responsibility, even in cases of agency negligence, it simultaneously places that onus on manufacturers.

Most egregious, CMS would require that manufacturers "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, the Manufacturer, or dispensing entities."[15] The agency cannot lawfully require manufacturers to indemnify the agency's third-party contractors while also disclaiming any liability for the agency's or contractors' own actions, including negligence.

CMS cannot purport to exempt itself from basic administrative law procedures by asserting its theory that this is, in fact, a "negotiation." CMS's draft provisions clearly make it a one-sided negotiation process—enforced by coercive regulatory powers—that negate any rights the manufacturer might have in this agreement.

---

[10] Draft MTF Program Agreement, section II(d); Draft MTF DM Agreement, section II(i); Draft MTF PM Agreement, section II(g).
[11] Draft MTF DM Agreement, section V(b); Draft MTF PM Agreement, section V(b).
[12] IRA, 42 U.S.C. § 1320f–2(c).
[13] Draft MTF Program Agreement, section IX(a).
[14] Draft MTF Program Agreement, section IX(e).
[15] Draft MTF Program Agreement, section IX(c).

CMS should strike and remove all of these improper provisions. Moreover, given CMS's decision to require manufacturers to rely on third-party contractors to effectuate MFP, CMS should also incorporate a provision that would hold harmless manufacturers that make good faith efforts to comply with the MTF to effectuate the MFP while acting in reliance on the information made available to the manufacturer by the MTF DM and PM.

III. Several provisions within these agreements are vague, inconsistent, or overly broad and should be revised or struck from these agreements.

There are several provisions within the draft agreements that are vague, inconsistent, or otherwise overly broad. These provisions should be withdrawn or revised.

First, CMS seeks to establish a credit/debit ledger system that, as defined, would mean "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."[16] These provisions are ambiguous and lack clarity. It is of critical importance that manufacturers understand how this system will be implemented, given the volume of claims that are expected to be processed through this system. The draft agreements also use inconsistent language that appears to suggest in some places that manufacturers must utilize the MTF PM when, in fact, it is voluntary and manufacturers may use the system for some, but not all of their selected drugs. We request that CMS use consistent language in these agreements to make clear that the agency intends to afford manufacturers flexibility to use the MTF PM for some selected drugs and not others. To ensure that manufacturers can appropriately track claims for reimbursement, the credit/debit ledger system should track credits at the claim level in addition to the NPI-level. CMS also should provide manufacturers with access to the credit/debit ledger system, even if the manufacturer opts to provide access to MFP outside the MTF PM, which would enable manufacturers to maintain a central resource to track MFP payments.

Consistent with our previous comments, we continue to believe that CMS must establish a robust dispute and complaint process, with clear procedures and timelines.[17] Manufacturers should be allowed to dispute claims, provided there is a reasonable basis for doing so, during the 14-day payment window. This would help prevent payment of erroneous claims, which then would be subject to an adjustment and credit or clawback process. Manufacturers also should be able to utilize the credit/debit ledger system as part of the upfront dispute process that should be incorporated into these draft agreements.

The draft agreements also seek to authorize the "MTF PM to send to dispensing entities a payment equal to the total refunds to be paid as indicated in the Manufacturer's reported claim-level payment elements, regardless of any credits which may be applied under the Ledger System."[18] They also purport to require that manufacturers provide the MTF DM Contractor with

---

[16] *E.g.,* Draft MTF Program Agreement, section I(d).

[17] See Novo Nordisk Comments on Medicare Drug Price Negotiation Program: Draft 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 (MFP) in 2026 and 2027, July 2, 2024.

[18] *E.g.,* Draft MTF Program Agreement, section II(j)(4).

banking information and keep that information up to date.[19] It, however, remains unclear whether the MTF PM agreement would authorize the MTF DM Contractor to effectuate a direct debit from the manufacturer's bank account or whether manufacturers will be required to pay each claim that is processed through the MTF PM. We recommend that CMS clarify that the MTF PM can utilize a direct debit from a manufacturer's bank account to effectuate MFP refund payments, similar to how payments are effectuated under the Medicare Coverage Gap Discount Program.

Second, the draft agreements are unclear as to how adjustments that occur within the 14-day prompt MTF payment window should be addressed, especially in cases where manufacturers may have already processed the claim and adjustments within that window are no longer feasible.[20] CMS should enable manufacturers to pay the original claim if an adjustment occurs within the 14-day payment window, as the manufacturer may have already processed the original claim such that it can no longer be reversed or revised. CMS should therefore afford manufacturers the ability to continue with the claim as initially submitted and address the adjustment through a reversal, where the manufacturer would process the adjustment by reversing the entirety of the original payment, and then processing a new claim for the adjusted amount.

Third, these draft agreements should be revised to provide a safe harbor for manufacturers that act in reliance on data provided by the MTF DM and PM. Manufacturers should not be held liable when acting in reliance on the data provided by the MTF DM and PM to reimburse claims, including in situations where timely distribution of reimbursement may be impacted as the result of system outages or errors.

Fourth, inconsistencies in the document retention and destruction provisions in the draft MTF Program Agreement render such provisions functionally inoperable. CMS would require manufacturers maintain records for "at least ten years" while also requiring in a separate provision that manufacturers must only maintain records for "up to ten (10) years" and that anything beyond that would need to be approved in advance by CMS.[21] These provisions are in contradiction and would frustrate compliance with both provisions. Manufacturers also may be subject to other federal or state requirements to retain documents beyond CMS's prescribed period. CMS should therefore withdraw this limitation on maintaining documents for up to ten years given that it is in

---

[19] *See, e.g.*, Draft MTF PM Agreement, section II(d).

[20] *See* Draft MTF Program Agreement, section II(i)(3).

[21] Section II(f) of the draft MTF Program Agreement requires manufacturers to retain records that the manufacturer may create in connection with the MTF, and any audits and investigations for at least ten years from the date of the sale of the selected drug(s) to which the record relates. Further, section V of the draft MTF Program Agreement provides that HHS, CMS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any information described in section II(f), 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 sale of the selected drug(s) to which the record relates.

Section (b)(2)(vi) of the draft MTF Program Agreement's Exhibit A provides, "The parties to this Agreement mutually agree that CMS Data shall be retained by the Manufacturer for a period of up to ten (10) years from the date of sale of the selected drug(s) to which the record relates. … The Manufacturer may retain the data beyond the ten (10) year timeframe if CMS Data is 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 Manufacturer agrees to promptly destroy CMS Data once the pending matter is resolved."

conflict with the draft agreements and potentially other federal and state requirements to retain certain documentation.

Fifth, CMS should withdraw the requirement that a manufacturer "must" implement administrative, technical, and physical safeguards that comply with the HIPAA Security Rule and maintain compliance with the HIPAA Privacy and Security Rules.[22] Except in exceptional circumstances, pharmaceutical manufacturers are not HIPAA covered entities. They also are not structured for compliance with the HIPAA Security Rule. CMS erroneously asserts that the HIPAA regulations apply here, and that CMS can impose HIPAA obligations under its IRA authority. CMS should strike any reference to HIPAA in this agreement.

Sixth, the Data Use Provisions of the draft MTF Program Agreement would require a Manufacturer that "inadvertently receives any direct beneficiary identifiers, or discovers any other Breach or Incident involving CMS Data, loss of CMS Data or disclosure of CMS Data to any unauthorized persons" to report that occurrence to CMS within one hour of discovery of the occurrence.[23] This timeframe is unusually short as compared to other data breach standards and establishes an unreasonable expectation that a manufacturer would assess the veracity of such occurrence and report it to CMS in such a short timeframe. As this is a government program, CMS should provide for a review timeframe that is otherwise consistent with federal law—specifically, the FTC's Health Breach Notification Rule—and provide at least 60 calendar days to address data breaches.[24]

IV. CMS should issue these draft agreements through appropriate notice-and-comment rulemaking.

Novo Nordisk takes issue with the origin of these draft agreements, particularly as they have not been promulgated through proper notice-and-comment rulemaking. As drafted, these agreements are contracts of adhesion and seek to impose binding substantive requirements and obligations on manufacturers as regulated entities. When an agency imposes substantive obligations that go beyond a statute's express requirements, the agency must comply with rulemaking procedures with an opportunity for public notice and comment followed by judicial review.[25] These procedural requirements—as reflected in both the Administrative Procedure Act[26] and the Social Security Act[27]—are essential to securing "the values of government transparency and public participation"[28] by ensuring that agencies provide reasoned explanations for their decisions after evaluating and responding to comments.[29] They also are an essential part of a compromise that has allowed executive agencies to wield legislative rulemaking powers while accounting for the significant separation-of-powers concerns that arise from delegating such authority to executive agencies.

---

[22] *See* Draft MTF Program Agreement, Exhibit A, sections (b)(2)(vii), (viii)(a).
[23] Draft MTF Program Agreement, Exhibit A, section (b)(2)(xiii).
[24] *See* 16 C.F.R. § 318.4.
[25] *See Hoctor v. U.S. Dep't of Agric.*, 82 F.3d 165, 170-71 (7th Cir. 1996); *see also Catholic Health Initiatives v. Sebelius*, 617 F.3d 490, 495 (D.C. Cir. 2010).
[26] *See* 5 U.S.C. § 553 *et seq*.
[27] *See* 42 U.S.C. § 1395hh(a)(2).
[28] *Iowa League of Cities v. EPA*, 711 F.3d 844, 873 (8th Cir. 2013).
[29] *See Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1816 (2019).

These draft agreements were not published in the Federal Register and are not subject to the necessary notice-and-comment rulemaking procedures. Rather, they were distributed via email and posted online. They are unaccompanied by agency explanation or rationale, as is required for proper rulemaking. We acknowledge that Congress has directed CMS to implement the statute's requirements through guidance.[30] But that does not mean that CMS may read the word "guidance" to be a blank check that allows it to avoid all proper rulemaking procedures when it seeks to impose binding obligations on regulated parties. Nor is there good cause to waive essential notice-and-comment rulemaking requirements. The exceptions to rulemaking procedures are "narrowly construed and reluctantly countenanced."[31] As a result, good cause for dispensing with rulemaking requirements never exists absent a showing of an emergency with the risk of "real harm."[32] Accordingly, we urge CMS to use notice-and-comment rulemaking when imposing requirements on manufacturers intended to have the force and effect of law.

* * *

Thank you for considering Novo Nordisk's comments. We would be pleased to discuss this feedback with you in further detail. If you have questions, please contact Farruq Jafery, Vice President of Pricing, Contract Operations and Reimbursement.

Sincerely,

Farruq Jafery
VP, Pricing, Contract Ops & Reimbursement
Novo Nordisk, Inc.

[30] *See* IRA § 1198(c).
[31] *Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 93 (D.C. Cir. 2012).
[32] *NRDC v. Evans*, 316 F.3d 904, 911 (9th Cir. 2003).

Submitted electronically via IRARebateandNegotiation@cms.hhs.gov **.**

January 31, 2025

Jeff Wu
Acting Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Transaction Facilitator (MTF) Agreements

Dear Acting Secretary Fink and Acting Administrator Wu:

Thank you for the opportunity to provide feedback on the Medicare Transaction Facilitator agreements for manufacturers, CMS, MTF Data Module and Payment Module contractors, and Dispensing entities as part of the Inflation Reduction Act (IRA) Rebate and Negotiation process, released on December 17, 2024.

CVS Health serves millions of people through our local presence, digital channels, and our nearly 300,000 dedicated colleagues – including more than 40,000 physicians, pharmacists, nurses, and nurse practitioners. CVS Health offers Medicare Advantage Prescription Drug (MAPD) plans in 44 states and D.C. and Aetna also offers robust standalone prescription drug plans (PDPs) to individuals in all 50 states and D.C. Our unique healthcare model gives us an unparalleled insight into how health systems may be improved to help consumers navigate the healthcare system–as well as their personal healthcare–by eliminating disparities, improving access, lowering costs, and being a trusted partner for every meaningful moment of health.

CVS Health appreciates the ongoing communication and opportunity provide feedback on the agreements for CMS to consider and finalize within the agreements.

CVS Health is invested as a collaborative stakeholder as new processes are implemented to support the objectives of the Inflation Reduction Act, Section 11001: Providing For Lower Prices For Certain High-Priced Single Source Drugs.

We appreciate CMS's efforts to provide secure and accurate transmission of data essential to support MFP payment effectuation. The following comments outline queries and concerns raised during the comment review process related to MTF Agreements. CVS Health thanks CMS for their continued engagement with stakeholders impacted by the implementation of the provisions of the Inflation Reduction Act and looks forward to continuing our collaboration in ensuring a smooth initiation of the program in January of 2026.

Draft Medicare Transaction Facilitator Data Module Contractor Agreement; Dispensing Entities

Re: Section II. Dispensing Entity's Responsibilities:

Subsection II(e) states:

Dispensing Entity shall ensure its agents, including, as applicable, any Third-Party Support Entity contracted comply with the terms of this Agreement, including Exhibit A of this Agreement, and applicable guidance, regulations, and technical instructions. The Dispensing Entity shall retain sole responsibility for compliance with the terms of this Agreement and applicable guidance, regulations, and technical instructions notwithstanding any actions that any Third-Party Support Entity may perform on the Dispensing Entity's behalf.

CVS Health is concerned about the absolute and broad nature of expressing that the Dispensing Entity "shall ensure" that Third-Party Support Entities contracted comply with the terms of this Agreement. In lieu of the current language stating, "shall ensure," CVS Health recommends replacing this subsection with the following:

"To the extent a Dispensing Entity utilizes any agent, including a Third-Party Support Entity, to assist it in performing any of the Dispensing Entity's obligations herein, the Dispensing Entity shall remain responsible for compliance with such obligations."

CVS Health would also like to understand why parallel language is not incorporated within the Manufacturer agreements. It would be the expectation that Manufacturers are also responsible for their selected Third-Party Support Entity's compliance with Manufacturer obligations.

Re: Section III. MTF Data Module Contractor Responsibilities and IV. Mutual Obligations

Subsection IV(a) states:

The MTF Data Module Contractor and the Dispensing Entity further agree that the security access code(s) that the MTF Data Module Contractor issues to the Dispensing Entity shall be legally sufficient to verify the identity of the Dispensing Entity and to authenticate actions taken by the Dispensing Entity.

Subsection IV(b) states:
The MTF Data Module Contractor shall validate with the Dispensing Entity and the MTF PM the Dispensing Entity's banking information, which shall be subject to a precertification period in which all bank accounts are verified by the qualifying financial institution before any electronic transfers of funds are made

These paragraphs exempt the MTF DM Contractor from responsibility for properly authenticating a Dispensing Entity and the Dispensing Entity's corresponding banking information. CVS Health believes the responsibility to validate the accuracy of the Dispensing Entity's information should be included in Section III, stating the MTF Data Module Contractor will be responsible for properly authenticating a Dispensing Entity and its corresponding banking information.

Subsection IV(c) states:

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.

The MTF DM Contractor should hold the primary responsibility to maintain and protect the data in accordance with all HIPAA regulations, including privacy. The Contractor is not a HIPAA business associate of CMS as CMS is not acting as a health plan. The Contractor should agree to privacy and security protections aligned with HIPAA as the Dispensing Entity is already subject to HIPAA.

Re: Section V. Confidentiality and Data Use

CVS Health requests language to be added providing that the Contractor is directly obligated to limit the use and disclosure of Dispensing Entity data strictly to such uses and disclosures necessary to facilitate payment to the Dispensing Entity.

Re: Section VIII. General Provisions

Subsection (a), related to Force Majeure, is broad and contemplates very different requirements for the Dispensing Entity as compared to the Contractor. Given the critical role the Contractor will play, CVS Health believes the Contractor should be responsible for disaster recovery and backup systems. The Contractor should be obligated to maintain disaster recovery policies and procedures as well as data controls aligned with HIPAA. In addition, this section should specifically mandate notification by the Contractor not later than 24-hours after the discovery of an event.

Subsection (d) details the MTF Data Module Contractor's right to include additional provisions, requirements, or terms as deemed necessary for the administration of the program. CVS Health understand there may be unforeseen matters requiring changes; however, Dispensing Entities should have the right and opportunity to reject or amend any changes to the agreement. We recommend adding a provision requiring any amendments to the agreed upon terms comply with applicable law and by mutually agreed to by the Contractor and the Dispensing Entity.

Subsection (i)(1) related to Construction identifies the incorporation of a corporate parent under the Dispensing Entity. CVS Health believes that the Dispensing Entity should be specific to the entity enrolled and entitled to reimbursement.

Subsection (i)(2) appears to be redundant with subsection (II)(e), and our comments mirror the concerns stated above with respect to Dispensing Entity and Manufacturer obligations when utilizing a Third-Party Support Entity.

Subsection (j) provides that the Dispensing Entity's obligations under the Agreement are automatically assumed by any entity that acquires the Dispensing Entity. CVS Health recommends amending this section to incorporate language recognizing that an acquiring entity that has an existing agreement for its Dispensing Entities may incorporate the acquired Dispensing Entity into its existing Agreement.

Re: Section XI. Signatures for the Dispensing Entity

Subsection C. refers to execution of the "MTF Program Agreement." CVS Health requests clarification as this section should be covering the "MTF DM Data Use Agreement."

Subsection D. requires the Dispensing Entity to "ensure" that any Third-Party Support Entity engaged by it complies with all applicable terms, conditions and requirements of the Agreement. CVS Health has the same concerns with this language as stated above with respect to similar language in subsections (II)(e) and VIII(i)(2) .. Accordingly, we suggest the language of this subsection be amended to read as follows:

"The undersigned individual further attests that to the extent a Dispensing Entity utilizes any agent, including a Third-Party Support Entity, to assist it in performing any of the Dispensing Entity's obligations herein, the Dispensing Entity shall remain responsible for compliance with such obligations."

Subsection E. contains references to an attestation by an individual stating that he or she has "obtained access" to the MTF DM as an Authorized Signatory Official of the Dispensing Entity. As the agreement hasn't been executed, CVS Health believes the attestation should indicate that the undersigning individual "will obtain access" when executing the agreement.

Subsection G. requires the Dispensing Entity to certify 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). It is not clear why this issue related to Part D compliance is included in the Agreement, since the Dispensing Entity is not a first-tier, related, or downstream entity (FDR) of Contractor. This issue and all other aspects of compliance with Part D requirements by network providers are addressed in the agreement between the Part D

sponsor and the Dispensing Entity, and required to be monitored and enforced by the Part D sponsor. This is not the role or purpose of the Contractor Lastly, the MFP is specific to drug costs, and professional services do not factor into this matter. We recommend that this provision be deleted from the Agreement.

Draft Medicare Transaction Facilitator Program Agreement; Dispensing Entities

Re: Section I. Definitions

Subsection I(b) defines "claim-level data elements" that CMS transmits to manufacturers via the MTF DM for each claim for selected drugs "dispensed" to an MFP-eligible individual. Since prescription claim data is being leveraged to obtain this information, the definition should be revised to indicate the information will be passed along for each claim for selected drugs "adjudicated" for an MFP-eligible individual.

Subsection I(i) defines the MTF DM Agreement as the agreement between the Dispensing Entity and the MTF Data Module Contractor. There will also be an MTF Agreement with manufacturers. For clarity, CVS Health recommends adding "Dispensing Entity" in front of this term.

Re: Section II. Dispensing Entity's Responsibilities

Subsection II(a) outlines that a Dispensing Entity shall enter into and have in effect an agreement with the MTF DM Contractor, "under the terms and conditions approved by CMS." However, the terms and conditions are not within the Dispensing Entity's control as the Contractor has the right to unilaterally amend the terms.

Subsection II (b) requires the Dispensing Entity to enroll with the MTF DM and keep that enrollment information current. Consistent with CVS Health comments on the CY 2026 Medicare Advantage and Part D proposed rule,[1] in situations where the MTF is unable to enroll a pharmacy or finds incomplete or inaccurate information has been supplied, we recommend that CMS or the MTF should have a process for pharmacy outreach to help educate pharmacies regarding the program and to assist them with enrollment.

Subsection II(d) contains notification requirements for the Dispensing Entity to comply with and prescribes timelines for compliance. In each instance of a timeline mandate, CVS Health recommends the addition of, "when possible and applicable." For example, there may be instances when the timeline to a change in ownership does not afford 45-days advance notice.

[1] CMS-4208-P, 89 FR 99340. https://www.federalregister.gov/documents/2024/12/10/2024-27939/medicare-and-medicaid-programs-contract-year-2026-policy-and-technical-changes-to-the-medicare

With respect to Special Carve-Outs and Notification Requirements, CVS Health wishes to understand why the Dispensing Entity has these additional notification responsibilities when the manufacturer does not have the same responsibilities. Additionally, we would like to understand why these additional provisions are necessary if updates to information are already mandated under Subsection (II)(d) to keep the enrollment information current.

Subsection II(h) references the Dispensing Entity's obligation to follow all applicable laws including the "Anti-Kickback Statute." CVS Health requests clarification on how Anti-Kickback laws are relevant to, or impact, the MTF DM processes.

Subsection II(i) reiterates similar language found in the MTF DM and Dispensing Entity Agreement with respect to Third-Party Support Entities. Similar to our recommendation within that Agreement, we suggest amending this subsection as follows:

"To the extent a Dispensing Entity utilizes any agent, including a Third-Party Support Entity, to assist it in performing any of the Dispensing Entity's obligations herein, the Dispensing Entity shall remain responsible for compliance with such obligations."

Re: Section III. CMS' Responsibilities

Subsection III(e) details that CMS will provide a dispute mechanism within the MTF DM to address technical challenges or issues with a technical aspect of the MTF DM or PM systems and processes. For clarity, we recommend adding a reference to Section 90.2 of the final guidance to reflect mechanisms available through CMS for disputes that cannot be resolved directly with the manufacturer.

Subsection III(i) makes reference to CMS using information related to this Agreement to "promote compliance." It is unclear what is meant by promoting compliance. CVS Health believes that this reference should be struck as CMS should not have the authority to condition receipt of reimbursement on making Dispenser Entity data available "to promote compliance."

Re: Section IV. Penalty Provisions

CVS Health is concerned that this section suggests that there are MFP obligations that fall on pharmacies. Committing fraud or a similar crime should result in penalties, but an alleged violation of the MTP Program Agreement, absent fraud or a similar crime, should not lead to the withholding of reimbursements owed to the Dispensing Entity and should certainly not lead to the imposition of penalties on the Dispensing Entity.

Re: Section VI. Confidentiality Provisions

CVS Health is concerned that the language regarding "receiving" and "disclosing" parties is too narrow. CMS may receive information about a Dispensing Entity from sources other than the Dispensing Entity. Due to this, we prefer a more general

confidentiality obligation with respect to any data about the other party obtained in connection with the Negotiation Program.

Additionally, CVS Health recommends that the language clearly state that confidential information should only be used or disclosed solely to the extent necessary to obtain reimbursement for Dispensing Entities from a manufacturer and for no other purpose.

Re: Section VII. Data Use Provisions

This section references data CMS provides to the Dispensing Entity. CVS Health is curious as to what data would be conveyed by CMS to a Dispensing Entity that the Dispensing Entity does not already possess.

Re: Section VIII. Effective Date, Term, Renewal, and Termination

Subsection (d)(1) refers to termination if a Dispensing Entity has engaged in conduct that is inconsistent with the efficient and effective administration of the Negotiation Program. It is unclear what this means. CVS Health recommends indicating that such termination would be as a result of a breach of Dispensing Entity obligations. In addition, the language references "safeguarding against fraud or similar fault" rather than actual or suspicion of actual fraud. Subsection (d)(1) A. ii. goes on to reference CMS's sole discretion in providing a reasonable opportunity for corrective action by the Dispensing Entity. This authority should be limited to and predicated on circumstances where there is clear evidence of wrongdoing by the Dispensing Entity.

Re: Section IX. Disclaimers

CVS Health is concerned that CMS contracts with the MTF DM and PM entities but absolves itself from any and all shortcomings of the contracted entities if they fail to deliver on the expected services.

The disclaimers under Section IX are extremely one-sided and take away all recourse the Dispensing Entity may otherwise have under law. This is especially troubling given enrollment in the MTF program is mandated for pharmacies, which may exceed CMS authority under the Inflation Reduction Act (IRA), an act that imposes no obligations on any Dispensing Entity.

Re: Exhibit A Data Use Provisions

CVS Health would like to understand why Dispensing Entities must sign off on this provision when pharmacies are already bound by HIPAA and will be essentially accessing data related to its own activity and claims.

Subsection (b) details the financial information contained within the MTF DM. CVS Health is concerned that the language of this subsection limits a Dispensing Entity's

ability to utilize its own data as that is what predominantly makes up the information within the MTF DM.

Subsection (b)(7) references the MTF data that must be physically moved, transmitted, or disclosed in any way. Please clarify whether this provision prohibits the utilization of secured cloud storage hosted by a cloud-based vendor.

Subsection (b)(12) prohibits transmission, storage, processing, or access outside of the United States without advance written approval of CMS. Neither HIPAA nor Medicare Part D requires advance written prior approval for the handling of personally identifiable information offshore. CMS does require Part D sponsors to notify CMS if they engage any FDRs to handle PHI offshore, and to attest that such offshore FDRs will comply with certain protections with respect to that PHI. This Agreement should require no more than that.

Subsection (b)(12)iii references the establishment of encryption standards for data in transit and at rest. This provision is not currently required by HIPAA. While HHS has issued a proposed rule requiring this action, the language doesn't specify what "data" must be encrypted.
Subsection (b)(12)vi mandates prompt notification of a breach or unauthorized access involving offshore entities. When the Breach Notification Rule was issued, CMS required HIPAA entities to comply with the Rule which no longer required reporting to CMS outside of that Rule's requirements, which already require reporting to the individual and the HHS Office for Civil Rights. CVS Health is interested in knowing why reporting to CMS is required. In addition, subsection (b)(12)vii contains a detailed documentation of offshore data handling that is not seen elsewhere in CMS's scope.

Thank you for considering our comments and recommendations. CVS Health is committed to collaborating with CMS as it finalizes the applicable Medicare Transaction Facilitator agreements to facilitate the secure and accurate transmission of MTF data and payments to pharmacies. We support affordable, comprehensive care that provides beneficiaries with innovative coverage choices to meet their needs. We welcome any follow-up questions you may have and stand ready to support CMS as it works to refine the Program to ensure it achieves its intended goals as smoothly and efficiently as possible.

Sincerely,

Melissa Schulman
Senior Vice President, Government & Public Affairs
CVS Health

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

January 31, 2025

VIA email submission at IRARebateandNegotiation@cms.hhs.gov

Christina Ritter
Director
Medicare Drug Rebate and Negotiations Group (MDRNG)
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Draft Medicare Transaction Facilitator (MTF) Agreements

Dear Director Ritter:

On behalf of Johnson & Johnson (J&J), we submit the following comments in response to the Centers for Medicare & Medicaid Services' (CMS, the Agency) **Draft Medicare Transaction Facilitator (MTF) Agreements (the *Draft MTF Agreements*).** At J&J, we are driven by a passion to achieve the best version of health for everyone, everywhere, for as long as possible. In the next decade, we will see more transformation in health than in the past century – and we are ready to lead the way. Focusing exclusively on transformational healthcare innovation allows us to move with purpose and speed to tackle the world's toughest health challenges. Innovating across the full spectrum of healthcare solutions puts us in a unique position today to deliver tomorrow's breakthroughs to our current and future patients, including Medicare, Medicaid, and Marketplace beneficiaries. Our strength in both biology and medical technology means we are accelerating advances in care – from cell therapy to AI-assisted robotic surgery. We are using our wide range of expertise to address healthcare challenges that can be tackled by medical technology and innovative medicine, such as cancer, cardiovascular disease, and eye health. Our reach and depth across a continuum of healthcare and technology solutions give J&J the ability to impact health for humanity profoundly.

J&J appreciates the opportunity to provide comments on the Draft MTF Agreements. We seek to work with CMS to revise the Draft Agreements to reflect the partnership we have built with the Agency through our engagements focused on co-developing a workable model for effectuating the "Maximum Fair Price" ("MFP") in the Medicare Drug Price "Negotiation" Program (Program) so that manufacturers working in good faith are able to comply with the IRA statutory obligations. Considering the urgent timeline leading up to the start of IPAY 2026, we are increasingly concerned that there will not be a workable MTF system for "MFP" effectuation by January 1, 2026, resulting in access risks to Medicare beneficiaries, negative cashflow impact for pharmacies, and civil monetary penalties for manufacturers acting in good faith and making significant investments to comply.

Johnson & Johnson

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

A recent analysis published by the National Community Pharmacists Association (NCPA) highlights the significant financial risk facing pharmacies under the current "MFP" effectuation model, including payment delays resulting in $11,000 weekly cashflow loss and $43,000 annual revenue loss.[1] An NCPA membership survey found that the financial risk facing pharmacies will disrupt Medicare beneficiaries' access to selected drugs. The survey found that the majority (93 percent) of independent pharmacists are considering not stocking the first ten drugs listed in the "Negotiation" Program, and over one-third (32 percent) have already decided not to stock one or more of the selected drugs.[2]

To mitigate the significant risk of impeding beneficiary access to their medications, inadequate pharmacy reimbursement, and civil monetary penalties (CMPs) to manufacturers acting in good faith, **J&J continues to urge the Agency to leverage its statutory authority to pre-fund the "MFP" discounts for selected drugs.** See Appendix A for an updated memo outlining CMS' legal authority to pre-fund the "MFP" discounts. A "pre-fund" model ensures beneficiary access to selected drugs and timely payment to dispensing entities, and enables manufacturer compliance with statutory requirements.

CMS Must Substantially Revise and Reissue the Draft MTF Agreements

J&J cannot accept the terms of Draft MTF Agreements without substantial revisions. The Draft MTF Agreements lack acknowledgement of or reference to the Agency's implementation obligations under the law, which departs from standard contractual language contained in other government program agreements, including the Program Agreement with CMS.[3] We are concerned that the Draft MTF Agreements would shift all liability for effectuation of the "MFP" to manufacturers despite the statute's broad directive for CMS to carry out the Program.[4] This is especially troubling because CMS and its MTF contractors have yet to establish the technical requirements to support the very challenging system build to effectuate the "MFP". Precluding a party to the Agreement from knowing and assessing contract terms defies basic contracting principles which require a meeting of the minds on contract terms, and undermines the Agency's assertion that participation in the Program is voluntary and reflective of a true negotiation.

J&J strongly urges CMS to adopt the following revisions to the Draft MTF Agreements:

- Remove the Broad and Unreasonable Liability Disclaimer
- Remove Open-Ended Language Obligating Manufacturers to Agree to Vague or Unknown Terms that Could be Re-defined in Future Technical Instruction or Guidance
- Limit the Overly Broad Records and Audit Provisions
- Ensure Protection of Confidential and Proprietary Manufacturer Information
- Clearly Define MTF Data Module (DM) and Payment Module (PM) Processes and Specifications to Enable a Full Assessment of Terms Prior to Entering into Agreements

---

[1] *Unpacking the Financial Impacts of Medicare Drug Price Negotiation Analysis on Pharmacy Cash Flows*. January 2025.
2 https://ncpa.org/sites/default/files/2025-01/1.27.2025-FinalExecSummary.NCPA_.MemberSurvey.pdf
[3] https://www.cms.gov/files/document/inflation-reduction-act-manufacturer-agreement-template.pdf
[4] SSA § 1196(a)(3).

Johnson&Johnson
Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA
T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

- Remove Language that May Limit a Manufacturer's Use of Data to Prevent Duplicate Discounts
- Add Language to Provide Protections to Account for Operational Contingencies

Below, J&J offers additional detail and examples to support our recommendations for the required revisions to the Draft MTF Agreements.

J&J Recommendations for Reasonable and Balanced Contract Provisions that are Consistent with Agreements in Other Government Programs

J&J is a member of PhRMA and is aligned to and supports their comments in response to the Draft MTF Agreements. Note that J&J's comments apply across the three manufacturer Draft MTF Agreements where there are similar provisions. J&J's recommendations are as follows:

Remove the Broad and Unreasonable Liability Disclaimer

J&J urges CMS to remove the broad and unreasonable liability disclaimer language under Section IX of the Draft MTF Agreement between the Manufacturer and CMS (the Draft MTF Program Agreement). The subsections (a) through (e) contained in Section IX, Disclaimers, shift all liability and obligations to manufacturers. Despite having no visibility to the MTF DM and PM end-to-end system requirements, Section IX(a) of the Draft MTF Program Agreement inexplicably would require manufacturers to accept the MTF system on an "as-is" basis without any representation or warranty of "fitness for a particular purpose". J&J opposes any requirement in the Draft MTF Agreements for manufacturers to accept the MTF system without knowing how or if it will work to fulfill its intended purpose to facilitate the effectuation of the "MFP", in addition to accepting all liability for the MTF. For example, Section IX(b) requires the manufacturer to accept all liability for the MTF, including for direct damages arising out of the manufacturer's use of the MTF. Section IX(c) would require manufacturers to indemnify CMS for the manufacturer's actions. While this is customary in other government program contracts, Section IX(c) also requires manufacturers to indemnify the conduct of the CMS chosen MTF DM and PM and dispensing entities – none of whom manufacturers have any ability to control legally, contractually or otherwise.

J&J strongly opposes the inclusion of subsections (a) through (e) because manufacturers have no control over the selection of the MTF vendors, their scope of work, and the establishment of the MTF systems, and therefore cannot disclaim the MTFs and CMS of all damages and liability. As is typical in other contracts, each party should remain liable for its own responsibilities. Under the IRA, CMS is responsible for implementing the Program and establishing procedures with respect to Medicare beneficiaries eligible to receive the "MFP", and computation and application of the "MFP".[5] In addition, through its Guidance, CMS stated its intent to establish the MTF DM

[5] The IRA assigns CMS specific functions related to the administration of the Drug Price "Negotiation" Program, including establishment of procedures "to carry out the provisions of this part" with respect to Medicare beneficiaries eligible to receive the MFP. SSA § 1196(a)(3). The IRA also calls on CMS to establish procedures related to the computation and application of the MFP. See SSA § 1196(a)(1)-(2).

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

and PM to facilitate the exchange of data between manufacturers and dispensing entities, and to facilitate prompt payment to dispensing entities.[6] Thus, CMS must remain liable for its conduct in executing these obligations.

Lastly, the provisions of Section IX are inconsistent with Section X(g). While Section X(g) contains reciprocal obligations requiring each party to be responsible for its contractors' responsibilities, Section IX would hold the manufacturer responsible for CMS' contractors' responsibilities. Such inconsistencies raise questions on which provisions would govern the MTF Agreements, and we urge CMS to remove the overly broad disclaimer language under Section IX.

Remove Open-Ended Language Obligating Manufacturers to Agree to Vague or Unknown Terms that Could be Re-defined in Future Technical Instruction or Guidance

J&J opposes sections of the Draft MTF Agreements, such as Section X(a) in the Draft MTF Program Agreement, that would grant CMS overly broad and unilateral amendment authority which could bind manufacturers to future and unknown terms resulting from un-defined sub-regulatory guidance. The Agreements should not obligate manufacturers to unknown terms that CMS and its contractors can change or expand through sub-regulatory guidance or technical instruction. For example, we are concerned that Section II(d) of the Draft MTF Program Agreement outlining manufacturer responsibilities states "Manufacturer shall comply with the MTF Data Module Contractor's and, as applicable, the MTF Payment Module Contractor's, instructions, processes, and requirements." This is concerning because MTF DM and PM instructions, processes and requirements have yet to be defined and therefore are unknown to manufacturers. Given the short timeline and significant work ahead to establish the MTF DM and PM, we lack confidence that such instructions, processes and requirements will be defined within requisite timeframes to enable manufacturers to perform their obligations under the law. The MTF Agreements should not require manufacturers to blindly agree to instructions, processes or requirements unless they are known to the Manufacturer and have been unambiguously defined or referenced in the MTF Agreements.

Section II(b) further states "When utilizing the MTF DM, Manufacturers shall comply with all requirements and conditions for "MFP" effectuation and CMS monitoring thereof, including, without limitation, all applicable CMS guidance, regulations, and technical instructions." We ask CMS to remove this language because technical instruction should not be used as a way to affect legal obligations. Moreover, as outlined in PhRMA's comments, in line with the Department of Health and Human Services Good Guidance Practices Rule, compliance with sub-regulatory guidance is legally binding only when there is explicit and unambiguous reference to such

[6] October 2024 Final MFP Guidance

Johnson&Johnson

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

guidance in the agreement.[7] Aligned to this rule, we recommend that CMS specifically list all guidance, regulations or technical instructions that exist as of the date that manufacturers are required to sign the MTF Agreements as an exhibit or schedule to the MTF Agreements that is only subject to change by mutual agreement or amendment of the Agreement.

Limit Overly Broad Records and Audit Provisions

J&J opposes Section II(f) which requires manufacturers to maintain "all records that the Manufacturer may create or receive in connection with the MTF..." for at least 10 years. This provision is overly broad and unclear, as CMS provides no clarification on what constitutes a record, and how it defines "in connection with the MTF". For example, a "record" could conceivably include any meeting notes or documentation that is (1) proprietary/confidential, (2) not relevant to the manufacturer's obligations under the agreement and/or (3) not maintained in the ordinary course of business. Such a broad requirement would exceed CMS' authority.

In addition, it contradicts Section V(d)(5) of the Draft MTF Program Agreement which would require manufacturers, in conflict with obligations under Sarbanes Oxley, to destroy claim-level data elements and provide certification of such destruction upon termination.[8] J&J urges CMS to remove the language under II(f) and V(d)(5). As is typical in other program agreements, information required to be maintained should be limited only to specific data fields outlined in the agreement that are relevant for determining MFP-eligible individuals and "MFP" refunds paid. Similarly, we urge CMS to revise Section V(b) which provides CMS with overly broad authority to request that manufacturers disclose any information "necessary" to monitor compliance. Any such information should be limited to specific data fields defined in the MTF Agreements.

The MTF Agreements Must Ensure Protection of Confidential and Proprietary Manufacturer Information

J&J is concerned about the lack of protection in the Draft MTF Agreements for confidential and proprietary manufacturer information and unauthorized expansion of non-governmental agents and designees' rights to access sensitive manufacturer information. The MTF Agreements must allow manufacturers to identify proprietary information and challenge any potential release of such data prior to release. J&J supports PhRMA's comments related to protection of confidential and proprietary information.

---

[7] https://www.federalregister.gov/documents/2020/12/07/2020-26832/department-of-health-and-human-services-good-guidance-practices

[8] https://www.regulations.gov/comment/CMS-2010-0196-0032 (citing Pub. L. 107-204, 116 Stat. 745 (2002) §§ 302, 404, 906).

Johnson & Johnson

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

Additionally, the Federal Procurement Data System website reflects that CMS awarded the MTF-PM contract.[9] Given that the selected entity is a subsidiary of a health plan with potential conflicts of interest, it is imperative that the MTF Agreements clearly define data security and data exchange protections, including with the MTF PM's parent company as well as between the MTF DM and PM. In addition, the MTF Agreements should explicitly state that the MTF PM's only permissible data use is for the sole purpose of MTF payments, and outline data use limitations including for marketing or contracts, in addition to outlining the MTF PM's data security and firewall measures that will be undertaken to prevent unauthorized use.

Provide Clear Transparency Around MTF DM and PM Processes and Requirements to Enable a Full Assessment of Terms Prior to Entering into Agreements

As of January 31, 2025, manufacturers of selected drugs for IPAY 2026 have not received critical transparency as it relates to the end-to-end requirements and specifications of the MTF DM and PM. Without clarity on system requirements and functionality, J&J will be unable to enter into these MTF Agreements. It is imperative that CMS provide manufacturers with required transparency, and several examples are provided below:

- Section II.J.6., would require manufacturers to "Comply with the terms of the Ledger System described in applicable regulations, guidance, and technical instructions" despite manufacturers having limited visibility into the functionality and requirements of the Ledger System. Manufacturers require clarity around the accessibility to the Ledger System, including functionality to enable the manufacturer to download/live feed and visualize Ledger System data. CMS should also provide clarification that manufacturers will be able to seamlessly reopen the claims including to process 340B reconciliation offsets via the Ledger System, and that the MTF PM will update the Ledger on a daily basis so that the Ledger System is always up to date.
- Manufacturers require clarification on the MTF PM payment transfer process. Section II(j)4 states that "Manufacturer's return of the claim-level payment elements shall constitute the authorization for the MTF PM to transmit the "MFP" refund payments *from the bank account the Manufacturer has on file* with the MTF DM to the dispensing entities identified in the claim-level payment elements." J&J asks CMS to clarify the process to stipulate that manufacturers would make payment to either CMS or an MTF PM bank account, and that the MTF would then withdraw those deposited funds from their account to transmit the dispensing entities. This clarification is critical because internal controls may limit a manufacturer's ability to participate in the MTF PM if the

[9]https://www.fpds.gov/ezsearch/fpdsportal?q=national+government+DEPARTMENT_FULL_NAME%3A%22HEALTH+AND+HUMAN+SERVICES%2C+DEPARTMENT+OF%22+UEI_NAME%3A%22NATIONAL+GOVERNMENT+SERVICES%2C+INC.%22+VENDOR_FULL_NAME%3A%22NATIONAL+GOVERNMENT+SERVICES%2C+INC.%22+CONTRACTING_AGENCY_NAME%3A%22CENTERS+FOR+MEDICARE+AND+MEDICAID+SERVICES%22+PIID%3A%2275FCMC25FJ026%22&s=FPDS.GOV&templateName=1.5.3&indexName=awardfull&x=0&y=0&sortBy=SIGNED_DATE&desc=Y

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

process requires MTF PM access to and authority to withdraw funds directly from manufacturer bank accounts.

- CMS must clearly define the dispute resolution and appeals process. A robust and transparent dispute resolution and appeals process will safeguard stakeholder interests and ensure program integrity. We also recommend that CMS add language to the MTF Agreements to account for disputes in which data transmitted to manufacturers is incomplete and "MFP" refund amount cannot be validated.
- To enable manufacturer compliance, the MTF Agreements should outline that the MTF PM will be held to public company audit and requirements arising under Sarbanes Oxley pertaining to its role in facilitating payments between manufacturers and dispensing entities.
- Section II(i)2 of the Draft MTF Program Agreement states that manufacturers must "Transmit complete and accurate claim-level payment elements to the MTF DM within the 14-day prompt "MFP" payment window." However, manufacturers require additional clarity around the 14-day prompt payment window. For example, CMS should clarify that the 14-day prompt payment window will account for periods including over weekends and banking holidays when banking systems cannot transmit funds outside the manufacturer's control. We also recommend that CMS include language to extend the 14-day prompt payment window in circumstances when the MTF is not functioning or when manufacturers dispute claims because they receive incomplete data from the MTF. We are concerned that Section II(i)3 states that "The existence of an adjusted claim does not affect the Manufacturer's obligation to respond to the original claim within the 14-day prompt "MFP" payment window even if the claim-level data elements for the adjusted claim are sent to the Manufacturer during the original claim's 14-day prompt "MFP" payment window." J&J urges CMS to revise this provision to state that the 14-day window would restart based on an adjusted claims to allow time for manufacturer validation of the adjusted claims data. The MTF Agreements should specify the need for a smooth reopening of claims using the Ledger to allow for adjustments on previously closed or disputed units that require modification.

Remove Language that May Limit a Manufacturer's Use of Data to Prevent Duplicate Discounts

While J&J appreciates that the Draft MTF Agreements acknowledge manufacturers' required use and linkage of the CMS data to avoid duplicate discounts with 340B and the "MFP", J&J is concerned that the language does not account for other manufacturer validation processes to avoid statutorily prohibited duplicate discounts, including with Medicaid for dual eligible beneficiaries, as well as with discounts under commercial contracts. For example, under 2.xi of Exhibit A for Data Use Provisions, CMS states that "The Manufacturer may link records within CMS Data in order to validate that a claim has not been duplicated or that retroactive adjustments have been made." Therefore, we ask CMS to revise the language to clarify that the

Johnson&Johnson

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

data can be used by the Manufacturer to comply with statutory requirements to avoid duplicate discounts across all programs.

Add Language to Provide Protections to Account for Operational Contingencies

J&J opposes the 180-day notice language outlined in Section VIII(d)(1) of the Draft MTF Program Agreement, which states "CMS may terminate this Agreement if CMS determines it will no longer provide the MTF as a service to manufacturers and dispensing entities. CMS shall provide the Manufacturer with at least one hundred eighty (180) calendar day notice prior to the effective date of termination pursuant to this section VIII(d)(1)." A notice period of 180-days is wholly insufficient for manufacturers to set up a new system to effectuate "MFP" discounts. In this case, manufacturers would require protection from CMPs while establishing a new system. We ask CMS to revise this language to provide at least 365 days and establish reasonable protections from CMPs.

J&J is deeply concerned about the significant work ahead of CMS and the MTF DM and PM to build, test and implement a workable "MFP" effectuation program. It is troubling that the Draft Agreements seek to shift CMS' obligation under the IRA to implement the Program and liability for CMS MTF contractors and their systems to manufacturers without providing adequate protections to account for operational contingencies. The complexity of the build and urgent timeline necessitate CMS' establishment of protections for parties working in good faith, including if the MTF system(s) are not ready or malfunctions. Manufacturers should not be subject to CMPs if CMS and its contractors fail to define technical and business requirements in a timely manner and deliver a workable system that enables manufacturers working in good faith to comply.

We urge CMS to add language within these agreements that accounts for operational contingencies for parties working in good faith to comply. CMS must include a hold harmless or safe harbor provision that would allow a manufacturer that complies with the MTF requirements to be deemed to have provided the "MFP" as stated under the law to avoid CMPs.

****

J&J appreciates the opportunity to provide these comments to advance a workable model for "MFP" effectuation by January 1, 2026. For questions or more information, please contact Jacqueline Roche, Head of Payment & Delivery Policy, at jroche8@its.jnj.com.

Sincerely,

Jacqueline Roche

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

Jacqueline Roche, DrPH
Head, Payment, and Delivery Policy & Global Policy Institute
Johnson & Johnson

Appendix A:

M E M O R A N D U M

January 13, 2025

To: Johnson & Johnson

From: Kelly M. Cleary

Re: Role of CMS in the Implementation of the Maximum Fair Price and Non-Duplication Provisions

You have asked us to consider what role, if any, the Centers for Medicare & Medicaid Services (CMS) has in ensuring access to the maximum fair price (MFP) and preventing duplication of discounts available under the 340B Program. You have also asked us whether CMS can facilitate access to the MFP of selected drugs by advancing funding to cover the spread between a dispensing entity's acquisition cost and the MFP, and thereafter recouping such funds from the manufacturer.

After review of the relevant authorities and precedent, we have reached the following conclusions:

1. CMS has an affirmative obligation to establish procedures that will, among other things, ensure the MFP is accurately calculated and applied through the Part D and Part B benefit programs.

2. CMS has an affirmative obligation to effectuate Social Security Act (SSA) section 1193(d)'s prohibition on duplication with the 340B ceiling price, and must ensure that no manufacturer is required to provide access to the MFP when it would duplicate the discount already available under the 340B Program.

3. CMS has the authority to advance funding to effectuate the MFP, and has already set a precedent for doing so in its implementation of the Medicare Coverage Gap Discount Program.

I. Background

Section 11001 of the Inflation Reduction Act (IRA) (Pub. L. 117-169) adds a new "Part E" to Title XI of the Social Security Act. The new SSA section 1191(a) directs the Secretary to

establish a Drug Price Negotiation Program ("Negotiation Program") and to enter into agreements with manufacturers of selected drugs that set a "maximum fair price" for those drugs. Under these agreements, manufacturers must provide eligible Medicare beneficiaries with "access" to the MFP at the point of sale. Manufacturers must also provide access to the MFP to the pharmacy, mail order service, or other dispensing entity ("dispensing entities"). The manufacturer's obligation to provide access to the MFP hinges on whether the drug being dispensed is already subject to a discount under the 340B Program. Where a drug is a 340B- covered drug and the ceiling price is lower than the MFP, the statute prohibits CMS from requiring the manufacturer to provide access to the MFP (the "non-duplication" provision).[1]

Beyond the requirements related to manufacturer agreements, Congress imposed a number of other duties on CMS related to the administration of the Negotiation Program. For instance, the statute includes a broad directive to CMS to "establish procedures to carry out the provisions of this part" with respect to eligible Part D and Part B beneficiaries.[2] There are also specific directives to CMS to establish procedures designed to ensure that the MFP for a selected drug is computed and applied correctly.[3]

The IRA incorporates the MFP into the Part D prescription drug benefit program by adopting the MFP as a cap on the negotiated prices used for payment of the selected covered Part D drugs.[4] Under Medicare Part D, the Part D plan sponsors (or MA organizations offering MA- PD plans) are obligated to administer the benefit, and must provide their enrollees with access to the negotiated prices (or, in the case of selected drugs, the MFP).[5] CMS is responsible for the administration of the Drug Price Negotiation Program[6] and the Part D Program.[7]

---

[1] Social Security Act (SSA) § 1193(d).

[2] *Id*. § 1196(a)(3).

[3] *Id*. § 1196(a)(1), (2).

[4] *Id*. § 1860D-2(d)(1)(D).

[5] *Id.* §§ 1860D-2(d)(1)(A), (D). CMS has stated that while the IRA requires manufacturers to provide access to the MFP to MFP-eligible individuals, Part D plan sponsors will "facilitate" access "in the normal course of operations." CMS, *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 (MFP) in 2026 and 2027*, at 196 (Oct. 4, 2024), https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer- effectuation-mfp-2026-2027.pdf [hereinafter "October 2024 Final MFP Guidance"].

[6] The IRA assigns CMS specific functions related to the administration of the Drug Price Negotiation Program, including establishment of procedures "to carry out the provisions of this part" with respect to Medicare beneficiaries eligible to receive the MFP. SSA § 1196(a)(3). The IRA also calls on CMS to establish procedures related to the computation and application of the MFP. *See* SSA § 1196(a)(1)-(2).

[7] *Id.* § 1808(a).

The statute is silent as to what it means to "provide access" to the MFP and does not prescribe the means by which the manufacturer provides access. CMS has defined providing access to mean "ensuring that the acquisition cost of the dispensing entity for the selected drug …is no greater than the MFP."[8] CMS has said it expects manufacturers to "provide access" to the MFP in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP; or (2) retrospectively providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP (a "retrospective refund") within 14 days of the date of notification that an MFP-eligible individual filled a prescription.[9]

With respect to the retrospective refunds, CMS has stated it intends to contract with a Medicare Transaction Facilitator (MTF) to facilitate the exchange of data between manufacturers and dispensing entities in order to support the verification that the selected drug was dispensed to an MFP-eligible individual – the MTF Data Module, or "MTF DM." Further, the MTF will facilitate prompt payment of the MFP refund and collect confirmation from manufacturers that the MFP refund was paid – the MTF Payment Module, or "MTF PM".[10] CMS will require manufacturers to participate in the MTF DM, but is making participation in the MTF PM optional.[11] CMS has also proposed to make enrollment in the MTF DM mandatory for pharmacies, through requirements on Part D plan sponsors to include MTF enrollment in network pharmacy agreements.[12]

Beyond the establishment of an MTF to administer a retrospective refund model, CMS has declined to take on an active role in effectuating the MFP. CMS has recognized that "timely movement of funds is important" to minimize the financial burden on dispensing entities, and that having CMS prefund the MTF PM payment accounts "would offer advantages."[13] However, CMS rejected the prefunding approach, stating that the "IRA did not include an

---

[8] October 2024 Final MFP Guidance, at 196.

[9] *Id.*

[10] *Id*. at 197-98.

[11] *Id.*

[12] Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 89 Fed. Reg. 99,340, 99,443-45 (Dec. 10, 2024).

[13] October 2024 Final MFP Guidance at 78-79.

\

appropriation to 'prefund' MFP refund payments."[14] CMS instead said it will look to manufacturers to come up with approaches to mitigate dispensing entities' cashflow challenges.[15]

CMS has also declined to assume any responsibility for effectuating the statute's nonduplication provision.[16] In doing so, CMS has taken the position that section 1193(d) of the Act, which prohibits duplicate discounts, does not require CMS to prevent duplication from happening. According to CMS, the burden is on the manufacturer to identify and attempt to recover duplicate payments. The agency promises to "monitor the extent to which MFP is made available where appropriate" and "also monitor the extent to which the manufacturer faces challenges with deduplicating between the 340B ceiling price and the MFP."[17]

II. Analysis

CMS is obligated to establish procedures necessary to implement all aspects of the Negotiation Program, including the provision of the MFP and the prohibition on duplicate discounts. Further, under its existing authorities, CMS can receive and distribute funds from manufacturers, either directly or through a third-party administrator (like the MTF).[18] CMS can make advance payments, subject to reconciliation or recoupment, as necessary to ensure that dispensing entities have timely access to the MFP.

A. Congress Issued a Broad Directive to CMS to Carry Out the Program Consistent with the Statute, Including the Prohibition on Duplicate Discounts

CMS' narrow view of its own role in the effectuation of the MFP in the Part B and D programs is at odds with clear congressional directives. Section 1196 directs CMS to establish procedures for the administration of the Negotiation Program, and, among other things, to "carry

---

[14] *Id.*

[15] *Id.*

[16] *Id.* at 230-31 (stating that "CMS will not, at this time, assume responsibility for nonduplication of discounts between the 340B ceiling price and MFP" and that "CMS is not charged with verifying or otherwise reviewing whether a particular drug claim is 340B-eligible.").

[17] *Id.*

[18] Unlike the authorities governing the ACA's Coverage Gap Discount Program and the IRA's Manufacturer Discount Program (*see* SSA §§ 1860D-14A(d)(2)(A), 1860D-14C(d)(2)), the statutory provisions establishing the Drug Price Negotiation Program do not prohibit CMS from receiving or distributing any funds of a manufacturer under the Program.

out the provisions of this part" with respect eligible beneficiaries in the Part D and Part B programs.[19] The reference to "this part," necessarily includes the provisions in Part E of Title XI regarding access to the MFP and nonduplication of 340B discounts. Under the latter provision, CMS cannot require a manufacturer to provide access to the MFP for covered drugs provided to 340B-eligible patients if the ceiling price of the drug is lower than the MFP. It is therefore incumbent upon CMS to establish a mechanism to determine whether or not a manufacturer is in fact obligated to provide access to the MFP in any given transaction.

B. CMS Has the Authority to Prefund the MFP

In rejecting a prefunding approach, CMS reasoned that the IRA did not include an appropriation to prefund the MFP refund payments. CMS has not, however, addressed the availability of the Federal Supplementary Medical Insurance Trust Fund ("Trust Fund").

Social Security Act section 1860D-16 establishes a Medicare Prescription Drug Account within the Trust Fund. This section authorizes funds for "such amounts as the Secretary certifies are necessary to make payments to operate the program under [Part D], including—" various statutory subsidies and administrative expenses. The use of the word "including" is presumed to mean that the list is not an exhaustive list,[20] and the Secretary therefore has considerable discretion to determine which amounts are necessary to administer the Part D program.

While many of the Negotiation Program's provisions reside in Title XI of the Social Security Act, the MFP is applied through the Part D and Part B programs. It is offered to eligible Medicare beneficiaries as part of their Medicare prescription drug benefits. Effectuation of the MFP for Part D drugs, therefore, is unquestionably part of the administration of the Part D program. CMS could draw on Trust Fund dollars to prefund the MTF PM because those expenditures (which would be temporary outlays) are necessary to ensure that the Negotiation Program works as Congress intended, and that beneficiaries have sufficient access to their prescription drugs at the MFP.

C. CMS Can Prefund MFP Refunds by Utilizing the Infrastructure Already Established for the Coverage Gap Discount Program

---

[19] SSA § 1196(a)(3).

[20] *See generally* ANTONIN SCALIA & BRYAN A. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS, at 132 (2012).

There is precedent for a prefunding approach in the Part D program.[21] Specifically, CMS makes advance payments to Part D sponsors to effectuate manufacturer discounts under the Medicare Coverage Gap Discount Program ("Discount Program").[22] Created by the Affordable Care Act, the Discount Program makes drug manufacturer discounts available to eligible Medicare beneficiaries at the point of sale when receiving applicable covered Part D drugs while in the coverage gap phase.

The Discount Program's authorizing legislation sets up a structure whereby manufacturers must agree to provide eligible Medicare beneficiaries access to discounted prices at the point of sale. It also charges the Secretary with establishing procedures to ensure the discounts are properly applied at the point of sale, and that the dispensing pharmacies are reimbursed for the difference between the negotiated price (inclusive of any discounts) and the acquisition cost of the drug within a set timeframe (14 days for claims submitted electronically).[23] The statute prohibits CMS from receiving or distributing manufacturer funds, and instead requires that CMS contract with a third party to facilitate the transfers.[24]

In implementing the Discount Program, CMS recognized that "[w]hile manufacturer discounts under the Discount Program must be made available at point-of-sale, the Affordable Care Act does not specify how this should be done."[25] Exercising the considerable discretion afforded to it under the statute, CMS ultimately determined that the best and most accurate way to effectuate manufacturer discounts at the point of sale was to require Part D sponsors to provide the discounts on the manufacturer's behalf.[26] In justifying this approach, CMS noted

---

[21] CMS also uses advance payments in other Medicare payment systems. For instance, CMS has on occasion made advanced payments to Part B physicians and other suppliers. In 1989, in response to a backlog of pending claims, CMS authorized its contractors to make conditional partial payments to suppliers on claims that the contractors were unable to process within the prescribed time limits. These partial payments were subject to later recoupment once the claims were actually processed. This was designed to avoid untimely payments to the suppliers. CMS later codified this practice in regulation and has since used advanced payments to address cash flow challenges related to the COVID-19 pandemic and, most recently, the Change Healthcare breach. *See* 42 C.F.R. § 413.64(g).

[22] *See* 42 C.F.R. § 423.2320. CMS is taking a similar approach in implementing the new Manufacturer Discount Program established by the IRA and codified at section 1860D-14C of the Social Security Act.

[23] SSA § 1860D-14A(c)(1)(A)(iv), (g)(3)(A).

[24] *Id.* § 1860D-14A(d)(2), (3).

[25] Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes, 77 Fed. Reg. 22,072, 22,079 (April 12, 2012).

[26] *Id*. at 22,086.

that the only entity that could effectively provide the discount at the point of sale was the Part D sponsor, because no other entity would have access to the information necessary to effectuate the discount.[27] The manufacturers, in turn, could discharge their obligation by reimbursing Part D sponsors in accordance with quarterly invoices.[28]

Under the structure established by CMS, Part D sponsors are obligated to reimburse pharmacies on discounted drugs within 14 days, per statutory requirements, but do not receive payments from manufacturers until later in the process (38 calendar days after distribution of quarterly invoices).[29] Thus, Part D sponsors have to make a sizable cash outlay to meet the statutory prompt pay requirement. CMS determined it necessary to provide "interim coverage gap payments" to Part D sponsors, which were designed to "ensure that Part D sponsors will have the funds available to advance the manufacturer discounts to applicable beneficiaries at the point of sale."[30] CMS established the process now codified at 42 C.F.R. § 423.2320, whereby CMS makes monthly interim payments to allow Part D sponsors to advance discounts to beneficiaries, and reconciles interim payments with amounts invoiced to manufacturers. These advance payments appear to be funded through the Part D Account in the Trust Fund.[31]

D. The Statutory Authority Underlying the Negotiation Program is Materially Similar to that of the Coverage Gap Discount Program, and Would Support CMS Effectuating the MFP Using a Process that Resembles the Payment Process for Coverage Gap Discounts

---

[27] *See* CMS, *Medicare Coverage Gap Discount Program Memorandum*, at 3 (April 30, 2010), https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/2011CoverageGapDiscount_043010v2.pdf. At the time, CMS also considered using a third-party administrator to directly adjudicate the discount payment to pharmacies, but determined that then-existing HIPAA billing standards could not support the transfer of information necessary to implement the discount.

[28] *Id* at 4.

[29] 42 C.F.R. § 423.2315(b)(3).

[30] 77 Fed. Reg. at 22,086.

[31] *See, e.g.*, BDS. TRS., FED. HOSP. INS. & FED. SUPPLEMENTARY MED. INS. TR. FUNDS, 2023 ANNUAL REPORT OF THE BOARDS OF TRUSTEES OF THE FEDERAL HOSPITAL INSURANCE AND FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUNDS, at 108-09 (Mar. 31, 2023), https://www.cms.gov/oact/tr/2023.

As far as statutory authority, there are no material differences between how discounts are made available under the Discount Program and how the MFP is made available through the Negotiation Program:

> 1. *In both programs, the manufacturer is responsible for providing access to the discount/MFP to eligible beneficiaries.*[32]

Even though the authorizing statute for the Discount Program made the manufacturer responsible for providing the discount, CMS required the Part D sponsor to make applicable discounts available at the pharmacy, by mail order service, or at any other point of sale for applicable drugs.[33] The manufacturer, in turn, is obligated to promptly pay back the Part D sponsors within 38 days of receiving a quarterly invoice.[34] CMS reasoned that the Part D sponsor, rather than the manufacturer, had the information necessary to provide the discount at the point of sale, and it was therefore appropriate to require Part D sponsors to provide the discount on the manufacturer's behalf.[35]

CMS could similarly require Part D sponsors to provide the MFP at the point of sale. While section 1193(a) requires manufacturers to "provide access" to the MFP to both beneficiaries and dispensing entities, CMS could effectuate this statutory mandate by requiring the Part D sponsor to provide the MFP on behalf of manufacturers and require manufacturers to provide refunds to the Part D sponsor. As with the coverage gap discount, Part D sponsors have the information necessary to provide the MFP to the beneficiary at the point of sale and have an

---

[32] SSA §§ 1860D-14A(b)(1)(A) (Medicare Coverage Gap Discount Program) ("An agreement under this section shall require the manufacturer to provide applicable beneficiaries access to discounted prices…"), 1860D- 14C(b)(1)(A) (Manufacturer Discount Program) ("An agreement under this section shall require the manufacturer to provide, in accordance with this section, discounted prices…"), 1193(a)(3) (Manufacturer Agreements under the Drug Price Negotiation Program) (providing that "access to the maximum fair price . . . shall be provided by the manufacturer to" eligible beneficiaries).

[33] CMS, MEDICARE COVERAGE GAP DISCOUNT PROGRAM AGREEMENT, at 8, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/downloads/ManuAgreement.pdf (last accessed Jun. 21, 2024).

[34] *Id.* at 6. 42 C.F.R. §§ 423.2315(b)(3).

[35] Medicare Program; Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Proposed Changes; Considering Changes to the Conditions of Participation for Long Term Care Facilities, 76 Fed. Reg. 63,018, 63,021–22 (Oct. 11, 2011).

independent obligation to account for the MFP in determining the negotiated price in order to determine beneficiary cost sharing and administer the benefit at the point of sale.[36]

2. *Both programs allow for retrospective reimbursement to dispensing entities*.[37]

Under section 1193(a), manufacturers must provide access to the MFP to both the eligible beneficiary and to the dispensing entity. However, the statute only requires point-of-sale access with respect to eligible beneficiaries. The Discount Program similarly, and more expressly, allows for the pharmacy to be made whole *after* the point of sale.[38] Neither statute requires the manufacturer to directly reimburse the dispensing entity. Just as CMS has allowed manufacturers to discharge their obligations to discount-eligible beneficiaries through repayment to Part D sponsors, CMS could allow manufacturers to discharge their MFP-related obligations to dispensing entities through repayment to Part D sponsors who pay retrospective refunds on manufacturers' behalf.

3. *Under both programs, the Secretary is given broad authority to establish procedures necessary to carry out the statutory directives, including establishing procedures for providing "access" to the discount/MFP*.[39]

The statutes authorizing the Discount Program and the Negotiation Program both create obligations for manufacturers to "provide access" to discounts/MFP, but neither define what it means to provide access or prescribe how access is provided. Instead, both statutes give CMS broad authority to establish procedures necessary to administer the programs. Further, CMS also has statutory authority to implement both programs through program instruction in initial years,[40] and has the authority to makes such rules "as may be necessary to the efficient administration of the functions with which [it] is charged under this Act."[41] CMS therefore has significant

---

[36] SSA § 1860D-2(d)(1)(D).

[37] *See id.* §§ 1193(a)(3)(A) (Manufacturer Agreements under the Drug Price Negotiation Program), 1860D-14A(c)(1)(A)(iv) (Medicare Coverage Gap Discount Program).

[38] *Id.* § 1860D-14A (c)(1)(A)(iv) (providing for procedures to ensure that the dispensing entity is reimbursed for the difference between the negotiated price and the discounted price *after* the product is dispensed).

[39] *Id.* §§ 1196(a), 1860D-14A(c), 1860D-14A(c).

[40] *Id.* § 1860D-14A(d)(5); IRA § 11001(c).

[41] SSA §1102(a).

discretion in determining the most effective and efficient means of ensuring that beneficiaries and dispensing entities are able to access the MFP.

Given the similarities outlined above, there is no reason why CMS could not effectuate the MFP in the same manner as the discounts under the Discount Program, including making advance monthly MFP payments to Part D sponsors in order to ensure that Part D sponsors will have the funds available to advance the manufacturer's MFP to applicable beneficiaries (and dispensing entities). CMS could adopt the same framework as currently laid out in 42 C.F.R. § 423.2320(a), and, just as CMS has done for the advance coverage gap discount payments, it could draw from the Part D Account in the Trust Fund.

E. Alternatively, CMS Could Effectuate the MFP by Prefunding Refunds Paid by the MTF.

CMS could implement retrospective refunds through a contract with the MTF, which would adjudicate the retrospective rebates directly between dispensing entities and manufacturers (i.e., without advancement of funds by the Part D sponsor).[42] Indeed, there is nothing in the law that would prohibit CMS (or its contractor) from receiving or distributing manufacturer funds to effectuate the MFP,[43] and CMS has already decided to utilize the MTF to administer retrospective refunds.[44]

To ensure that dispensing pharmacies are timely reimbursed for the difference between the MFP and acquisition costs, CMS could require that the MTF contractor pay invoices from the dispensing entity within 14 days (or some other period). Further, CMS could establish a payment schedule under the MTF contract that provides a funding stream adequate to cover invoice payments. Costs the MTF incurs in collecting refund payments from manufacturers

---

[42] CMS considered this model in 2010 for the Coverage Gap Discount Program, but declined to use that model because at the time there was no approved billing standard that could support the transfer of information from the Part D sponsor that would be necessary to accurately determine payment. *See*, CMS, *Medicare Coverage Gap Discount Program beginning in 2011*, at 3 (Apr. 30, 2010), https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/2011CoverageGapDiscount_043010v2.pdf.

[43] Unlike the authorities governing the Discount Program, *see* SSA § 1860D-14A(d)(2)(A), the statutory provisions establishing the Negotiation Program do not prohibit CMS from receiving or distributing any funds of a manufacturer under the Program.

[44] October 2024 Final MFP Guidance at 197-98.

(including any costs associated with the need to advance refund payments to dispensing entities) would be administrative costs that CMS could reimburse under the contract.

III. Conclusion

CMS has the duty and the authority to establish procedures necessary to effectively and efficiently manage how the MFP is provided under the Part D benefit. If CMS determines that it must advance manufacturer payments in order to ensure that dispensing pharmacies are timely repaid for providing the MFP, it can establish procedures for making such advance payments and recovering funds from manufacturers. These advance funds could be paid through the Part D Account or through programmatic appropriations as contract costs.

670 Maine Avenue, SW • Suite 1000, Washington, DC 20024 • PHRMA.ORG

January 31, 2025

VIA Email Submission

Christina Ritter
Director
Centers for Medicare and Medicaid Services
Medicare Drug Rebate and Negotiations Group (MDRNG)

Re: Draft Medicare Transaction Facilitator (MTF) Agreements

Dear Director Ritter:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS, the Agency) on the draft Medicare Transaction Facilitator (MTF) agreements, which CMS released on December 17, 2024. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. Over the last decade, PhRMA member companies have invested more than $800 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States.[1]

Below, PhRMA provides comments and requests significant revisions across the draft Medicare Transaction Facilitator agreements with Manufacturers. In addition to this feedback, we encourage CMS to provide additional information and clarity as soon as possible on timelines for how manufacturers of selected drugs can test the systems developed by the Medicare Transaction Facilitator Data Module (MTF DM) and Payment Module (MTF PM). Early opportunities for systems testing will be crucial as manufacturers of selected drugs develop MFP effectuation plans and for the smooth effectuation of Maximum Fair Prices (MFPs) under the IRA. Based on the significant administrative, technical, and operational systems development required of manufacturers to interact with the MTF systems (and manufacturer obligations outlined in the draft agreements), we request that these early testing opportunities begin by May 2025 to help ensure successful effectuation of the MFP beginning January 1, 2026.

Of note, to the extent our comments on an agreement provision would apply to a substantially similar provision(s) in the same agreement or another agreement(s) (e.g., several termination provisions in the MTF DM Agreement are substantially similar to those in the MTF Program Agreement), CMS should read our comments as also applying to those other provisions.

More broadly, and as we have previously communicated with the Agency, PhRMA continues to believe that the best, least burdensome, and most efficient way to effectuate the MFP would be for CMS to utilize an approach similar to the Part D Coverage Gap Discount Program (CGDP), including pass-through of CMS pre-funded MFP refund amounts to dispensers on behalf of Primary Manufacturers at the time of claim adjudication. If CMS were to adopt this approach, the Agency likely would improve the efficiency of the program by eliminating the need for the development and review of MFP effectuation plans, as well as the need for dispensers to enter into agreements with the MTF and the need for manufacturers to develop cash flow mitigation plans.

[1] PhRMA. (August 16, 2024). 2024 PhRMA Annual Membership Survey. Available at: https://phrma.org/resource-center/Topics/Research-and-Development/2024-PhRMA-Annual-Membership-Survey

We recommend that CMS change course, implementing an approach similar to the CGDP and reissuing necessary draft agreements with more reasonable terms. We are happy to meet with CMS to discuss terms that might be more reasonable, reflecting each party's responsibility under the Program, while also ensuring that the Agency is not liable for MFP refunds, credits or debits that would not accord with the IRA or otherwise applicable law.

* * *

Table of Contents

* * *

I. CMS Violates Basic Contracting Principles

As an initial matter, and as discussed further in Section III below, the draft agreements are not contracts. CMS is seeking to impose legislative rules on manufacturers but label them as voluntary agreements. Even if these were contracts, across the draft agreements, CMS uses open-ended clauses in ways that violate fundamental canons of contract law. PhRMA has previously commented on this issue, noting that parties to a contract cannot be bound to "unknown terms which are beyond the ranges of reasonable expectation."[2] Even if the MTF agreements were the result of true negotiation (which, as PhRMA has consistently noted, they are not) the agency cannot incorporate an unknown guidance document or technical instruction into an agreement and then claim that a signatory has agreed to the later-adopted provisions. In an analogous context, CMS recognized that 'catchall' clauses that generically purport to bind the signatory to "all guidance ever issued by the Department" do not result in that subsequent guidance becoming legally binding.[3] Instead, "[i]f the government intends for a guidance document incorporated into a contract by reference to have independent legal basis, the government must make that intention clear through unambiguous language."[4]

Nevertheless, CMS continues to use open-ended clauses requiring manufacturers to agree to unknown terms. In the draft agreement between CMS and manufacturers, examples of these open-ended, significantly troubling clauses are noted below; this is not an exhaustive list, but rather, a highlight of some of the most egregious clauses:

- Section II(b) and (d) note, "When utilizing the MTF DM, Manufacturer shall comply with all requirements and conditions for MFP effectuation and CMS monitoring thereof, including, without limitation, all applicable CMS guidance, regulations, and technical instructions," and "Manufacturer shall comply with the MTF Data Module Contractor's and, as applicable, the MTF Payment Module Contractor's, instructions, processes, and requirements," without providing any contract mechanism for manufacturers to dispute improper, wrong or harmful contractor instruction, processes and/or requirements. It is particularly egregious for the federal government to bind a regulated entity to agree to abide by a government *contractor's* instructions; of note, such instructions do not yet exist, and as such, the Agency is asking manufacturers to blindly agree to such instruction at this time.
- Section V(b) seemingly grants CMS broad authority to request any information "necessary to" monitor compliance, without specifying exactly what that information is, or allowing for a period of comment as to whether requested information is "necessary" for monitoring compliance.
- Section X(a) states that CMS may "unilaterally amend" the MTF Program Agreement. Such amendments may "include" amendments that reflect changes in law, regulation, or "guidance," and are not limited to changes required by law. Moreover, the provision notes only that CMS will "endeavor" to provide 60 days' notice of an amendment. This is an overly broad amendment power. We recommend changes to the agreement occur only when required by a change of law, or upon the mutual agreement of both parties.

---

[2] *See* PhRMA comments on IPAY 2026 Initial Guidance at 16 (Apr. 14, 2023), available at: https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/G-I/PhRMA-Comments-on-CMS-Initial-Guidance-on-Medicare-Drug-Price-Negotiation-Program22948.pdf, *citing* Restatement (Second) of Contracts § 211 (1981).

[3] 85 Fed. Reg. 78,770-02, 78,779 (Dec. 7, 2020).

[4] *Id. See also* Advisory Op. 20-05 on Implementing *Allina*, HHS—2020-F-8163 (Dep't of Health & Hum. Servs., Off. of Gen. Couns. Dec. 3, 2020) (concluding that CMS may enforce contractual provisions incorporating guidance document "where those provisions, even if originally issued in the form of a guidance document, are expressly and specifically referenced as an obligation of the party to the contract or agreement.").

Examples of concerning open-ended clauses and vague terms in the draft agreement between Manufacturers and the MTF Payment Module Contractor are noted below:

- Section II(g) states, "Manufacturer shall comply with any instructions, processes, and requirements as directed by the MTF Payment Module Contractor." This again leaves manufacturers without any reasonable or corrective course for improper, wrong or harmful contractor instruction, processes and/or requirements. It also delegates improper authority to a government contractor.
- Section II(h) states, "Manufacturer shall utilize the MTF PM consistent with the Manufacturer's MFP Effectuation Plan and make any updates to the MFP Effectuation Plan within the timelines and in accordance with all requirements established by applicable guidance, regulations, and technical instructions." However, manufacturers do not have enough detail at this time to fully understand what requirements "established by applicable guidance, regulations, and technical instructions" entail. Holding manufacturers to an unknown expectation is unreasonable and beyond CMS' authority.
- Under Section VIII(e), CMS grants a non-governmental actor (a government contractor) overly broad, inherently governmental,[5] amendment power by stating, "The MTF Payment Module Contractor reserves the right to include additional provisions, requirements, or terms and the right to amend this Agreement as it deems necessary or appropriate for the administration of the MTF PM, on its own or at the direction of CMS, subject to applicable laws, guidance, or regulations and the prior approval of CMS. Any such provisions, once approved by CMS, shall be communicated in writing to the Manufacturer and incorporated into this MTF PM Agreement. As feasible, the MTF Payment Module Contractor will endeavor to provide the Manufacturer at least sixty (60) calendar day notice of any amendment to this Agreement." As noted above, contract amendments should occur only when required by law or based on mutual consent of the parties.

PhRMA requests that CMS expeditiously revise the draft agreements to provide clear terms consistent with canons of contract law.

II. CMS Exceeds Statutory Authority

PhRMA reiterates the fact that the price setting authority under the IRA is so overly broad that it amounts to an unconstitutional delegation of legislative authority. For example, CMS has arbitrarily offered conflicting interpretations of what entities qualify as a "manufacturer" subject to price setting—imposing vicarious responsibility and liability on Primary Manufacturers for the information and actions of unrelated corporate entities that the Agency deems "Secondary Manufacturers," while simultaneously asserting that only a subsidiary corporation listed on an FDA application (and not a parent entity) has standing to sue.[6] In this way, CMS has quickly demonstrated how unconstrained it views its authority. Indeed, CMS has even told a federal court that it is empowered to misread statutory language that is "clear as a bell," without any opportunity for judicial review.[7] Now, CMS seeks to require that Primary

[5] Government contracts "shall not be used for the performance of inherently governmental functions." Federal Acquisition Regulations, 48 C.F.R. § 7.503(a). Determination of agency policy, "such as determining the content and application of regulations, among other things" is an inherently governmental function. *Id.* § 7.503(c)(5).

[6] *Merck v. Becerra*, Case No. 1:23-cv-01615 (D.D.C.), ECF No. 24 at 19-20 (arguing lack of standing due to a subsidiary holding the NDA for the selected drug); *Dayton Area Chamber of Comm. v. Becerra*, Case No. 3:23-cv-00156 (S.D.Ohio), ECF No. 71 at 13-14 (arguing that Pharmacyclics, a subsidiary of AbbVie, is the only entity harmed by price setting).

[7] *AstraZeneca v. Becerra*, Case No. 1:23-cv-00931, Tr. Oral Argument at 99-100 (D. Del. Jan. 31, 2024) ("THE COURT: Let's say this is. I read the statute. It's clear as a bell . . . So let's just say I agree with AstraZeneca on that. When would a drug company be able to challenge your designation of its blockbuster product? Let's say it only makes one product. When can it do that? MR.

Manufacturers ensure that any Secondary Manufacturer comply with the draft MTF agreements. This language in the draft agreements continues the Agency's conflicting guidance and is a clear example of Agency overreach via guidance documents.

The draft agreements are rife with additional examples of Agency overreach. The clauses noted below are illustrative, but not exhaustive, examples of such overreach from the draft MTF Program Agreement:

- In Section II(f), CMS requires that not only CMS, but also its "agents, designees or contractors" or "any other authorities representatives of the United States Government, or their designees or contractors" must have access to all records the manufacturer creates or receives in connection with the MTF at "such times, places, and in such manner as such entities may reasonably request for the purposes of audits, inspections and examinations." However, there is no exception for proprietary information. The statute requires that manufacturer proprietary information is to be used only by the Secretary, or in select cases the GAO, to carry out Part E of Title XI, and not for any other purpose. Entities outside of HHS or GAO are not authorized to access the proprietary information per IRA restrictions. *See* § 1193(c) of the Social Security Act ("SSA").
- Section II(j)(1) overstates a manufacturer's obligation to utilize the MTF PM ("shall typically use the MTF PM for all its selected drugs"). This is Agency overreach and not stated in final guidance; manufacturers reserve the right to use the MTF PM on a drug-by-drug basis, if they so choose.
- Section II(j)(4) states that a manufacturer that uses the MTF PM must authorize the PM to send a dispensing entity a payment "equal to the total refunds to be paid as indicated in the Manufacturer's reported claim-level payment elements, *regardless of any credits which may be applied under the Ledger System*," (emphasis added). This statement implies that manufacturers are required to <u>pay more</u> than obligated under statute. Further, it goes against long-standing common law principles. As the Supreme Court has emphasized, "The right of setoff (also called 'offset') allows entities that owe each other money to apply their mutual debts against each other, thereby avoiding 'the absurdity of making A pay B when B owes A.'"[8]
- Under Section II(k), CMS seeks to require that a new owner of a drug is responsible for subsequent adjustments to prior MFP refunds and that this applies "notwithstanding that the effective date" of the ownership transfer may occur "before the effective date" of the MTF Agreement.
- Section III(g) includes a provision that "in its sole discretion," CMS may use information "related to this Agreement," including "without limitation, information generated by the Manufacturer," and disclose such information to "law enforcement and regulatory authorities" to "promote compliance with the statutes, regulations and written directives of Medicare, Medicaid and all other Federal health care programs." *See the above discussion of 1193(c) on page 6 under the first bullet point* as CMS cannot use manufacturer proprietary information for any purpose other than price-setting, and such information is to be used "only by the Secretary" (or GAO).

NETTER: So it wouldn't be able to, Your Honor. THE COURT: Ever? MR. NETTER: Ever? Well, unless they could try to convince Congress to change the statutory bar. But it's Congress' prerogative. THE COURT: That doesn't bother you, that you could have -- again, imagine it was, again, that there was no other ambiguity in the statute to shed doubt on AstraZeneca's interpretation. So you're saying that an Agency can come along and can issue a regulation that absolutely contradicts the explicit statutory text of Congress? And here -- and you're saying, tough noogies, there's no review? MR. NETTER: That is the outcome of the standard analysis on judicial bars.").

[8] *Citizens Bank of Maryland v. Strumpf*, 516 U.S. 16, 18 (1995) (quoting <u>*Studley*</u> *v. Boylston Nat'l Bank*, 229 U.S. 523, 528 (1913)).

- Under Section VI(a) and Exhibit A(b)(1)(i), CMS claims it and the MTF government contractor(s) can use proprietary information "as otherwise required by law." But section 1193(c) of the SSA does not contain this provision, and CMS does not explain what it would mean for a disclosure to be "otherwise required by law," or whether it would litigate to protect such proprietary information. Further, it is not clear what CMS means by its statement that the restriction does not limit the OIG from using proprietary information to "fulfill the Inspector General's responsibilities." The HHS-OIG is part of HHS, and the IRA limits all of HHS from using information in ways that are beyond carrying out Part E of Title XI.
- Under Sections VI(d); VII(b); VIII(d)(9), CMS cites no authority for extending manufacturer compliance obligations once a manufacturer does not renew or terminates the Agreement(s).
- Much of the disclaimer section in Part IX is patently unreasonable. Subsections (a)-(j) should be struck in their entirety, with the provisions in (b), (c), and (e) being particularly objectionable. All such provisions extend beyond what CMS has included in prior agreements, such as the CGDP and Manufacturer Discount Program Agreements. CMS seeks to impose liability on manufacturers (including requiring indemnification in IX(c)), but then disclaims any liability for its own actions (including negligence). CMS cites no authority for these additional provisions. In IX(e), CMS states that no legal theory will support a claim against CMS for any indirect, special, incidental, or consequential damages, including a tort claim, but cites no exception to the Federal Tort Claims Act or any otherwise applicable law that would support this statement.

Moreover, an additional example of Agency overreach from the draft MTF PM Agreement is under Section V(b) in which CMS states that the MTF PM Contractor can decide what is proprietary, as submitted by the Manufacturer. That is beyond the terms of the statute, which permits only HHS to make that decision. See above comments regarding "otherwise required by law." The draft MTF DM Agreement includes a similarly flawed provision under Section V(b).

III. Draft Agreements Underscore Lack of True Negotiation Terms

The IRA and CMS label government price setting as "negotiation." Indeed, CMS' IPAY 2027 Guidance used the term "negotiation" nearly 400 times. But simply repeating the word does not make it true. In reality, the IRA provides for highly limited exchanges between manufacturers of selected drugs and CMS. As noted by those with experience in the negotiations that occur between insurance companies and biopharmaceutical manufacturers in the private sector, the Drug Price Negotiation Program (DPNP) in no way resembles such negotiations, and should not be mistaken for such.[9] Put simply, CMS has the unilateral, nearly unconstrained authority to both set any price it wishes below a statutory ceiling and impose severe penalties on manufacturers who do not agree to the CMS-set price, with little-to-no transparency on how CMS reached this price in the first place.

The draft MTF agreements are further evidence that the price-setting program is a coercive program. CMS has included terms in the draft agreements that no party truly negotiating an agreement would ever accept. For example, the draft MTF Program Agreement, under Section IV, conceivably binds manufacturers to penalties of $1 million per day[10] for failing to comply with still unknown Agreement

[9] Shah S. (June 20, 2024). Here are four reasons Medicare drug-price 'negotiation' in NJ isn't truly a negotiation. Courier Post. Available at: https://www.courierpostonline.com/story/opinion/2024/06/13/medicare-drug-price-negotiation-in-nj-isnt-truly-a-negotiation/73896264007/.

[10] Presumably penalties could reach $1 million/day given that Section IV cites to section 1193(a)(5) of the Social Security Act. *See* SSA § 1197(c).

provisions, such as those that may subsequently be included in forthcoming "technical instructions." A true and reasonable negotiation agreement would never include such punitive and unchecked penalties.

As a second example, the Section IX disclaimers under the MTF Program Agreement insulate only one side of the so-called "agreement" – CMS – from liability, even where the Agency is at fault, and further impose liability on a manufacturer when the manufacturer is not at fault. CMS includes terms stating it has no responsibility or liability. CMS states that the manufacturer must indemnify CMS from all "liability, loss, damage costs or expenses" and that this is the case even when the loss is caused by "negligent action, inaction, or willful misconduct" of government contractors (such as the MTF DM or PM) or even dispensing entities. Manufacturers, however, do not have insight into the terms governing such contractors, meaning that manufacturers could be liable for government contractor responsibilities where the terms governing such responsibilities remain proprietary. As noted above, Section IX is almost entirely unreasonable, demonstrates how the DPNP does not represent true and good faith negotiations between two parties, and extends beyond provisions in prior agreements, such as the CGDP or Manufacturer Discount Program Agreements.

In further examples, only one party is empowered to terminate the MTF Program Agreement – CMS. Section VIII(d) states: "CMS is the sole party with the authority to terminate this Agreement." And while CMS may unilaterally amend the Agreement, the Manufacturer must attest that it has made no "alterations, amendments or other changes to this MTF Program Agreement." *See* X(a) and XI(d) of the MTF Program Agreement.

IV. CMS Abandons Good Stewardship of Program Responsibilities

Lack of Fair Dispute Process

The draft MTF agreements with manufacturers are evidence that CMS intends to abandon a governmental responsibility to carry out the program to ensure a level playing field and equitable treatment for all parties involved. For example, the draft MTF Program Agreement states that while a manufacturer cannot rely on the MTF entity for disputes with pharmacies or to recover overpayments, manufacturers face potentially destructive civil monetary penalties for complaints filed by dispensing entities.

In the MTF Program Agreement under Section II(j)(6)(iii) CMS states that if a manufacturer terminates its participation in the "Negotiation Program" altogether, or if the manufacturer stops participating in the MTF PM, it is nevertheless incumbent upon the manufacturer to obtain any outstanding credits from pharmacies. CMS will not treat the credits as "unclaimed funds." Further, CMS states that credits are not within the scope of the dispute or complaint process and "must be taken up directly with the applicable dispensing entities." This is an irrational and unreasonable position for CMS to take; it is incumbent upon CMS to provide a fair and rational dispute process to administer disputes between pharmacies and manufacturers and to treat credits as within the scope of that process.

Deduplication of Discounts

PhRMA continues to have significant concerns with a lack of action by both CMS and the Health Resources and Services Administration (HRSA) to play a role in identifying Part D claims subject to an agreement under Section 340B of the Public Health Service (PHS) Act (340B-eligible units). As previously communicated with the Agency, PhRMA strongly believes that identifying 340B-eligible units through a clearinghouse and through the use of mandatory 340B and non-340B claim modifiers with

accountability for 340B covered entities (CEs) would be the best approach to identify claims involving 340B-eligible units and would represent the best approach to efficiently prevent duplicate discounts.

However, in light of CMS's position that it "will not, at this time, assume responsibility for deduplicating discounts between the 340B ceiling price and MFP" and will not require dispensers to indicate to Primary Manufacturers which selected drug claims are for 340B-eligible units,[11] PhRMA urges HHS to recognize Primary Manufacturers' good faith efforts to deduplicate these discounts. Providing 340B pricing through rebates, instead of continuing to rely on the opaque replenishment model, is one approach that could decrease the risk of340B-MFP duplicate discounts. Rebates are commonly used in federal health care programs, and their use here would be a common-sense approach to prevent 340B-MFP duplicate discounts, ultimately ensuring compliance with the IRA statute, while also providing critical improvements in 340B program transparency and integrity. HRSA's position on manufacturers' 340B rebate policies under the Biden Administration was untenable, as PhRMA stated in an October 11, 2024 letter to HRSA,[12] and served to further enshrine rent-seeking behavior by 340B covered entities and middlemen. We urge the Trump Administration to support, not impede, manufacturer implementation of various payment models, including 340B rebates, that improve transparency and help ensure compliance with statutory requirements.

In lieu of 340B rebates, the CMS and HRSA must appreciate that the prevailing 340B replenishment model presents significant challenges in appropriately identifying individual prescription claims that are the basis for CE replenishment requests at the applicable 340B price, and CEs have historically not always been cooperative partners with manufacturers in identifying 340B-eligible units and resolving duplicate discounts.

In any case, a Primary Manufacturer should not be subject to an HHS enforcement action under the IRA or section 340B if the Primary Manufacturer can demonstrate it has engaged in reasonable, good faith efforts to fulfill the manufacturer's obligations under section 1193 of the SSA and section 340B(a)(1) of the Public Health Service Act, as applicable.

V. Draft Agreements Lack Consistent, Clear, and Rational Policies

Across the draft MTF agreements with manufacturers, in numerous instances, the Agency seeks to hold manufacturers responsible for terms and conditions that are neither clear, consistent, nor rational.

Specifically, Section V of the draft MTF Program Agreement provides strict instructions for manufacturers to retain records for 10 years, yet later under Part V(d)(5), the draft agreement states manufacturers have to destroy claim-level data elements and provide certification of such destruction upon termination. Section (b)(2)(vi) of Exhibit A also potentially conflicts with such destruction requirement, holding that a Manufacturer must retain CMS data for up to 10 years, and may retain the data beyond the 10-year timeframe in certain scenarios. Manufacturers must be able to retain claim-level data elements upon termination for ten years if instances of disputes, audits or other necessary events

[11] "CMS is not mandating that dispensing entities add a 340B claim indicator to claims at this time. The 340B claim indicator data element passes through information on the 340B status of a claim that the dispensing entity voluntarily provides. Neither CMS nor the MTF DM will verify that a claim was or was not billed as a 340B-eligible drug." Final IPAY 2027 Guidance, at 54.
[12] "PhRMA urges HRSA not to impede new 340B pricing approaches to improve transparency and integrity." October 18, 2024. Accessed via: https://phrma.org/Blog/PhRMA-urges-HRSA-not-to-impede-new-340B-pricing-approaches-to-improve-transparency-and-integrity#:~:text=PhRMA's%20letter%20detailed%20persistent%20abuses,transparency%20and%20improve%20program%20integrity.

arise. Manufacturers also are obligated to shareholders and investors to exercise due diligence and ensure that the refunds paid are actually owed, and to retain documentation to support these payments. PhRMA has also previously commented on obligations under the Sarbanes Oxley Act for pharmaceutical companies that file reports containing financial information with the Securities and Exchange Commission.[13]

In addition, in numerous instances across the draft agreements, for example under Section VI(a) of the MTF Program Agreement, CMS states that it will not disclose information deemed proprietary. However, the draft agreements provide no process for manufacturers to indicate which data they believe are proprietary nor recourse for manufacturers if proprietary data are released. As noted above, CMS' MTF DM and PM Agreements would even conceivably allow government contractors to make inherently governmental determinations as to which data are proprietary and can be released. It is critical to the business interests of the manufacturers that CMS modify the Agreements to allow manufacturers to identify proprietary information and challenge any potential release of such data prior to release.

Moreover, CMS is inconsistent in its approach to the MFP refund process and requirements. Across the draft agreements with manufacturers, the Agency repeatedly states it is the manufacturer's responsibility to provide access to the MFP[14]; however, CMS seeks to bind the manufacturer to ever-more onerous terms through multiple agreements and information collections under threat of destructive penalties.

CMS' brief notification window for termination of the MTF is also inappropriate. Under Section VIII(d)(1) of the draft MTF Program Agreement, CMS states, "CMS may terminate this Agreement if CMS determines it will no longer provide the MTF as a service to manufacturers and dispensing entities. CMS shall provide the Manufacturer with at least one hundred eighty (180) calendar day notice prior to the effective date of termination pursuant to this section VIII(d)(1)." Such a change would create significant disruption to the process of providing access to the MFP, particularly if the date of termination falls within a Part D plan year. PhRMA urges CMS to extend this timeline to 365 calendar days and to only be effective at the start of a Part D plan year in order to ensure manufacturers have sufficient time to adjust contracting, business, and operational systems. Manufacturers will spend considerable time and resources to work with the MTF and will require reasonable and rational timelines to create entirely new systems if CMS terminates the MTF. If CMS stops operating the MTF PM without adequate notice, not only manufacturers, but pharmacies and other supply chain entities, will experience disruption in how the MFP refunds are received – and such disruption would take significant lead time to address.

Finally, under Exhibit A to the MTF Program Agreement, a number of provisions are misguided and inappropriate. We offer comments on two of these provisions:

- (b)(2)(vii). This provision states that the Manufacturer "must" implement administrative, technical, and physical safeguards that comply with the HIPAA Security Rule. (b)(2)(viii) also mentions HIPAA Privacy and Security. The HIPAA regulations are not applicable to pharmaceutical manufacturers in the MFP context (and generally, are not applicable to them at all). Under the HIPAA regulations, CMS clearly has authority to disclose Protected Health Information (PHI), as defined in the HIPAA rules (45 C.F.R. § 160.103) to pharmaceutical manufacturers for MFP rebate payment purposes because that is a

[13] https://www.regulations.gov/comment/CMS-2010-0196-0032 (citing Pub. L. 107-204, 116 Stat. 745 (2002) §§ 302, 404, 906).
[14] Draft MTF Program Agreement, under II. (a) "Manufacturer shall utilize the MTF DM to provide access to the maximum fair price (MFP) for the selected drug(s) to pharmacies, mail order services, and other dispensing entities with respect to MFP-eligible individuals who are dispensed such drug(s)."

disclosure for purposes of "payment."[15] The HIPAA regulations contain no requirement that CMS impose privacy or security obligations on a manufacturer that receives PHI for such purposes. We object to the erroneous implication that the HIPAA regulations apply, or that CMS can impose HIPAA obligations under its IRA authority.

    - The most appropriate approach would be to make the Data Use Provisions consistent with the Manufacturer CGDP Agreement and the Manufacturer Discount Program Agreement, which provide that "the Manufacturer agrees to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the CMS Data and to prevent unauthorized use [of] or access to it."

- (b)(2)(xi) should be revised to allow Manufacturers to link records to comply not just with section 1193(d)(1), but also section 340B of the Public Health Service Act and to ensure that the MFP refunds are appropriately paid (for example, that MFP refunds are not paid on ineligible dispenses). We recommend that the first sentence be amended to add at the end: ", to ensure compliance with section 340B of the Public Health Service Act, or to ensure MFP refunds are appropriately claimed and paid."

VI. The Agreements Should Be Issued through Notice and Comment, in the Federal Register, and the Terms of the Agreement Are Subject to Judicial Review

Although CMS attempts to engineer a release from "all claims, demands, and damages," and to forestall any liability to the Manufacturer under "any legal theory," CMS cannot evade judicial review by including terms in an agreement (*see* IX.(b) and (e) of the MTF Program Agreement). Courts have historically prohibited agencies from seeking to evade judicial review of agency actions merely by incorporating agency actions into contracts and arguing that the party "agreed" to the policies.[16] This is particularly the case with the MTF Agreements, which are contracts of adhesion where manufacturers have no ability to negotiate the terms, CMS can unilaterally amend the terms, and only one party has the authority to terminate. CMS cannot limit judicial review of agency policies merely by incorporating those policies into the agreement, including review under the Administrative Procedure Act (APA)[17] and section 1871 of the Social Security Act.

---

[15] *See, e.g.*, FAQ 455, stating: " The Privacy Rule permits a health plan to disclose protected health information, such as prescription numbers, to a pharmaceutical manufacturer for purposes of adjudicating claims submitted under a drug rebate contract." https://www.hhs.gov/hipaa/for-professionals/faq/455/does-hipaa-permit-health-plans-to-disclose-information-to-pharmaceutical-manufacturers/index.html. *See also* FAQ 456-Does the Privacy Rule permit state Medicaid agencies to disclose protected health information to pharmaceutical manufacturers | https://www.hhs.gov/hipaa/for-professionals/faq/456/does-hipaa-permit-state-medicaid-agencies-to-disclose-information-to-pharmaceutical-manufacturers/index.html.

[16] For example, the D.C. Circuit addressed a contract providing that "[a]ll rulings and interpretations of the Davis–Bacon and Related Acts contained in 29 CFR parts 1, 3, and 5 are herein incorporated by reference in this contract." Invoking the strong presumption of reviewability under the APA, the court rejected the argument that this contractual provision "forecloses all judicial review of the validity of the Secretary's regulations when those regulations are later applied to a particular contractor in an adjudicatory setting." *Ball, Ball & Brosamer, Inc. v Reich*, 24 F.3d 1447, 1450 (D.C. Cir. 1994). The court observed that "[s]uch an attempt to limit judicial review runs counter to the fundamental principles of reviewability underlying the Administrative Procedure Act." *Id. See also Nat'l Park Concessions, Inc. v. Kennedy*, No. CIV. A-93-CA-628 JN, 1996 WL 560310, at *11 (W.D. Tex. Sept. 26, 1996) (rejecting arguments that interpretive rules were incorporated into a contract); *McBride Cotton & Cattle Co. v. Veneman*, 296 F. Supp. 2d 1125, 1136 (D. Ariz. 2003) (regulations may be challenged if the federal government "insists" on contract incorporation of its regulations to shield the regulations from administrative challenge" or the regulation is *ultra vires*).

[17] 5 U.S.C. § 553 *et seq.*

Further, under section 1871 of the Social Security Act, CMS is required to engage in a notice-and-comment process, in the Federal Register, to impose mandatory substantive legal standards on Primary Manufacturers. Although the IRA directs CMS to use "guidance" in the initial years of the program,[18] the Supreme Court has held that guidance refers to an agency's non-binding statements of its views.[19] If CMS wishes to adopt substantive legal standards (such as those included in the disclaimers and other provisions of these Agreements), it is, at a minimum, required to comply with the notice-and-comment requirements of section 1871.[20] Instead, CMS has requested comment on its draft agreements solely via email and posting on the CMS website. CMS has not published its policies in the Federal Register, explained the statutory basis and purpose of its policies, explained why its requirements are not arbitrary/capricious, or otherwise committed to respond to comment.

VII. Miscellaneous

PhRMA encourages CMS, under Section II(i)(3) of the draft MTF Program Agreement, to restart the 14-day payment window when there is an adjustment to a claim, particularly if the adjustment significantly lowers the MFP refund.

Moreover, the draft agreements with manufacturers should include provisions to account for cases in which the system is not operating in accordance with usual business standards, through no fault of the manufacturer, and relevant deadlines should be accordingly extended (e.g., the 14-day payment window; the 30-day window to update enrollment information).

PhRMA strongly encourages CMS to include a hold harmless provision that would allow a manufacturer that complies with MTF DM and PM requirements to be deemed to have provided access to the MFP.

PhRMA agrees with the provision in the draft MTF Program Agreement under Section IX(l) that the Agreement's terms are not enforceable by third-party beneficiaries.

Furthermore, PhRMA encourages CMS to provide access to the credit/debit ledger system to manufacturers that choose to utilize alternative arrangements outside the MTF PM to provide access to the MFP. Because manufacturers using alternative arrangements will still be reporting claims-level payment information to the MTF DM, this information can be used to populate a simple, non-dynamic credit/debit record system. While we understand this simple version of the credit/debit ledger system could not be used to alter payments for manufacturers utilizing alternative arrangements, it will still be useful to manufacturers in having a central record of payments within the MTF system.

Additionally, to lessen the burden on all stakeholders in the supply chain, PhRMA recommends that CMS aggregate or batch complaints and disputes for dispensers by parent organization or by Pharmacy Services Administrative Organization (PSAO) for dispensers participating in a PSAO. With over 80,000 dispensing entities in the United States,[21] allowing disputes from individual dispensers could quickly lead to an unmanageable volume. Aggregating or batching complaints and disputes would lessen the volume of separate disputes and improve efficiency.

---

[18] Inflation Reduction Act § 11002.
[19] *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92 (2015).
[20] *Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019) (holding that the concept of a "substantive legal standard" under the Social Security Act is somewhat broader than the concept of a substantive rule under the APA).
[21] 89 Fed. Reg. 99340, 99444 (Dec. 10, 2024) https://www.federalregister.gov/documents/2024/12/10/2024-27939/medicare-and-medicaid-programs-contract-year-2026-policy-and-technical-changes-to-the-medicare.

Finally, PhRMA seeks clarification regarding the application of these draft MTF Program agreements to future implementation of the "Negotiation Program." Specifically, we request that CMS immediately clarify that these draft agreements do not apply to MFP effectuation for Part B selected drugs, as CMS has previously stated in IPAY 2027 Guidance that, "Part B reimbursement as it relates to the IRA is outside the scope of this final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 and will be addressed in future guidance or rulemaking, as appropriate."[22] It is critical that since CMS has asked manufacturers to wait until future guidance to discuss broader MFP Part B implications, that CMS also ensure that applicable manufacturers have an opportunity to review the MTF agreements after the release of such future guidance (e.g., IPAY 2028 guidance). We also request that CMS acknowledge that manufacturers will have an opportunity to provide comment, via a notice-and-comment process (as described under Section VI of this letter), on draft agreements for MFP effectuation for Part B selected drugs following finalization of IPAY 2028 guidance or such other CMS guidance that includes details pertaining to MFP effectuation for Part B selected drugs.

* * *

On behalf of PhRMA and our member companies, thank you for consideration of our comments. Should you have any questions, please feel free to reach out to us at the email addresses below.

/s/ Kristen Soderberg Bernie
_____
Vice President
Policy and Research
kbernie@phrma.org

/s/ Judy Haron
_____
Deputy Vice President
Law
jharon@phrma.org

[22] Final IPAY 2027 Guidance, at 158.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

January 31, 2025

The Honorable Jeff Wu
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Submitted via email: IRARebateandNegotiation@cms.hhs.gov

Re: MTF Agreements Feedback

Dear Acting Administrator Wu:

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment on the Center for Medicare and Medicaid Services' (CMS) draft Manufacturer-CMS Agreement, Manufacturer-MTF Payment Module Contractor Agreement, Dispensing Entity-CMS Agreement, and Dispensing Entity-MTF Data Module Contractor Agreement for the Manufacturer Drug Price Negotiation Program ("Negotiation Program").

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists, across the country. Additionally, they fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability.

Pharmacies are facing a crisis due to escalating reimbursement challenges, especially in Medicare Part D. **These challenges stem from 1) below-cost reimbursements by insurer-PBMs, 2) insurer-PBM consolidation and patient steering to affiliated pharmacies, and 3) egregious PBM schemes like quality measures and cost-plus models that financially strain neighborhood pharmacies**. The absence of comprehensive PBM reform worsens these issues, affecting patient access, pharmacy sustainability, healthcare costs, and the pharmacy's goal to support overall health and wellness. Insurer-PBMs' opaque practices, including unfair reimbursement and misuse of performance measures in Medicare, inflate drug prices, restrict medication access, increase healthcare costs, lead to prescription abandonment, and reduce competition in healthcare.

NACDS urges CMS to consider the challenges chain pharmacies already face as you review our comments and finalize the draft agreements.

1. NACDS Comments on the Dispensing Entity-CMS Agreement

Section III. CMS' Responsibilities

Page 5:

After (a), NACDS requests that CMS add a new paragraph (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."

NACDS believes that this paragraph is crucial for program integrity and to protect from overburdening Dispensing Entities.

Section IX: Disclaimers

Page 9:

(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.

NACDS urges CMS to strike the above clause (c) that would require the Dispensing Entity and, as applicable, any third-party support entity utilized by the Dispensing Entity, to indemnify CMS against any liability arising out of or in connection with any negligent action, inaction, or willful misconduct not only of the Dispensing Entity, but also of the MTF Data Module Contractor, the MTF Payment Module Contractor, and drug manufacturers. Dispensing Entities cannot reasonably indemnify CMS for actions of the MTF Data Module Contractor and the MTF Payment Module Contractor, both of which are contractors of CMS, or for actions of drug manufacturers, over which the Dispensing Entities have no control. We would note that indemnification and broad disclaimers were not required for the COVID-19 vaccine agreements with CDC.

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.

(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).

NACDS believes that manufacturers should be required to participate in the MTF PM. We fail to understand the logic of CMS having the authority to require manufacturers to participate in the MTF DM but not the MTF PM.

Moreover, not requiring manufacturers to participate in the MTF PM will impose unreasonable burdens on pharmacies, which may have to enter into financial arrangements with many different manufacturers.

Page 10:

(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.

As we have commented to CMS extensively, even though Congress has made clear that manufacturers are responsible for implementing the Negotiation Program, and that pharmacies should not be impacted negatively, CMS is planning to implement the Negotiation Program in a manner that requires pharmacies to pre-fund the very refund they will receive. In other words, pharmacies will have to provide a financial float in order to make the program work. The Inflation Reduction Act (IRA) does not provide CMS with the authority to require this of pharmacies. Pharmacies will face untenable financial burdens unless CMS prefunds the Negotiation Program or requires manufacturers to prefund the program.

Section X. General Provisions

Page 11:

(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.

The draft provides that CMS may unilaterally amend the agreement, and that as feasible, CMS will endeavor to provide the Dispensing Entity at least sixty calendar days' notice of any such amendment. NACDS urges CMS to provide prior notice of an amendment, not only will it "endeavor to." Prior notice of an amendment should be required, not optional. "Endeavoring to provide" does not provide pharmacies with adequate protections and is reminiscent of PBMs' one-sided, "take-it-or-leave-it" contracts.

Page 12:

(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.

NACDS urges CMS to clarify the definition of MFP, as it seems vulnerable to post-adjudication clawbacks like DIR. In its final guidance, CMS did not regulate PBM payments to pharmacies for MFP drugs, nor fair reimbursements or

dispensing fees. In fact, CMS stated that Part D plans might reimburse at or below MFP plus a dispensing fee, allowing PBMs to pay less than MFP and exclude dispensing fees.[1] NACDS seeks pharmacy reimbursement to include: 1) a negotiated price no lower than MFP, and 2) coverage of acquisition costs plus a professional dispensing fee consistent with Medicaid fee-for-service, paid within Medicare prompt pay requirements.

Exhibit A – Data Use Provisions

Page 14:

(b)(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, 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.

NACDS recommends that CMS remove this text, as Dispensing Entities will use this data for other purposes such as uploading it to pharmacy management systems, switches, and PBMs.

Page 15:

(b)(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.

The draft language would require Dispensing Entities to destroy any MTF data after ten years, unless such data are the subject of an unresolved audit, government investigation, or litigation, or if required by another applicable law. NACDS urges CMS to reconsider this ten-year destruction requirement. It is unclear why Dispensing Entities would not be permitted to keep this data, and requiring them to destroy it would be unnecessarily burdensome. Dispensing Entities would need to create whole new processes for this data to ensure it follows this destruction requirement even though the data would remain protected by HIPAA privacy and security rules and the confidentiality provisions of this agreement.

(b)(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

[1] 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.

Entity without advance written approval from CMS unless such movement, transmission, or disclosure is required by a law.

Section (b)(7) of Exhibit A is problematic for chain pharmacies because it requires the Dispensing Entity (or any Third-Party Support Entity) to agree 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. With respect to Third-Party Support Entities, we are concerned that such entities cannot feasibly agree to meet this requirement. It should be sufficient so long as the parties comply with the confidentiality requirements of the agreement and HIPAA privacy and security rules. Imposing these additional obligations on pharmacies and their vendors with respect to the data is unreasonably burdensome and unnecessarily restrictive.

Page 16:

(b)(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.

Having to notify CMS about a breach or security incident involving MTF data within one hour of discovery is unreasonable and without parallel or precedence. NACDS questions the need to provide additional reporting beyond what is reported to the Office for Civil Rights (OCR) and individuals subject to a breach under the HIPAA privacy rules with respect to protected health information (PHI). Any reporting to CMS should be limited to breaches of the confidentiality requirements and should not encompass privacy breaches and security incidents.

However, if privacy breaches and security incidents are required to be reported, and for breaches of the confidentiality requirements, CMS should follow the HIPAA reporting requirement for the reporting of breaches, which is within 60 days of discovery; we believe this is a more realistic timeframe. In the alternative to a 60-day reporting requirement, we would urge a reporting requirement of no fewer than three days, as this is the industry standard for reporting breaches and security incidents. We would also note that we are not aware of any reporting requirement more promptly than within 24 hours of discovery.

(b)(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)

Again, NACDS is concerned about the provisions of Section (b)(11), which requires that pharmacies comply with additional information security policies. As we have stated above, following HIPAA privacy and security rules and complying with confidentiality requirements of the agreement should be sufficient.

Page 17:

(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.

The draft 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. NACDS 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. NACDS urges CMS to delete clause (b)(12). Implementing requirements above and beyond the requirements of HIPAA is unnecessarily burdensome and unnecessary to protect the privacy and security of MTF data.

2. <u>NACDS Comments on Dispensing Entity- MTF Data Module Contractor Agreement</u>

As a threshold matter, NACDS requests that CMS include an indemnification clause in this agreement to protect pharmacies from any fault or negligence on the part of the MTF DM contractor. Pharmacies should be protected for any downstream claims or consequences of the data they provide being illegally accessed or used. NACDS requests that CMS include the following clause in this agreement:

"The MTF Data Module Contractor shall indemnify and hold harmless the Dispensing Entity 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."

Section III. MTF DATA MODULE CONTRACTOR'S RESPONSIBILITIES

Page 5:
To best protect pharmacies in this program, NACDS proposes 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 should also provide a means by which Dispensing Entities can dispute issues arising under this Agreement and the Service Legal Agreement (SLA). Consequently, NACDS 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.

Section V. CONFIDENTIALITY AND DATA USE

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

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 chain pharmacies.

Section VIII. GENERAL PROVISIONS

Pages 6-7:

(d) Additional Provisions and Amendments. The MTF Data Module Contractor reserves the right to include additional provisions, requirements, or terms, and the right to amend this Agreement as it deems necessary or

appropriate for the administration of the MTF DM, on its own or at the direction of CMS, subject to applicable laws, guidance, or regulations and the prior approval of CMS. Any such provisions, once approved by CMS, shall be communicated in writing to the Dispensing Entity and incorporated into this MTF DM Agreement. As feasible, the MTF Data Module Contractor will endeavor to provide the Dispensing Entity at least sixty (60) calendar day notice of any amendment to this Agreement.

The draft provides that the MTF DM on its own or at the direction of CMS may unilaterally amend the agreement, and that as feasible, the MTF DM will endeavor to provide the Dispensing Entity at least sixty calendar days' notice of any such amendment. NACDS urges that the MTF DM be required to provide prior notice of an amendment, not only will it "endeavor to." Prior notice of an amendment should be required, not optional. "Endeavoring to provide" does not provide pharmacies with adequate protections and is reminiscent of PBMs' one-sided, "take-it-or-leave-it" contracts.

Page 7:

(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.

NACDS suggests CMS explore mediation or arbitration for resolving disputes over improper payments, cybersecurity incidents, and other issues without full litigation.

(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.*** *(emphasis added)*

NACDS argues that Maximum Fair Price (MFP) is not clearly defined in the statute. We believe MFP excludes DIR or similar fees, but CMS has not confirmed this. NACDS asserts that CMS must clarify what constitutes MFP, as it may involve post-adjudication clawbacks like DIR. In its final guidance, CMS did not regulate PBM payments to pharmacies for MFP drugs, including reimbursement and dispensing fees. Rather, CMS stated Dispensing Entities might be reimbursed below MFP plus a dispensing fee, allowing PBMs to pay less than MFP and exclude dispensing fees. NACDS urges that pharmacy reimbursement should include a negotiated price no lower than MFP, cover acquisition costs plus an appropriate dispensing fee, and adhere to Medicare prompt pay requirements.

3. NACDS Comments on the Manufacturer-CMS Agreement

General Comments: As mentioned above, NACDS believes that manufacturers should be required to participate in the MTF PM. We fail to understand the logic of CMS having the authority to require manufacturers to participate in the MTF DM but not the MTF PM. Moreover, not requiring manufacturers to participate in the MTF PM will impose unreasonable burdens on pharmacies, which may have to enter into financial arrangements with many different manufacturers.

II. Manufacturer Responsibilities

Page 4:

(i)3. When claim-level data elements are sent for an adjusted claim, transmit complete and accurate claim-level payment elements to the MTF DM within the 14-day prompt MFP payment window that begins with the date of MTF DM transmission to the Manufacturer of the claim-level data elements for the adjusted claim. The existence of an adjusted claim does not affect the Manufacturer's obligation to respond to the original claim within the 14-day prompt MFP payment window even if the claim-level data elements for the adjusted claim are sent to the Manufacturer during the original claim's 14-day prompt MFP payment window, though the Manufacturer's claim-level payment elements sent in response to the original claim may incorporate information from the adjusted claim and the Manufacturer may provide a response to the adjusted claim that indicates payment was provided on the original claim.

NACDS supports this provision as it relates to adjusted claims as it should help minimize the time pharmacies will have to wait to be fully reimbursed the MFP.

Exhibit A

Page 15:

(b)1.ii. CMS or the MTF Data Module Contractor will disclose to the Manufacturer only the minimum data necessary for the Manufacturer to fulfill its obligations under the Negotiation Program Agreement(s), other applicable guidance, regulations and technical instructions, and this Agreement.

NACDS supports this provision as it helps to protect the confidentiality, security, and privacy of patient data.

Page 16:

(b)2.v. The Manufacturer agrees that, within the Manufacturer's organization and the organizations of its agents, access to CMS Data covered by this Agreement shall be limited to the minimum amount of data necessary and minimum number of individuals who need access to CMS Data for permitted activities (i.e., individual's access to CMS Data will be on a need-to-know basis).

As above, NACDS supports this provision as it helps to protect the confidentiality, security, and privacy of patient data.

4. NACDS Comments on the MTF Payment Module Contractor-Manufacturer Agreement

General Comments: As mentioned above, NACDS believes that manufacturers should be required to participate in the MTF PM. We fail to understand the logic of CMS having the authority to require manufacturers to participate in the MTF DM but not the MTF PM. Moreover, not requiring manufacturers to participate in the MTF PM will impose unreasonable burdens on pharmacies, which may have to enter into financial arrangements with many different manufacturers.

5. <u>Pharmacies should not be Required to Pre-fund or Float the Negotiation Program</u>

Even though Congress has made clear that manufacturers are responsible for implementing the Negotiation Program, and that pharmacies should not be impacted negatively, CMS is planning to implement the Negotiation Program in a manner that requires pharmacies to pre-fund the very refund they will receive. In other words, pharmacies will have to provide a financial float in order to make the program work. The IRA does not provide CMS with the authority to require this of pharmacies.

CMS continues to allow PBMs in the Medicare D program to under-reimburse pharmacies for prescription medications. This is occurring at the same time as pharmacies continue to suffer from PBM tactics in Medicare and also commercial plans. NACDS fears that this CMS requirement could further accelerate the closing of pharmacies nationwide. Pharmacy closures are leading to patient harm as patients find it more and more difficult to access their life-saving prescription medications and pharmacy services. Pharmacies are among the most accessible health care providers—and they are the most convenient health care providers, especially in rural areas. Pharmacies are the closest healthcare providers for a majority of Americans, and have the greatest ability to positively impact patient health and to feel and share their burdens. It is unfortunate that the healthcare providers that are closest to the American people continue to struggle from costs and burdens being shifted downstream to them, such as this latest CMS requirement.

NACDS has four main concerns, outlined below, about CMS' current implementation plans that would be resolved if the Negotiation Program were to operate in the same manner as the Coverage Gap Discount Program (CGDP).

First, the implementation plan does not ensure that pharmacies will be reimbursed for the full medication cost and dispensing fee. Consequently, Part D plan sponsors and their PBMs could exploit this program by keeping for themselves funds that should be provided to pharmacies.

Second, CMS' implementation plan would lead to pharmacies not being fully reimbursed for the affected medications for up to a month due to how CMS has structured the program. CMS's approach shifts the obligation to effectuate the MFP to pharmacies, contrary to the statute. By allowing manufacturers to provide access to the MFP by retrospectively reimbursing pharmacies, CMS would in effect be requiring pharmacies to pre-fund the MFP refund that those pharmacies would receive, as mentioned above. Imposing such a mandate on pharmacies is misaligned with statutory intent and exceeds CMS's authority, as mentioned above.
Pharmacies continue to suffer from inadequate reimbursement, Part D plan, and PBM clawbacks in the Part D program. Pharmacies do not have the financial ability to pre-fund the Negotiation Program. Pharmacies are so often reimbursed below cost for medications dispensed to Part D beneficiaries that pharmacies in some cases must consider whether they can even stay financially afloat. Pharmacies should not be responsible for pre-funding or floating the Negotiation Program as pharmacies and pharmacists have the immediate responsibility to assure optimal outcomes for all patients and sustain pharmacy clinical services despite the underwater reimbursement challenges from PBMs.

Third, there is no standardization in how pharmacies will be reimbursed. CMS plans to establish an MTF PM to provide a clearinghouse that manufacturers may use to provide the MFP to pharmacies. However, CMS does not require manufacturers to utilize the MTF PM, it is purely voluntary. Without requiring manufacturers to use the MTF PM, pharmacies could potentially have to set up reimbursement relationships with every manufacturer of a selected drug. This is administratively unworkable and untenable for pharmacies.

Fourth, CMS will ask pharmacies to self-identify whether they anticipate having material cashflow concerns due to the reliance on retrospective MFP refunds. CMS will provide this information to manufacturers to assist in the development of their MFP effectuation plans. CMS will require manufacturers to include their approach to mitigating material cashflow concerns in their MFP effectuation plans.

Although NACDS appreciates CMS' providing the opportunity for pharmacies to self-identify whether the program will impose material cashflow concerns, NACDS strongly believe that this is woefully inadequate to ensure that pharmacies are properly reimbursed in a timely manner. CMS does not require manufacturers to do anything with the information about pharmacy cashflow concerns nor does CMS have any requirements for how manufacturers should respond, should they decide to do so.

To address NACDS' numerous concerns, CMS should design the Negotiation Program to operate in the same manner as the Medicare Coverage Gap Discount Program (CGDP). A critical feature of the CGDP is that CMS pre-funds the program to ensure that it operates smoothly and that pharmacies are promptly and accurately reimbursed. CMS has clear authority to pre-fund the Negotiation Program. This authority hinges on whether it has both statutory authority and an appropriation to do so. NACDS believes that CMS's $3 billion IRA appropriation may cover its prospective funding of the MTF.

In the alternative, should CMS not pre-fund the Negotiation Program, CMS should use its authority under the IRA to require manufacturers to pre-fund the Negotiation Program.

6. Conclusion

NACDS thanks CMS for the opportunity to comment on the draft MTF agreements. We urge CMS to continue to engage with the chain pharmacy industry to implement the Negotiation Program in the most effective, efficient, and least burdensome manner, including adopting our recommendations herein. For questions or further discussion, please contact NACDS' Christie Boutte, Senior Vice President, Reimbursement, Innovation and Advocacy at CBoutte@NACDS.org or 703-837-4211.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer

Biotechnology Innovation Organization
1201 New York Avenue NW
Suite 1300
Washington, DC, 20005
202-962-9200

VIA ELECTRONIC DELIVERY

Mr. Jeff Wu
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

January 31, 2025

Re: Draft Medicare Transaction Facilitator Agreements

The Biotechnology Innovation Organization (BIO) appreciates this opportunity to comment on the draft Medicare Transaction Facilitator (MTF) Agreements to outline the responsibilities of each party that will be engaged in the MTF.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than thirty other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, delay the onset of such diseases, or prevent them in the first place. As a result, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes but also have reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO's members include biologic and vaccine manufacturers, which have worked closely with stakeholders across the spectrum, including the public health and patient advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

It is deeply concerning that CMS is requiring manufacturers to sign these MTF Agreements at a time when key operational features of MFP effectuation remain undefined. Through the MTF Agreements, the Agency attempts to absolve itself of critical aspects of implementation and oversight, leaving manufacturers to shoulder all the risk and resource demands of MFP effectuation. It is unreasonable for the Agency to shift program accountability onto manufacturers when manufacturers have not had any insight or involvement in the selection and scope of work for the MTF DM and PM. As BIO has stated in previous comments, there are still significant operational challenges and technical requirements that need to be clarified, including but not limited to data transfer standards, frequency of data and payment transfers, system limitations, details regarding the dispute resolution process, and other MTF-DM and PM functionality. It is unreasonable to hold manufacturers accountable for the entirety of MFP effectuation when shortcomings may stem from the Agency's own lack of guidance. Without clear guidance and insight into the MTF's technical functionality, manufacturers have no way of knowing if the terms outlined by the MTF Agreements are operationally feasible or within the manufacturer's working capabilities. As it stands, the harsh penalty provisions outlined by the Agreement create a coercive environment where manufacturers are not given any reasonable course of action.

Given the problematic nature of the contractual language contained in these Agreements, BIO encourages CMS to provide opportunities for further discussion and revision of the MTF Agreements. As the MTF Agreements are revised, it is important that CMS account for operational contingencies for parties working in good faith to comply with the MTF requirements. Accordingly, we request that manufacturers be given a safe harbor for their good faith effort to comply with MTF requirements and make the MFP available to the

Biotechnology Innovation Organization
1201 New York Avenue NW
Suite 1300
Washington, DC, 20005
202-962-9200

dispensing entity. We also continue to encourage CMS to exercise good governance and commit to ensuring proper implementation of the effectuation program, including transparent communication with manufacturers, a de-duplication mechanism to ensure compliance with the 340B non-duplication requirement, reasonable timelines to support thorough and accurate submissions, and ongoing process improvements to alter MTF functionalities as seen necessary.

Our specific comments on the MTF Agreements are as follows:

Draft MTF Program Agreement Between CMS and Manufacturers

II. Manufacturer's Responsibilities

BIO is deeply concerned that the Agreement obligates manufacturers to agree to unknown terms that may or may not be set forth in future guidance, including technical requirements between the MTF and the manufacturer that have yet to be created. It is unreasonable to make manufacturers commit to these obligations without knowing the full scope of the MTF's operational and technical capabilities. Manufacturers cannot make informed decisions or adequately plan for compliance when technical instructions and guidance are still forthcoming. It is evident that the manufacturer responsibilities outlined in the Agreement place an unreasonable burden on manufacturers to adapt to undefined and unknown future demands.

The Agreement states that manufacturers shall maintain all records in connection with the MTF for at least ten years from the date of the sale of the selected drug(s). BIO is concerned by this overly broad and intrusive requirement, which would unnecessarily create excessive administrative and financial burden on manufacturers. Even other government programs do not consist of such broad record-keeping mandates and auditing authority, as record-keeping mandates are typically focused on specific data elements directly related to the program. It is critical that CMS revise this language so that it is targeted around specific relevant records without imposing excessive burden on manufacturers.

Throughout the Agreement, CMS is given the authority to modify the terms of the Agreement through non-binding technical instruction. This unilateral ability of CMS to alter the Agreement without proper negotiation is extremely problematic and undermines the mutual understanding and accountability between parties. BIO urges CMS to allow all parties the opportunity to provide input before CMS finalizes any technical instruction that may significantly impact the operations, planning, or obligations outlined in the Agreement.

IX. Disclaimers

BIO opposes the disclaimer language that broadly releases CMS from all liability for activity related to the MTF. It is deeply problematic that the Agency continues to shift responsibility of implementation and oversight of MFP effectuation onto manufacturers when manufacturers had no authority in MTF selection or design and limited to no insight into the decision-making process. BIO also opposes the disclaimer language obligating manufacturers to accept the MTF "as-is" while manufacturers continue to not have any visibility into the MTF end-to-end system requirements.

Biotechnology Innovation Organization
1201 New York Avenue NW
Suite 1300
Washington, DC, 20005
202-962-9200

VIII. Effective Date, Term and Renewal, Application to Multiple Selected Drugs, Termination, and Transfer of Selected Drug(s)

It is extremely problematic that CMS has the unilateral authority to terminate the Agreement and no longer provide the MTF with only a 180 days' notice. The MTF is essential to fulfill the statutory obligation to effectuate the MFP and many parties will rely heavily on the MTF DM and PM's functionality. The potential for sudden termination of the Agreement makes manufacturers and dispensers extremely vulnerable, as a termination would jeopardize ongoing payment and data transfers and cause financial and operational instability for all parties. The lack of a mutual termination process leaves manufacturers and dispensers with no recourse or ability to mitigate the extensive operational interruptions and unanticipated costs from a potential sudden loss of the MTF. BIO urges CMS to reconsider the effects of this termination language, which would create an inequitable and destabilizing dynamic that would ultimately harm all parties' ability to properly effectuate the MFP.

We look forward to continuing to work with the Agency on MFP effectuation. Should you have any questions, please contact us at 202-962-9200.

Sincerely,

/s/
Melody Calkins
Director
Healthcare Policy
Biotechnology Innovation Organization

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.

Page 5

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.

Page 6

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.

Page 7

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,

Steve Postal, JD
Senior Director, Policy & Regulatory Affairs
National Community Pharmacists Association

teva | Legal Group

January 30, 2025

By Electronic Mail
IRARebateandNegotiation@cms.hhs.gov

William N. Parham III
Director, Division of Information Collections and Regulatory Impacts
Regulations Development Group
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room C4-26-05, 7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: MTF Agreements Feedback

Dear Director Parham:

Teva Branded Pharmaceutical Products R&D, Inc. ("Teva") appreciates the opportunity to comment on the Draft Manufacturer-Centers for Medicare & Medicaid Services ("CMS") Medicare Transaction Facilitator ("MTF") Program Agreement ("Draft MTF Program Agreement"), Draft Manufacturer MTF Data Module ("DM") Contractor Agreement ("Draft MTF DM Agreement"), and Draft Manufacturer MTF Payment Module ("PM") Contractor Agreement ("Draft MTF PM Agreement") (collectively, the "Draft MTF Agreements") released on December 17, 2024.[1]

Teva is a global pharmaceutical company, committed to helping patients around the world to access affordable medicines and benefit from innovations to improve their health. Teva operates worldwide, with a significant presence in the United States, Europe, and many other markets around the world. We are a global leader in generics and a leading specialty pharmaceuticals company developing and manufacturing innovative treatments for disorders of the central nervous system, including neurological and neurodegenerative disease, migraine, and movement disorders, as well as products in oncology and respiratory.

Teva has serious concerns about the liability that would be assumed by a manufacturer under the Draft MTF Agreements, particularly given the lack of well-developed and clear standards and

[1] CMS, Draft MTF Program Agreement Between CMS and Manufacturer (2024), https://www.cms.gov/files/document/manufacturer-cms-mtf-program-agreement.pdf; CMS, Draft MTF DM Agreement (2024), https://www.cms.gov/files/document/manufacturer-mtf-data-module-contractor-agreement.pdf; CMS, Draft MTF PM Agreement (2024), https://www.cms.gov/files/document/manufacturer-mtf-payment-module-contractor-agreement.pdf. As a manufacturer, Teva limits its comments to the draft agreements involving a manufacturer party, but, to the extent that the draft agreements involving a dispensing entity party contain comparable language addressed in these comments, our concerns may also be relevant to CMS's development of those agreements.

Teva Pharmaceuticals
400 Interpace Pkwy, Bldg. A | Parsippany, NJ 07054 | Cell 862-246-5273 | marc.eida@tevapharm.com | www.tevausa.com

procedures, under both the agreements and the Negotiation Program more broadly. We urge CMS to, at a minimum, take the following actions before finalizing the Draft MTF Agreements to help ensure that (1) the Drug Price Negotiation Program comports with applicable law and (2) those agreements are internally consistent and fundamentally fair:

1. Clarify that the manufacturer's release of claims against CMS in section IX(b) of the Draft MTF Program Agreement encompasses only claims directly stemming from the operation of the MTF, and not also claims stemming from Negotiation Program law, policy, or other operations; and

2. Add an express "best knowledge" qualifier to the provisions in sections II(i)(2), II(i)(3), and XI(b) requiring the manufacturer to submit accurate claim-level payment elements, and to attest to such accuracy.[2]

1. Release of Claims

We urge CMS to revisit and clarify the language in section IX(b) of the Draft MTF Program Agreement, which, as drafted, provides: "The Manufacturer shall release CMS from all claims, demands, and damages arising out of or connected with the MTF." The draft language "arising out of or connected with the MTF" is overly broad, both within the context of the draft agreement itself and within the broader program context. It is imperative that CMS revise section IX(b) to more precisely and appropriately describe its scope.

Based on the nature of the agreement and the Negotiation Program itself, we understand the intent of section IX(b) is to target only those potential claims directly stemming from the operation of the MTF. We are concerned that the "arising out of or connected with the MTF" language in section IX(b) could be misconstrued to encumber the rights and responsibilities of manufacturers, no less than other program stakeholders, to help ensure that the Negotiation Program comports with applicable law—including, where appropriate, by bringing claims that have only attenuated connections to the operational activities governed by the Draft MTF Agreements. Accordingly, CMS should substitute "directly stemming from the operation of the MTF" for the draft language, as shown below, and otherwise make clear its more limited intent.

> The Manufacturer shall release CMS from all claims, demands, and damages ~~**arising out of or connected with**~~ **directly stemming from the operation of the MTF DM or PM Agreements**.

That CMS did not intend for the draft language to be understood so broadly appears confirmed by the scope of other provisions throughout the Draft MTF Agreements. In particular, clarification of the draft language is necessary to harmonize section IX(b) with the language in section X(d) that "[n]othing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or CMS under any applicable law." By its express terms, section X(d) affirms the default intent to err on the side of preserving the parties' legal rights. CMS should revise the release of claims language in section IX(b) to eliminate any perceived incompatibility with the expansive preservation of legal rights provided for in section X(d).

[2] In addition, we support the comments of the Biotechnology Innovation Organization.

Teva Pharmaceuticals
400 Interpace Pkwy, Bldg. A | Parsippany, NJ 07054 | Cell 862-246-5273 | marc.eida@tevapharm.com | www.tevausa.com

We note that, should CMS decline to clarify the draft language, Teva will continue to understand the release of claims language in section IX(b), particularly in light of the preservation of legal rights language in section X(d), not to constrain its right to challenge the legal validity of the Negotiation Program as a whole, or any aspect of the program's implementation. Teva hereby expressly reserves the right to sue over any such legal violation. For the reasons discussed above, this reservation of rights comports with the overall nature of the agreement and the program.

2. Requirement and Certification of Strict Accuracy

Teva also has significant concerns about the feasibility and fairness of the draft provisions in sections II(i)(2), II(i)(3), and XI(b) requiring a manufacturer to submit complete and accurate maximum fair price ("MFP") claim-level payment elements through the MTF DM and to certify the truth, completeness, and accuracy of such information.[3]

Teva's concerns are exemplified by the interface between the literal text of the draft provisions and the statutory MFP-340B nonduplication provision, under which a manufacturer need only provide the lower of the MFP or the 340B ceiling price on a given unit, where such unit would otherwise be subject to both.[4] Given that CMS has established a 14-day prompt MFP rebate payment window,[5] a manufacturer has only a short period of time in which to determine whether a given unit is a 340B unit, and to provide the MFP or the 340B ceiling price accordingly.[6] As stakeholders have previously advised, however, it typically is not possible for a manufacturer to know with certainty, within the 14-day prompt MFP payment window, whether the MFP is in fact owed on a given unit due to the absence of a mechanism to timely validate 340B eligibility.[7] Under the product replenishment model commonly used by 340B covered entities, a unit is typically not identified as eligible for the 340B ceiling price until long after it has been dispensed.[8] And, even

---

[3] *Id.* § II(i)(2) (requiring the manufacturer to "[t]ransmit complete and accurate claim-level payment elements to the MTF DM within the 14-day prompt MFP payment window"), § II(i)(3) (requiring, in the event of an adjusted claim, the manufacturer to "transmit complete and accurate claim-level payment elements to the MTF DM within the 14-day prompt MFP payment window that begins with the date of MTF DM transmission to the Manufacturer of the claim-level data elements for the adjusted claim"), § XI(b) (providing for the manufacturer to attest that "[a]ll information the Manufacturer provides to the MTF DM is and will be true, complete, and accurate").

[4] SSA § 1193(d).

[5] *See* CMS, 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 § 40.4 (Oct. 2, 2024) [hereinafter "IPAY 2027 Final Guidance"], https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

[6] *Id.*

[7] *See, e.g.*, *id.* at 55 ("[C]ommenters raised concerns that nonduplication with the 340B ceiling price will . . . not be possible within the 14-day prompt MFP payment window" because "point-of-sale identification of 340B claims is incompatible with" the "replenishment model used by the majority of covered entities.").

[8] *See, e.g.*, *FAQs*, Health Res. & Servs. Admin., https://www.hrsa.gov/opa/faqs?categories=All&keywords=replenishment (last visited Jan. 24, 2025) (providing guidance on systems a covered entity should have in place for compliant use of the replenishment model); *340B Prime Vendor Program, FAQ ID 1352*, Apexus (Dec. 10, 2024), https://www.340bpvp.com/search#q=replenishment&tab=all (explaining that "[t]he accumulation for specific

Teva Pharmaceuticals
400 Interpace Pkwy, Bldg. A | Parsippany, NJ 07054 | Cell 862-246-5273 | marc.eida@tevapharm.com | www.tevausa.com

then, the manufacturer is typically not privy to information sufficient to effectuate MFP-340B nonduplication.[9] Because CMS has declined to provide a mechanism for timely identification of 340B units,[10] there is a real risk that it will be impossible for a manufacturer to accurately determine whether a particular unit is due the MFP or the 340B ceiling price within the 14-day prompt payment window. Accordingly, a requirement and certification of *strict* accuracy in the Draft MTF Program Agreement risks subjecting a manufacturer to significant penalty—despite the impossibility of the manufacturer ensuring such accuracy.

As a matter of fundamental fairness, CMS should clarify the draft provisions to subject the requirement and certification to a "best knowledge" qualifier. For example, section XI(b) should be revised as follows:

> All information the Manufacturer provides to the MTF DM is and will be true, complete, and accurate **to the best of their knowledge**; . . . .

Notably, adding a "best knowledge" qualifier would be fully consistent with other provisions of the Draft MTF Agreements:

- Section II(g) of the Draft MTF DM Agreement provides that "Manufacturer shall return claim-level payment elements for each claim within the 14-day prompt MFP payment window and ensure that the claim-level payment elements returned are timely, complete and accurate to the *best of their knowledge*" (emphasis added);
- Section II(c) of the Draft MTF PM Agreement provides that "Manufacturer shall ensure that electronic funds transfers or other payments to dispensing entities are timely, complete, and accurate to the *best of their knowledge*" (emphasis added).

Teva assumes that the absence of a conforming qualifier in the draft agreement between the manufacturer and CMS was an oversight and urges CMS to correct it.

We note that, if CMS declines to make the recommended change, we nevertheless will continue to understand the MTF Program Agreement to incorporate a "best knowledge" standard, consistent with the other MTF agreements and with the practical realities of the prescription drug supply chain.

* * *

---

accounts is based upon 340B patient eligibility status" and "will *eventually* produce replenishment orders" (emphasis added)).

[9] *See, e.g.*, IPAY 2027 Final Guidance, at 55, 66 ("[C]ommenters claimed Primary Manufacturers alone are unable to identify 340B units dispensed to MFP-eligible individuals and thereby prevent duplicate discounts . . . One commenter asserted that it would be arbitrary and capricious for CMS to finalize a policy under which a manufacturer is required to pay an MFP refund by the end of a prompt MFP payment window, or risk a civil monetary penalty, where the manufacturer does not have the data necessary to determine whether the unit is not subject to the 340B price.").

[10] *Id.* § 40.4.5.

Teva Pharmaceuticals
400 Interpace Pkwy, Bldg. A | Parsippany, NJ 07054 | Cell 862-246-5273 | marc.eida@tevapharm.com | www.tevausa.com

teva | Legal Group

In addition to the specific recommendations noted above, we note that we have serious overarching concerns about the parties' rights and obligations under the Draft MTF Agreements. The draft agreements are ambiguous and open-ended, purporting to obligate a manufacturer to agree to unspecified terms that may be defined only in future guidance or clarified only through enforcement.11 Manufacturers cannot meaningfully consent to being bound by an MTF agreement while MTF technical guidance is still forthcoming and the very underpinning of the agreements—the MTF—remains undeveloped. These many uncertainties are especially troubling given CMS's proposed assumption of liability by manufacturers, such as through the disclaimer language proposed in the Draft MTF Agreements,12 and despite manufacturers' complete lack of power over, or insight into, the development of the MTF. We urge CMS to rectify the imbalance and unfairness reflected in the Draft MTF Agreements; at a minimum, CMS should relieve a manufacturer of any liability for any action taken in good faith to seek to comply with the terms of the Agreements.

Teva appreciates CMS's consideration of these comments. Please do not hesitate to contact Marc Eida at (862) 246-5273 or marc.eida@tevapharm.com with any questions.

Sincerely,

Marc Eida

Marc Eida
General Counsel
U.S. Innovative Medicines and Biosimilars

[11] For example, a manufacturer must agree to submit accurate claim-level payment elements, but the term "[c]laim-level payment elements" is defined by reference to certain data "as described in applicable guidance, regulations and technical instruction." *Id.* §§ I(c), II(i).

[12] *See, e.g., id.* § IX ("The Manufacturer 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 Manufacturer's use of the MTF.").

Teva Pharmaceuticals
400 Interpace Pkwy, Bldg. A | Parsippany, NJ 07054 | Cell 862-246-5273 | marc.eida@tevapharm.com | www.tevausa.com

abbvie

January 31, 2025

Submitted via Email to IRARebateandNegotiation@cms.hhs.gov

Re: MTF Agreements Feedback

AbbVie Inc. ("AbbVie") appreciates the opportunity to offer feedback on the draft Medicare Transaction Facilitator agreements posted by the Centers for Medicare & Medicaid Services ("CMS"). These drafts are entitled *Medicare Transaction Facilitator Program Agreement* ("MTF Program Agreement"), *Medicare Transaction Facilitator Data Module Contractor Agreement* ("MTF DM Agreement"), and *Medicare Transaction Facilitator Payment Module Contractor Agreement* ("MTF PM Agreement") (collectively, "MTF Draft Agreements"). AbbVie is submitting these comments because it remains deeply concerned by CMS's extra-statutory implementation of the Inflation Reduction Act ("IRA"), which the agency again illustrates through these draft agreements.

As AbbVie has previously commented, we support good-faith efforts by CMS to carry out implementation of agency-imposed "maximum fair prices" ("MFPs") under the IRA in an efficient and cost-effective manner. Consistent with that position, AbbVie initially supported CMS's proposal to spearhead a Medicare Transaction Facilitator ("MTF"), with the understanding that CMS would adopt a fair, rational, and non-arbitrary process to avoid illegally stacking MFP rebates on top of 340B discounts. To date, however, CMS has not provided any operational information on the challenging MTF build. Instead of addressing pressing concerns, the draft agreements exacerbate them by failing to grapple with key operational defects.

CMS has an obligation to implement the MFP regime fairly, lawfully, and consistent with the requirements of the IRA. What CMS cannot do, however, is erect complex, opaque, and ultimately insufficient arrangements that authorize commercial third parties to regulate and dictate terms to participating manufacturers backed up by a threat of excessive penalties not contemplated by law. CMS's proposal seeks both to aggregate to itself powers not delegated to it by Congress and to deputize commercial third parties to serve as its agents and enforcers.

CMS also seeks to use the MTF Draft Agreements—which are not explicitly authorized under the statute—to impose inconsistent, unclear, and unreasonable obligations on manufacturers. The proposed agreements would delegate improper and unchecked authority over manufacturers' participation to commercial third-party contractors without any explicit statutory basis. They double down on CMS's problematic application of the MFP to both "primary" and "secondary" manufacturers, which is likewise not authorized by the statute. And they propose to impose onerous extra-statutory penalties for non-compliance. Critically, amid all this overreach, CMS *fails* to propose or identify any mechanism by which 340B nonduplication—which is explicitly *required* by the statute—can be achieved. AbbVie urges CMS to significantly revise the Biden Administration's approach to these crucial agreements.

Given the cost of implementation—CMS has awarded a $60 million contract of taxpayer dollars for the MTF-DM alone—CMS's unlawful approach is adding to the unnecessary costs and burdens of the IRA's "Drug Price "Negotiation" Program", and simultaneously failing to comply with the most basic statutory obligations of implementation—nonduplication with 340B discounts.

I. CMS's MTF Draft Agreements Are Inconsistent, Unclear, and Mandate Unreasonable Obligations for Primary Manufacturers.

We are deeply concerned by several proposals in the MTF Draft Agreements. As we describe below, CMS improperly proposes to build in inconsistent, unclear, and unreasonable terms throughout the MTF Draft Agreements. In many provisions within the MTF Draft Agreements, CMS has also exceeded the lawful bounds of its authority under the IRA. Moreover, the highlighted examples reinforce our long-standing view that the IRA's Medicare Drug Price Negotiation Program ("Program") is not a negotiation, and CMS's implementation of it goes beyond the statute. Rather than welcoming manufacturers to participate as partners in an appropriate process, CMS is exercising coercive regulatory powers to impose unfair and unlawful extra-statutory obligations. We urge CMS to revise the MTF Draft Agreements to comply with the statute and other limits on its authority.

A. The Draft Agreements Impose Unreasonable Obligations on Primary Manufacturers.

The MTF Draft Agreements would require that only the "primary manufacturer" sign the agreement while also seeking to obligate the primary manufacturer to ensure that any entities deemed by CMS to be "secondary manufacturers" *also* comply with the agreements, even though secondary manufacturers are not parties to the agreement, and the primary manufacturer may have no contractual relationship with a secondary manufacturer. The draft MTF Program Agreement further requires that primary manufacturers "ensure any Secondary Manufacturer(s) of the selected drug(s) for which MFP will be effectuated pursuant to this Agreement complies with the terms of this Agreement, including but not limited to the obligations related to confidentiality and data use established in [] this Agreement."[1] CMS is thus seeking to impose obligations on primary manufacturers to enforce performance by non-parties.

This proposed approach is not only contrary to statute, which specifically incorporates the pre-existing definition of "manufacturer" without regard to "primary" and "secondary," but it also exacerbates the agency's conflicting guidance regarding the application of the MFP to primary and secondary manufacturers. CMS's draft agreements would impose binding requirements on primary manufacturers to ensure that secondary manufacturers comply with the terms of the agreements in a way that Congress did not intend. Primary manufacturers, for the most part, do not control the prices at which secondary manufacturers sell their goods, or how they otherwise might or might not comply with the terms of the MTF Draft Agreements. CMS cannot reasonably

[1] Draft MTF Program Agreement, section II(e).

impose requirements on one manufacturer to dictate the conduct of an independent entity nor is CMS authorized to do so under the law.

B. The Draft Agreements Improperly Seek to Bind Manufacturers to Future CMS Guidance.

Throughout the MTF Draft Agreements, CMS uses open-ended clauses that propose to bind manufacturers to future guidance and technical instructions. For example: "When utilizing the MTF DM, Manufacturer shall comply with all requirements and conditions for MFP effectuation and CMS monitoring thereof, including, without limitation, all applicable CMS guidance, regulations, and technical instructions."[2] The draft MTF DM Agreement further provides that the "Data Module Contractor reserves the right to include *additional* provisions, requirements, or terms … on its own or at the direction of CMS, subject to applicable laws, guidance, or regulations and the prior approval of CMS. Any such provisions, once approved by CMS, shall be communicated in writing to the Manufacturer and incorporated into this MTF DM Agreement."[3] CMS cannot require manufacturers to sign an agreement that incorporates unknown and unpublished guidance and technical instructions.

Congress did not authorize CMS to impose binding extra-statutory requirements through guidance. Nor has CMS followed the essential procedures required under the Administrative Procedure Act to impose binding requirements through a non-statutory contract. Nor did Congress provide CMS with unilateral, unchecked authority to demand that manufacturers agree to accept the requirements of future and as-of-yet-unknown guidance.

CMS should amend the General Provisions of the draft agreements to remove those statements that unlawfully attempt to bind manufacturers to future guidance, regulations, and technical instructions.

C. The Draft Agreements Provide CMS with Unreasonable Unilateral Authority to Amend or Terminate These Agreements.

The MTF Program Agreement purports to give CMS the authority to "unilaterally amend" the agreement, "including to reflect changes in law, regulation, or guidance," and that "[a]s feasible, CMS will endeavor to provide the Manufacturer at least sixty (60) calendar day notice of any amendment to this Agreement."[4] That isn't an agreement; it is a blank check, and one not authorized by statute. That the unilateral amendment power is proposed to be shared with third-party, commercial contractors makes the provision particularly unreasonable and contrary to law (*see* Section III).

[2] Draft MTF Program Agreement, section II(b).

[3] Draft MTF DM Agreement, section VIII(e) (emphasis added).

[4] Draft MTF Program Agreement, section X(a).

CMS also proposes that it be the "sole party" permitted to terminate the MTF Program Agreement.[5] This provision underscores CMS's efforts to wield coercive authority. Parties to an agreement must be able to terminate the agreement; otherwise, it is an edict, not an agreement. Accordingly, at a minimum, CMS should make clear that (i) neither party has the authority to unilaterally amend any of the agreements; and (ii) both parties have the authority to terminate all of the agreements.

D. The Draft Agreements Improperly Disclaim All Liability and Responsibility for CMS While Asserting That Only Manufacturers May Be Subject to Penalties.

CMS's draft MTF Program Agreement contains a robust section of "Disclaimers," many of which no reasonable party would agree to, including, for example:

- CMS seeks to provide its MTF Data Module ("DM") and Payment Module ("PM") "as-is" and "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."
- CMS asks that manufacturers "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, the Manufacturer, or dispensing entities."
- CMS also disclaims any liability of the agency, noting that "under no circumstances and under no legal theory, whether tort (including negligence), contract, or otherwise, shall CMS be liable to the Manufacturer" nor shall CMS be liable or obligated to the Manufacturer "for any losses incurred or sustained by the Manufacturer," even at the "fault, delay, omission, inaccuracy by or termination of the MTF DM or PM."[6]

These provisions confirm that CMS is exercising coercive regulatory powers and is not acting as a market participant; rather, the agency proposes to require manufacturers to subscribe to an unclear, untested, extra-statutory process under threats of serious liabilities and penalties. CMS cannot lawfully require manufacturers to indemnify the agency while also disclaim liability for its own actions, including negligence. Nor can it claim that it is exempt from basic administrative law procedures on the theory that the parties have been engaged in a "negotiation" and then render the process entirely one-sided by exercising coercive regulatory powers to strip away manufacturers' rights.

Indeed, compounding these problems, CMS asserts that compliance with the terms of the draft *MTF Program Agreement* is necessary pursuant to the Program's *Manufacturer Agreement*

[5] Draft MTF Program Agreement, section VIII(d).

[6] Draft MTF Program Agreement, sections (IX)(a), (c), (e).

(in Social Security Act section 1193(a)(5)). CMS contends that "for the purposes of administering and monitoring compliance with the Program, participation by manufacturers in the MTF DM *shall be mandatory*."[7] But nowhere in the IRA does the statute mandate manufacturer participation in a data module or mention the MTF Program Agreements, nor does it authorize CMS to so require. Nevertheless, CMS threatens to "take enforcement action against Manufacturer for a violation of this Agreement including without limitation, requests for implementation of corrective action plans, referrals to the Office of the Inspector General or other federal law enforcement agencies and assessment of civil monetary penalties (CMPs)."[8] This provision would penalize manufacturers for failing to comply with the provisions of these MTF Draft Agreements, many of which are vague, unreasonable, or may be imposed at a future date as part of forthcoming guidance and technical instruction.

The MTF Draft Agreements also lack any protection for good faith efforts by manufacturers to effectuate MFP based on reliance on information provided by CMS's third-party contractors (the MTF DM and PM Contractors). This protection would be appropriate because these entities are the agency's own entrusted contractors, and CMS should support and encourage manufacturers' reliance on the data they provide to help effectuate the MFP. This reliance is particularly critical for manufacturers because under the IRA, they face significant penalties, including those that CMS seeks to impose through guidance

Further, through these draft agreements, CMS attempts to require manufacturers to agree to egregious extra-statutory requirements, such as those contained within the "Disclaimers" section, to effectuate an unfairly "negotiated" MFP. CMS should therefore strike the disclaimers provisions from section IX and hold harmless manufacturers that comply with the MTF to effectuate the MFP based upon information made available to the manufacturer, particularly when that information is provided by CMS's own contractors.

E. <u>The Draft Agreements' Audit and Record Retention Policies Are Overly Broad and Inconsistent Within the Agreements.</u>

CMS states that it "shall monitor compliance by the Manufacturer with the terms of this Agreement, any applicable guidance and regulations, and the Program Agreement(s)."[9] Further, the Department of Health & Human Services ("HHS"), CMS, the Comptroller General or their designees would, under the draft MTF Program Agreement, have the "right to audit, evaluate, and inspect" "all records that the Manufacturer may create or receive in connection with the MTF."[10] CMS fails to adequately define the scope of records that may be subject to an audit. CMS's policies underscore the one-sided nature of these draft agreements: CMS subjects only the manufacturer to

[7] Draft MTF Program Agreement, introduction (emphasis added).

[8] Draft MTF Program Agreement, section V.

[9] Draft MTF Program Agreement, section III(f).

[10] Draft MTF Program Agreement, sections V, II(f).

enforcement but provides no mechanism by which manufacturers may also audit, evaluate, and inspect information from CMS's third-party contractors.

Moreover, the MTF Draft Agreements include inconsistent requirements related to the retention of documents. For example, CMS requires that manufacturers retain all records that they may create or receive in connection with the MTF, audits, and investigations for at least ten years from the date of sale while also separately mandating in that same agreement that manufacturers must only retain records for "up to ten (10) years," and if the manufacturer seeks to retain the records for a longer time, then CMS must approve that extension in advance, in writing.[11] These proposed requirements are confusing and appear to be incompatible. They also fail to contemplate potential document retention obligations that manufacturers may have under other state or federal laws. CMS should therefore reconcile these provisions and remove any such provision that would attempt to impose document destruction requirements, given the potential for such provision to conflict with other federal and state law.

II. CMS Proposes Unreasonable Data Use Restrictions on Manufacturers.

The draft agreements would impose unreasonable requirements restricting a manufacturer's use of data. For example, CMS proposes to require that manufacturers agree not to "attempt to link records included in CMS Data to any individually identifiable source of information or for the purpose of creating any individually identifiable source of information, except for the purpose of identifying claims that may qualify for the exception under section 1193(d)(1) of the Act (i.e., determining whether the claim was 340B eligible)."[12] This provision is vague and leaves manufacturers guessing at what it means to "link records" and when it may be permissible, particularly as flexibility to link records may be necessary for even such things as validation. For example, may manufacturers use the data to identify potential non-340B duplicate discounts? In the context of 340B, what exactly are manufacturers permitted to do (or not do) to identify duplicate discounts?

As AbbVie mentioned in its December 23, 2024, comment letter, HHS not only shirks its responsibility to ensure that manufacturers can comprehensively and accurately track 340B units, but it also refuses to permit manufacturers to use a rebate model to identify claims eligible for the 340B price. AbbVie incorporates that letter, ID CMS-2024-0323-0014, herein by reference. CMS continues to seek to impose unclear, unreasonable, and unworkable burdens on manufacturers while failing to establish protections for manufacturers that make good faith efforts to validate 340B claims. CMS should clarify this draft contract provision and revisit the points raised in AbbVie's previous comment letter.

CMS also proposes to impose sweeping data requirements across multiple actors through these agreements. The draft MTF agreements would require that "[i]n the event that the

[11] Draft MTF Program Agreement, section II(f); Draft MTF Program Agreement, Exhibit A, section (b)(2)(vi).

[12] Draft MTF Program Agreement, Exhibit A, section (b)(2)(xi).

Manufacturer inadvertently receives any direct beneficiary identifiers, or discovers any other Breach or Incident involving CMS Data, loss of CMS Data or disclosure of CMS Data to any unauthorized persons," the manufacturer must report the occurrence to CMS. The Program involves several actors that will have access to and/or be involved in maintaining the data, including manufacturers and third-party vendors, CMS, third-party contractors, pharmacies, and other dispensing entities, and yet manufacturers alone are subject to obligations to report on data breaches. CMS fails to appreciate that several actors within this complex system bear responsibility for identifying breaches or incidents with CMS data, and that it is not reasonable to impose responsibility on manufacturers for identification and reporting on data breaches from any number of actors within the system.

III. CMS's Draft Agreements Unlawfully Delegate Significant and Undue Authority to Commercial Third Parties.

CMS proposes to delegate significant and undue authority to commercial third parties, specifically the MTF DM Contractor and the MTF PM Contractor. Language in the draft MTF Program Agreement sets the stage for these contractors' seemingly unchecked authority. Specifically, the agency states that, "Manufacturer shall comply with the MTF Data Module Contractor's and, as applicable, the MTF Payment Module Contractor's, instructions, processes, and requirements."[13] CMS thus proposes to require manufacturers to blindly agree to comply with unknown and unspecified "instructions, processes, and requirements" developed not by CMS but by commercial third-party contractors, which are *themselves* unnamed in the draft agreements.

Through these draft agreements, CMS proposes to bind manufacturers to the authority of the agency's contractors. Moreover, CMS asks manufacturers to do this *without* the protection of contractual safeguards through which manufacturers could challenge the contractors' improper or inconsistent instructions, processes, and requirements. We urge CMS to revise these draft agreements to limit the third-party contractors' improper authority over participating manufacturers. At the very least, CMS should include in the MTF Draft Agreements provisions that deem manufacturers that comply with MTF DM and PM Contractors' requirements to be in compliance with their MFP effectuation responsibilities. CMS should also ensure that any requirements proposed to be imposed by contractors are first ratified by CMS as reasonable and consistent with the aims of the Program.

The draft MTF DM Agreement and draft MTF PM Agreement also reserve the right for the contractors to amend the agreement either on their own or at the direction of CMS. They must simply "endeavor to provide the Manufacturer at least sixty (60) calendar day notice of any amendment to this Agreement."[14] As it stands, this power is one-sided, overly broad, and impermissibly granted to commercial third-party contractors. As mentioned, this aspect of the draft agreements is entirely one-sided and wholly coercive. The IRA requires that CMS shall be

[13] Draft MTF Program Agreement, sections II(b), (d); *see also* Draft MTF DM Agreement, section II(i); Draft MTF PM Agreement, section II(g).

[14] Draft MTF DM Agreement, section VIII(e); Draft MTF PM Agreement, section VIII(e).

responsible for administering the program and engage in compliance monitoring. It does not provide that CMS may cede its statutory obligation to a third-party contractor and grant that third-party such broad unilateral authority. Again, we ask that at the very least, CMS revise the MTF Draft Agreements to permit amendments only upon the mutual agreement of both parties. We also ask that CMS permit manufacturers the authority to terminate participation in any of the agreements, not just the MTF PM Agreement, as currently proposed.

CMS also proposes that the *third-party, commercial contractors* identify which pieces of any information disclosed by the manufacturer are "proprietary."[15] The IRA permits only HHS to make that determination.[16] Accordingly, as proposed, this is an inappropriate assignment of responsibility to government contractors, particularly as they likely will be unfamiliar with manufacturers' highly sensitive information. It is business-critical that CMS revise the MTF Draft Agreements to entrust manufacturers with the task of identifying their proprietary information and negotiating the potential release of such information before disclosure.

Further, the draft agreements appear to frame the MTF PM, once a manufacturer signs up for the MTF PM, as the default method for effectuating the MFP. This, however, is inconsistent with CMS's guidance, which describes the MTF PM as "a *voluntary* option to pass payment for MFP refunds from Primary Manufacturers to dispensing entities."[17] The guidance also outlines ways manufacturers can make the MFP available outside the MTF PM.[18] We request that, consistent with its guidance, CMS clarify in the applicable agreements that manufacturer participation in the MTF PM does not preclude use of other payment methods.

IV. The Draft Agreements Raise Troubling Privacy and Confidentiality Concerns.

AbbVie is deeply concerned by the confidentiality and data use provisions in the draft MTF Program Agreement. They grant CMS inappropriately broad discretion to use information generated under the Agreement, including information provided by manufacturers. For example, CMS proposes, "In its sole discretion, CMS may use information related to this Agreement, including, without limitation, information about and generated by the Manufacturer, and, to promote compliance with the statutes, regulations and written directives of Medicare, Medicaid and all other Federal health care programs …, CMS may disclose such information to law enforcement and regulatory authorities."[19] This provision could expose trade secret and confidential information. Further, the scope of this provision is unclear and potentially

[15] Draft MTF DM Agreement, section V(b); Draft MTF PM Agreement, section V(b).

[16] IRA, 42 U.S.C. § 1320f–2(c).

[17] *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* ("Revised IPAY 2027 Guidance") § 10 Introduction (emphasis added).

[18] *See id.* Table 3: Primary Manufacturer Payment Approaches to MFP Effectuation.

[19] Draft MTF Program Agreement, section III(g).

unrestrained; does authority to use this data extend outside HHS or even outside the federal government? This incredibly broad assertion of authority directly contradicts the text of the IRA, which expressly limits the use of information submitted by manufacturers to HHS and the Government Accountability Office for purposes of administering the Program.[20] We urge CMS to clarify the bounds of this power and ensure the MTF Draft Agreements mirror the protections established by the IRA.

Not only does CMS attempt to reserve for itself significant and unrestrained power related to data use, but the agency also seeks to impose myriad requirements for and penalties on *manufacturers'* use of the information. In the draft MTF Program Agreement's Exhibit A, CMS outlines nearly three full pages of data use responsibilities for manufacturers, all while listing only three bullets pertaining to its own responsibilities. Further, draft Exhibit A contains a section on penalties for noncompliance that appears to only pertain to a *manufacturer's* breach of the data use provisions, not a breach by CMS's third-party contractors. In terms of penalties, manufacturers are asked to acknowledge potential penalties under section 1106(a) of the Social Security Act (related to confidentiality of official disbursement records) and the Privacy Act (5 U.S.C. § 552a(i)(3)) may apply, such as "a fine not exceeding $10,000 or imprisonment not exceeding five (5) years, or both," or "a misdemeanor and fine[] [of] not more than $5,000."[21] Thus, the responsibilities and penalties outlined in draft Exhibit A are unbalanced and ripe for revision.

These penalty provisions would be *in addition to* the significant extra-statutory penalty measures that CMS seeks to impose on manufacturers for failure to comply with the MTF. For example, manufacturers that fail to register with the MTF DM or "fail to meet the MTF data exchange requirements" are subject to penalties *in excess of $1,000,000 per day*.[22] These coercive penalties are particularly galling given there is currently no operational information on the MTF build or timeline for readiness. Such extra-statutory penalties should be eliminated.

[20] IRA, 42 U.S.C. § 1320f–2(c).

[21] Draft MTF Program Agreement, exhibit A, section (b)(3).

[22] *See* Revised IPAY 2027 Guidance § 40.4.2.1 Primary Manufacturer Participation in the MTF DM ("Failure by the Primary Manufacturer to register with the MTF DM or to meet the MTF data exchange requirements, including maintaining functionality to receive certain claim-level data elements from the MTF DM and transmission of claim-level payment elements to the MTF DM within the 14-day prompt MFP payment window, would be a violation of the Agreement pursuant to section 1193(a)(5) of the Act and may cause the Primary Manufacturer to be subject to CMPs under section 1197(c) of the Act.")

V. CMS Continues to Issue Binding Requirements on Regulated Entities Without Appropriate Notice-and-Comment Rulemaking.

The IRA permits the Secretary of HHS to implement the Program in the first three years through "guidance,"[23] which lacks the force and effect of law.[24] Through guidance, agencies share non-binding statements of policy and statements of their interpretation of statutory terms. Guidance alone cannot bind regulated entities. By the terms of the Administrative Procedure Act, notice-and-comment rulemaking is required to do that. CMS, however, under the guise of "guidance," has inappropriately imposed on manufacturers a sweeping array of binding requirements related to the Program. Now, through the MTF Draft Agreements, CMS again attempts to circumvent proper notice-and-comment rulemaking. CMS attempts to require that manufacturers release the agency "from all claims, demands, and damages arising out of or connected with the MTF,"[25] and the agency also seeks to escape liability under any "circumstance" and any "legal theory."[26] As discussed, these draft contracts grant CMS unequal and undue power to unilaterally amend and terminate.

Through disclaimers, CMS seeks to impose binding, substantive requirements on regulated entities in violation of necessary notice-and-comment rulemaking procedures. Indeed, these draft agreements were merely promulgated by CMS, rather than published in the Federal Register to properly put the public on notice, share the agency's rationale and justifications, and invite meaningful and productive partnership with stakeholders and citizens. When seeking to impose binding requirements and obligations on regulated entities, CMS must abandon its misuse of agency "guidance" and instead use the notice-and-comment rulemaking procedures set forth in the Administrative Procedure Act.

* * *

Thank you again for considering AbbVie's feedback. We would be pleased to discuss this feedback with you in further detail. If you have questions, please contact Whitney Hubbard, Director, U.S. Policy at whitney.hubbard@abbvie.com.

Sincerely,

Hayden Kennedy

Vice President, Global Policy & U.S. Access Strategies

[23] IRA, 42 U.S.C. § 1320f, note.

[24] *See* Kisor v. Wilkie, 139 S. Ct. 2400, 2420 (2019); Perez v. Mortg. Bankers Ass'n, 575 U.S. 92, 97 (2015).

[25] Draft MTF Program Agreement, section IX(b).

[26] Draft MTF Program Agreement, section IX(e).

On behalf of AbbVie Inc.