NATIONAL ASSOCIATION OF Community Health Centers

December 20, 2024

Meena Seshamani, M.D., Ph.D.,
Centers for Medicare & Medicaid Services
Deputy Administrator and Director of the Center for Medicare
7500 Security Boulevard
Baltimore, Maryland 21244-1859

RE: Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (CMS-10912)

Dear Deputy Administrator Seshamani:

The National Association of Community Health Centers (NACHC) is the leading national membership organization dedicated to promoting Federally Qualified Health Centers (also known as FQHCs or health centers) as the Employer, Provider, and Partner of choice in all communities, as well as the foundation of an equitable health care system, free from disparities.

Community Health Centers are the best, most diverse, most innovative, and most resilient part of our nation's health system. For nearly sixty years, health centers have provided high-quality, comprehensive, affordable primary and preventive care, dental, behavioral health, pharmacy, vision, and other essential health services to America's most vulnerable, medically underserved patients in urban, rural, suburban, frontier, and island communities. Today, health centers serve 1 in 11 people at over 15,000 locations. This includes more than 5 million uninsured people, over 15 million Medicaid patients, over 3 million Medicare patients, and over 1 million patients experiencing homelessness.

In addition to medical services, health centers provide dental, behavioral health, pharmacy services, and other "enabling" or support services that facilitate access to care for individuals and families in medically underserved communities, regardless of insurance status or ability to pay. NACHC maintains its role as the national voice for health centers and believes that high-quality primary health care is essential in creating healthy communities. The collective mission and mandate of NACHC and the 1,487 health centers around the country is to close the primary care gap and provide access to high-quality, cost-effective primary and preventative medical care.

Health centers strive to make medications affordable for all their patients. Because patients aged 65+ are the fastest growing patient population for health centers, we applaud CMS as it implements the Inflation Reduction Act (IRA) provisions to help decrease financial barriers for Medicare patients for prescription drugs and seek to continue partnering with the agency. NACHC, however, remains concerned about how health centers will get access to 340B-priced drugs, especially with the rollout of the Medicare Transaction Facilitator (MTF), and how manufacturers will reconcile differences in the Maximum Fair Price (MFP) and the 340B price. We understand provisions have been finalized via 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. We seek to share reiterate concerns around the burden of participating in the MTF, especially because the MTF Payment Module (PM) does not have mandatory participation and guidance allows manufacturers leeway on how to furnish the MFP price to entities.

NACHC recommends CMS create more flexibility to permit entities to identify 340B drugs through a retroactive process.

We believe most of the data processed through the MTF is reasonable; we further appreciate CMS allowing dispensing entities the option of including a 340B Claims Indicator for the MTF Data Module. Determining whether a prescription can and should be filled with a 340B purchased drug can be a complicated, data-intensive process that often cannot be completed when the prescription is filled and the claim is submitted to the payer or at the point of sale. Point-of-sale identification for 340B drugs is difficult because it would require the pharmacy to resubmit claims that were classified incorrectly at the point-of-sale, leading to an increased administrative burden.

Under the 340B program, pharmacies have the discretion to use a variety of inventory models, including for tracking drugs at contract pharmacies. A covered entity will work with a third-party administrator (TPA) to implement a 340B drug inventory system for contract pharmacy arrangements, usually implementing the pre-purchased inventory model or the replenishment inventory model.[1] Both systems can run a compliant 340B program to avoid duplicate discounts but track inventory differently. Specifically, under the replenishment model, a contract pharmacy uses its non-340B purchased drugs when filling prescriptions on behalf of the covered entity. Because 340B eligibility is determined retrospectively in a replenishment model, most contract pharmacies do not know at the point of sale if the drug they are dispensing will ultimately qualify as a 340B drug and would have extreme difficulty implementing a point-of-sale modifier for 340B drugs. Additionally, even if a contract pharmacy uses the pre-purchase inventory model, that does not guarantee the pharmacy has 340B price drugs for all the health center patients' needs.

We continue to request the ability for health center pharmacies to use both prospective and retrospective claim identification to accommodate all types of pharmacy models, which is currently how a model in Oregon functions, and appreciate CMS' acknowledgement of exploring said model. The state's retroactive 340B claims file process allows 340B covered entities to avoid duplicate discounts when contracting with retail pharmacies to dispense 340B-stocked medications to patients of the covered entity. Retroactively identifying which pharmacy encounter claims were filled with 340B drugs allows those claims to be excluded from the Medicaid Drug Rebate process by the Oregon Health Authority.[2] This clearinghouse model can enhance accurate claims identification while easing provider burden by minimizing disruptions to pharmacy workflow and allowing claim identification after submission, given the difficulty of placing a claims modifier on 340B drugs at the point of sale as mentioned previously.

NACHC continues to harbor significant concerns about health center pharmacies getting retrospective reimbursement (i.e., MFP rebates) and needing to pay a higher price for drugs upfront, given the thin financial margins health centers operate on.

At 40.4, CMS guidance states that manufacturers can provide access to MFP to covered entities 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 (Sections 40.4.1 and 90.2 draft guidance), or 2. Retrospectively providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP (section 40.4.3 draft guidance), which includes a 14-day prompt pay window after a verified dispense. Many 340B covered entities, including health centers, operate with a physical inventory. They seek to ensure they have the medications their patients need, highlight any recurring inventory issues, reduce waste, and identify differences between inventory stock and actual stock.[3] Additionally, health centers operate on razor-thin

[1] https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf
[2] https://www.oregon.gov/oha/HSD/OHP/Tools/340B%20State%20Policy.doc
[3] https://dclcorp.com/blog/inventory/physical-inventory-count/#:~:text=Physical%20inventory%20counts%20can%20help,help%20to%20improve%20customer%20satisfact

financial margins while serving some of the most vulnerable, lower-income populations. Health center patients are four times more likely to have income at or below the Federal Poverty Level (FPL) and twice as likely to have income under 200% of FPL as compared to the U.S. population. Health center patients are also more than twice as likely to be uninsured as compared to the U.S. population. Around 11% of patients at a health center have Medicare, with over 4% being dually eligible for Medicaid as well.[4] [5] Health centers provide healthcare services to all patients, regardless of their ability to pay, and evaluate patients, both those without insurance and those underinsured, on a sliding fee scale to help lower the cost they pay for services based on family size and income. Furthermore, health center entity-owned and contract pharmacies offer prescription assistance programs to help patients with lower incomes be able to afford their medications. Another example is copay assistance programs, which lower the copay patients see when acquiring their prescriptions at the pharmacy. Health centers put their patients first, stretching their scarce federal resources as far as possible while discounting services to ensure healthcare remains affordable and accessible to all their patients. More than half of community health centers operate with margins below 5%, and 11 million patients were served by health centers operating with negative margins in 2022.[6] These facts show that forcing a rebate model would not be economically or financially feasible for health center pharmacies. All pharmacies, but especially the safety-net 340B covered entities, should have the opportunity to purchase MFP drugs prospectively at their discretion, not at the individual manufacturer's discretion.

NACHC appreciates the opportunity to respond to this information collection request and looks forward to continuing to engage with CMS on this important issue. Health centers are eager to work in concert with CMS to implement provisions of the IRA and provide affordable medications to Medicare patients. If you have any questions, please contact Elizabeth Linderbaum, Deputy Director of Regulatory Affairs, at elinderbaum@nachc.org.

Sincerely,

Joe Dunn
Chief Policy Officer

[4] https://www.nachc.org/wp-content/uploads/2023/07/Community-Health-Center-Chartbook-2023-2021UDS.pdf
[5] https://data.hrsa.gov/tools/data-reporting/program-data/national/table?tableName=Full&year=2022
[6] https://www.nachc.org/wp-content/uploads/2023/07/Community-Health-Center-Chartbook-2023-2021UDS.pdf

340B HEALTH

Submitted via http://www.regulations.gov/

December 27, 2024

William Parham
Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
OMB Control Number: 0938–New
Room C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Comments on Proposed Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request (OMB Control Number: 0938-New)

Dear Mr. Parham:

340B Health represents over 1,600 hospitals that participate in the federal 340B drug pricing program. We are writing in response to the Centers for Medicare & Medicaid Services' (CMS) October 28, 2024 proposed collection of information from pharmaceutical manufacturers of drugs covered under Medicare Part D selected for negotiation under the Inflation Reduction Act (IRA) for the initial price applicability years 2026 and 2027 and the dispensing entities that dispense the selected drugs to MFP-eligible individuals. We ask CMS to add to the information collection request (ICR) statements to ensure manufacturers are aware of limitations on their maximum fair price (MFP) effectuation plans related to 340B claim identification, and to modify the ICR to make clear that 340B contract pharmacies can indicate if they have material cashflow concerns because of reliance on retrospective MFP refunds.

In addition to the comments below that directly pertain to the ICR, we continue to urge CMS to permit covered entities (CEs) to choose to retrospectively submit 340B claims data to CMS' Medicare Transaction Facilitator (MTF) and require that the MTF use the data to identify and withhold 340B claims from being submitted to the manufacturer. We also urge CMS to require manufacturers to sell drugs at MFP to CEs. Further, CMS should require manufacturers to sell drugs at the 340B price even if the MFP is lower than the 340B price and to make CEs whole by promptly providing the difference between the MFP and the 340B price.

I. CMS Should Add Statements to the ICR to Ensure Manufacturers Are Aware of Limitations on the Section of Their MFP Effectuation Plans Related to 340B Claim Identification

Consistent with CMS' final guidance for manufacturer effectuation of MFP in 2026 and 2027, the ICR requires manufacturers to include in their MFP effectuation plans information on their process for deduplicating 340B units pursuant to IRA section 1193(d). We ask that CMS explicitly incorporate into the ICR the prohibitions against mandating use of 340B modifiers on claims and using a National Provider Identifier (NPI) to identify a claim as 340B. The addition of this information will ensure manufacturers are aware of these limitations when submitting their MFP effectuation plans to CMS.

The ICR requires manufacturers to describe a valid and reliable process for identifying 340B-eligible claims. We ask CMS to add to that instruction that a manufacturer cannot require a CE or contract pharmacy to apply modifiers to claims to identify them as 340B-eligible.[1] The final guidance states that, if dispensers choose *voluntarily* and proactively to indicate on a claim that it is 340B-eligible, the MTF will pass along the information to the manufacturer. A manufacturer plan requiring CEs or contract pharmacies to apply modifiers to claims to identify them as 340B-eligible would be inconsistent with the final guidance.

We also ask CMS to add a statement that a manufacturer cannot rely on a prescriber's or provider's NPI alone to determine that a claim is 340B-eligible. The final guidance states prescriber's or provider NPI alone will not constitute sufficient evidence that a claim was 340B-eligible, as not all individuals served by CEs are necessarily eligible to receive a drug purchased at the 340B ceiling price.[2] A manufacturer plan relying on a prescriber's or provider's NPI alone would conflict with the guidance.

II. CMS Should Modify the ICR to Make Clear That 340B Contract Pharmacies Can Indicate if They Have Material Cashflow Concerns

Consistent with the final guidance, the ICR allows dispensers to identify themselves as having material cashflow concerns because of reliance on retrospective MFP refunds.[3] CMS will provide manufacturers a list of dispensers that indicated they have such concerns. In the ICR, CMS said it expects certain types of dispensers may have material cashflow concerns, including 340B CEs with in-house pharmacies. The ICR includes a field allowing a dispenser to identify itself as a "340B Eligible Entity, or a Dispensing Entity contracted to handle 340B claims" and a separate field for a dispenser to indicate whether it has material cashflow concerns. We appreciate CMS' recognition that 340B CEs are among the types of dispensers that might be

[1] 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 231 (Oct. 2, 2024).
[2] *Id.* at 230.
[3] *Id.* at 210.

concerned about cashflow related to MFP effectuation. We ask that CMS change the second field description to "340B Eligible Entity, or a *340B Contract Pharmacy*." This change will make clear that contact pharmacies, including health-system-owned contract pharmacies, can indicate if they have material cashflow concerns. Pharmacies owned by a health system, such as a specialty pharmacy, may serve patients of multiple 340B hospitals owned by the same system as contract pharmacies, and may have material cashflow concerns.

* * *

Thank you for considering our comments. Please feel free to reach out to me if you have any questions or if we can provide any additional information.

Sincerely,

Maureen Testoni
President and CEO
340B Health

abbvie

December 23, 2024

Submitted via Electronic Filing: www.regulations.gov

William N. Parham, III
Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs, CMS
Document Identifier: CMS–10912
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Agency Information Collection Activities: Proposed Collection; Comment Request, Appendix B: Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form

AbbVie Inc. ("AbbVie") appreciates the opportunity to comment on the proposed informational collection request ("ICR") issued by the Centers for Medicare & Medicaid Services ("CMS"), and in particular *Appendix B: Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form* ("Appendix B"). In its current form, Appendix B raises several concerns, particularly as it relates to information collection with respect to identification of 340B-eligible claims and identification of dispensing entities with material cashflow concerns.

I. CMS's Proposed ICR Appendix B Plan Form Data Collection Requirements Raise Significant 340B-Related Concerns

In the context of ensuring a process for nonduplication of claims that are 340B-eligible and could also be erroneously subjected to a "maximum fair price" ("MFP") under the Inflation Reduction Act ("IRA"), CMS inappropriately proposes in Appendix B to require manufacturers to develop and submit a "valid and reliable process for identifying 340B eligible claims" no later than September 1, 2025, for IPAY 2026, and September 1, 2026, for IPAY 2027. Imposing that extra-statutory requirement on manufacturers is both ineffectual and unduly burdensome. It is also unreasonable because the Department of Health & Human Services ("HHS")—the Department tasked with overseeing both the IRA and 340B programs—is not only shirking its responsibility to ensure that manufacturers can comprehensively and accurately track 340B units, but it is also refusing to take steps necessary to allow manufacturers to meet the requirements that CMS seeks to impose and provide the necessary transparency and data through collaboration with the Health Resources and Services Administration ("HRSA"), which administers the 340B program. If manufacturers are deprived of the tools necessary to identify units subject to 340B claims, the requirement to provide a "valid and reliable process for identifying 340B eligible claims" is undue and infeasible, and the statutory mandate requiring deduplication is unmet.

The IRA makes clear that manufacturers are not obligated to provide duplicate 340B and MFP discounts on the same unit.[1] CMS's revised guidance documents for both IPAY 2026 and IPAY 2027 acknowledge this important feature of the statutory scheme.[2] When units are subjected to duplicate discounts—under both the IRA and the 340B program—manufacturers are forced to sell their products at prices that, by definition, are arbitrary and confiscatory.

CMS has nonetheless failed to institute the tools needed to comply with the statute and prevent significant program abuse. That failure is particularly egregious because the risk of MFP-340B duplicate discounts is not theoretical. Multiple reports, including those published by the Government Accountability Office ("GAO") and the HHS Office of Inspector General ("OIG"), detail the significant risk of duplicate discounts in an analogous context: the Medicaid Drug Rebate Program and the 340B program.[3] GAO has repeatedly recommended that HHS address the issue of statutory duplicate discount violations, among numerous other program integrity deficiencies, even cautioning that "[w]ithout addressing [these] recommendations . . ., HHS does not have assurance that covered entities are complying with program requirements, which puts manufacturers at risk of being required to erroneously provide duplicate discounts for Medicaid

[1] 42 U.S.C. § 1320f-2(d).

[2] *See Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026* ("Revised IPAY 2026 Guidance") § 40.4.1 Nonduplication with 340B Ceiling Price; *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") § 40.4.5 Nonduplication with 340B Ceiling Price.

[3] *See, e.g.*, GAO, 340B Drug Discount Program: Information about Hospitals that Received an Eligibility Exception as a Result of COVID-19, GAO-23-106095 (May 11, 2023), https://www.gao.gov/products/gao-23-106095 (stating, "[a]ccording to HRSA, as of July 2022, the agency had audited 25 of the 53 excepted hospitals. Our review of HRSA documentation found that the agency issued a total of 19 findings related to noncompliance for 14 of these hospitals as a result of these audits. Five of the hospitals had more than one finding of noncompliance. The most common finding among the excepted hospitals that were audited related to the potential for duplicate discounts . . . ."); OIG, State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates, OEI-05-14-00430 (Jun. 6, 2016), https://oig.hhs.gov/reports/all/2016/state-efforts-to-exclude-340b-drugs-from-medicaid-managed-care-rebates/ (finding that, "to identify 340B drug claims and correctly collect rebates for [Managed Care Organizations] MCO drugs, most States use methods that identify providers using 340B purchased drugs. However, we found that these provider-level methods may not accurately identify all individual 340B drug claims, creating a risk of duplicate discounts and forgone rebates. By contrast, we found that methods that operate at the claim level can improve accuracy in identifying 340B drug claims, and thereby, help States correctly collect rebates.").

prescriptions."[4] HHS—which includes both CMS and HRSA—must heed GAO's recommendations and address stakeholders' concerns by properly and lawfully implementing the IRA in a way that provides the transparency necessary to ensure that MFP-340B duplicate discounts do not occur.

A. CMS Requires Manufacturers to Do That Which the Agency Itself Is Unwilling to Do, and Blindfolds Them in the Process

As drafted, the Appendix B collection request form imposes an obligation on manufacturers to "identify[]" 340B-eligible claims, but CMS has failed to take any of the steps that would be necessary to allow manufacturers to identify those claims. In particular, CMS's revised guidance improperly blindfolds manufacturers by depriving them of the modest and appropriate claims-level data necessary to identify duplicate discounts. That is unreasonable, arbitrary, and capricious. CMS cannot, on one hand, impose an obligation on manufacturers and then, on the other hand, deny manufacturers the tools necessary to satisfy that obligation.

CMS has deemed the claims-level data element of "340B Claim Indicator" as one that can be "voluntarily reported by [the] dispensing entity."[5] But voluntary reporting is not reporting in any useful sense. Covered entities will *not* provide the claims-level detail necessary to effectuate § 1320f-2(d) absent an incentive, such as an effective federal mandate. CMS states that it "disagrees that there is no incentive for covered entities to voluntarily identify 340B claims, as the 340B ceiling price may be lower than the MFP and thus covered entities would be incentivized to identify claims to receive the 340B discount at the time of purchase."[6] It is self-evident—and confirmed by real-world experience—that 340B covered entities will aggressively avoid providing any data to manufacturers, particularly if doing so would diminish their ability to obtain *duplicate* discounts and maximize 340B profits.[7] CMS need look no further than the disputes over data relating to contract pharmacy utilization to see that 340B covered entities will not act voluntarily to improve program integrity or compliance with statutory nonduplication requirements. In fact, even when faced with a statutory obligation of preventing duplicate discounts in Medicaid, covered entities routinely seek to hide 340B claims data to illegally extract 340B pricing on Medicaid claims. A mandatory 340B Claim Indicator is necessary for manufacturers to satisfy the proposed ICR's Appendix B's requirement to describe a process to ensure the nonduplication of claims. Moreover, this is not an unreasonable or onerous ask; the data requirements for inclusion of a 340B Claim Indicator are similar to other data requirements required to facilitate other federal programs.

[4] GAO, Priority Open Recommendations: Department of Health and Human Services, GAO-19-364SP (Mar. 28, 2019), https://www.gao.gov/products/gao-19-364sp.

[5] Revised IPAY 2027 Guidance at 53, 203.

[6] *Id.* at 56.

[7] This is especially true given HRSA's recent attempts to block manufacturers' lawful proposals to obtain claims level data, (*see, e.g.*, *supra* n.8); as well as improper attempts by state legislatures to regulate manufacturer obligations under the federal 340B program.

While CMS is failing to do its part to prevent the nonduplication of claims, at the same time, HRSA is attempting to block the other currently viable approach to deduplication for manufacturers. Consistent with the 340B statute, manufacturers have proposed rebate models designed to obtain claims-level data sufficient to identify claims eligible for the 340B price. Despite such proposals being permitted by the 340B statute and consistent with common commercial practice, HRSA has threatened manufacturers with federal program withdrawal if implemented.[8] That not only exceeds HRSA's authority, but also directly contradicts CMS's advocacy for voluntary claim-level data reporting—an example of HHS's continued interference with manufacturers' attempts to improve 340B claim transparency and enhance program integrity. Indeed, manufacturers' rebate proposals were designed explicitly to meet IRA claims duplication concerns and yet were rejected by HRSA almost out of hand.

There is no excuse for these failures. The 340B program was implemented to help covered entities stretch scarce federal resources as far as possible.[9] AbbVie is committed to the intended purpose of the 340B program and believes that for the 340B program to fulfill its important mission of improving access to medicines for uninsured and vulnerable patients, program integrity challenges must be addressed. As a condition of participation, covered entities are required to maintain records adequate to ensure that duplicate discounting does not occur. There is therefore no reason HHS should *not* require covered entities to produce those records and support the transparency necessary for implementation of the IRA and 340B programs with statutorily required nonduplication. Instead of enforcing the statutory requirements that Congress devised, at every turn, HHS undermines compliance with the plain statutory bar and throws back at manufacturers' feet an obligation to identify 340B eligible claims, while failing to provide them the information necessary to meet that obligation.

CMS has repeatedly disclaimed involvement in addressing duplication issues, even though it is the agency administering the IRA.[10] CMS cannot lawfully abdicate its obligation to ensure that the statute operates as it is explicitly designed. Indeed, the Secretary of HHS, who oversees both HRSA and CMS, is tasked with implementing the IRA. Considering the limitations faced by manufacturers and the responsibilities entrusted to HHS, we respectfully urge CMS to require that covered entities provide the modest claims-level data that is necessary to identify 340B claims,

[8] *See, e.g.*, Letters from Chantelle V. Britton, Dir., Off. of Pharmacy Affs., HRSA (Aug. 14, 2024) and Carole Johnson, Adm'r, HRSA (Sept. 17, 2024, and Sept. 27, 2024), to Johnson & Johnson (Complaint for Declaratory and Injunctive Relief at Exs. 5, 9, and 11, Johnson & Johnson Health Care Sys. Inc. v. Becerra et al., No. 1:24-cv-03188 (D.D.C. Nov. 12, 2024)); Letters from Chantell V. Britton, Dir., Off. of Pharmacy Affs., HRSA (Nov. 12, 2024) and Carole Johnson, Adm'r, HRSA (Dec. 13, 2024), to Sanofi-Aventis U.S. LLC (Complaint for Declaratory and Injunctive Relief at Exs. B, and F, Sanofi-Aventis U.S. LLC v. HHS et al., No. 1:24-cv-03496 (D.D.C. Dec. 16, 2024)).

[9] *See*, HRSA: 340B Drug Pricing Program, https://www.hrsa.gov/opa.

[10] *See, e.g.*, Revised IPAY 2027 Guidance at 54, 55, 60, 231.

and to prioritize its work with HRSA to facilitate greater transparency in the 340B program such that manufacturers are able to reliably identify 340B claims.

B. When 340B Is Not Operationalized at Point-Of-Sale, a Reliable Process is Not Achievable

In the proposed Appendix B, CMS appears to ignore duplicate discounts arising as a result of the fact that covered entities frequently seek discounts after the point-of-sale.[11] For example, through dispensing entities' product replenishment processes, a commercial dispensing entity (a "contract pharmacy") will provide a product to a Medicare patient at the MFP, submit data to the product's manufacturer for reimbursement at the MFP, then at some point later, the contract pharmacy's covered entity partner will demand product replenishment at the 340B price for the same unit. This may occur long after the Primary Manufacturer has provided reimbursement for the difference between the dispensing entity's acquisition cost and the MFP.

It remains unclear how CMS expects manufacturers to identify and address this critical issue. AbbVie proposes that HHS require identification at the time an MFP rebate is demanded if the unit was *or is reasonably expected to be* subject to 340B replenishment. Only by recognizing the complexity of the 340B replenishment process—which does not occur outside the context of 340B—will CMS appreciate how vital claims-level data is to the lawful implementation of the MFP.

II. CMS's Proposed ICR Appendix B Plan Form Data Collection Requirements Related to Dispensing Entities Cashflow Mitigation Are Overly Burdensome

In late October of this year, the National Community Pharmacists Association ("NCPA") released the results of its survey of roughly 4,135 independent pharmacy owners and managers and found that under the IRA's "Drug Price Negotiation Program," pharmacies will likely be waiting over 30 days for the manufacturer MFP refund payments, and the average pharmacy will have to float over $27,000 every month waiting to be made whole from manufacturer refund payments.[12] Fifty-one percent of respondents say they are strongly considering not stocking these drugs, and additional 40 percent are somewhat considering not stocking them.[13] Instead of CMS implementing policies that would meaningfully mitigate the cashflow issues that MFP effectuation would create for pharmacies, CMS has put the burden and responsibility on manufacturers, even though manufacturers do not have the tools to meaningfully mitigate these concerns.

[11] *See also id.* at 55.

[12] NCPA, Report for Fall Survey of Independent Pharmacy Owners/Managers Executive Summary at 1 (Oct. 2024), https://ncpa.org/sites/default/files/2024-10/NCPA-FallSurvey2024-ExecSummary.pdf.

[13] *Id.*

The Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form requires that a manufacturer include both a process for mitigating material cashflow concerns for dispensing entities and the qualifying criteria for dispensing entities to participate in the "Primary Manufacturer's" process to assist dispensing entities with material cashflow concerns, including but not limited to the dispensing entities that have self-identified.

This requirement is unreasonable and unduly burdensome for two distinct reasons.

A. No Reasonable Way Exists for Manufacturers to Mitigate Cashflow Concerns

Under CMS guidance, the prompt payment period for pharmacies is shortened to an unreasonable 14 days. AbbVie and other manufacturers have consistently explained to CMS that the way they have proposed to implement MFP effectuation makes accurate payment in 14 days extremely challenging, particularly given CMS's failure to require a 340B Claim Indicator to limit the data verification that manufacturers require for data integrity in the prompt payment period. Given the already unreasonable prompt payment period, it is unclear what viable method CMS believes may exist for manufacturers to mitigate pharmacies' cashflow concerns. Given CMS's implementation decisions, paying pharmacies more quickly is not a reasonable expectation to place on manufacturers, and requiring manufacturers to report/submit a mitigation strategy that cannot actually be implemented is an undue burden on manufacturers.

B. CMS Does Not Have Any Way for Manufacturers to Determine Cashflow Concerns

Perhaps understanding that all 60,000+ pharmacies would likely self-identify as having cashflow issues, CMS requires manufacturers to design "the qualifying criteria for dispensing entities to participate in the Primary Manufacturer's process to assist dispensing entities with such material cashflow concerns, including but not limited to the dispensing entities that have self-identified." By requiring manufacturers to submit information on this process, CMS places an undue burden on manufacturers. CMS has not proposed any collection of information requirements from pharmacies that have self-identified as having cashflow issues; how, therefore, are manufacturers supposed to develop qualifying criteria to determine whether a pharmacy has cashflow issues that require mitigation OR have the information necessary to determine if a pharmacy meets those criteria?

It remains unclear how CMS reasonably expects manufacturers to address cashflow concerns or develop "qualifying criteria" to determine whether a self-identified pharmacy should have their cashflow concerns mitigated.

* * *

Thank you again for considering AbbVie's comments. We stress the importance of these key concerns. If CMS does not provide manufacturers with the resources necessary to identify and deduplicate 340B claims from claims subject to the MFP within the prescribed time periods, the requirements set forth in the current draft of the ICR's Appendix B are unworkable and inconsistent with the statutory mandate. Further, CMS continues to place undue burden on manufacturers in the current draft of the ICR's Appendix B with unreasonable and unworkable submission requirements that are not supported by CMS's implementation of the MFP effectuation process. We would be pleased to discuss these comments with you in further detail. If you have questions, please contact Whitney Hubbard, Director, US Policy, at whitney.hubbard@abbvie.com.

Sincerely,

Hayden Kennedy
Vice President, Global Policy & U.S. Access Strategies
Government Affairs
On behalf of AbbVie Inc.

Greg Portner
Senior Vice President

Global Government Affairs & Policy
601 Thirteenth Street, NW
Suite 1100 North
Washington, DC 20005
Phone: 202.585.9649
Email: gportner@amgen.com
www.amgen.com

December 20, 2024

VIA ELECTRONIC DELIVERY

William N. Parham III
Director, Division of Information Collections and Regulatory Impacts
Division of Regulations Development
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: Document Identifier/OMB Control Number: 0938-NEW
Room C4-26-05, 7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Medicare Transaction Facilitator for 2026 and 2027 Under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (CMS-10912)

Dear Director Parham:

Amgen Inc. (Amgen) appreciates the opportunity to submit comments on the Medicare Transaction Facilitator (MTF) for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (ICR) posted on the Centers for Medicare & Medicaid Services (CMS) website and in the Federal Register on October 28, 2024 (MTF Effectuation ICR).[1]

Amgen is committed to using science and innovation to dramatically improve people's lives, improving access to drugs and biologics (collectively, "drugs," consistent with CMS's convention), and promoting high-quality care for patients. Amgen develops innovative medicines as well as biosimilar biological products. Thus, our interest is to ensure a robust market for, and improve patient access in the United States to, both innovative and biosimilar biological products.

We are pleased to provide CMS with feedback on the MTF Effectuation ICR, with a particular focus on Appendix B: Drug Price Negotiation Program MTF DM Primary Manufacturer MTF Effectuation Plan Form. However, Amgen remains concerned that the government price controls on certain medicines provided to Medicare beneficiaries under the guise of price "negotiation" under the Inflation Reduction Act of 2022 (IRA) are stymieing biopharmaceutical innovation at

[1] 89 Fed. Reg. 85,538 (Oct. 28, 2024); CMS, Medicare Transaction Facilitator for 2026 and 2027 Under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (CMS-10912) (Oct. 28, 2024) (MFP Effectuation ICR).

precisely the time when the world needs more new medicines to treat an aging population. This government price setting is forcing biopharmaceutical companies to stop pursuing research and development (R&D) on many new drugs. Companies are having to rethink how and where they invest in biopharmaceutical innovation, with the government essentially picking winners and losers by discouraging the development of some types of treatments for certain patient populations. Although we continue to maintain that the Drug Price Negotiation Program is unlawful, we submit these comments as part of our ongoing commitment to patients and in an effort to bring to CMS's attention the myriad problems the IRA contains and creates.

Amgen's comments can be summarized as follows:

Appendix B: Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form

- Instead of relying on manufacturers to deduplicate 340B and maximum fair price (MFP) eligible claims, CMS should require the use of 340B and non-340B modifiers to avoid MFP/340B ceiling price duplicate discounts, supported by a clearinghouse and a claw back mechanism, and adopt a policy of non-enforcement where 340B eligibility cannot be timely validated.
- CMS should specify that payment of the Standard Default Rebate Amount (SDRA) is a true default.
- CMS should not require manufacturers to provide mitigation plans for dispensers that self-identify as having cash flow concerns.
- CMS should affirmatively establish procedures for manufacturers to identify information submitted as part of the MFP effectuation process that is proprietary or otherwise confidential.

Appendix C: Medicare Drug Price Negotiation Program Primary Manufacturer Payment Elements Form

- CMS should clarify the unit of measurement for the quantity of selected drug to represent packages.

Additional Comments

- CMS should provide clear timelines for testing of the MTF to ensure readiness for 2026 effectuation.

In addition, Amgen supports the comments of the Pharmaceutical Research and Manufacturers of America and Biotechnology Innovation Organization.

Comments on Appendix B: Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form

I. Q4: Details on Primary Manufacturers' processes for 340B nonduplication - Instead of Relying on Manufacturers to Deduplicate 340B and MFP Eligible Claims, CMS Should Require the Use of 340B and Non-340B Modifiers to Avoid MFP/340B Ceiling Price Duplicate Discounts, Supported by a Clearinghouse and

a Claw Back Mechanism, and Adopt a Policy of Non-Enforcement Where 340B Eligibility Cannot Be Timely Validated

A. Deduplication of 340B-Eligible and MFP-Eligible Units

By statute, a manufacturer of a selected drug cannot be required to offer both the MFP and the 340B price on the same unit and instead is required only to offer the lower of these two prices.[2] In the Initial Price Applicability Year (IPAY) 2027 Final Guidance, CMS states that it "will not, at this time, assume responsibility for nonduplication of discounts between the 340B ceiling price and MFP" and is not requiring pharmacies to submit data to manufacturers to support validation of eligibility for the 340B ceiling price so that manufacturers can police duplication instead.[3] Instead, CMS is charging manufacturers with effectuating the 340B-MFP nonduplication requirement through the MFP effectuation plan form by requiring manufacturers to describe their process for deduplicating claims eligible for both the 340B ceiling price and MFP at Question 4.[4] But the statute does not direct that the burden of 340B-MFP deduplication be placed on the manufacturer. And, because manufacturers do not have direct access to the data that are needed to identify whether claims are 340B eligible, given the absence of support from CMS, 340B-MFP deduplication is a nearly impossible task.

Amgen therefore continues to urge CMS to mandate use of 340B and non-340B modifiers (as applicable) to identify 340B-eligible and 340B-ineligible units on any claim submitted for Part D reimbursement as a condition precedent to the start of the prompt MFP payment window as well as a condition of Part D reimbursement.[5] These data would serve to help identify 340B-eligible and 340B-ineligible units on any claim submitted for reimbursement under Part D in order to facilitate deduplication. CMS has already adopted 340B modifiers (but not non-340B modifiers) with respect to Part B units, which, effective January 1, 2024, all 340B covered entities that submit Part B claims must use to identify 340B units.[6] The contemplated 340B and non-340B modifiers would be included in the claims-level data provided by the MTF to the manufacturer. These modifiers would help ensure that manufacturers do not provide the MFP on any units identified as 340B-eligible where the 340B ceiling price is lower than the MFP.

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

[3] *See* CMS, IPAY 2027 Final Guidance § 40.4.2.1 (Oct. 2, 2024) (specifying that 340B indicators in the PDE record may be "*voluntarily"* applied to a Part D claim to indicate that the claim is for a 340B drug) (emphasis added).

[4] MFP Effectuation ICR, Appendix B at 3-4.

[5] CMS has authority to require the appropriate use of these modifiers as a condition of Part D reimbursement. To appropriately implement Part D inflation rebates under section 1860D-14B of the SSA, CMS needs to be able to identify whether a Part D unit of a selected drug is subject to the MFP or the 340B price to determine whether the unit should be excluded from such rebates. See SSA § 1860D-14B(b)(1)(B). CMS may condition payment of a clean claim on the appropriate use of these modifiers. See, e.g., SSA § 1860D-12(b)(3)(D) (general authority to add Part D contract terms); see also §§ SSA 1102(a), 1871(a) (general rulemaking authority).

[6] 89 Fed. Reg. 97,710, 98,248-50 (Dec. 9, 2024); CMS, Part B Inflation Rebate Guidance: Use of the 340B Modifiers (Dec. 20, 2022), *available at* https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf.

Because 340B covered entity compliance with the use of the modifiers may not be unfailing, Amgen further supports the use of a neutral clearinghouse to help validate 340B eligible units and avoid MFP-340B duplication.[7] The clearinghouse could further help CMS by identifying 340B-eligible units for purposes of other programs, including for purposes of excluding such units from the Part D inflation rebate calculation.

In addition, where offsetting is not possible, it is imperative that CMS provide for an enforceable claw back mechanism by which a manufacturer can readily recover the MFP should a covered entity receive a lower 340B ceiling price on the same unit after the payment of the MFP.

Deduplication is most likely to be successful if enabled by the agency measures described above, i.e., the 340B and non-340B modifiers and the clearinghouse.

B. Non-Enforcement Where 340B Eligibility Cannot Be Timely Validated

Moreover, Amgen reiterates that, given CMS's lack of support for deduplication of the MFP and the 340B ceiling price, and the challenges of identifying 340B units on account of the 340B replenishment model, CMS should not pursue enforcement against a manufacturer for failure to timely provide an MFP rebate if the manufacturer, despite good faith efforts, cannot timely identify whether the 340B ceiling price might instead be due on a given unit because data are insufficient to determine whether the unit is or is not a 340B unit.

With respect to units dispensed under 340B contract pharmacy arrangements, the 340B ceiling price (if lower than the MFP) would be owed to the 340B covered entity and the MFP (if lower than the 340B ceiling price) would be owed to the 340B contract pharmacy.[8] With no claw back mechanism in place for manufacturers to recover an MFP paid to a 340B contract pharmacy, and where offsetting is not possible, if it is ultimately determined that the unit is instead subject to 340B pricing, it is essential that manufacturers are able to validate eligibility of a given unit for the 340B ceiling price before paying the MFP. Under the 340B replenishment model, 340B covered entities determine only after a unit was dispensed whether the individual to whom the unit was dispensed was a 340B "patient," in which case the 340B covered entity later purchases a replacement unit at the 340B ceiling price. Thus, it necessarily takes considerable time to validate eligibility of a given unit for the 340B ceiling price and therefore also to determine whether the MFP or the 340B ceiling price is due on that unit.

II. Q6 – Q7: Primary Manufacturers' plans for calculating the MFP Refund amount - CMS Should Specify That Payment of the SDRA Is a True Default

CMS should specify that, where opted by a manufacturer under Question 6 of the proposed MFP effectuation plan form, the SDRA serves as a true default measure of the MFP rebate amount

[7] A 2023 report by IQVIA found that use of the Part B 340B modifier across a variety of 340B covered entities was limited, with a particular lack of compliance by rural referral centers and sole community hospitals. R. Martin, et al., IQVIA. Can 340B Modifiers Avoid Duplicate Discounts in the IRA? IQVIA (Feb. 2023), *available at:* https://www.iqvia.com/locations/united-states/library/white-papers/can-340b-modifiers-avoid-duplicate-discounts-in-the-ira.

[8] *See* Public Health Service Act § 340B(a)(1); SSA § 1193(a)(3).

due for a selected drug so that there is certainty that payment of the SDRA is sufficient. As pharmacy acquisition costs are typically lower than WAC, using the SDRA as a true default would ensure that the obligation to pay the MFP is fully satisfied.[9]

Amgen also urges CMS to clarify that the MFP rebate amount can never be higher than the SDRA, including where acquisition costs are higher than WAC, despite the statements in the IPAY 2027 Final Guidance indicating "that the SDRA may not be universally appropriate or sufficient to effectuate the MFP" and where "the dispensing entity's acquisition cost was greater than WAC, and therefore, the MFP was not made available to that dispensing entity . . . ."[10] It may be the case that pharmacies sometimes purchase drugs at a price higher than WAC; however, where that purchase is made through wholesalers and distributors, the costs above WAC are not representative of a price offered by the manufacturer in the market. Rather, the costs reflect upcharges by the wholesalers and distributors. If CMS were to require manufacturers to pay an MFP rebate that covers these additional costs, it would not only impose on manufacturers an obligation that exceeds that specified in the law but also create adverse incentives for pharmacies and others in the pharmaceutical supply chain to increase profits by artificially inflating acquisition costs and thus MFP rebate amounts.

For example, prior to January 2024, Part D plan sponsors were permitted to agree to a Part D negotiated price with pharmacies that was higher than the amount of the final payment from the Part D plan sponsor to the pharmacy, thus artificially inflating the amount of the Coverage Gap Discount Program (CGDP) discount and the beneficiary coinsurance amount, which are calculated as a percentage of the Part D negotiated price. CMS has since prohibited this practice.[11] The Brookings Institute similarly has observed that vertical integration "permits [Medicare Advantage (MA)] plans to circumvent regulations aimed at constraining the profits that can be earned from the MA program."[12] Specifically, "a vertically integrated MA plan can move profits from the MA plan to the related business. This increases the MA plan's [medical loss ratio (MLR)] without reducing the parent company's profits, weakening the MLR constraint."[13]

III. Q22: Interactions with dispensing entities with material cashflow concerns

Amgen is opposed to the requirement to develop mitigation plans for dispensers with material cashflow concerns. While we share the Agency's goal of ensuring dispensers are paid promptly, we continue to believe that a less burdensome and more efficient way to effectuate the MFP would be for CMS to utilize an approach similar to the Part D CGDP, including CMS prefunding of refund amounts and pass-through such amounts to dispensers on behalf of Primary Manufacturers at the time of claim adjudication.

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[9] *See* NADAC Equivalency Metrics, Myers and Stauffer, (Mar. 25, 2024), *available at:* https://www.medicaid.gov/medicaid/prescription-drugs/downloads/retail-price-survey/nadac-equiv-metrics.pdf.

[10] IPAY 2027 Final Guidance at 69, § 90.2.

[11] 87 Fed Reg 27,704, 27,847 (May 9, 2022).

[12] Frank RG, Milhaupt C. Related Businesses and Preservation of Medicare's Medical Loss Ratio Rules. *Brookings*, (Jun. 2023), *available at* https://www.brookings.edu/articles/related-businesses-and-preservation-of-medicares-medical-loss-ratio-rules/.

[13] *Id*.

In addition, Amgen has significant concerns with the fact that the mitigation plan requirement was not included in the draft guidance for MFP effectuation in 2026 and 2027.[14] By introducing this new concept solely in the Final Guidance, CMS deprived stakeholders, including manufacturers, of the opportunity to provide comment and input.

If the Agency continues to decline to adopt an MFP effectuation model similar to the CGDP and moves forward with requiring manufacturers to develop mitigation plans, then we would strongly encourage CMS to provide more transparency about the types of mitigation plans the Agency is expecting. While we appreciate the ability of Primary Manufacturers to develop qualifying criteria for their mitigation plans under Question 22C, the lack of clarity from CMS on what types of qualifying criteria and types of mitigation plans the Agency would consider acceptable presents significant uncertainty and compliance burden on Primary Manufacturers.[15] Finally, CMS should affirmatively acknowledge that Primary Manufacturers are permitted to require that any pharmacies claiming material cashflow concerns provide documentation to support such claims.

IV. CMS Should Affirmatively Establish Procedures for Manufacturers to Identify Information Submitted as Part of the MFP Effectuation Process That Is Proprietary or Otherwise Confidential

In the IPAY 2027 Final Rule, CMS states that it will limit distribution of MFP effectuation plans to dispensers through the MTF-DM, and that "[it] may release a redacted version of [MFP effectuation] plans to other applicable stakeholders (e.g., supply chain entities) upon request as CMS anticipates that these plans may be subject to FOIA requests in the future."[16] In the supporting statement to the MTF effectuation forms ICR, CMS further states that respondents submitting information shall not be required to "[s]ubmit proprietary, trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law."[17] For CMS to be able to successfully reconcile these two statements, it is critical that manufacturers be expressly given the opportunity to identify which information they are submitting is confidential and thus which information should be redacted or withheld from release through the MTF-DM and in response to any FOIA request or with respect to any other contemplated public disclosure. Amgen urges CMS to give manufacturers this opportunity through the revised ICR. In addition, prior to effectuation plans being distributed, CMS must ensure that Primary Manufacturers are provided an opportunity to object to the distribution of any confidential commercial information, as required by HHS' FOIA procedures in 45 C.F.R. Part 5, Subpart D.

Appendix C: Medicare Drug Price Negotiation Program Primary Manufacturer Payment Elements Form

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[14] *See* https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf

[15] *See* Final Guidance, p. 287: "CMS will consider the information provided by a Primary Manufacturer in its mitigation process when conducting a risk assessment of the Primary Manufacturer's MFP effectuation plan."

[16] IPAY 2027 Final Guidance at 134.

[17] MTF Effectuation ICR Supporting Statement at 8.

V. Payment Element 4: Quantity of Selected Drug – CMS Should Clarify the Unit of Measurement for the Quantity of Selected Drug to Represent Packages

CMS publishes MFP prices on a per unit and per package basis. It is not apparent from the ICR if CMS intends for manufacturers to populate the quantity field with number of units or number of packages of the selected drug to include in the MFP refund amount. In order to ensure consistency across manufacturer reporting, we recommend that CMS further specify that this field should be populated at the package level. This will also ensure consistency and compatibility with other systems expected to be used in the effectuation process.

Additional Comments

VI. CMS Should Provide Clear Timelines for Testing of the MTF To Ensure Readiness for 2026 Effectuation.

Amgen encourages 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). There are many questions yet to be answered about the MTF operations, e.g., file extension format, transfer mechanics, and other technical specifications. Early opportunities for systems testing will be crucial as selected manufacturers develop MFP effectuation plans and for the smooth effectuation of Maximum Fair Prices under the IRA. We also recommend that CMS consider mechanisms for end-to-end solution development and testing, inclusive of external vendors that manufacturers may retain to support timely effectuation of MFP.

* * * * *

We appreciate CMS' consideration of these comments. Please do not hesitate to contact Yola Gawlik at (202)320-1159 or ygawlik@amgen.com if you have any questions.

Sincerely,

Greg Portner
Senior Vice President
Global Government Affairs & Policy

December 27, 2024

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS–10912
Room C4–26–05
7500 Security Boulevard
Baltimore, Maryland 21244–1850

Re: Agency Information Collection Activities: Proposed Collection; Comment Request [Docket No. CMS–10912] - CMS–10912 Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request-Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Enrollment Form

Docket Management Staff,

The American Society of Consultant Pharmacists (ASCP) and Senior Care Pharmacy Coalition (SCPC) appreciates the opportunity to provide joint comments to Docket No. CMS–10912 - Agency Information Collection Activities…

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.

The Senior Care Pharmacy Coalition (SCPC) is the only Washington-based organization exclusively representing the interests of long-term care (LTC) pharmacies. SCPC's membership includes 80 percent of all independent LTC pharmacies. Our members serve one million residents daily in skilled nursing facilities and assisted living communities across the country.

Appendix A

Page 2: We encourage CMS to ensure alignment with the NCPDP Registry: The NCPDP Registry provides accurate, up-to-date and secure management of pharmacy-PSAO and insurer connections. The Registry serves as a centralized, authoritative source for pharmacy profiles—covering long-term care, chain, independent, speciality and mail-order pharmacies—and is trusted by commercial, Medicaid, and Medicare payers alike. It is the foundation for pharmacy enrollment in Part D plans. As such, each pharmacy maintains control over its profile with robust

security measures, ensuring that only the pharmacy or its authorized proxy can make modifications. CMS has a ready-built, capable model that, even if augmentations are needed, can scale quickly to meet the price effectuation date of January 1, 2026.

Page 5: In Section 2, Question 2, we ask CMS to provide greater clarification as to how "combination shops," – a common pharmacy, especially in rural areas that has 2 NPI numbers and services long-term care and retail consumers – be included. We recommend the addition of "combination pharmacy (i.e.: LTC/retail) to the pre-populated lists instead of requiring these pharmacies to retain to profiles in the MTF DM, MTF PM or other Effectuation Plan model and select "other" requiring further explanation in a triggered text field.

On page 6, question 3, we appreciate CMS specifically citing "long-term care pharmacies" as expecting to experience "material cashflow concerns" in its proposition of question 3. We appreciate CMS' continued engagement with us to understand, anticipate and mitigate the known challenges for pharmacies serving long-term care communities.

We ask CMS to consider the comments of the National Community Pharmacists Association (NCPA) highlighting that each community pharmacies will need to float, on average $27,000 per month.[1] In effectuation plans, we hope to see language that simply requires self-identification as the sole qualifies as having "material cashflow concerns."

On page 8, ASCP and SCPC asks CMS to further define "aggregated, single amount on a recurring basis," specifically frequency.

Appendix B

Global Comments: The U.S. drug supply chain is complex and interconnected. As manufacturers and CMS look to effectuate MFPs, we believe the system, especially pharmacies and vendors, need time to prepare. CMS requires manufacturers to provide the Effectuation Plans no later than September 1st of the year before the price takes effect. We encourage manufacturers to make key elements of their Effectuation Plans known as soon as possible. Key elements such as: intention to use the MTF PM, cashflow mitigation plans, enrollment materials (if not leveraging MTF PM), and more so patients, pharmacies and vendors can plan and take necessary implementation steps.

Furthermore, we ask that CMS work to ensure that pharmacy associations and professional societies have access to the MTF DM to access Effectuation Plans and provide education to members. Likewise, we encourage public access to these plans, with sensitive data redacted, to provide appropriate industry coordination, research and problem-solving.

In response to CMS question provided in Question 5 regarding the "Frequency of Transmission of Claim-Level Payment Data to Medicare Transition Facilitator Faciliatory Data Module (MTF

[1] https://ncpa.org/sites/default/files/2024-11/one-pager-mdpn.pdf

DM)," we recommend daily transfers of data to the MTF DM as the required standard to facilitate timely payment throughout the system.

Regarding "Q22C: Qualifying Criteria for Dispensing Entities to Participate in Program Designed to Mitigate Material Cashflow Concerns," we believe that self-identification through the Medicare Transition Facilitator Data Module (MTF DM) should be the only criteria to access a manufacturer's mitigation plan and CMS nor manufactures should not require additional evidence for participation.

Appendix C

In previous guidance and in Appendix B, CMS requires that Primary Manufacturers establish Effectuation Plans that include plans to mitigate the "material cashflow concerns" of pharmacists, including long-term care pharmacies. However, in "Payment Element 2: Method for Determining MFP Refund Amount," CMS only provides "3 No Refund Transmitted - Prospective MFP Access" as the mitigation option. We recommend the wording be amended to "3 No Refund Transmitted – Cashflow Mitigation Alternative." Within the drop down, CMS may retain a "No Refund Transmitted - Prospective MFP Access" option as a higher numeric value within the code values of Table 1.

Additionally, and not alternatively, we recommend that the code for response value "2" be clarified to state, "2 Amount Other than Standard Default Refund Amount Transmitted (ie cashflow mitigation plan.) We believe that cashflow mitigation can be achieved through different mechanisms and we hope to work with Manufactures to identify the best and most appropriate options, especially in non-traditional pharmacy settings like long-term care.

Appendix D

ASCP and SCPC recommend that CMS provide more explanatory text in Q1A for "D: Non-Chain Dispensing Entity." As noted, Q1B is triggered by the selection of this option and provides an extensive list of pharmacy types. We recommend the option text be amended to read, "Non-Chain Dispensing Entity (ie: LTC, community, VA, independent, etc)" and work with the pharmacy community to educate independent, long-term care and other small pharmacies that they should select this option when submitting disputes.

We appreciate the need for disputes to be initiated by a "L: Trade or Advocacy Association, or other Interested Organization" as a pre-populated "submitter type" in Q1A. We ask that CMS continue to work with trade associations and professional societies to ensure access to all elements of the MTF DM and MTF PM, as appreciate to submit disputes collectively to support access to medications at the MFP. We encourage CMS to consider allowing this question to trigger question Q1B.

Again, ASCP and SCPC thanks CMS for the comment opportunity and we stand ready to work with the agency on solutions related to IRA implementation. Please feel free to contact James

Lewis of ASCP at jlewis@ascp.com with any questions or follow-up requests. We appreciate CMS' attention to this matter and continued engagement regarding our concerns.

Sincerely,

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

Alan Rosenbloom, JD
President & CEO
Senior Care Pharmacy Coalition (SCPC)

December 27, 2024

Submitted Electronically

William N. Parham, III
Director
Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS-10849/OMB Control Number 0938-1452
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS 10912 (Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA))

Dear Director Parham:

AstraZeneca appreciates this opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the proposed Information Collection Requests (ICRs) for the implementation of Maximum Fair Price (MFP) and the Medicare Transaction Facilitator (MTF) for 2026 and 2027.[1]

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of diseases in three therapy areas: Oncology, Cardiovascular, Renal & Metabolism (CVRM) and Respiratory & Immunology. We are also working to solve the challenges for rare disease patients through Alexion, AstraZeneca Rare Disease. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide.

In general, AstraZeneca appreciates the commitment of CMS to providing the ICRs for public comment through two rounds, and supports CMS providing as much information as possible, as soon as possible, for manufacturers and dispensing entities to prepare plans for MFP effectuation. Our comments, organized below by the four separate ICRs released, focus on the areas raised through the ICRs published in November and are not necessarily exhaustive of AstraZeneca's potential concerns with the MFP effectuation process, especially as many uncertainties remain regarding implementation. As outlined herein, we urge CMS to provide additional clarity to help inform our comment submission on the second round. We also identify

[1] https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pra-listing/cms-10912

several mechanisms for CMS to reduce manufacturer burden in MFP effectuation, which we recommend incorporating into the next draft of the ICR.

Appendix A: Dispensing Entity Enrollment (Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Entity Enrollment Form)

The dispensing-entity enrollment ICR requests that dispensing entities provide their National Council for Prescription Drug Programs (NCPDP) identification numbers, as well as information that is ordinarily provided in NCPDP format. It is important, for ease of transmitting and processing the information included in this ICR to manufacturers, that this information be transmitted to the Data Module (DM) of the MTF in NCPDP format, and then transmitted from the DM to manufacturers in the same format. NCPDP is the format currently used for these types of claims-level data exchanges, and it would be helpful for CMS to confirm that this will continue to be the case.

AstraZeneca also wishes to reiterate its support for CMS' proposals in the Contract Year (CY) 2026 proposed Part D rule to require dispensing entities contracting with Part D plans to participate in the MTF DM, as well to shorten the time period for initial submission of Part D Event (PDE) records within seven days.[2] Failure to require dispensing entities' participation in the DM and to submit the initial PDE records within seven days will make MFP effectuation impossible as a practical matter, so AstraZeneca strongly supports CMS' efforts to finalize these proposals.

Appendix B: Manufacturer Effectuation Plan ("Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form")

As an initial matter, AstraZeneca notes that the timeframes for the submission of manufacturers' plans for MFP effectuation may leave very little time to address potential concerns from CMS regarding the plans. While we appreciate that the submission of these plans in September 2025 for IPAY 2026 will provide maximum time for manufacturers to develop these plans and for CMS to refine requirements and expectations, the short time frame between submission of these plans and the MFP's effective date will require CMS to be as responsive as possible to any concerns during that time frame.

More generally, it is difficult for AstraZeneca to provide feedback on all of this ICR's content and estimated burden because so much remains unknown, at this point, about the functionality of the MTF. With that in mind, we provide the below feedback.

Question 3: This question requests information from manufacturers regarding their process for contacting, receiving, and responding to inquiries from dispensing entities regarding MFP effectuation. It is very difficult to estimate the potential burden this process will represent for manufacturers, because the volume of expected inquiries is completely unknown, and it will also

[2] 89 Fed. Reg. 99340 (Dec. 10, 2024).

be difficult for manufacturers to design and describe such a process in detail without a sense of the volume of inquiries it will receive.

Some other uncertainties remain that would affect AstraZeneca's ability to respond to this question, where more clarity would be helpful to inform our comments on the second round of the ICR, including for instance:

Are manufacturers obligated to respond to such inquiries, and is CMS considering imposing a standard required response time?

If the manufacturer chooses to use the MTF Payment Module (PM), will the MTF PM play a role in communication with dispensing entities?

Question 4: This question requests information regarding the manufacturer's plans for preventing duplicate discounts from the MFP and the 340B program. First, it is important to note that AstraZeneca intends to comply with CMS' expectations for a nonduplication process, and that manufacturers need not also separately seek approval from the Health Resources and Services Administration (HRSA) regarding the proposed process.

Further, AstraZeneca raises the following concerns and questions:

It appears that some of these elements may not be necessary if a manufacturer is using the MTF PM for payment processing. To inform our comments on the second round, it would be helpful for CMS to clarify how the information expected would be different for manufacturers using the PM versus manufacturers using their own payment facilitator. We also encourage CMS to consider what role the MTF PM could play in communication with dispensing entities in relation to possible duplicate discounts.

In releasing the CY 2025 final Physician Fee Schedule Rule, CMS stated that it "will explore establishing a Medicare Part D claims data repository to comply with the statutory obligation for removal of 340B units from Part D drug inflation rebate calculations."[3] More recently, CMS issued such a proposal in *the 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* proposed rule.[4] The availability, frequency, and timing of this information will be crucial to manufacturers' ability to address concerns around duplicate discounts, so it would be helpful for CMS to provide further information on this claims data repository as soon as possible, ideally in time to inform our comments on the second round of this ICR. The potential clearinghouse may also inform manufacturers' responses to Question 21 of the ICR, which concerns manufacturers' "approach for completing internal auditing to ensure all transactions effectuate MFP in compliance with the final guidance and Negotiation Program requirements." Effectuating MFP while avoiding

[3] https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2025-medicare-physician-fee-schedule-final-rule
[4] https://public-inspection.federalregister.gov/2024-27939.pdf.

duplicate discounts will be a significant challenge in any event, but the availability of a Part D claims repository contemplated by CMS would be a significant aid to this effort.

Questions 22A–C: This question relates to manufacturers' plans for mitigating potential "material cashflow concerns" relayed by dispensing entities. In considering this issue, AstraZeneca reiterates its support for CMS' shortening the 30-day timeline for Part D sponsors to submit data regarding claims to the Drug Data Processing System to 7 days. AstraZeneca is also appreciative that the ICR suggests that manufacturers will have discretion to verify whether a dispensing entity has material cashflow concerns, and is not bound to a dispensing entities self-identification as having such concerns. Generally speaking, with the expectation that dispensing entities will receive MFP refunds within 14 days and therefore generally should not face significant cashflow issues. It will therefore be important for manufacturers to have flexibility to assess the seriousness of concerns reported by dispensing entities.

However, manufacturers that plan to rely on the MTF PM may be limited in their ability to describe their plans for mitigating material cashflow concerns if operational details regarding the MTF PM remain uncertain through next summer (i.e., until close to, or after, the submission date for the IPAY 2026 MFP Effectuation ICR). We urge CMS to address this uncertainty to reduce burden on manufacturers.

Further, there are likely to be significant differences between the cashflow concerns posed for dispensing entities by different drugs (given different prices and different gaps between likely pharmacy acquisition cost and MFP). CMS should clarify that plans for addressing material cashflow concerns may address drug-specific cashflow concerns.

Similarly, the cashflow concerns cited by dispensing entities are likely to evolve over time, and CMS should recognize that manufacturers' plans for addressing such concerns likely will have flexibility to evolve as dispensing entities adjust to MFP effectuation. Finally, Primary Manufacturers cannot be practically accountable for Secondary Manufacturers' choices regarding MFP implementation and mitigation material cashflow concerns. CMS should clarify that Primary Manufacturers' plans for addressing material cashflow concerns need not encompass efforts by a Secondary Manufacturer.

Appendix D: Disputes and Complaints ("Drug Price Negotiation Program Complaint and Dispute Intake Form")

In the overview of the dispute and complaint process, CMS states that complaints and disputes "must be submitted to CMS no later than 120 calendar days from the date of the subject of the complaint or dispute." As an initial matter, CMS should provide more detail on the meaning of this 120 day requirement: For instance, in the event that a dispensing entity does not receive a retrospective refund, would the "subject of the complaint or dispute" be the date on which the drug was dispensed, the date on which the dispensing entity conveyed the PDE record to the DM, or the date on which the refund would have been due? In the interest of clarity, AstraZeneca

recommends that CMS begin the 120 day period from the date on which the complaining entity first directly raised the complaint or dispute with the entity against which the complaint or dispute has been raised.

The agency also does not provide detail on how quickly the complaint or dispute will be provided by the system to manufacturers (or other parties). It would be helpful for CMS to discuss the timeframe it expects to use for the dissemination of complaints and disputes, and the timeframe expected for responses. Given the 120 days provided for the initiator of the complaint or dispute to submit the matter to CMS, the agency should consider using the same, 120-day period for the timeframe for the initial response by the entity against which the complaint or dispute has been raised.

Further, while AstraZeneca appreciates CMS' proposal to track complaints and disputes, complaints or disputes lodged against manufacturers or other entities may contain proprietary information or other information that should not be made public. CMS should state clearly that the agency intends to ensure any complaints or disputes filed will be kept confidential given the sensitivity of the information involved and, if possible, provide details on how it plans to ensure such complaints and disputes are kept confidential.

* * *

Thank you for your consideration of AstraZeneca's comments on the four ICRs. AstraZeneca appreciates CMS' commitment to working with manufacturers and dispensing entities to ensure smooth and successful effectuation of MFP, and AstraZeneca is ready to provide feedback on CMS' evolving plans. If you have any questions or would like additional information, please contact me at sarah.arbes@astrazeneca.com.

Sincerely,

Sarah C. Arbes

Head of Federal Affairs and Policy

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

VIA ELECTRONIC DELIVERY

December 20, 2024

Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Centers for Medicare & Medicaid Services

Re: CMS-10912 Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request

The Biotechnology Innovation Organization (BIO) appreciates this opportunity to comment on the Information Collection Request (ICR) regarding information collected from manufacturers to facilitate the effectuation of the MFP utilizing the Medicare Transaction Facilitator (MTF) for 2026 and 2027.

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.

As BIO has stated in previous comments, it is critical that CMS prioritize effectuating the MFP properly by ensuring compliance with the 340B non-duplication requirement. Currently, the lack of mechanism to prevent both MFP and 340B discounts on the same drug unit is concerning as the MFP and the 340B discount are expected to be effectuated through post-transaction adjustments, with patient eligibility unclear at time of dispensing. CMS' lack of any action to implement the IRA's nonduplication provision is simply unworkable and inconsistent with statute, which clearly requires that the 340B status of a claim be known before a manufacturer is required to provide any MFP discount. The potential for diversion of MFP units is not merely a theoretical concern. In contrast to the Negotiation Program, the 340B Program, which is generally administered via upfront discounts, features a statutory audit right, a statutory dispute resolution mechanism, and agency authority to impose sanctions, including termination of access to the 340B price. Yet even this constellation of statutory safeguards against diversion has proven deeply inadequate to prevent diversion of 340B units. While we appreciate CMS' intent to establish a Medicare Part D claims data repository through future rulemaking, in the meanwhile, manufacturers are still constrained by the fact that there is currently no concrete means of identifying 340B eligible claims versus MFP claims. BIO strongly believes that Covered Entities should be required to furnish claims level data to manufacturers as required to process an individual claim, including the 340B or non-340B claims modifier, and for any sales to contract pharmacies.

In addition, it is important for CMS to recognize that MFP effectuation will come with significant financial and operational burden. It is a monumental undertaking for manufacturers to establish

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

direct payment relationships with a large volume of dispensers, as evidenced by the development of the MTF PM. While we appreciate the work that CMS has done thus far in the creation of the MTF PM, it is evident that the complexity of ensuring consistent compliance and payment accuracy across such a vast network demands a significant coordinated effort between CMS, the MTF DM and PM, dispensers, and manufacturers. BIO remains concerned that the current operational timeline for effectuating the MFP does not provide manufacturers with appropriate time to develop the effectuation plan by September 2025, given that there are still many operational questions that remain, including data transfer standards, frequency of data and payment transfers, details regarding the dispute resolution process, and also the MTF-PM has yet to be announced. As CMS continues to develop guidance, we encourage CMS to select an MTF-PM with robust, end-to-end payment and communication capabilities. After MTF-PM selection, CMS should recognize that manufacturers need appropriate time to establish payment connections, agreements, and mechanics for payment exchange between parties. As such, we encourage CMS to exercise good governance and commit to ensuring proper implementation of the effectuation program with consistent coordination with manufacturers, reasonable timelines to support thorough and accurate submissions, and ongoing process improvements to alter MTF functionalities as seen necessary.

Finally, BIO is concerned that the forms contained in this ICR do not allow manufacturers to indicate that certain information is confidential. CMS must fully protect the confidentiality of all proprietary information submitted in relation to this ICR and revise the forms accordingly so that confidential information can be marked as such. In addition, it is problematic that the forms only allow text submission, without the opportunity to upload supplemental documents. BIO recommends that CMS include an option for manufacturers to upload supplemental documents to support thorough and accurate submission of the forms.

Our specific comments on the Primary Manufacturer MFP Effectuation Plan Form, Primary Manufacturer Claims-level Payment Elements Form, and Complaint and Dispute Intake Form are as follows.

Drug Price Negotiation Program MTF DM Primary Manufacturer Maximum Fair Price (MFP) Effectuation Plan Form

Section 2: Information Requested from All Primary Manufacturers

Q4. Describe the Primary Manufacturer's process for nonduplication of claims that are 340B eligible and not subject to MFP availability.

BIO appreciates CMS' willingness to establish a Medicare Part D claims data repository, as indicated in the CY 2025 Medicare Physician Fee Schedule Final Rule, to comply with the statutory obligation for removal of 340B units from Part D drug inflation rebate calculations. As we have stated in previous comments, BIO urges CMS to quickly move forward with claims modifier requirements, as well as establishment of the repository well in advance of 2026. Such requirements are necessary to enforce the statutory prohibition on inflationary rebates on 340B units, as well as the requirement that manufacturers offer eligible entities the lower of the 340B ceiling price or the "maximum fair price," but not both. It is imperative that the repository and the

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

MTF cooperate in identification of 340B claims to ensure appropriate removal of 340B claims from the Inflation Rebate Program and the effectuation of the MFP.

Q6 &7. Describe the Primary Manufacturer's general plan for calculating the MFP refund amount and Describe the Primary Manufacturer's methodology for determining the amounts it will reimburse dispensing entities when the Primary Manufacturer is not calculating an MFP refund using the Standard Default Refund Amount.

BIO is concerned that Questions 6 and 7 do not consider the scenario where a manufacturer is providing the MFP prospectively. Although all manufacturers are required to complete those questions, the options listed in the drop-down menu only apply if a manufacturer is effectuating an MFP as a refund payment, and would not apply if a manufacturer offers the MFP prospectively. Therefore, BIO urges CMS to specify that Questions 6 and 7 should be completed only if a manufacturer is offering the MFP retrospectively.

In addition, BIO suggests that the MFP refund should be capped at the Standard Default Refund Amount to avoid any potential gaming or overstating of costs.

Q10. Requires a manufacturer to upload a list of NPIs of dispensers with which it has agreed to an alternative arrangement to effectuate MFP.

BIO urges CMS to streamline this question given the significant number of dispenser NPIs that a manufacturer would have to list. Notably, there are approximately 70,000 pharmacies that bill for Medicare Part D.[1] BIO suggests that if a manufacturer effectuates an MFP prospectively for all dispensers, there should be an option to indicate that the same methodology applies to all dispensers, without the need to list all NPIs.

Q14-18. Address how the Primary Manufacturer intends to engage with any Secondary Manufacturers

BIO continues to note our concern with the proposal to hold a Primary Manufacturer responsible for submitting applicable information concerning a Secondary Manufacturer, which poses significant confidentiality concerns, particularly with the effectuation of the MFP. A Primary Manufacturer has no inherent legal authority to compel a Secondary Manufacturer to act or not act, including to share information on operational processes established for MFP effectuation. We note that this same concern pervades the Final IPAY 2027 Guidance, given the numerous contexts in which CMS proposes to hold a Primary Manufacturer responsible for the action or inaction of a Secondary Manufacturer.

Finally, BIO requests that CMS require the MTF to share information from Appendix A, Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Enrollment Form with manufacturers, to help facilitate the exchange of necessary information needed to effectuate the program.

[1] "Key Medicare Tools to Safeguard Against Pharmacy Fraud and Inappropriate Billing Do Not Apply to Part D," Office of Inspector General, US Department of Health and Human Services, March 2020. https://oig.hhs.gov/oei/reports/oei-02-15-00440.pdf Accessed: May 27, 2024.

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

Section 4: Assisting Dispensing Entities with Material Cashflow Concerns

CMS states that reliance on retrospective MFP refunds may cause pharmacy cashflow concerns due to potential delays. BIO strenuously disagrees with the new requirement imposed by CMS that manufacturers should be responsible for mitigating these cashflow challenges for dispensing entities, as this new requirement is not found in statute. Manufacturers have no ability, as well as no statutory obligation, to address pharmacy cashflow concerns. In addition, potential pharmacy cashflow concerns may be inherent in the implementation of the law rather than the result of any manufacturer's actions. To better address pharmacy cashflow concerns, CMS could prefund MFP discounts, similar to the process under the Coverage Gap Discount Program (CGDP).

Drug Price Negotiation Program MTF DM Primary Manufacturer Payment Elements Form

As stated in previous comments, BIO is deeply concerned that the 14-day prompt-pay window does not provide enough time for manufacturers to process all MFP claims accurately and thoroughly. It is critical that the prompt pay window be expanded so that manufacturers can effectively make the determination of the lower of the 340B or the MFP and scrub for duplicate claims and errant claims. As manufacturers scrub data to process the claim, they not only verify patient eligibility, but also must verify that the quantity is correct and that each claim is unique and has not been previously submitted or duplicative of another claim. Accordingly, the 14-day window is insufficient and creates significant operational challenges for manufacturers who must support intensive claim verification.

In addition, BIO suggests that CMS provide examples of MFP refund payment transactions by describing possible situations and clarifying how refund payments could be calculated. For example, CMS could simulate their efforts with the Medicare Prescription Payment Plan (MPPP), in which CMS provides examples on their website of how the payment plan could work in different situations and provides mathematical breakdowns under each situation. A similar model would significantly help clarify payment situations in the MFP refund context, including potential rounding errors and other potential issues.

Drug Price Negotiation Program Complaint and Dispute Intake Form

As we have stated in previous comments, it is imperative that CMS should establish an enforceable dispute process for MFP recoupment. This dispute process would cover matters where post-MFP payment, it is determined that the unit is not in fact MFP-eligible, as well as an enforceable mechanism for 340B recoupment where, post-340B payment, it is determined that the unit is MFP-eligible. This mechanism should at the very least allow for manufacturers to receive direct repayments. In addition, there could also be an option for overpayment of MFP to be treated as a credit toward future MFP discounts.

In addition, to avoid unfairly penalizing manufacturers for good faith disputes of the initial rebate calculations, CMS should establish a policy whereby:

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

- If a manufacturer timely contests the amount on an initial 2025 invoice within the 10-day window and does not pay the contested amount, CMPs would not be assessed on the disputed amount until the agency completes the reconciliation process and makes a final determination.
- Manufacturers would still be required to pay any uncontested amounts within the 30-day deadline to avoid CMPs on those amounts.

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,

Melody Calkins
Director, Health Policy
Biotechnology Innovation Organization

Bristol Myers Squibb™

VIA ELECTRONIC DELIVERY

December 23, 2024

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator, Director of the Center for Medicare
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (CMS-10912)

Dear Dr. Seshamani,

Bristol Myers Squibb (BMS) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) *Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request ("MTF ICR")*.[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" policies contained in the *Inflation Reduction Act (IRA)*. We are extremely concerned by the impact that these policies will have on clinical research in addition to current and future innovation for patients.[2]

[1] CMS, "Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)" (Oct. 28, 2024), *available at* https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pra-listing/cms-10912.

[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.

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 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 ICR, 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 this ICR, 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 weight 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.

In general, an ICR is not an adequate mechanism for providing public input and dialogue on establishing important processes for how manufacturers must provide access to the MFP to MFP-eligible individuals and entities, as well as data and payment elements. 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.

Key comments include:

- **Financial and Operational Burdens on Manufacturers:** Despite CMS' proposals, BMS notes our significant financial and operational concerns with the MTF. We are generally supportive of the MTF becoming a "platform" for carrying out critical front- and back-end functions of MFP effectuation, including the necessary ability to communicate with stakeholders directly involved in the MTF process; however, in the absence of additional Agency action to remedy these serious concerns in advance of January 1, 2026, and to help ensure a transparent and administratively efficient operationalization of the MFP, we continue to ask that CMS provide flexibility for manufacturers to establish the appropriate data sets, timeframes, and processes to support compliance. In addition, given the many operational concerns we have highlighted, BMS notes that it will be very challenging, if not impossible, for manufacturers to submit a plan by September 1, 2025. We ask CMS to give manufacturers

[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.

additional flexibility, either with the elements of the effectuation plan, the timeline, or both, and keep MFP Effectuation Plans confidential and only distribute them on a limited basis. Additional comments include:

- Payment Timelines: 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.
- Cashflow Concerns: While the financial strain on dispensing entities is undoubtedly an unfortunate outcome of the IRA and one that manufacturers have flagged often for CMS to fix, we do not believe it to be a manufacturer's responsibility to establish a process for remedying potential cashflow concerns as manufacturers will also be experiencing significant financial strain to effectuate and operationalize MFP payments to dispensing entities. Just as many dispensing entities will be financially impacted, so, too, will manufacturers, not only by the cost of effectuating MFP, but by significant market shifts as a function of IRA. It is both unrealistic and impossible for manufacturers to take on the responsibility of validating legitimate cashflow concerns and potentially remedying them. Additionally, BMS is concerned that if CMS does not address dispensing entity concerns, we could see significant patient impacts due to new financial incentives which could steer patients towards other, non-MFP medicines. We strongly urge CMS to remove manufacturers from this process and work with Congress to remedy dispensing entity cash flow concerns in advance of January 1, 2026.
- MFP/340B Non-duplication: BMS understands that CMS does not have the appropriate data inputs to fully operationalize the MFP/340B non-duplication provision, and we implore the Health Resources and Services Administration (HRSA) to work with CMS to provide adequate specificity to effectuate this provision in advance of January 1, 2026. In the absence of this Agency collaboration, however, the burden continues to be put on manufacturers to create a valid and reliable process for identifying 340B eligible claims. Given CMS' position that manufacturers must resolve these issues independently, but given the challenges if not impossibility of doing so now, BMS urges CMS and more broadly the Secretary of Health and Human Services (HHS) to acknowledge that a 340B rebate model is an appropriate and viable solution and would help both manufacturers and CMS implement MFP effectuation. In the absence of Agency action, and in light of the vast complexity of the 340B Program, CMS should expressly acknowledge that manufacturers may establish, receive, review, and as necessary, audit MFP validation data to ensure manufacturers have provided MFP access in accordance with the statute.

- **Necessary Components and Capabilities of the MTF:** We urge CMS to ensure the MTF is an end-to-end platform by January 1, 2026. Accordingly, this MTF platform must have communication capabilities so that manufacturers and dispensers, as well as other relevant stakeholders, can effectively and efficiently communicate. As a first step, BMS asks CMS to require the MTF share all dispensing entity information (Appendix A) with manufacturers to facilitate a more compliant and transparent MFP effectuation process.

- **Payment Elements Examples:** We ask CMS to create numeric/strawmen examples in support of Appendix C, similar to the user-friendly mathematical guides CMS had created to support implementation of the Medicare Prescription Payment Plan, to aid in both CMS and manufacturer compliance related to the payment elements. We believe that having these examples will not only aid in transparency and oversight but perhaps also uncover unique circumstances related to dollar amounts and refunds that may not fit neatly into CMS' pre-determined payment elements, which might warrant additional refinements to Appendix C in advance of January 1, 2026.

- **Complaints and Disputes:** BMS thanks CMS for creating a two-track complaint and dispute functionality within the MTF to aid in compliance and operationalization, but we ask CMS to further refine this process to ensure sufficient procedural protections, including by establishing a formal appeals process for disputes to provide additional guardrails and recourse for manufacturers. We also seek additional guidance from the Agency on how to handle payment obligations during and after the dispute process.

Supporting Statement (Part A)

- Burden Estimates: The MTF and MFP effectuation process represents a significant financial and operational burden for manufacturers, yet CMS' burden estimate is not even on the correct order of magnitude for manufacturers—and likely the Agency as well—to complete the ICR submission and all associated processes. We urge CMS to reconsider the burden estimate to be more in line with the significant workload that this process demands. To do this, CMS could consider engaging manufacturers who are going through the process to confidentially discuss their experiences and seek to leverage lessons learned to reduce burden in the future.

Appendix B: Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Form

We thank CMS for the opportunity to provide detailed comments on the necessary information needed by and from manufacturers to effectuate the MFP. We offer specific feedback on Appendix B below:

- MTF Functionality and Capability: BMS appreciates CMS' ongoing efforts to create an MTF process with end-to-end transaction capabilities and is generally supportive of the MTF becoming a "platform" for carrying out critical front- and back-end functions of MFP effectuation, including the necessary ability to communicate with stakeholders directly involved in the MTF process.

  While we recognize the potential of the MTF process to ease the burden on all stakeholders, including manufacturers, BMS notes that in its current state, the MTF would fall short of this goal. MFP effectuation will come at a significant financial and operational cost to manufacturers, particularly for high volume, high value products. We hope to work with the Agency to ensure operational success, but in the absence of additional Agency action to remedy these serious concerns in advance of January 1, 2026, and to help ensure a transparent and administratively efficient operationalization of the MFP, we continue to ask that CMS provide flexibility for manufacturers to establish the appropriate data sets, timeframes, and processes to support compliance.

  BMS appreciates that CMS is also issuing Appendix A: Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Entity Enrollment Form; while providing suggestions and edits to Appendix A are not specifically germane to our comments, we, too, agree with CMS that "dispensing entity enrollment in the MTF DM is needed for necessary operations related to the administration of the Negotiation Program…" and acknowledge the importance of "collect[ing] the necessary information to process dispensing entity enrollment in the MTF DM."[4] We strongly urge CMS to mandate the MTF share this dispensing entity information with manufacturers to further communication across stakeholders and compliant MFP effectuation.

  As noted in previous BMS and industry comments, we strongly reiterate that manufacturers do not currently have direct contractual relationships or obligations with all 60,000+ dispensing entities and rely on additional

[4] MTF ICR, Appendix A, p. 1.

stakeholders to effectuate and distribute our products as ordered with often limited-to-no visibility. This will make it difficult, if not impossible, for manufacturers to include in the MFP Effectuation Plans a "process for contacting, receiving, and responding to communications from dispensing entities regarding MFP effectuation… includ[ing] any proactive outreach to dispensing entities related to the Primary Manufacturer's MFP Effectuation Plan and its related policies and procedures, plans for disseminating or publishing key information, and the approach the Primary Manufacturer intends to establish for intaking and responding to communications initiated by dispensing entities" (Question 3).[5] CMS itself estimates that up to 95,000 pharmacies, including both chain and non-chain pharmacies, may enroll in the MTF,[6] and it is unrealistic for manufacturers to have a direct relationship with even a small fraction of these dispensing entities without CMS intervention.

We urge CMS to ensure the MTF is an end-to-end platform by January 1, 2026. Accordingly, this MTF platform must have communication capabilities so that manufacturers and dispensers, as well as other relevant stakeholders, can effectively and efficiently communicate. As a first step, BMS asks CMS to require the MTF share all dispensing entity information (Appendix A) with manufacturers to facilitate a more compliant MFP effectuation process.

- MFP/340B Non-duplication: BMS understands that CMS does not have the appropriate data inputs to fully operationalize the MFP/340B non-duplication provision, and we implore HRSA to work with CMS to provide adequate specificity to effectuate this provision in advance of January 1, 2026. In the absence of this Agency collaboration, however, the burden continues to be put on manufacturers to create "[a] valid and reliable process for identifying 340B eligible claims" among other mandatory 340B claims processing considerations (Question 4).[7]

  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. Currently, covered entities assert that they have an unlimited amount of time to comb through claims, retroactively identify 340B "patients," and issue chargebacks to manufacturers. Multiple third-party administrators have identified this as a profit center and created a business model around identifying 340B claims for covered entities. This model is another way for-profit businesses profit from the 340B Program and makes it extremely difficult to know and verify if the patient served was actually a 340B patient under any patient definition. The chargeback model with replenishment often results in audits that are costly to HRSA and manufacturers.

  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, data must be exchanged between covered entities and manufacturers. Accurate and robust data collection is essential to the integrity of both the 340B Program and IRA implementation. 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

[5] MTF ICR, Appendix B, p. 3.
[6] MTF ICR, Supporting Statement Part A, p. 9.
[7] MTF ICR, Appendix B, pp. 3-4.

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.

Given CMS' position that manufacturers must resolve these issues independently, but given the challenges if not 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. In the absence of Agency action, and in light of the vast complexity of the 340B Program, CMS should expressly acknowledge that manufacturers may establish, receive, review, and as necessary, audit MFP validation data to ensure manufacturers have provided MFP access in accordance with the statute.

- Payment Timelines and Facilitation: In general, and as we discussed in our IPAY 2026 and 2027 comments, it is BMS' strong belief that CMS should lengthen the 14-day prompt MFP payment window, given the new processes that need to be developed to facilitate compliant MFP effectuation, including the additional 340B Program complexity and the short timeframe for developing an MFP effectuation plan. Based on our significant experience with transaction processing, we again reiterate the compliance concerns related to verifying claims data within this timeline. Currently, manufacturers must validate data from health plans and other entities to ensure proper identification of duplicate claims, fraud, etc., which can take many weeks, if not longer. The compliance risk is even more heightened for manufacturers when effectuating and providing the MFP—meaning it is imperative that manufacturers separately validate MTF-related claims data. Despite CMS' stated goals, this will still place an incredible financial and operational burden on manufacturers. Therefore, 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.

  To the extent possible, we urge CMS to aid in effectuating the MFP by utilizing an approach similar to the Coverage Gap Discount Program (CGDP), 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.

  The financial strain on dispensing entities is undoubtedly an unfortunate outcome of the IRA, yet we have serious concerns regarding a manufacturer's role in the process of dispensing entities indicating they have material cashflow concerns. We do not believe it to be a manufacturer's responsibility to establish a process for "assist[ing] dispensing entities with such material cashflow concerns, including but not limited to the dispensing entities that have self-identified" (Question 22).[8] A manufacturer's obligation under the law is to provide the MFP to MFP-eligible individuals, and to pharmacies, mail order services, other dispensing entities, providers and suppliers with respect to such MFP-eligible individuals who are dispensed that selected drug during a price applicability period—*not* to remedy cash flow concerns of other stakeholders that may or may not be occurring due to changes in the IRA. And practically speaking, it will place a huge, if not impossible, financial and operational strain on manufacturers to not only validate legitimate cash flow concerns but also to remedy

[8] *Id.* at p. 10.

them—instead of reducing burden on manufacturers, CMS has perhaps chosen the most burdensome process for addressing cashflow concerns. Furthermore, BMS is concerned that entities may choose medicines with more favorable cashflow terms, instead of those with a more favorable clinical profile, which can lead to patient steering and adverse outcomes for patients. We strongly urge CMS to remove manufacturers from this process and work with Congress to remedy dispensing entity cash flow concerns in advance of January 1, 2026.

- MFP Effectuation Plan Timeline and Burden: While BMS appreciates that CMS extended the manufacturer timeline to submit an MFP Effectuation Plan to September 1, 2025, and while we also recognize that CMS created the MTF process to ease operational concerns and that this timeline will allow for CMS to better evaluate a manufacturer's effectuation plan, BMS implores CMS to give manufacturers additional flexibility, either with the elements of the effectuation plan, the timeline, or both. Given the many operational concerns we have highlighted, BMS notes that it will be very challenging, if not impossible, for manufacturers to submit a plan by September 1, 2025. In addition, we ask CMS not to publicly post manufacturer plans online, regardless of whether proprietary information is redacted—CMS should limit the distribution of a manufacturer's plan to stakeholders (*e.g.*, dispensing entities) on a need-to-know basis. For example, we note that a manufacturer's process for deduplicating 340B claims is proprietary information and should be redacted from the written MFP effectuation plans which CMS intends to publish.

Appendix C: Medicare Drug Price Negotiation Program Primary Manufacturer Payment Elements Form

We thank CMS for sharing the proposed manufacturer payment elements in support of CMS' oversight and administration of the MTF effectuation process. In order to benefit both Agency and manufacturer compliance, we ask CMS to create numeric/strawmen examples in support of Appendix C, similarly to the user-friendly mathematical guides CMS had created to support implementation of the Medicare Prescription Payment Plan. We believe that having these examples will not only aid in transparency and oversight but perhaps also uncover unique circumstances related to dollar amounts and refunds that may not fit neatly into CMS' pre-determined payment elements, which might warrant additional refinements to Appendix C in advance of January 1, 2026. Should CMS choose not to issue these examples in coordination with the next ICR, we urge the Agency to provide and work through these examples during the recently announced monthly manufacturer MTF calls. We look forward to working with CMS on this topic further.

Appendix D: Drug Price Negotiation Program Complaint and Dispute Intake Form

BMS thanks CMS for creating a two-track complaint and dispute functionality within the MTF to aid in compliance and operationalization. We ask CMS to further refine this process to ensure sufficient procedural protections, including by establishing a formal appeals process for disputes to provide additional guardrails and recourse for manufacturers. In addition, we ask CMS to clarify that if a claim is going through the dispute process that the obligation for manufacturers would be essentially "frozen" until after CMS makes a determination—and relatedly, that once CMS makes a determination, the 14-day prompt payment window would then restart. Finally, CMS must ensure that dispensers/other stakeholders engage in good faith efforts with manufacturers to resolve MFP disputes prior to submitting complaints through CMS' formal process.

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BMS appreciates the opportunity to comment on the MTF ICR. 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

Submitted electronically via www.regulations.gov.

December 27, 2024

The Honorable Xavier Becerra
Secretary, Department of Health and Human Services

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare & Medicaid Services

Meena Seshamani, MD, Ph.D.
Director, Center for Medicare
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)

Dear Secretary Becerra, Administrator Brooks-LaSure, and Director Seshamani:

Thank you for the opportunity to respond to the Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) ICR released on October 25, 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 46 states and D.C. 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. And we do it all with heart, each and every day.

CVS Health appreciates the ongoing communication and opportunity to respond to this information collection request (ICR) for CMS to collect information from manufacturers and the dispensing entities that dispense the selected drugs to MFP-eligible individuals.

Dispenser feedback is critical as it will be used to support Maximum Fair Price (MFP) effectuation, electronic fund transfer (EFT), electronic remittance advice (ERA), and the dispute/complaint processes.

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 establish new systems and processes to support MFP effectuation; however, the timetable associated with these enhancements for the 2026 applicability year leaves us with serious concerns that critical steps may not be vetted and tested. A premature implementation could result in impediments to patient access and significant financial risks for dispensers.

To mitigate these risks, CVS Health requests that CMS considers the following areas of concern and recommendations to reduce risks while meeting the objectives of the statute. We also ask CMS to review the additional comments below, addressing concerns and recommendations for the specified ICR sections.

Effectuation of the Drug Price Program must not impose undue burden on or impair the legal rights of dispensing entities. Pharmacy stakeholders have voiced concerns regarding significant cash flow concerns the program creates. These cash flow concerns impact pharmacies of all sizes as the risk and volume is amplified based on the dispensing frequency of selected drugs. Additional concerns that could impact dispensing entities that require attention include:

- Confidentiality and protection from disclosure of dispensing entity proprietary information, such as acquisition costs, including disclosure pursuant to Exemption 4 under FOIA, or otherwise.
- Dispensing entity liability protection in the event of any inadvertent disclosure or a data breach relating to protected health information or other confidential information the dispensing entity is required to provide; and
- Primary Manufacturer binding commitments to all participating dispensing entities, expressing that the obligation to make MFP refund payments survives any sale, disposition, divestiture, liquidation of all or some of the assets or securities of the manufacturer.

Industry preparedness is of utmost importance to facilitate MFP implementation. Factors that may compromise industry readiness for the January 01, 2026, program implementation date are outlined below. CVS Health is concerned that the following risk factors may result in dispensing entities' inability to dispense the selected drugs to Medicare beneficiaries, creating access to care barriers and compromising healthcare outcomes.

- Dispensing entities may not have sufficient time to establish internal system enhancements to support the varied manufacturer effectuation pathways selected and mitigate cash flow impact if the MFP effectuation pathways are not declared until September of 2025 as indicated in the final guidance.

- Manufacturers electing to bypass the MTF-PM to support the EFT/ERA process must ensure vendors are identified and aligned to support system certification steps with all dispensing entities. This process will take longer than the three-month period following the end of September.

- The Medicare Prescription Payment Plan (M3P) implementation has provided insight into the challenges associated with the readiness timeline of dispensing entities. MFP effectuation's impact on claim billing and financial systems and reconciliation will compound this impact and could lead to a significant portion of dispensers taking action to protect their assets while creating patient access issues.
    - M3P and MFP effectuation will impact pharmacy claim billing and financial systems, requiring external stakeholder process modification and coordination.
    - Technical specification, statements of work, and trading partner agreements must be in place before system development, testing, and implementation can occur.

- The proposed MFP refund payment flow, as outlined under figures 3 and 4 of the final guidance, impacts existing pharmacy claim payment reconciliation processes requiring a new dispenser reconciliation process.
    - Dispensing entities' lack of visibility of data sent from the Part D plan through the process and back from the manufacturers requires pharmacy providers to establish a new payment reconciliation process.
    - Dispensing entities must create a 'ghost' claim using estimated pricing returned in an optional message field that represents the expected manufacturer MFP refund amount.
    - This is conflicts with current processes where all payments and remittances are aligned to the financials returned in the point of service claim response required pricing fields.

- The proposed MFP refund payment flow will also require dispensing entities to develop comprehensive financial tracking and reconciliation processes across prescription claims, inventory/procurement processes, and 340B covered entity detailed data, when available.
    - Dispensing entities sold prescription data compared to transaction level detail managed by the DDPS, MTF-DM, and manufacturer provide no visibility to the dispenser. This will result in a significant volume of retrospective adjustments without the dispensing entity's ability to reconcile financials at any specific point in time.
    - Dispensing entities also lack visibility to PDE transmission and Part D claim conveyance to the DDPS, including the timing of transmission and the presence of PDE rejects that would impede data conveyance to the MTF-DM

- MTF-DM will not receive claim information for a selected drug when incorporated into a multi-drug compound. Dispensing entities will have no system-based means of collecting the MFP refund for the selected drug used in the compound.

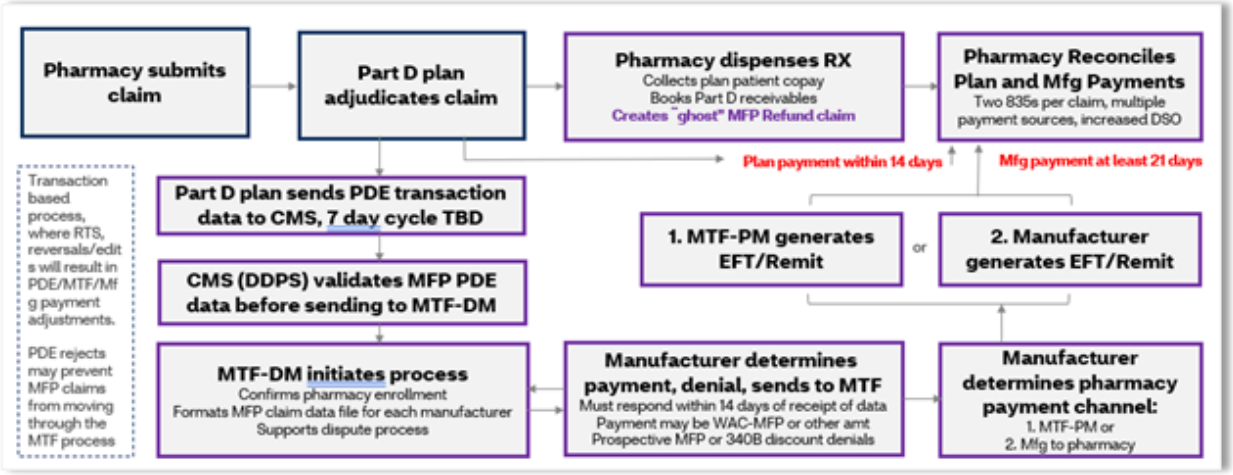


Figure 1: CMS proposed MFP effectuation process flow with new processes to dispensers and Part D plans designated in purple

The MTF-DM approach, as outlined to date, does not address how the MFP refund process will work when Medicare Part B drugs are selected for the 2028 implementation year.

- Part B claims do not produce PDE records, and they are not included in the DDPS system. Therefore, availability of Part B FFS and Medicare Advantage claims within DDPS is uncertain.
- The initial proposal of the MFP refund process does not address all components of the statute that would mitigate unnecessary implementation costs and gaps within the dispute process and overall MFP data analysis.
- The number of regulatory changes impacting the pharmacy industry between 2025 and 2028 that require industry coordination, strategic planning, budgets, and resources must be outlined as soon as possible to support streamlined implementations of MFP, SCRIPT Standard v2023011, Real Time Pharmacy Benefit v13, and Telecommunication Standard vF6.

    - These are core processes to implement impending requirements. When these changes and corresponding enhancements are competing with stakeholder innovative business process to meet the needs of pharmacy patients and Medicate beneficiaries, a lack of predictability becomes an impediment.

Cash flow concerns are shared by dispenser stakeholders at-large. The MTF-DM model, at a minimum, will take 21 days before the dispensing entity obtains the MFP

refund. The proposed PDE processing timeline could be extended or halted due to PDE rejects that will further delay the MTF-DM processing timeline and Manufacturer 14-day payment requirement. This delay will create significant cash flow risks for all pharmacies from independents to large chains.

Recommendations

CVS Health encourages CMS to consider alternate approaches to implement MFP to mitigate industry risk factors and support processes that will facilitate beneficiary access to the selected drugs. The outlined enhancements and associated cost of reconciliation by dispensing entities places an undue burden that surpasses the pharmacy reporting pathway previously proposed. With that in mind, the following recommendations have been provided for your consideration. CVS Health welcomes the opportunity to discuss these in further detail.

- Recognition of the impediments and challenges posed to dispensing entities under the fast-approaching implementation date that jeopardizes the sustainability of pharmacies participating in the program. Urgent collaboration with dispensing entities is an imperative.
- CMS could enable dispensing entities to create and submit the MFP effectuation request directly to the MTF-DM to align with current claim and payment operational and financial tracking processes.
    - The NCPDP vF6 claim billing transaction, named under HIPAA (CMS-0056-F), can support claim reporting under a Part D or Part B plan where the vF6 transaction includes confirmation from the payer of the Medicare program type, Medicare paid claim reconciliation ID (transaction tracking ID)the member ID as recorded in CMS 4RX data for Part D claims or MBI for Part B claims, the MFP selected drug NDC, dispensed quantity, and other critical elements needed to effectuate the monies owed to pharmacy.
    - Please note that the Telecommunication vF6 includes a new field called “Submission Type Code,” where a specific value could be defined for the manufacturer MFP Refund, differentiating this transaction from a coordination of benefits transaction to allow MFP financials to be calculated as expected.

This proposal would enable transactions to be submitted real-time, in a nightly batch, or post the point-of-sale transaction indicating the patient has received the medication. The process would not include a coordination of benefit transactions. Rather, an additional claim transmission requesting the MFP refund, triggered off the Medicare Part D or B paid claim response with the applicable MFP indicators. For reference, this process would be like that leveraged by plans that require one transaction for vaccine drug product and a separate transaction for the vaccine administration. These transactions are dependent on each other but are not coordinated benefits. This NCPDP transaction could utilize similar functionality pharmacy claim billing systems put in place to support the Medicare Prescription Payment plan by leveraging detail returned on the Medicare

Claim Response (Approved Message Code 548-6F field) to trigger the creation of another claim transaction.

Permitting dispensing entities to submit the MFP refund transaction requests to the MTF-DM eliminates the risks associated with PDE rejects and gaps created by pharmacy providers creating a “ghost” claim for a potential payment from the MTF-PM or manufacturer. The frequency in which the pharmacy would submit the manufacturer MFP Refund transaction requests will also reduce the volume of retrospective adjustments the pharmacy, manufacturer, MTF-DM and MTF-PM would need to support. Pharmacies would have better control of their cash flow risks as the manufacturer would return the MFP refund payment within 14 days of processing the NCPDP transaction, eliminating the delays associated with the plan to use the PDE and DDPS to MTF-DM transmission pathway. The approach would eliminate the administrative costs that will be incurred by plans and DDPS to support the more frequent PDE files transmission mandated in the final guidance.

Admittedly, the NCPDP Telecommunication vF6 claim billing transaction would require system enhancements by dispensing entities; However, this work can be incorporated into vF6 development and testing. As noted above, this approach leverages dispensing system claim billing automation that may have been put in place to support the Medicare Prescription Payment Plan. These MFP recommendations could also enhance the Medicare Prescription Payment Plan, where additional dispensing entities implement automated claim billing processes.

CVS Health recognizes the statutory mandate of the 2026 implementation. That said, preparing the industry to adjust processes for the January 2028 phase of implementation would provide more time for the MTF-DM to implement NCPDP Telecommunication claim billing software, ensure the use of HIPAA named standards across MFP processes, and mitigate future cash flow and Part B complexities. The use of the NCPDP Telecommunication vF6 transaction to support the MFP refund request also supports aligning a HIPAA covered transaction with a HIPAA covered remittance. Whereas the current proposed MTF-DM process will leverage a proprietary data set, compromising HIPAA security objectives.

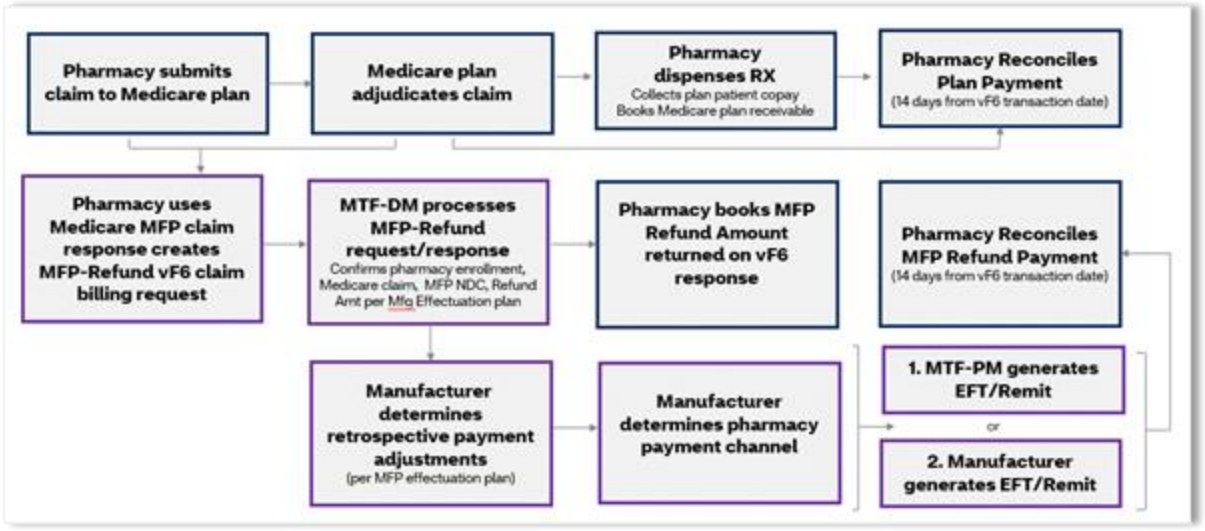


Figure 2: Proposed 2028 effectuation flow with new processes highlighted in purple

CVS Health reiterates its understanding of the complexities and statutory constraints placed on CMS in developing the MFP effectuation pathway. We support the objectives of the Medicare drug price negotiation program and stand ready to support CMS with the complex implementation efforts to mitigate unintended outcomes.

To further the efforts of this implementation and provide key information in the current ICR, we ask CMS to consider the following comments.

Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Enrollment Form (Appendix A)

Re: Section 1; Pharmacy Enrollment Form

"To be eligible, the Authorized Signatory Official must meet one or more of the following criteria: (1) serve as the Chief Executive Officer (CEO), where the individual has been duly appointed by the organization's board or other governing body; (2) serve as the Chief Financial Officer (CFO), where the individual has been duly appointed by the organization's board or other governing body; (3) serve in a role other than as the CEO or CFO, where the individual has authority that is equivalent to a CEO or CFO; or (4) serve in a role, where the individual has been granted directly delegated authority to legally bind the organization on behalf of one of the individuals previously noted in (1)-(3)."

CVS Health recommends including the collection of the authorized individual within the pharmacy organization who manages existing pharmacy enrollment processes with payers to be the authorized submitter for MTF-DM enrollment within the pharmacy enrollment form along with the necessary data elements to identify the individual or

group within the pharmacy organization who will be responsible for managing the MFP dispute process.

- This would ensure that the data associated to the pharmacy organization is kept secure within the MTF-DM system, leveraging multi-factor authentication tools before the MTF-DM releases any data to an individual or entity submitting or researching a dispute or complaint.
- Identifying the individual or group responsible for the dispute or complaint process within the pharmacy enrollment data will also support expediting resolutions, as the person attesting to the pharmacy enrollment information may not have access to the broader Medicare and MFP refund data to support the dispute/compliant process.
- For chain pharmacies, these additional data elements in the pharmacy enrollment form should be aggregated at the chain level and will need to support the contact information for an individual or specified group within the pharmacy organization. As a validation point to initiate the dispute or complaint process, a corporate NPI associated to the chain pharmacy could be associated to individual or group's information.

Re: Sections 2 and 3; Dispensing Entity Selection and Identification information

CVS Health requests clarity on the maintenance of individual pharmacy identification information. Whereas Section 2 allows for chain pharmacy designation, Section 3 requests individual pharmacy identification information. It is unclear how the MTF-DM will maintain the individual pharmacy identification information and what processes may be impacted if changes occur within the NCPDP Pharmacy file that is not represented within the MTF-DM pharmacy enrollment data.

Questions 3a and 3b of Section 3 request the pharmacy to designate any anticipated cash flow concerns at each individual pharmacy location but does not contemplate cash flow concern at the chain pharmacy level.

"This dispensing entity is self-identifying as a dispensing entity that anticipates material cashflow concerns for at least one location at the start of the initial price applicability year due to the shift from payment by the Part D plan sponsor to a combination of Part D plan sponsor payment plus a potentially lagged MFP refund. If "Yes" was selected in response to Question 3A, please list the pharmacy NPIs for which the anticipated material cashflow concerns apply or upload a file that contains the applicable list of pharmacy NPIs."

CVS Health recommends that CMS take the following actions to aid in pharmacy enrollment and maintenance:

- Clarify the pharmacy enrollment maintenance process to ensure the manufacturer MFP refund payment to the pharmacy is not compromised as a result of pharmacy identifier data discrepancies.

    - The MTF-DM could leverage the NCPDP pharmacy file product “dataQ®” to capture updates to detailed pharmacy information. This would mitigate the need and burden associated with the pharmacy provider making the updates within the MTF-DM system. Pharmacy Benefit Managers leverage this process to streamline pharmacy network maintenance and mitigate potential access to care barriers.
    - Incorporation of pharmacy chain codes in the dispensing entity enrollment and manufacturer MFP refund payment processes is needed to support one payment or remittance file per chain code. This information is available within the NCPDP dataQ®, and will reduce unnecessary administrative steps for the dispensing entity, manufacturer, MTF-DM and MTF-PM.
        - Payment sent at the individual pharmacy level will require daily 835 file concentration into one physical file for transmission by the MTF-PM or manufacturer. Producing payments and remittance files at the individual pharmacy level for a chain will lead to complexities when the MTF-PM is not used by the manufacturer and the chain must attempt to coordinate across multiple payment processing vendors.

- Ensure that pharmacy MTF-DM enrollment information streamlines pharmacy access to the MTF portal to obtain applicable electronic fund transfer remittance data (EFT/ERA) and to support the dispute and resolution process.
    - This could be supported through the registration of delegates and the ability to submit real-time updates to change, remove or add roles. We also ask CMS to require the MTF-DM and MTF-PM vendor systems to be established with the required services to support EFT/ERA certification testing no later than August 2025. Note, if the manufacturer elects to use a vendor other than the MTF-PM to support the EFT/ERA process, these vendors must also be ready to support certification testing by August 2025.
- Clarify, within guidance and the applicable forms, that manufacturers cannot use the dispensing entity MTF-DM enrollment information to globally interpret all claims associated to a 340B contract pharmacy as receiving the 340B discount.
    - Identification of Medicare claims subject to 340B discount should be confirmed by the 340B covered entity.
- Remove the "340B" attribute from the pharmacy information data file.
    - The pharmacy enrollment data file will not provide accuracy necessary for operationalization. The status can change frequently and 340B eligibility is determined at the claim level not the pharmacy level. This means 340B information is not available within the NCPDP Pharmacy File. The 340B registration information is publicly available via the HRSA/OPA OPAIS database with the latest status on Covered Entity & Contract Pharmacy Participation.

- Identify the date in which the MTF-DM dispensing entity enrollment systems and user interfaces will be available, and the deadline in which all dispensing entities must submit their information.
    - Based on CMS's final guidance, manufacturers must communicate their process to support dispensing entities listed in the MTF-DM enrollment system with cash flow concerns within the Manufacturer MFP Effectuation Plan. Dispensing entities may not be able to complete the enrollment information before trading partner agreements have been established with respect to the method of effectuation. Defining specific deadlines and coordinating processes with less than 12 months remaining before the 2026 applicability year presents significant risks to all stakeholders.
- Update the pharmacy enrollment form for pharmacy organizations, rather than just by individual pharmacy NPI, to enable the reporting of cash flow concerns caused by the delay in the MFP refund process.
- Provide guidance to manufacturers detailing the minimum necessary steps the manufacturer must take to address pharmacy cash flow risks and reduce the SDRA payment timelines.
    - This is critical for long term care pharmacies that must adhere to dispensing timelines that lead to claims being processed, after patient administration, leveraging the post consumption billing process.

Re: Section 4; Dispensing Entity Financial Information

This section indicates that pharmacy banking information will be disclosed to a vendor without defining the contract between the pharmacy and the MTF-DM. Subsequently, the MTF-DM will be required to share pharmacy banking information with manufacturers, including manufacturers that chose to not use the MTF-PM service. Questions 4 and 5 of this section present concern with this process.

Question 4: To verify the banking information provided, please upload one of the following documents to your submission: either (1) voided check for the account listed, which shows the account holder's name, bank account number, and routing number—ensure that the check is clearly marked as "VOID" across the front; or, (2) letter from bank, printed on official bank letterhead, that confirms the account holder's name, account number, and routing number—the letter must be signed by a representative of the bank and include their contact information for verification purposes.

Question 5: CMS plans to make available through the MTF DM the bank account information and designated destination for ERAs or remittances for dispensing entities enrolled in the MTF DM to support the Primary Manufacturer's creation and transmission of an ERA or remittance to the dispensing entity based on the preferred payment method indicated by the dispensing entity during MTF DM enrollment. Please indicate your acknowledgment and acceptance.

- CVS Health requests that CMS develop a standard default contract template between the MTF-DM and the enrolled pharmacy providers to ensure banking and

other pharmacy information remains secure within the MTF-DM system and is not shared with other entities unless approved by the pharmacy's authorized representative. This default contract template should include minimum necessary information to align with applicable data security and ownership laws and allow the pharmacy to amend the terms to address proprietary business needs.

- Additionally, CMS proposes this provision must require the pharmacy to maintain and certify, with CMS, that the enrollment information provided in the MTF DM is accurate, complete, and up to date pursuant to applicable terms and conditions of participation with the MTF DM.
    - CVS Health requests clarity on how the NCPDP file will be used to mitigate delays in the MTF-DM by providing up to date information.

Appendix B: Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form

Appendix B details the following sections contained within the draft that must be completed and published by a specific date.

1. Primary Manufacturer MFP Effectuation Additional Points of Contact Information
2. Information Requested from All Primary Manufacturers
3. Information Requested of Primary Manufacturers Declining Use of the MTF PM
4. Assisting Dispensing Entities with Material Cashflow Concerns
5. Primary Manufacturer Acknowledgements Regarding MFP Availability; and
6. Certification Technical assistance for Primary Manufacturers will be made available.

CVS Health requests clarification from CMS on the following:

- Is the primary manufacturer required to complete an MFP Effectuation form for each pharmacy and chain provider enrolled with the MTF-DM?
    - The effectuation process and payment terms may differ per pharmacy or pharmacy chain.
- Is the MFP effectuation form a default contract between the pharmacy and the manufacturer and how will the associated proprietary information be confidential and protected with respect to the dispensing entity's interests, including prompt payment of all applicable MFP payments?
    - The decision to apply the CMS Standard Default Refund Amount of WAC-MFP, or a proprietary cost basis such as the pharmacy's acquisition – MFP, as well as payment process through the MTF-PM or outside vendor selected by the manufacturer must be a legal agreement between the manufacturer and the pharmacy and not a unilateral manufacturer decision.

- How and when will the dispensing entity be notified to be able to coordinate internal system changes when the manufacturer updates their MFP effectuation plan and has 90 days to provide this information to CMS?
    - There is an absence of clarity in the final guidance with respect to whether the primary manufacturers of selected drugs should submit a Manufacturer MFP Effectuation form by the stated deadline for all new NDC 9's subject to the negotiated price in price applicability years 2026 and 2027.
        - All impacted dispensing entities need to be alerted to any potential changes to the manufacturer's MFP effectuation plan with sufficient time to coordinate processes before the effective date of the change.

CVS Health requests CMS to encourage manufacturers to make completed MFP effectuation forms available to enrolled pharmacies no later than the end of March 2025. This is critical for pharmacy providers to coordinate internal system enhancements, contract with external vendors and prepare for the significant financial impact the MFP effectuation process will cause. Without sufficient time to coordinate new processes, patient access to care could also be compromised. If manufacturers are unable to complete the full effectuation form by this timeline, we request CMS consider a phased approach where critical information is reported by the end of March of each negotiated price year and require additional detail to be reported by the end of September. At a minimum, the following questions within the draft form should be considered critical and made available by end of March:

- Q4: Describe the Primary Manufacturer's process for nonduplication of claims that are 340B eligible and not subject to MFP availability.
- Q5: Describe the Primary Manufacturer's planned frequency of submission of the report of payment-related data, to align with the maximum 14-day window.
- Q6: Manufacturer to include in its MFP Effectuation Plan for making the MFP available whether it will use the dispensing entity's actual acquisition cost or a reasonable proxy for such a cost, such as wholesale acquisition cost (WAC).
- Q9: Manufacturer to indicate if it will establish, alternative arrangements for providing access to the MFP outside of the MTF PM.
- Q10: If alternate process outside the MTF-PM is used, describe the process.

CVS Health requests that CMS specify that manufacturers using a retrospective payment process, outside the MTF-PM, must use the X12-835 remittance standard as named under HIPAA. Regardless of the MTF-PM or other payment process used by the manufacturer, the payment data elements returned by the manufacturer, as outlined under Appendix C, must also map to X12 Claims Adjustment Reason Codes (CARCs) and Remittance Advice Remark Codes (RARCs) available for use as of January 01, 2026. These data elements must also be sufficient and include the applicable manufacturer and MTF-DM transaction tracking IDs for the pharmacy provider to research the manufacturer determined over or under-payments from situations such as adjusted claim information. For example, 340B claims, claim reversals and edits.

CVS Health recommends the inclusion of the following clarifying points within the Manufacturer MFP Effectuation:

- Clarifying guidance requiring payment of all outstanding MFP refunds in the event of manufacturer divestiture of MFP products or the sale, liquidation, or bankruptcy of the manufacturer; and
- Clear language under Q4 detailing the manufacturer's approach to address disputes or concerns raised by dispensing entities regarding Primary Manufacturer's 340B and MFP reconciliation process.

Appendix C: Medicare Drug Price Negotiation Program Primary Manufacturer Payment Elements Form

CVS Health views the information contained within Appendix C as a critical component of effectuation for manufacturers, dispensing entities, and the MTF-DM to reconcile MFP refund claim data. With this importance, we are seeking clarity on the various data element tables outlined in the final guidance.

Specifically, the data elements listed in Appendix C - Manufacturer Payment Elements Form, correspond to the data elements outlined in Table 6 entitled "Manufacturer Payment Data Elements When Not Using the MTF-PM;" However, the instructions within the document indicate that the manufacturer must return these data elements to the MTF-DM for all MFP refund claims received by the manufacturer, regardless if the manufacturer uses the MTF-PM or an entity other than the MTF-PM for the EFT/ERA process. The Final Guidance also references Table 4 entitled, "Example Manufacturer Claim Level Payment Elements List for Primary Manufacturers Passing Payment Through the MTF-PM." With the exception of the "MFP Refund Transmission Date and Time" element from Table 6, the elements are the same.

Table 4 (Final Guidance)

Payment Elements	Purpose
Method for Determining MFP Refund Amount	Indicates the basis on which MFP refund amount was determined (refer to Table 5).
NPI of the Entity Receiving the MFP Refund	Documents the recipient of MFP refund.
Quantity of Selected Drug	Documents the number of units of selected drug included in MFP refund paid.
Amount of Payment to be Transmitted as the MFP Refund by the MTF PM	Indicates the amount the MTF PM should pay to the dispensing entity, prior to the application of any credits.
MFP Refund Adjustment (Yes or No)	Indicates if the MFP refund payment was adjusted to a new MFP refund payment amount.

Table 6 (Final Guidance and ICR Appendix C)

Payment Elements	Purpose
MFP Refund Transmission Date and Time	Indicates when the MFP refund was transmitted by the Primary Manufacturer.[111]
Method for Determining MFP Refund Amount	Indicates the basis on which MFP refund amount was determined (refer to Table 5 in section 40.4.3.1 of this final guidance).
NPI of the Entity Receiving the MFP Refund or Prospective Sale	Documents the recipient of the MFP refund or prospective sale.
Quantity of Selected Drug	Documents the number of units of selected drug included in MFP refund paid.
Amount of Payment Transmitted as the MFP Refund	Documents the amount of MFP refund transmitted. Payment element should be populated with the final MFP refund amount if payment was an adjustment to a previous claim.
MFP Refund Adjustment (Yes or No)	Indicates if the MFP refund payment was adjusted to a new MFP refund payment amount.

CVS Health requests clarification on the business needs for tables 4 and 6, who will receive the completed data file, and the required timing for the manufacturer to deliver the data file.

Additionally, CVS Health seeks clarification on how dispensing entities will have visibility to the MFP refund status for Medicare claims paid as MFP that did not cycle through the MTF-DM process to effectuate payment from a manufacturer.

CVS Health recommends CMS support a single data element file to capture the manufacturer MFP refund information regardless of the manufacturer's use of the MTF-PM or alternate method to support the EFT/ERA (X12-835) processes. The MFP Refund Transmission Date and Time data element should be readily available within the data file for incorporation in the MTF-DM and accessibility for dispensing entities. Manufacturers should also identify the name of the entity who will be supporting the EFT/ERA (X12-835) for the associated MFP refund records under an added element to the data file.

CVS Health requests this data file be made available to dispensing entities in coordination with the EFT process. Additional data elements should be added to the file for dispensing entities to initiate the payment reconciliation process, aligning the EFT payments that correspond to the information within this data file, with the X12-835 detail.

CVS Health recommends the following data elements be included in the Manufacturer Payment Elements Form and that this form be used for all manufacturer MFP refund responses regardless of the EFT/ERA vendor.

- MFP Refund Transmission Date and Time
- EFT/ERA Vendor Name

- Manufacturer, Manufacturer EFT/ERA vendor or MTF-PM's check number for the associated MFP refund payment. The check number should also be recorded in the associated 835 documents.
- Drug Name and NDC for the associated dispensed quantities within the MFP refund payment.

Appendix D: Dispute and Complaint Intake Form

CVS Health is aligned with the importance of enabling parties to file disputes and complaints with challenges in the MFP effectuation process. It is essential for dispensers to have a means of escalating effectuation shortcomings caused by system and process deficiencies that are outside of their control. For example, MFP refund claim data that fails to make it to the DDPS or MTF-DM system. CVS Health asks CMS to ensure that sufficient information is required based on the dispute or complaint, and proprietary information that is not relevant to the dispute or complaint is not conveyed to parties that should not have access to entity proprietary information.

CMS Final Guidance indicates that the dispute and complaint process is intended to make information available to CMS for monitoring and oversight. CVS Health believes it is critical to have this process leveraged to report effectuation concerns and shortcomings related to compliance under the law and gain support from CMS if the matter is not being resolved between the impacted parties. Without this recourse, dispensers could be left with significant financial burden requiring additional costs in seeking a resolution.

CVS Health recommends the following actions to enhance the process and protect the information available to resolve MFP disputes and complaints effectively and efficiently.

- Allow disputes and complaints to be filed within a reasonable period from the date the complainant discovered the potential conflict.
    - The "date of the subject" reference within the ICR is unclear. This could be referring to the Medicare claim date of service, the date the MTF-DM received the claim data, or the date the manufacturer processed the MFP refund response. These dates may not be visible to the submitter of the complaint or dispute.
    - We understand the need to set some limits to better control access to the associated detail within the MTF-DM, manufacturer, and dispensing entity systems; however, 120 days could be insufficient depending on the event.
        - Examples: DDPS PDE rejects, long-term care post consumption billing, and manufacturer timelines to identify 340B duplication that could not be resolved directly between the dispensing entity and the manufacturer.

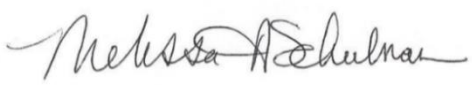
- Define the “date of support” as the original date the dispute or complaint was submitted within the MTF-DM portal or online form available to non-MTF-DM users.
- Ensure dispute forms support the submission of multiple claims impacted by the same manufacturer and similar conflict.
    - This could be achieved with enabling the submitter to upload a spreadsheet detailing the relevant claim information.
- Ensure all marketed drug names and authorized generics are included within the drop down on the intake form.
- Modify the language related to the submitter of an issue category, under Question 3, to accommodate an organization-level response rather than just the perspective of an individual.
        - Example*: ~~I am~~ This submission is reporting an issue related to the Medicate Drug Negotiation Program 340B Program processes*
- Ensure that proprietary information is not required to be submitted within the initial dispute or complaint inquiry.
    - This level of detail should only be shared once the compliant/dispute has moved to the resolution stage where the proprietary information can be uploaded and stored in a secure manner with access limited to individual responsible for resolution under executed privacy and security trading partner agreements.
- Clarify that the dispute or complaint intake form permission attestation statement is limited to complaints submitted by a non-MTF-DM registered user and is not applicable to claim information submitted by a dispensing entity.
    - CMS has included language requiring the submitter to obtain permission from all parties with information on the form. This could create challenges when the submitted information refers to claim-level data inclusive of beneficiary information.
- Ensure the privacy and security language on the form protects the release of business entity proprietary information. This would include banking and acquisition cost detail as well as prevention from disclosure of proprietary business artifacts, including pursuant to Exemption 4 under FOIA, to entities other than the owner of such information.
- Establish the MTF-DM interface as a single point of entry for all dispensing entity disputes.
    - The process of resolving disputes directly with manufacturers will offer challenges in tracking if each manufacturer creates a separate portal or reporting process.
    - Centralization of the MFP refund dispute process within a secure environment enables CMS oversight and monitoring while simplifying the process for dispensing entities.
    - Include support and monitoring of service level process with weekly updates that includes, at a minimum, an initial response indicating status and the next step in the process.
- Create a form that outlines the information CMS will return to the submitter of the dispute or complaint. The contents of this form should contain the submitter, date

reviewed, reference to prior dispute and complaint records under the same issue or claim, projected timing of response, and the entity responsible for resolution.

- Facilitate technical support for the dispute and complaint system with adequate availability to assist with responses. Ideally, this would be accessible daily during common hours of operation for all U.S. based entities.
    - Any call center leveraged must authenticate the inquiring party as an authorized representative of the enrolled entity, such as a registered corporate NPI.

Thank you for considering our comments and recommendations. CVS Health is committed to collaborating with CMS as it implements the Medicare Transaction Facilitator process and other policies to promote affordable, comprehensive care and 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

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

December 23, 2024

VIA Electronic Filing – http://www.regulations.gov

William N. Parham, III
Director
Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS-10912, OMB 0938-NEW

Re: Information Collection Request: Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) (CMS-10912, OMB 0938-NEW)

Dear Director Parham:

On behalf of Johnson & Johnson (J&J), we submit the following comments in response to the Centers for Medicare & Medicaid Services' (CMS, the Agency) **Information Collection Request (ICR): Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) (CMS-10912, OMB 0938-NEW).**

At Johnson & Johnson (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 is committed to collaborating with CMS to achieve a workable model for the effectuation of the "Maximum Fair Price" ("MFP") for IPAY 2026. We appreciate our ongoing engagement with CMS to work collectively toward our shared implementation goals; however, we are deeply concerned about the significant work ahead to achieve a successful implementation model that is workable for all stakeholders. As we move closer to January 1, 2026, J&J strongly urges CMS

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

and the Medicare Transaction Facilitator(s) (MTF) to collaborate closely with manufacturers of selected products to co-create and test the MTF processes for IPAY 2026. Urgency in establishing a governance model and cadence for meaningful collaboration is critical, as clarity on specific MTF requirements and process flows is needed to inform manufacturer process design and build for operational readiness.

CMS must act now to advance joint decision-making to define critical MTF system and process requirements, implement a CMS solution for 340B data transparency, and adopt a pre-fund model to address pharmacy cashflow concerns. Comments on these recommendations are below.

I. CMS Must Act Now to Advance Joint Decision Making on System and Process Requirements

Clarity on operational requirements is needed so manufacturers can build, test, and execute systems effectively for January 1, 2026 "go-live." The MTF and manufacturers must collaborate to define these requirements to ensure successful process integration and system operability. To promote alignment on critical decisions for the "MFP" effectuation process, CMS should form a joint governance model that prioritizes transparency with manufacturers. For example, manufacturers need visibility to CMS' detailed development timeline with clear development milestones for MTF systems and processes (for example, data exchange to and from the manufacturer). MTF requirements should be shared transparently with manufacturers and should not be considered proprietary because this level of transparency is needed for manufacturer system builds and to and enable successful integration between manufacturers and the MTF.

- *Immediate Alignment on MTF Requirements Needed to Enable Fully Operational Manufacturer Systems by September 1, 2025*

Given the September 1, 2025 deadline for manufacturers to submit MFP effectuation plans to CMS, and the need for testing and implementation prior to "go-live," manufacturer systems must be fully operational by September 1, 2025. Despite this urgent timeline, we are concerned that foundational components of the effectuation process remain unclear, undeveloped, or otherwise still need to be addressed by CMS, which will delay the manufacturer development process and the ability for manufacturer compliance. Manufacturers cannot design and build systems without clearly understanding CMS submission requirements.

To enable manufacturer process design, manufacturers need visibility to MTF technical requirements, including the MTF's capabilities to receive payment data, details of the credit/debit ledger including its design and functionality, the MTF DM data transmission process including format (i.e. Secure File Transfer Protocol (SFTP) or other methods), transmission cadence details (i.e. day of transmission = day zero), clarification on when CMS will provide list of NPIs of participating dispensing entities to manufacturers, and details on the dispute and appeals process. We stress that the time is now for joint decision-making on these system and process for a successful go live on January 1, 2026.

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

- *CMS Should Commit to Providing CMP Relief to Manufacturers Making Good Faith Efforts to Comply if MTF Systems and Requirements Are Not in Place*

Section 1197 of the Act states that manufacturers may be subject to civil monetary penalties (CMPs) for failure to ensure access to the MFP for MFP eligible individuals.[1] CMS Guidance further specifies that manufacturers may be subject to CMPs for failure to process timely and complete reimbursement under a retrospective reimbursement structure as provided in the Guidance.[2] CMS has stated that it will establish an MTF to facilitate effectuation of the "MFP" for IPAY 2026. If CMS does not define critical details required for manufacturers to build and test systems to effectuate the "MFP" through the MTF (including MTF processes and data submission requirements), manufacturer compliance with the statute will be infeasible. This will result in significant risk to beneficiary access to selected drugs and CMPs for manufacturers, despite manufacturers' good faith efforts and willingness to meet compliance obligations and provide access to the "MFP".

Manufacturers cannot be subject to CMPs on the basis that they failed to ensure access to the MFP or process timely and complete reimbursement under a retrospective reimbursement structure for factors outside of their control, including if CMS has not defined critical requirements before March 1, 2025. J&J asks CMS to clarify that the Agency will establish a safe harbor from CMPs for manufacturers making good faith efforts to comply with the statute if the Agency fails to define by March 1, 2025 the critical requirements and/or the Agency fails to establish an operational MTF before January 1, 2026.

II. CMS Must Provide a Solution for 340B Claims Transparency to Enable Statutory Compliance

The IRA stipulates that the "MFP" for a selected drug must be provided in a nonduplicated amount to the 340B ceiling price when a CE or contracted pharmacy of a CE dispenses or administers a selected drug to an eligible patient.[3] We strongly urge CMS to provide a solution to enable 340B claim transparency required for manufacturers to comply with the statute and avoid duplicate discounts on the same claim.

Without a CMS solution for 340B transparency, manufacturer efforts to meet statutory requirements and maintain fiduciary responsibility will require the use of unregulated, incomplete, and non-standardized third-party data. Most 340B data received from third-party agreements will not be available to deduplicate payments in the 14-day payment window envisioned by CMS. Data that may be made available through third-party agreements is typically received up to 6 months after a claim (if at all), and not all manufacturers have access to this third-party 340B data. As a result, avoiding duplicate discounts in compliance with the statute

[1] Social Security Act (SSA) § 1197(c)
[2] https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf
[3] SSA § 1193(d)(1)

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

will not be possible for all claims. This will result in a high volume of disputes, and certain 340B duplicate claims will never be identified due to data challenges.

- *Mandatory 340B Modifiers Paired with the Establishment of a Comprehensive 340B Data Repository Are Needed to Support Program Integrity and Statutory Compliance*

J&J strongly urges CMS to establish a 340B Part D Claims Repository that has utility across CMS programs and is not limited to the Inflation Rebate Program. We urge CMS to act with urgency to establish this Repository that can also be used to support compliance with the statutory prohibition of duplicate 340B and "MFP" discounts under "MFP" Effectuation. In establishing the Repository, we recommend that CMS require CE participation, including mandating accurate and complete CE reporting of claims data to the Repository, and that CMS ensure manufacturers receive claim level transparency to enable audits and data validation.

To ensure the accuracy of claims added to the Repository, J&J also urges CMS to mandate the use of 340B modifiers on all pharmacy claims that are applied consistently across all channels to help verify 340B claims. Voluntary use of modifiers is insufficient because, in our experience, a very limited number of CEs voluntarily provide the 340B modifier. We are concerned that a lack of sufficient 340B data transparency will impede program integrity and result in a high volume of future disputes. Mandatory and timely use of 340B claim modifiers is critical to enable manufacturers and CMS to accurately identify 340B claims to avoid duplicate discounts, as required by statute.

- *CMS Must Ensure Covered Entity Compliance and Accountability for Data Accuracy*

We note that a successful 340B data transparency solution will requires CE compliance and accountability for data accuracy. Flawed data and improper use of required modifiers introduce program integrity risks. Therefore, to ensure the accuracy and completeness of data added to the Repository, we encourage CMS to require attestations from CEs on the accuracy and completeness of data, conduct periodic audits of data in the Repository, and establish data validation processes. Additionally, to enforce CEs' compliance with required modifiers, we recommend that CMS reject Part D claims submitted without required modifiers and that CMS conduct periodic audits on their appropriate use.

III. CMS Should Pre-Fund the "MFP" Discount Amounts to Address Dispensing Entity Cash Flow Concerns

A workable model for MFP effectuation is critical to ensuring beneficiary access to their medications and adequate pharmacy reimbursement. Cash flow risks facing dispensing entities will negatively impact beneficiaries. J&J is concerned that as a result of these cash flow risks, over 90% of independent pharmacists have stated they cannot provide patients with access to their medications when the program goes into effect.[4] In meetings with CMS and in our past comment letters, J&J has urged the Agency to leverage its statutory authority to pre-fund the

[4] https://ncpa.org/newsroom/news-releases/2024/10/15/independent-pharmacies-reluctant-stock-drugs-medicare-negotiation

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

"MFP" discounts to mitigate these risks and other significant operational issues. We are very concerned that CMS has not implemented our proposed solution and instead intends for manufacturers to address these cashflow concerns through its guidance.

- *Manufacturers Have No Statutory Mandate and Lack the Ability to Address Pharmacy Cashflow Concerns*

CMS' envisioned process of requiring manufacturers to submit plans to address pharmacy cashflow concerns is perfunctory, as manufacturers have no capability or mandate to mitigate these concerns. Instead, a meaningful solution is for CMS to pre-fund the "MFP" discounts. Under a CMS pre-fund model, dispensing entities would receive the "MFP" discount amount on eligible claims in a timely manner while enabling a reconciliation process with manufacturers for those amounts on a regular quarterly billing cycle. A CMS pre-fund model reduces financial risk for pharmacies, thereby reducing negative consequences on beneficiary access. A CMS pre-fund improves workability for all stakeholders and also supports program sustainability as the number of manufacturers and selected products grows.

J&J's comments on the ICR Forms are below.

Supporting Statement Appendix:

- *CMS Is Underestimating Burden to Complete the ICR Forms*

  J&J is concerned that CMS is significantly underestimating the burden required of manufacturers to complete the ICR forms. CMS estimates do not reflect the considerable system demands, time, and personnel resources required to prepare and submit the manufacturer plans. This will involve significant effort and input from internal teams, outside legal counsel, and consultants. In addition, given the anticipated high volume of claims and disputes, CMS is also underestimating the burden of sampling and analyzing data for the MTF DM payment elements form and preparing and submitting disputes. We urge CMS to engage with manufacturers to provide more realistic burden estimates.

Drug Price Negotiation Program MTF DM Primary Manufacturer "Maximum Fair Price" Effectuation Plan Form (Appendix B)

- *Question 3: Primary Manufacturer's Process for Communicating with Dispensing Entities*

  J&J urges CMS to expressly recognize that Primary Manufacturers can use the MTF's credit/debit ledger to communicate "MFP" effectuation information to dispensing entities.

- *Question 4: Primary Manufacturer's Process for Identifying 340B Eligible Claims*

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

CMS requires Primary Manufacturers to describe their "valid and reliable" process for identifying 340B eligible claims. Given that manufacturers lack visibility to data required to identify 340B eligible claims, as described in our comments above, we ask CMS to acknowledge that it will defer to the Primary Manufacturer's definition of "valid and reliable", which will include reliance on non-standardized data sets that are not available to all manufacturers. Additionally, we note that a 340B reconciliation should not be considered a dispute, and manufacturers should be able to seamlessly reopen the claim and process 340B reconciliation offsets via the ledger.

Furthermore, we note that CMS has alluded to inconsistent standards for identifying 340B eligible claims through its various guidance documents and rules. In defining the Inflation Rebate Program in the CY2025 Physician Fee Schedule Rule, CMS noted that NPIs can be used to identify 340B claims.[5] However, CMS notes that NPI would not be sufficient in the IPAY 2027 Guidance.[6] We ask CMS to clarify this inconsistency and to adopt a standardized approach.

- *Question 5 – Frequency of Manufacturer Transmission of Payment Elements to the MTF DM*

  Primary Manufacturers are required to describe their planned frequency for transmitting claim-level payment elements to the MTF DM. To provide this information, manufacturers need CMS to provide details on the MTF DM's data capabilities and requirements for receiving data. We also recommend that CMS acknowledge that manufacturers cannot submit claim-level payment elements during certain times, such as banking holidays.

- *Question 6: Primary Manufacturers' Plans for Calculating the "MFP" Refund Amount*

  J&J urges CMS to clarify that "MFP" refunds should never exceed the Standard Default Refund Amount (SDRA, i.e., WAC—"MFP"). This is important not only because manufacturers have no control over the price at which dispensers purchase drugs from supply chain intermediaries that may exceed WAC, but also to remove potential perverse incentives for supply chain actors to improperly inflate prices to increase "MFP" refund amounts artificially. J&J is aligned with PhRMA's comments on this issue.

  Further, J&J recommends that CMS monitor how the Medicare Drug Price "Negotiation" Program impacts plan reimbursement to dispensers. For example, CMS should monitor and mitigate formulary tactics that would reduce patient access to or result in higher patient cost sharing for selected products, including increasing utilization management,

[5] 89 FR 97710; https://www.federalregister.gov/documents/2024/12/09/2024-25382/medicare-and-medicaid-programs-cy-2025-payment-policies-under-the-physician-fee-schedule-and-other

[6] *See* https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-"MFP"-2026-2027.pdf

requiring non-medical switching, or moving products to lower / coinsurance formulary tiers.

- *Questions 14 – 18: Information on "MFP" Effectuation for Selected Drugs with Secondary Manufacturers*

  J&J continues to assert that Primary Manufacturers cannot be held responsible for secondary manufacturers or third-party manufacturers with whom they have no contracts. We have reiterated this concern in our comments on the CMS' IPAY 2026 and 2027 Guidance. We continue to urge CMS to abandon the Primary and Secondary Manufacturer construct.

- *Question 22: Dispensing Entities with Material Cashflow Concerns*

  As outlined above, J&J is opposed to the requirement for manufacturers to develop mitigation plans for dispensing entities with cash flow concerns. We urge CMS to remove this question or make it optional for manufacturers.

  In addition, Question 22 requires the Primary Manufacturer to acknowledge that it "will be provided" a list of dispensing entities with material cashflow concerns. We note that manufacturers cannot acknowledge that something "will be" provided. Manufacturers can only provide this acknowledgment once the list is provided.

- Other Topics for Appendix B:

  Manufacturers have no visibility into CMS Confidentiality Practices to protect the confidentiality of manufacturer plans, including, for example, manufacturer-contracted prices outside of the standard default refund amount. We ask CMS to add a field to the "MFP" effectuation plan form that would enable Primary Manufacturers to indicate which information is proprietary and would need to be redacted upon distribution to dispensing entities through the MTF DM.

  In addition, we ask CMS to allow Primary Manufacturers to upload documents for a broader number of questions, including Questions 4, 10, 15, 16, 17, 21, and 22.

Drug Price "Negotiation" Program MTF DM Primary Manufacturer Payment Elements Form (Appendix C)

As with other aspects of this ICR, many details that Primary Manufacturers require clarity around are not addressed. For example, we ask CMS to clarify how many log-on credentials a manufacturer will be provided to the MTF DM system. This is important to inform the design of Primary Manufacturer processes. We note that manufacturers will require technical instructions

to access the MTF DM. Furthermore, Primary Manufacturers should have ample opportunity to submit test transmissions of payment and claim-level data elements.

We also ask CMS to clarify the process for manufacturer transmission of updated payment elements when adjustments are needed. In instances when a previously paid claim requires an adjustment to the corresponding payment amount, as determined by the Primary Manufacturer, we recommend that manufacturers should be able to retransmit the claim elements, with the ledger subsequently adjusting automatically to reflect the adjustment. This capability would minimize the manufacturer's burden in the adjustment process.

Drug Price "Negotiation" Program Complaint and Dispute Intake Form (Appendix D)

- *Overview*

  CMS notes that complaints and disputes must be submitted to CMS no later than 120 days after the subject of the complaint or dispute. We ask CMS to provide greater clarity by defining “date of the subject of the complaint or dispute”. For example, it could be the date of the claim for Rx fulfillment or the date of manufacturer payment.

  CMS outlines its plan for the MTF to route issues to either a “dispute” or “complaint” route. J&J asks CMS to clarify how the MTF will determine if a submission is routed as a complaint or dispute and to provide details on the timeline for making that determination.

- *Question 1: Contact Information*

  J&J recommends that CMS add Question 1C to require the submitter to identify whether they are a 340B Covered Entity or a Contract Pharmacy working for a Covered Entity. This should be required in the CMS form.

- *Question 3: Issue Category*

  J&J recommends that CMS reorder Questions 2 and 3 and that the issue category identified in Question 3 determine which responses under Question 2 (Selected Drug & Claim Information) are either optional or required. For example, if the submitter identifies the issue category as related to a claim issue, then responses to Questions 2A through 2I should be required and not optional. However, if the submitter identifies the issue category as related to a technical process issue, then Questions 2A through 2I could be optional.

  CMS provides an issue category for identifying issues related to the relationship between the “Negotiation” and 340B Programs. When this category is indicated for disputes involving a manufacturer-applied justification code of “4” for 340B, J&J recommends that CMS require the dispensing entity to provide evidence that the claim is not a 340B

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

claim or has not already been paid via 340B payment.

- *Question 5: Supporting Documentation*

  J&J recommends that CMS add zipped files and other archival/compression file types to the list of allowed extensions for document upload.

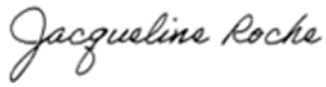
- *Other Complaint and Dispute Topics*

  J&J asks CMS to clarify the details of the complaint and dispute process. For example, manufacturers require details to understand how the dispute system will function, and we recommend that CMS clarify that the centralized complaint and dispute intake system will provide manufacturers with the ability to create, upload, download, and respond to disputes, including the ability to respond to thousands of lines at a time if needed. We note that to respond to disputes related to payment information, manufacturers will require visibility of claims level details and supporting documentation (redacted) to verify and resolve.

  Lastly, we ask CMS to clarify how it will protect patient-identifying information, including when supporting documentation is uploaded. We also ask CMS to provide the proper venue for encrypting, exchanging, and protecting any potential proprietary or confidential information.

Johnson & Johnson appreciates the opportunity to provide these comments. For questions or more information, please contact jroche8@its.jnj.com.

Sincerely,



Jacqueline Roche
Head, Payment and Delivery Policy
Johnson & Johnson

December 20, 2024

VIA ELECTRONIC SUBMISSION

Lilly USA, LLC

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

William N. Parham, III
Director, Division of Information Collections and Regulatory Impacts
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: (CMS-10912) Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request

Dear Mr. Parham,

Eli Lilly and Company (Lilly) appreciates the opportunity to respond to the Medicare Transaction Facilitator Information Collection Request (ICR). Lilly is one of the country's leading innovation-driven, research-based pharmaceutical and biotechnology corporations. Our company is devoted to seeking answers for some of the world's most urgent medical needs through discovery and development of breakthrough medicines and technologies and through the health information we offer. Ultimately, our goal is to develop products that save and improve patients' lives.

As a member of both the Pharmaceutical Researchers and Manufacturers Association of America (PhRMA) and the Biotechnology Industry Organization (BIO), Lilly largely joins those groups in their comments on this request and encourages CMS to carefully consider the input of those organizations. That said, Lilly would like to offer the following comments to highlight matters of concern and Lilly-specific positions.

I. CMS' Purported Requirement that Manufacturers Must Mitigate Pharmacy Cashflow Concerns is Unlawful

The final guidance established a process for certain pharmacies to self-identify if they anticipate cash flow concerns at the start of the initial price applicability year (IPAY) following a negotiation cycle due to the practical need to implement a Maximum Fair Price (MFP) retrospectively.[1] The final guidance was the first time CMS introduced the concept that manufacturers would be required to include a process for mitigating pharmacy cashflow concerns. Stakeholders were never given the opportunity to comment on this specific requirement prior to the finalized guidance nor was there even a hint that the agency was considering such a policy. Accordingly, this binding requirement fails the basic requirement of providing regulated entities the advanced opportunity to comment on agency proposals before they become effective and was clearly not a "logical outgrowth" of the proposed guidance.

More importantly, the requirement to ameliorate pharmacy cashflow issues goes well beyond the statutory command. Manufacturers are required to "provide access to" the MFP.[2] There is no cognizable reading of the phrase "provide access to" that permits CMS to mandate that manufacturers serve as piggy banks for retail pharmacies or other providers, solving financial problems that may – or may not – be actually related to the MFP program. Notably, many pharmacies are facing profitability problems for a variety of reasons that have nothing to do with MFPs, such as under reimbursement of independent pharmacies by

[1] Centers for Medicare and Medicaid Services (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 202. October 2, 2024. Available: https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.
[2] 42 U.S.C. § 1320f-2.

large health insurers[3], or liabilities associated with opioid-related litigation.[4] How will a manufacturer – or the government – know if the pharmacy's request for liquidity genuinely as to do with the MFP program as opposed to other business problems that pharmacy may be facing and why should this be a manufacturer's responsibility to resolve?

It is important to recognize that more than 90% of independent pharmacies indicated they may not sell Medicare Part D prescription drugs selected for price negotiation due to the lack of protocol ensuring fair reimbursement by pharmacy benefit managers and insurers once the negotiated prices take effect.[5] This issue was, or should have been, evident at the time of passage of the IRA but because that process sidestepped regular order and was rushed through Congress without any hearings, investigation, fact finding, or stakeholder input, several unintended consequences have emerged.

Against this legislative, administrative, and legal backdrop, CMS is issuing this ICR, which effectively enshrines and expands the decision to make manufacturers – rather than the government – the stopgap financier.[6] CMS cannot, and should not, seek to plug this hole in the legislation by imposing extra obligations on manufacturers, particularly the obligation to mitigate cashflow concerns that has no foundation in the IRA statute whatsoever.

II. CMS' Proposed Approaches to Addressing 340B Duplicate Discounts Must Be Strengthened

CMS has set forth expectations for manufacturers to develop comprehensive plans to address 340B duplication, ensuring that the MFP is effectuated correctly.[7] This includes submitting detailed information on how they will manage data exchange with the Medicare Transaction Facilitator (MTF) and comply with the 14-day prompt MFP payment window.

Manufacturers are required to ensure that the MFP is accessible to 340B covered entities when it is lower than the 340B ceiling price for a given medicine. However, CMS view that manufacturers are also be responsible for "deduplicating" these discounts is concerning given the lack of statutory requirement for such responsibility and the absolute opacity in the 340B system.

Moreover, CMS's decision to not require covered entities to take any steps to identify 340B/MFP prescriptions creates an operational void. There are currently no systems or incentives for covered entities to voluntarily identify these dispenses, which puts manufacturers at significant risk of extending duplicate discounts on drugs that fall under both MFP and 340B categories. Other provisions in the IRA, specifically the Part B and Part D inflation rebates, also prohibit duplicate discounts, yet CMS continues to evade responsibility for ensuring compliance by dispensing entities. It is imperative that CMS and HRSA promptly and collaboratively develop a holistic approach to address these issues. At a minimum, CMS should recognize – and endorse – recent manufacturer efforts to implement 340B prices through retroactive rebate or cash replenishment.[8] These programs, which do not harm covered entity 340B cashflow, will provide manufacturers the data necessary to avoid duplicate discounts and manage MFP/340B pricing dynamics.

If CMS and HRSA do not endorse manufacturer rebate programs, then, at a minimum, CMS should couple a requirement for 340B claims modifiers with the establishment of a clearinghouse-type entity. This approach is already being explored by CMS in the context of inflation rebates, to offer better certainty that all prescriptions subject to 340B agreements are appropriately identified across all claims billed to Medicare and Medicaid. The 340B clearinghouse would act as a claims verifier, reviewing data submitted

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[3] National Community Pharmacists Association (NCPA), Local Pharmacies on the Brink, New Survey Reveals. Feb. 27, 2024. Available: https://ncpa.org/newsroom/news-releases/2024/02/27/local-pharmacies-brink-new-survey-reveals.
[4] Reuters, *Rite Aid Bankruptcy Plan Approved, cutting $2 Billion in Debt* (June 28, 2024).
[5] National Community Pharmacists Association (NCPA). Report for Fall Survey of Independent Pharmacy Owners/Managers. October 15, 2024. Available: https://ncpa.org/sites/default/files/2024-10/NCPA-FallSurvey2024-ExecSummary.pdf.
[6] *See* ICR, Appendix B: Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form. Page 10.
[7] *See id*. at 3.
[8] *See e.g.,* Nyah Phengsitthy, *J&J, Bristol Myers Turn to Drug Rebates in Fight Over Price* Cuts, BLOOMBERG LAW (Dec. 4, 2024).

by 340B covered entities (or entities acting on their behalf) to determine the likelihood that a claim is subject to a 340B agreement, similar to the role played by 340B third-party administrators (TPAs) and split-billing vendors today but with transparency for the government and manufacturers' funding the 340B program. Units marked as subject to 340B agreements on either the claim or by the 340B clearinghouse would be excluded from MFP. Further, any clearinghouse contract must be a neutral entity. For example, the chosen clearinghouse should not be owned or overseen by covered entities. The selected clearinghouse should have demonstrated expertise in adjudicating claims in real-time for retail medicines and provider-administered medicines. This would enable a single clearinghouse to serve for claims across the government programs, simplifying the operational process.

III. CMS Should Define the Standard Default Rebate Amount (SDRA) as the Lesser of WAC Minus MFP and Acquisition Cost minus MFP to Prevent Gaming

The ICR provides an opportunity for manufacturers to indicate whether they will use the dispensing entity's actual acquisition cost (AAC) or a reasonable proxy for calculating the MFP refund amount.[9] The SDRA set forth in the final guidance relies on the notion that manufacturers must cover the mark ups charged by others in the supply chain which creates serious concerns. First, this concept creates incentives for gaming by encouraging middlemen, dispensers and other entities within the pharmaceutical supply chain to "jack up" prices because they know the manufacturer will come along and pay for these inflated costs. The argument might be that this would not occur because someone would have to "float" the inflated acquisition price, but as we have seen in other programs, there is no end to creativity intermediaries will deploy.

This problem is exacerbated by the fact that manufacturers lack influence over the prices dispensers pay to supply chain intermediaries, such as wholesalers. If CMS was the party at risk to such gamesmanship, we have no doubt the agency would take steps to prevent the misallocation of taxpayer dollars. But as the Department of Justice recently recognized in a similar situation, "it is arguably worse for the government to play fast and loose with others' (drugmakers') money on the line."[10] To prevent the possibility of artificially increased MFP reimbursements, Lilly urges CMS to implement a policy where the SDRA is determined by the lesser amount between WAC minus MFP and Acquisition Cost minus MFP. At a minimum, CMS should define that that MFP refunds cannot exceed the SDRA (i.e., WAC minus the MFP).

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Lilly is appreciative of the opportunity to respond to the ICR. We sincerely appreciate your thoughtful consideration of the issues discussed in this letter and look forward to working with you in the future to help ensure that patients have meaningful access to affordable health care benefits and prescription drug coverage. Please do not hesitate to contact Derek Asay at Asay_Derek_L@Lilly.com with any questions.

Sincerely,

Derek L. Asay
Senior Vice President,
Government Strategy and Federal Accounts

Shawn O'Neail
Senior Vice President,
Global Government Affairs

[9] *See* ICR, Appendix B: Drug Price Negotiation Program MF DM Primary Manufacturer MFP Effectuation Plan Form. Page 4.
[10] Reply Mem. (Doc. 24) at p. 17, *Albany Med. Health Sys. v. HRSA*, No. 23-3252 (D.D.C. Apr. 19, 2024).

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

December 20, 2024

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted via www.regulations.gov

Re: Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request; Document Identifier CMS–10912

Dear Dr. Seshamani:

The National Association of Chain Drug Stores (NACDS) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on the burdens associated with the Medicare Transaction Facilitator (MTF) for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA).

1. **Introduction**

NACDS has identified a number of unnecessary burdens on pharmacies that could be successfully addressed if CMS were to design the Medicare Drug Price Negotiation Program ("Negotiation Program") in the same manner as the Medicare Coverage Gap Discount Program, that is, if CMS were to pre-fund the program and to engage an entity similar to the True out-of-pocket (TrOOP) cost facilitator instead of the Medicare Transaction Facilitators (MTF), i.e., the MTF Data Module (DM) and Payment Module (PM).

The unnecessary burdens on pharmacies that would be addressed are as follows, in brief:

- The timeliness of pharmacies receiving the manufacturer fair price (MFP) refund;
- Pharmacies potentially having to develop financial connections with many multiple manufacturers just to receive the MFP refund; and,
- Although CMS is proposing a mechanism for pharmacies to self-identify whether they anticipate having material cashflow concerns at the start of the initial price applicability year due to the reliance on retrospective MFP refunds within the 14-day prompt MFP payment window, CMS is

not requiring manufacturers to develop, implement, and execute plans for manufacturers to mitigate cashflow concerns for all pharmacies that self-identify.

Again, all three of these burdens would be alleviated under a Negotiation Program design that mirrors the Coverage Gap Discount Program.

Under CMS's current proposal, manufacturers opting to provide retrospective payment to effectuate MFPs would need to ensure that dispensing entities receive reimbursement within 14 days of when the MTF DM sends data to the manufacturer verifying that the drug was dispensed to an MFP-eligible individual. This 14-day window aligns with CMS's prompt pay rules in Part D, but results in delayed payment of several weeks because the 14-day window begins only after the drug has been dispensed, a pharmacy submits a claim to a Part D plan, the plan submits prescription drug event (PDE) data to CMS, CMS verifies the data, CMS submits the data to the MTF DM, and the MTF DM submits the data to the manufacturer.

Pharmacies would essentially be required to pre-fund the program. Pharmacies would purchase the prescription drugs subject to the MFP at market price but would be reimbursed initially only for the MFP price. Because of the delayed payment described in the paragraph above, pharmacies would not be wholly reimbursed for several additional weeks—essentially pre-funding the program through a financial float of up to 30 days. Rather than forcing pharmacies to pre-fund the program, CMS itself has the authority to pre-fund the program.

2. **<u>CMS Possesses the Authority to Pre-Fund the Negotiation Program</u>**

CMS's authority to pre-fund the Negotiation Program hinges on whether it has both statutory authority and an appropriation to do so. We believe that CMS's $3 billion IRA appropriation may cover its prospective funding of the MTF.

Whether appropriated funds are legally available for a given obligation or expenditure hinges in part on whether the purpose of the obligation or expenditure is authorized. The "purpose" statute, 31 U.S.C § 1301(a), provides: "Appropriations shall be applied only to the objects for which the appropriations were made except as otherwise provided by law." That is, public funds can be used only for the purpose for which they were appropriated. Determining the purpose for which funds were appropriated requires looking at "the common meaning of the words in the appropriation act and program legislation it funds." (GAO, *Principles of Federal Appropriation Law*, 4th ed., 2017 rev., ch. 3, §A.)

CMS could use IRA funds to carry out any provisions of the IRA even though these are not responsibilities specifically assigned to CMS. The IRA appropriation provides: "In addition to amounts otherwise available, there is appropriated to the Centers for Medicare & Medicaid Services, out of any money in the Treasury not otherwise appropriated, $3,000,000,000 for fiscal year 2022, to remain available until expended, to carry out ***the provisions of***, including the amendments made, by this part." (Section 11004 (emphasis added).) By contrast, CMS's annually-appropriated Program Management discretionary account is provided to it "[f]or carrying out, except as otherwise provided, titles XI, XVIII, XIX, and XXI of the Social Security Act, titles XIII and XXVII of the PHS Act, the Clinical Laboratory Improvement Amendments of 1988, and other ***responsibilities*** of the Centers for Medicare & Medicaid Services, ..." (Further Consolidated Appropriations Act, 2024, H.R. 2882-203 (emphasis added).)

If Congress intended for CMS's IRA appropriation to be used solely to fulfill CMS's *responsibilities* under the IRA, it would have included such an express limitation (e.g., "to carry out its responsibilities, including amendments under, this part"), as it did under the Program Management appropriation. Instead, the IRA appropriation language specifies using money to carry out the "provisions of" the IRA, which could encompass more than CMS's specific obligations under the Act. For this reason, we believe that CMS can and should pre-fund the Negotiation Program; otherwise, it would become the pharmacies' responsibility to shoulder the cost to effectuate the Negotiation Program that is intended for manufacturers.

3. **CMS Possesses the Authority to Require Manufacturers to Pre-Fund the Negotiation Program**

In the alternative, CMS could use its authority to require manufacturers to pre-fund the Negotiation Program. As discussed above, the IRA imposes on manufacturers the obligation to make the MFP available to dispensers. Nothing in the IRA suggests manufacturers satisfy this obligation by retrospectively refunding pharmacies and other dispensers. Thus, CMS is exercising discretion in permitting manufacturers to effectuate MFP through retrospective refunds. As part of the retrospective process, CMS could require manufacturers to pre-fund the MTF to be able to make more immediate payments to pharmacies and other dispensers, which would be replenished when the manufacturer pays the refunds to the MTF. Most importantly, this alternative approach would also help ensure continuity of care for beneficiaries to access affordable medications under the new program and mitigate fiscal pressures on pharmacies nationwide.

4. **CMS Does Not Possess the Authority to Require Pharmacies to Pre-Fund the Negotiation Program**

In light of the foregoing, we believe that CMS's proposed approach of giving manufacturers three to four weeks to reimburse pharmacies for the discounts implied in the MFP has the effect of shifting 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. Imposing such a mandate on pharmacies is misaligned with statutory intent and exceeds CMS's authority.

As noted above, the IRA obligates manufacturers – not pharmacies or other dispensing entities – to effectuate the MFP. This direct responsibility for manufacturers to ensure the provision of MFPs to dispensing entities suggests that a pre-funding requirement imposed by CMS on dispensing entities themselves would require additional legislative authorization, which currently does not exist. CMS itself has noted repeatedly that manufacturers bear the sole obligation to effectuate the MFP. Indeed, we see no statutory language or evidence of legislative intent for dispensing entities to bear such a responsibility, especially when the mechanics of the retrospective refunds would require pharmacies to wait substantially longer than the 14 days they currently expect payment from Part D plans and their PBMs.

Moreover, pharmacies continue to suffer from inadequate reimbursement and Part D plan and PBM clawbacks in the Part D program. Pharmacies do not have the financial ability to pre-fund the Negotiation Program, as pharmacies are often reimbursed below cost for medications dispensed to Part D beneficiaries. As NACDS routinely comments to CMS, pharmacy DIR fees have grown exponentially in recent years to the point that pharmacies in some cases must consider whether they can even stay financially afloat. Therefore, pharmacies should not be solely 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 considering the underwater reimbursement challenges from PBMs.

5. **Alternative Approaches**

a. Shorten Reporting Timelines

However, in the alternative, should CMS not agree that it has the authority to pre-fund the Negotiation Program or to require manufacturers to pre-fund the program, then we urge CMS to shorten the PDE reporting period from 30 days to one calendar day, and to require MTF DMs to provide the requisite data to manufacturers on a daily (calendar) basis. Unless the reporting time frames are reduced to daily reporting, pharmacies will not be fully reimbursed for up to 30 days or more. This would be tantamount to CMS requiring pharmacies to pre-fund the program, which it does not have the authority to do.

42 U.S.C. 1395w-112(b)(4) provides that Part D sponsors must make payment for clean claims within 14 calendar days of the date on which an electronic claim is received. At the same time, 42 U.S.C. 1320f-2(a)(3) requires the manufacturer to provide the MFP to the pharmacy. We do not see that the provisions of 42 U.S.C. 1320f-2(a)(3) somehow nullify or supersede the prompt pay requirements of 42 U.S.C. 1395w-112(b)(4). Consequently, these statutory provisions must be read in concert. Since the Part D sponsor remains responsible for ensuring that clean claims are paid within the statutorily imposed deadlines, we urge CMS to work with Part D sponsors, the MTFs, and manufacturers to ensure that this deadline is met. This likely includes requiring plans to submit PDE records on a daily (calendar) basis and requiring the MTF DM to transmit files containing claims-level data to manufacturers on a daily (calendar) basis (as we recommend above) to help ensure that the manufacturers have sufficient time to process the reimbursement request from the pharmacy should CMS disagree with our pre-funded model recommendations.

b. Medicare Transactions Facilitator Payment Facilitation

CMS is considering two payment facilitation options. The first option would be for manufacturers to provide payments directly to pharmacies. The second option would be for the MTF PM to receive aggregated refund amounts from manufacturers and pass the refunds to pharmacies. 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, then pharmacies support a single platform for transmitting refund payments as it would create greater efficiency, standardization, and predictability in the execution of a high volume of continuous payments. Consequently, **NACDS urges CMS to require only the second option.** If CMS were to allow both options, then pharmacies could be placed in a predicament of having some of their MFP refunds come from the MTF PM and other payments come from multiple other sources. This type of arrangement would be unnecessarily burdensome to the point of being infeasible for pharmacies.

6. **Appendix A: Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Entity Enrollment Form**

On page 3, under Section 1: MTF DM User Roles," NACDS seeks clarification whether the three required roles of 1) Authorized Signatory Official, 2) Access Manager, and 3) Staff End User each must be a different individual or if these roles may be combined among one or two staff members, and if so, how.

Section 2, Question 2 lists options to select the industry segment or operating structure that best characterizes the dispensing entity based upon your response to Question 1. The field options list both independent pharmacy and franchise pharmacy. We request that CMS provide definitions for these two entities as some industry members may use these terms interchangeably.

Section 3, Questions 1 and 2 ask pharmacies to provide the National Council for Prescription Drug Programs (NCPDP) identification numbers and a complete and accurate roster of an organization's locations, including any associated dispensing entity locations. We believe this process could be streamlined if CMS were to pre-fill the NCPDP database DataQ file that contains information needed in these sections. In this way, a pharmacy would only have to verify the information is correct instead of filling out additional information that already exists with NCPDP.

We urge you to consider that not all pharmacies utilize NCPDP Payment Center ID or Remit and Reconciliation ID, so NOT all pharmacies would readily have that information to use when populating the form. Most PBMs/Payers utilize the Chain ID for central pay purposes.

Section 3, Question 3A provides a field for a dispensing entity to self-identify as a dispensing entity that anticipates material cashflow concerns for at least one location at the start of the initial price applicability year. It is unclear how selecting "Yes" will connect a pharmacy to a manufacturer's mitigation process. We request that CMS please provide information on how this will occur and how a pharmacy can be assured that the manufacturer is aware of the pharmacy's cashflow concerns.

Section 4, Question 3A outlines banking information fields needed to process payment. The construct of this question does not account for banking processes used by all pharmacies in the USA. We urge you to be inclusive of all pharmacy banking practices and update this question in your final form to reflect this.

Section 5 requests the dispensing entity contact information. We recommend CMS look for ways to simplify this process by pulling the Information from NCPDP file in order to pre-fill the form (if available), which would decrease the administrative burden on the pharmacies.

7. **Appendix B: Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form**

CMS is imposing an unreasonable requirement on manufacturers to establish individual MFP Effectuation Plans for each medication with an MFP negotiated under the Inflation Reduction Act. CMS has provided very little guidance to manufacturers regarding this process, nor sample Effectuation Plans.

On January 1st, 2026, ten MFP Effectuation Plans will enter effect. On January 1st, 2027, there will be twenty-five different Effectuation Plans with that number growing in future years of the program. We

believe that manufacturers, whenever possible, should coalesce around a unified Effectuation Plans to reduce the burden on pharmacies and manufacturers.

While CMS requires manufacturers to submit their Effectuation Plans by September 1st of the year before the negotiated MFP takes effect, pharmacies and technology providers need more than 122 days to establish systems, procedures and protocols to effectively participate in the Effectuation Plan. Manufacturers should publish their Effectuation Plans, in whole or in part, as early as feasible.

8. **Appendix D: Drug Price Negotiation Program Complaint and Dispute Intake Form**

CMS is proposing to require complaints and disputes to be submitted no later than 120 calendar days from the date of the subject of the complaint or dispute. However, CMS is not proposing a requirement for response time or for resolution of the complaint or dispute. We ask that CMS provide an estimated response time for complaints and disputes, or at a minimum, ensure that acknowledgement of receipt of complaints and disputes will be provided in a timely manner.

With respect to "Question 5: Supporting Documentation" we are concerned about the 5-document limit on the supporting documentation upload. It is possible that a chain pharmacy could submit complaints and disputes on a similar issue among multiple pharmacies and that more than 5 supporting documents would be necessary for proper documentation. We ask that CMS expand the allowed supporting document upload to be much greater than a 5-document limit to accommodate chain pharmacy reporting.

9. **Conclusion**

In conclusion, NACDS thanks CMS for this opportunity to submit comments and for considering our recommendations to minimize burdens on pharmacies. We look forward to continue working with CMS's IRA team on helping to help ensure beneficiary access and an overall smooth transition and sustainable reimbursement for the pharmacy community. If we can provide any additional information, please do not hesitate to contact Dr. Christie Boutte, Senior Vice President, Reimbursement, Innovation, and Advocacy, at cboutte@nacds.org.

Sincerely,

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

December 27, 2024

The Honorable Meena Seshamani, MD, Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted Electronically: www.regulations.gov

Re: CMS–10912; Information Collection Request; Medicare Transaction Facilitator for 2026 and 2027 Under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)

Dear Dr. Seshamani:

The National Association of Specialty Pharmacy (NASP) appreciates the opportunity to provide feedback on CMS-10912, the Information Collection Request (ICR) regarding the Medicare Transaction Facilitator (MTF) for 2026 and 2027 being established for the Medicare Drug Negotiation Program under the Inflation Reduction Act (IRA). The ICR describes the information that CMS proposes to collect from manufacturers, pharmacies and other dispensers to operate the MTF. **NASP continues to remain concerned that the process outlined by CMS through final guidance and through the proposed ICR does not accurately interpret the IRA statute, and as a result, will lead to significant administrative and financial pressures on specialty pharmacies and other pharmacies, working against the agency's goals in implementing the Medicare Drug Negotiation Program.**

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. While these problems pre-date implementation of the IRA and persist, it is essential that CMS consider pharmacy challenges – especially financial challenges – as it implements the IRA, so that pharmacy financial and administrative challenges are not further compounded and escalated through implementation of the IRA drug pricing program.

NASP shares the priority of ensuring beneficiaries must have affordable access to the medicines they need. We also believe it is most important to ensure that implementation of the IRA law and CMS' related regulations, guidance and ICRs ensure that 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 Medicare negotiated drugs.

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 manufacturers of specialty drugs, group purchasing organizations, wholesalers, distributors, integrated delivery systems, health systems, 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.

Third-Party Medicare Transaction Facilitator (MTF)

We appreciate the agency's engagement with NASP and the broader pharmacy community and effort to establish a system to ensure that pharmacies and other dispensing entities can access the "maximum fair prices (MFPs)" that result from the new Medicare Drug Negotiation Program. We also understand and support the need to establish a neutral third-party entity to facilitate a process for data exchange between pharmacies/other dispensing entities and manufacturers and to allow for a streamlined process for payment between pharmacies/dispensing entities and drug manufacturers. Establishment of a third-party neutral facilitator for data and payment is also important to support accurate and timely payments to 340B-eligible entities.

MTF Data Module (DM)

NASP appreciates CMS' efforts to require manufacturers and pharmacies to participate in the data module process to streamline and ensure the accuracy of information exchanged to support payment of the MFP between manufacturers and pharmacies/dispensing entities. What we do not understand is why CMS has determined it has the legal authority to require manufacturer and pharmacy/dispensing entity participation in a data module but does not have the authority to require manufacturer participation in a payment module.

Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Enrollment Form (Appendix A)

- Under Section 2, Question 2, CMS seeks to have pharmacies self-identify by type. Given that many of the selected negotiated drugs will likely be considered specialty drugs as the negotiation program continues, meaning they are not largely dispensed in a traditional pharmacy or online setting unless that pharmacy setting meets manufacturer and/or Plan Sponsor-required standards for dispensing and servicing those drugs, we

urge CMS to allow for the identification of "Specialty Pharmacy" among the pharmacy options listed on the form.

- Many of the requested details on this form are already available through NCPDP. NASP urges CMS to explore how this existing data source can be leveraged to reduce administrative burden on pharmacies/dispensing entities?
- NASP anticipates that most, if not all pharmacies will self-identify as experiencing material cashflow concerns because of the MFP process. NASP is significantly concerned that self-identification of this concern does not guarantee access to a manufacturer's mitigation process. NASP is also concerned if any mitigation processes will be in place to support pharmacies in addressing cashflow concerns, particularly given that manufacturers are expressing concerns about meeting the 14-day claims processing requirements. We request additional clarity from CMS on what process is considered acceptable and urge CMS to oversee this process and to receive information from manufacturers to clarify what this process includes to support pharmacies/dispensing entities.
- Many of the requested details for this form are already available in NCPDP; could this database be leveraged to reduce administrative burden?

Drug Price Negotiation Program MTF DM Primary Manufacturer Maximum Fair Price (MFP) Effectuation Plan Form (Appendix B)

- The need for standardizing the process for payment from manufacturers to pharmacies/dispensing entities is evident based on the complexity of the ICR Appendix B itself. The questions are open-ended, long-winded and complex, and the concern is that the information will not be clear to pharmacies/dispensing entities or CMS on how a manufacturer plans to effectuate the MFP. It is recommended to require the manufacturer to opt to select the MTF PM process or not, and if not, respond to why the manufacturer would instead opt for an alternative approach.
- The form allows for 90 days to address any changes to a manufacturers' approach to effectuate the MFP within the 14-day prompt payment statutory requirements or in making an adjustment to the standard default payment amount (SDRP). It is unclear in what timeframe a pharmacy/dispensing entity would be made aware of any changes in a manufacturers' process (as opposed to CMS being made aware) to support the pharmacy's understanding and possible adjustments to its own internal tracking process for payments.
- NASP would urge CMS to understand and acknowledge that not all pharmacies can or will use a third-party administrator to support the management of MFP-related payments from manufacturers. (Independent specialty pharmacies, for example, do not typically use PSAO's to support payment processes.)
- NASP is very concerned about the open-ended approach toward Appendix B's questioning of how a manufacturer would identify 340B claims and ensure against

duplication of discounts. Please see comments below on the need for CMS clarity on the rules to avoid manipulation of 340B pricing deemed to be in violation of the 340B statute by other HHS agencies with authority over the program. We urge CMS to collaborate with HRSA to structure rules that protect covered entity access to upfront 340B discount pricing.

Drug Price Negotiation Program MTF DM Primary Manufacturer Payment Elements Form (Appendix C)

- Under Payment Element 2 – Method for Determining MFP Refund Amount," CMS does not include a requirement on this form for manufacturers to provide information when the source of determining the pharmacy/dispensing entity acquisition cost differs from the CMS-recommended Standard Default Rate Amount of WAC. The form lists "no refund transited – other," which is ambiguous and does not provide a pharmacy/dispensing entity with any way of understanding the reason for the denial.
- NASP has specific concerns about the MFP payment process when there are circumstances that result in a drug being dispensed but never received by the MFP-eligible individual (e.g., a patient opts not to receive the medication due to cost, and it goes back into a pharmacy's stock) and other claim reversals and adjustments. A process under the model CMS has proposed would need to allow for a credit or at least a reasonable reversal process to be in place, if a pharmacy was in receipt of the MFP for a drug that has a claim that is ultimately reversed or not completed. The process would need to allow for information to be reported to and captured by the MTF to moderate a payment adjustment between the pharmacy and manufacturer in a non-burdensome and timely manner. It is not clear whether CMS envisions use of Appendix C for this information purpose.

MTF Payment Module (PM)

If CMS' goal is to streamline process to reduce administrative burden, ensure payment timeliness and accuracy, then permitting each drug company the opportunity to design its own payment process will create a system with significant burden for pharmacies/dispensing entities and one that does not lend itself to effective CMS oversight or audits. Every manufacturer could opt to set up its own payment process, requiring pharmacies/dispensing entities to manage and track payments from several different arrangements. The ICR is meant to consider the burden placed on entities behind the process outlined, and NASP is extremely concerned that as proposed, the ICR will result in massive operational cost and burden on pharmacies. As outlined, such as system would require pharmacies to invest in technology that could track potentially multiple payment arrangements and monitor when payments are made to effectuate the MFP under the terms outlined in statute. This becomes even more difficult when

a payment has to be resubmitted, reconciled or returned for myriad reasons. Effectuating the MFP must not be directly or indirectly left to the pharmacies/dispensing entities to figure out and manage, diverting pharmacy time and resources away from serving its patients and adding significant financial and administrative burden to pharmacies. The statute clearly did not explicitly or non-explicitly intend for pharmacies to shoulder the burden of MFP effectuation. **NASP continues to advocate for CMS to require drug manufacturers that decide to utilize a retrospective payment option for negotiated drugs to participate in the MTF payment process to reduce the administrative burden on pharmacies/dispensing entities, reduce the need for avoidable errors, and to ensure payment under the prompt payment standards in statute and outlined in CMS' guidance. CMS cannot accurately outline the cost burden of the ICRs that would be placed on pharmacies/dispensing entities in the absence of having a standardized payment system to pharmacies/dispensing entities.**

Addressing the 340B Program

The IRA law states that the Primary Manufacturer of a select drug is not required to provide access to the MFP for a select drug to MFP-eligible individuals who are eligible to be dispensed a drug subject to a 340B ceiling price under statute if the 340B ceiling price is lower than the select drug's MFP. The IRA law does not state that prospective access to 340B pricing is at the manufacturer's discretion. **NASP is increasingly concerned about any effort to skirt 340B pricing to contract entities and the pharmacies they engage to support the 340B program. Lack of guidance from CMS on 340B payments under the IRA seems to put the agency in a different position than other HHS agencies that have clearly called any manufacturer rebate models and other efforts to circumvent upfront 340B discounting of negotiated drugs unlawful. NASP urges CMS to codify that prospective access to 340B pricing must be maintained.**

Complaint and Dispute Processes

CMS states in final guidance that it is required by the IRA law to establish a robust program for monitoring compliance with the Negotiation Program. However, **NASP is concerned that CMS states it "may" audit any data related to the Primary Manufacturer providing access to the MFP, including where the selected drug is provided by a Secondary Manufacturer. NASP wants to emphasize the importance of CMS overseeing and requiring compliance with the process for data exchange to effectuate the MFP and reiterates that CMS should go further to require standardization and uniformity around payments to pharmacies/dispensing entities with CMS oversight and protections to ensure that pharmacies are not put at any financial risk for the requirements of the law addressing MFP payments. The process for any exchange of information between manufacturers and pharmacists must be part of a mandatory audit by CMS.**

Drug Price Negotiation Program Complaint and Dispute Intake Form (Appendix D)

- Under Q1B CMS seeks to have pharmacies self-identify by type. Given that many of the selected negotiated drugs will likely be considered specialty drugs as the negotiation program continues, meaning they are largely not dispensed in a traditional pharmacy or online setting unless that pharmacy setting meets manufacturer and/or Plan Sponsor-required standards for dispensing and servicing those drugs, we urge CMS to allow for the identification of "Specialty Pharmacy" among the pharmacy options listed on the form for the purpose of filing a complaint/dispute. It will be important for manufacturers and CMS to understand in which pharmacy setting certain complaints and disputes have been identified as entities seek to troubleshoot concerns.
- NASP is concerned about how a pharmacy can appropriately file a dispute on numerous claims. Will CMS provide optional formatting to submit multiple claims related to the same drug given there could be varied concerns?
- While a timeframe is enforced for dispute/complaint submission, NASP has concerns with the timeframe provided and what this means toward actualizing payment to a pharmacy when a dispute is resolved.
- NASP is concerned that CMS does not outline in guidance or in the ICR any terms for response time on a dispute or timelines for resolution of disputes.
- There are concerns about having a 5-document limit appropriate where a third-party entity submits a dispute on behalf of multiple pharmacies experiencing the same issue. To ensure each pharmacy's dispute is addressed, we suggest CMS consider allowing for a claim to be opened for each pharmacy experiencing the same concern/issue and having CMS provide optional formatting to submit multiple claims related to same drugs.

Conclusion

NASP looks forward to continued opportunities to work with CMS as it implements the Medicare Drug Negotiation Program. To address questions about our comments or for further information, please contact me at Sheila.Arquette@naspnet.org.

Sincerely,

Sheila Arquette, RPh.

President and CEO

Submitted electronically to: www.regulations.gov

December 20, 2024

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS–10912
Room C4–26–05
7500 Security Boulevard
Baltimore, Maryland 21244–1850

Re: Agency Information Collection Activities: Proposed Collection; Comment Request [Docket No. CMS–10912] - CMS–10912 Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request- Drug Price Negotiation Program Complaint and Dispute Intake Form

Docket Management Staff,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) to its docket: Agency Information Collection Activities: Proposed Collection; Comment Request [Docket No. CMS–10912] regarding the Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA). Our comments are limited to the Appendix D: Drug Price Negotiation Program Complaint and Dispute Intake Form.

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.

Appendix D provides scant details on the dispute process. A clearer process is needed to protect the legitimate concerns of pharmacies.

"**Complaint:** Any issue brought forward by an individual or entity that does not fall under the above definition of dispute; this covers a wide range of concerns from a broad range of interested parties. **Complaints related to a lack of MFP availability may not always require a specific resolution but will be reviewed by CMS and may trigger an investigation under CMS' obligation**

to administer the Negotiation Program and to provide monitoring and oversight of MFP availability." [NCPA emphasis]

NCPA believes that CMS' stipulation that a lack of MFP availability does not necessarily require restitution and investigation to be troubling. The voluntary nature of WAC-MFP as the Standard Default Refund Amount benchmark is especially concerning for dispensers, considering that pharmacies need to be reasonably compensated for these MFP drugs. NCPA advises CMS to require that the manufacturer provide the MFP refund to pharmacies using the Standard Default Refund Amount of WAC-MFP and that dispensers have sufficient protections for reasonable reimbursement and to make complaints.

Page 5

"Question 4: **Detailed Description of Issue** Please provide a detailed description of your complaint or dispute. Be as specific as possible, including the full names and addresses of people and businesses involved. Include all relevant dollar amounts, interactions, **timeframes**, and other pertinent details to aid in the potential investigation and resolution of your submission." [NCPA emphasis]

While a timeframe is required for dispute/complaint submission, there is no agreement in terms of response time or resolution to submitted disputes/complaints.

"Question 5: Supporting Documentation"

We have concerns about the 5-document limitation on the supporting documentation upload. For example, if the supporting documentation is submitted from a third-party entity or PSAO that could possibly be reporting a similar issue across multiple pharmacies, more than 5 supporting documents could be necessary to alleviate the administrative burden of submitting multiple disputes/complaint forms.

Other Concerns

Helpdesk

NCPA thanks CMS for granting NCPA's request requiring that all contractors engaged in implementing the MTF system maintain a helpdesk to address any operational issues relating to use of the MTF system. NCPA had commented in the draft guidance that it was concerned that the MTF contractor "helpdesk" was suggested and not required. **Further, NCPA suggests that this helpdesk be non-automated and that it be responsive to any concerns from dispensing entities during normal business hours accounting for all U.S. time zones.**

NCPA provides the following additional suggestions:

CMS must ensure that all Medicare Part D processors, including the MTF, DDPS, PBMs and plans, and manufacturers demonstrate compliance and validation of their technical and security infrastructure before implementation, or else they cannot participate in the MTF

payment process. Improper technical infrastructure and implementation by these entities will likely negatively impact and delay payment to pharmacy.

Additionally, CMS must establish a portal for the pharmacy to locate the status of MTF payments at the claim level. This portal could be read-only that pharmacies could log into with the MTF to research claims, for example that outlines the following: claim has been received, claim is being reviewed by the Manufacturer, claim has been paid, or claim has been rejected due to 'x' reason. **Additionally, NCPA asks that this portal be accessible by PSAOs and that they and pharmacies be able to download data through Electronic Remittance Advice, ASC X12N 835 files.**

NCPA advises CMS that pharmacy enrollment with the MTF can be streamlined, eliminating the need for individual enrollment forms/portal access for every pharmacy location. **NCPA recommends that the MTF leverage the NCPDP Pharmacy file for pharmacy demographics.**

Additionally, NCPA has concerns that the dispute/complaint process seems to limit issues to transaction data visible to the manufacturer. This creates concerns as the process could break in any one of the following steps:

- If the Medicare Part D plan or PBM: misapplies an MFP price (differences in MFP or WAC effective dates and/or price); lack of MFP identifier on claim response and/or PDE; timing or gaps in processing reversals; claim submissions (transaction date > date of service).
- If the DDPS: rejects PDEs that prevent the Medicare D claim from being forwarded to MTF, timing or gaps in processing reversals, claim submissions (transaction date > date of service)

CMS must provide guidance to ensure pharmacies are made aware by plans/processors if the PDEs are rejected on an MFP claim and cannot be corrected by the plans/processors. For example:

- MTF - misapplication of an MFP price (differences in MFP or WAC effective dates and/or price), lack of manufacturer WAC information, timing gaps in processing manufacturer MFP data files
- Manufacturer – if the manufacturer is the ultimate responsible party, will all the above concerns have to be resolved/supported by the manufacturer? At a minimum, the manufacturer will need to establish dedicated resources and processes to research and resolve disputes in a timely manner. Manufacturers also need to publish their process to identify 340B duplicates.
- Manufacturer Payment Codes (between manufacturer and MTF) will need to be mapped to existing (or request new 835 CARC and RARC codes) and provide pharmacies with a payment manual to use for reference.

Additionally, CMS should establish a Task Force to establish the applicable Manufacturer MFP response codes that can map to 835 CARC/RARC codes, allowing for existing payment

reconciliation processes to be used, and to create a standardized payment manual to be used by the MTF.

Dispute Resolution

As disputes will arise, we recommend that both parties submit any disputes using the specific X12 835 claim number. To facilitate continued pharmacy operation and access to medications by patients, we recommend that manufacturers do not interrupt payments to pharmacies during a dispute and that all claims be paid as the credit/debit ledger exists as a mechanism for manufacturers to recoup any over or incorrect payments. To ensure disputes are rapidly addressed, we believe manufacturers and pharmacies should agree to binding arbitration if they are unable or unwilling to resolve the dispute within 30 days on the initial complaint by one party. Finally, we recommend that both parties identify a singular point of contact for all disputes.

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

Submitted electronically to: www.regulations.gov

December 20, 2024

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS–10912
Room C4–26–05
7500 Security Boulevard
Baltimore, Maryland 21244–1850

Re: Agency Information Collection Activities: Proposed Collection; Comment Request [Docket No. CMS–10912] - CMS–10912 Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request- Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Enrollment Form

Docket Management Staff,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to CMS to its docket: Agency Information Collection Activities: Proposed Collection; Comment Request [Docket No. CMS–10912] regarding the Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA). Our comments are limited to the Appendix A: Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Entity Enrollment Form.

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.

Preliminary Roadmap of Comments/Concerns

Before addressing the specific questions on the proposed enrollment form, we request clarity on who will have access to the information in the MTF enrollment form, and how CMS will be protecting the confidentiality of this data.

Additionally, we argue that the Medicare Transaction Facilitator (MTF) should not require or collect redundant data. Pharmacies have already addressed ownership and related issues during their enrollment with Part D plans, making it unnecessary to revisit these details in the MTF enrollment process. Instead, the MTF enrollment should focus on collecting only the essential fields needed to accurately identify the pharmacy and ensure proper routing of payments and EDI 835s. We believe the process could be streamlined by relying, to the maximum extent possible, on the NCPDP Registry and the successful enrollment of pharmacies with Part D plans.

Page 1

On page one of the Enrollment form, CMS states that CMS intends to propose in future rulemaking a requirement that Part D plan sponsors include in their pharmacy agreements provisions requiring dispensing entities to be enrolled in the MTF DM. CMS has already proposed this in its proposed rule, *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*. **NCPA strongly opposes this mandatory requirement, as the impact of the Medicare Drug Price Negotiation (MDPN) Program, as it currently stands, will be devastating for independent pharmacies.** Based on CMS guidance implementing the MDPN Program released to date , we are not seeing anything from CMS to protect pharmacies from facing below cost reimbursements from PBM's for MPF drugs, including pharmacy price concessions being withdrawn due to CMS's unwillingness to "interfere" with PBM/pharmacy contracts -- even though Congress has provided CMS a specific exemption to do so [and CMS's own prior interpretation agreed that it can]. At the same time, we are seeing CMS interfere in PBM/pharmacy contracts when it dictates that any contract between the sponsor or its PBM and a pharmacy must include a provision requiring the pharmacy to be enrolled in the Medicare Transaction Facilitator Data Module (MTF DM). So, while CMS is willing to interfere with contracts concerning the data module, it is not willing to interfere in contracts that make certain pharmacies are paid fairly. For those reasons, we think this program has a high likelihood of failure and opens CMS up to potential legal claims that it can in fact interfere in PBM/pharmacy contracts but chooses not to do so.

Page 2

On page 2, CMS mandates that pharmacies need to maintain the accuracy of the information in the MTF DM: "The dispensing entity is responsible for determining and acquiring information necessary to complete Part I, and for maintaining the completeness and accuracy of the requested information in the MTF DM as long as the dispensing entity is enrolled in the MTF DM." **NCPA opposes this requirement, given the high administrative burden that updating this information would entail.**

PSAO/Pharmacy Relations, and Importance of NCPDP Registry

Establishing and accurately managing pharmacy-to-PSAO relationships is a dynamic and intricate process. Pharmacies use PSAO services, and every month, hundreds of them switch affiliations—often due to changes in distributors or buying groups. When payer records contain outdated or inaccurate relationship information, payments and remittance details may be sent

to the wrong PSAO, delaying fund transfers to pharmacies and complicating payment tracking and reconciliation.

The NCPDP Registry has since been enhanced and refined, providing much-needed clarity in managing pharmacy-PSAO connections. The Registry serves as a centralized, authoritative source for pharmacy profiles—covering chains, independents, and mail-order pharmacies—and is trusted by commercial, Medicaid, and Medicare payers alike. Each pharmacy maintains control over its profile with robust security measures, ensuring that only the pharmacy or its authorized proxy can make modifications.

This trusted system underpins the multi-step approval process for pharmacy-to-PSAO relationships. The process begins when a pharmacy submits an enrollment request to a PSAO. The PSAO, as part of its due diligence, thoroughly evaluates the request before formalizing the relationship through a contract—a process that typically takes 30 to 60 days. Once complete, the PSAO updates the NCPDP Registry to initiate its approval and sets a start date for the relationship. The final step requires the pharmacy to acknowledge the approval, completing the process.

If CMS does not adopt this proven industry solution, the MTF must establish similar systems and processes to accommodate joint approvals and future start dates. Without a centralized system like the NCPDP Registry, CMS will be required to build comparable capabilities to ensure the accuracy and efficiency of pharmacy-to-PSAO connections. This would include creating and maintaining an authoritative source for pharmacy profiles, which would be a complex and resource-intensive process. By leveraging the NCPDP Registry, CMS can avoid the duplication of efforts, reduce the burden on pharmacies, and streamline the implementation of the MTF.

We strongly urge CMS to adopt the NCPDP Registry as the primary authoritative source for maintaining pharmacy-to-PSAO connections. Pharmacies are currently in control of their profiles and they are required to be up to date to participate in Part D plans, so it does not make sense for CMS to require pharmacies to create another type of profile to put in this information.

Although we encourage CMS to adopt the NCPDP Registry as the sole mechanism for managing PSAO relationships, the MTF enrollment process should include an option for pharmacies to opt out of having their PSAOs manage payments. Pharmacies should still be able to direct their 835s to their PSAOs to facilitate refund reconciliation.

<u>Pharmacy Profiles</u>

We strongly recommend that the MTF adopt and integrate the NCPDP Registry as the authoritative source for pharmacy profiles. As the foundation for pharmacy enrollment in Part D plans, the NCPDP Registry already serves as a trusted and centralized resource for accurate and up-to-date pharmacy information. Ensuring alignment between the NCPDP Registry, Part D plans, and the Medicare Transaction Facilitator (MTF) is essential for maintaining consistency and streamlining processes.

Pharmacies are accountable for their profiles in the NCPDP Registry. When applicable, pharmacies must provide supporting documentation for validation and complete their profile. The Medicare Transaction Facilitator (MTF) should subscribe to and receive updates from the NCPDP Registry. These updates should populate profile fields within MTF systems and be displayed to the pharmacy. It is critical that these fields remain consistent and cannot be altered independently, as discrepancies would undermine the reliability and integrity of the enrollment process.

The NCPDP Registry serves as the definitive source for the fields it provides, ensuring that all stakeholders operate with a single, consistent set of data. Allowing mismatched profile fields across systems would lead to inefficiencies, increased administrative burden, and potential confusion for pharmacies. By leveraging the NCPDP Registry as the authoritative source, the MTF can enhance accuracy, reduce errors, and support a more seamless experience for pharmacies and other industry stakeholders. **The NCPDP Registry should be integrated as the authoritative source for pharmacy profiles to ensure consistency across systems.**

On page 2, the form also states that "dispensing entities…should only complete part 1 [while]…entities such as a PSAO…should only complete part 2." **NCPA has the following clarification questions:**

- What means/mechanisms to enroll are available – is this electronic only or can pharmacies submit via paper application?
- Who has access to this information? How can independent pharmacies know with whom this sensitive information will be shared? What privacy protections are available?
- Can PSAOs fill out these forms for independents?
- Do chain pharmacies submit part 1?
- Do independents under PSAOs have the PSAO submit part 2?
- What about independent pharmacies that do not have PSAOs, such as regional chain pharmacies? Are those payments coming directly to pharmacies in electronic or check payment? When pharmacies receive these payments, do they have access to the 835 files for reconciliation purposes? Do the independent pharmacies have to fill out part 1?
- Do refund payments go directly to PSAOs? For PSAOs that require payments to go through them, can CMS ensure that PSAOs will pass through these payments to pharmacies?
- Do PSAOs have the option to get payments in aggregate or to pass them through to individual pharmacies?

<u>Page 3</u>

Under "Section 1: MTF DM User Roles," **NCPA seeks clarification if the three required roles of 1) authorized signatory official, 2) access manager; and 3) staff end user each require a separate staff member, or if these roles can be combined in staff members, and if so, how.**

<u>Page 4</u>

Page 4, Section 2 refers to the type of dispensing entity enrolling, specifying that it can be a

CHO or a "dispensing entity under common ownership." However, the concept of ownership is not always straightforward, as many pharmacies share administrative functions but have different owners, making the classification of "common ownership" difficult to apply. Additionally, pharmacies have already addressed ownership questions when contracting with Part D plans, so it seems redundant for the MTF to require the same information. This question could cause unnecessary confusion and may not add value to the enrollment process. It would be more efficient to streamline the process by removing this question altogether, particularly given that the enrollment of non-common ownership entities, such as those with shared administrative functions, may raise further complexities regarding EIN requirements.

Page 5

The categories listed in Section 2, Question 2 of the CMS form are unclear and could lead to confusion. Many independent pharmacies operate under franchise agreements, which blur the distinction between 'Franchise Pharmacy' and 'Independent Pharmacy.' Additionally, many independent pharmacies service long-term care facilities, raising the question of whether they should be categorized as 'Long-Term Care Pharmacy.' Furthermore, some independent owners manage multiple locations—which might classify them as a 'Chain Pharmacy' despite being independently owned. These overlaps create ambiguity, and selecting the wrong category could result in misclassification, leading to unnecessary complications.

We contend that this classification question is unnecessary and could generate more confusion than clarity. If CMS needs to gather information about specific pharmacy types, it would be more effective to include separate checkboxes for those scenarios rather than forcing pharmacies to navigate overlapping or vague categories. This would allow for more accurate data and better serve both the pharmacies and the MTF system.

Page 6

On page 6, question 3 discusses "material cashflow concerns"**:**

> Question 3 provides an opportunity for dispensing entities to self-identify as having **material cashflow concerns** at the start of the initial price applicability year due to the shift from payment by the Part D plan sponsor to a combination of Part D plan sponsor payment plus a potentially lagged MFP refund. For example, CMS expects that **certain types** of dispensing entities—such as **sole proprietor rural and urban pharmacies with high volume of Medicare Part D prescriptions dispensed; pharmacies who predominantly rely on prescription revenue to maintain business operations; long-term care pharmacies; 340B covered entities with in-house pharmacies**; and Indian Health Service, Tribal, and Urban Indian (I/T/U) pharmacies—may have material concerns about cashflow related to the effectuation of MFP. [NCPA emphasis]

NCPA argues that all pharmacies, not just the types that CMS has stated, have "material cashflow concerns" under the Medicare Drug Price Negotiation Program. Under this model, each community pharmacy would need to float on average $27,000 per month, so all pharmacies

should qualify as having "material cashflow concerns" by default, or should be exempt from the MDPN program. Additionally, CMS' category of "pharmacies who predominantly rely on prescription revenue to maintain business operations" encompasses most pharmacies: according to the 2024 NCPA Digest, nearly all revenue (90 percent) of our membership comes from behind the counter.

Requiring pharmacies to state they are distressed due to cash flow concerns could have unintended negative consequences. Such a declaration may impact their banking relationships and loan agreements, as financial institutions may view this as a sign of financial instability. This could jeopardize the pharmacy's ability to secure future financing or loans, potentially restricting their access to necessary capital for operations, expansion, or unforeseen expenses.

Additionally, NCPA is concerned with manufacturer discretion of 1) sharing eligibility criteria for mitigation and 2) mitigation itself. Both are problematic for pharmacy protections under this program:

> As stated in section 90.2.1 of the Final Guidance, CMS will make the list of the self-identified dispensing entities available to Primary Manufacturers in the MTF DM prior to Primary Manufacturers' submission of MFP effectuation plans for 2026 and 2027 and will provide updates to the list on an ongoing basis as other dispensing entities enroll in the MTF DM and self-identify as having material cashflow concerns or dispensing entities update their self-identification over time. **CMS views sharing this list as informational and recognizes a Primary Manufacturer may establish its own eligibility criteria for determining which dispensing entities are included in its mitigation approach.** Aany such eligibility criteria should be outlined in the Primary Manufacturer's mitigation process in their MFP Effectuation Plan. **The Primary Manufacturer has discretion for dispensing entity inclusion criteria for any alternative approach; selecting "Yes" does not guarantee the dispensing entity will gain access to a Primary Manufacturer's mitigation process.**

On Section 3, question 1, regarding "NCPDP 'Parent Organization ID'" and "NCPDP 'Chain Relationship ID'", can CMS clarify what these numbers mean? Do the pharmacies need to enter a chain code for the PSAOs that they participate in? We do not fully understand the purpose of these fields but recommend that they have the same purpose as those used by Part D plans, and that the NCPDP Registry be considered the authoritative source for this field and all data fields that pertain to the pharmacy profile. This will ensure consistency across systems and reduce the burden on pharmacies having to maintain separate profiles.

<u>Page 7</u>
For the chart at the top of the page, do pharmacies need to submit this information for each location?

Page 8

On page 8, the form states the following:

> Dispensing Entity CHO: If the entity completing this section is a Dispensing Entity CHO, please indicate whether the Dispensing Entity CHO will accept MFP refund payments from Primary Manufacturers on behalf of all pharmacies under the Dispensing Entity CHO provided in response to Section 3, Question 2. **By selecting "Yes" in response to Question 1, of this section, the Dispensing Entity CHO authorizes the MTF PM to pass through MFP refund payments in an aggregated, single amount on a recurring basis from Primary Manufacturers directly to the payment address or bank account provided.** The Dispensing Entity CHO shall be responsible for disbursing MFP refund payment amounts to its chain pharmacies as applicable from the single payment passed through by the MTF PM. [NCPA emphasis]

NCPA asks CMS if it can further define what it means by "aggregated, single amount on a recurring basis."

Page 9

On page 9, the form states:

> Non-Chain Dispensing Entities or Dispensing Entity CHOs are responsible for maintaining the accuracy of information in this section and reporting any changes over time. Upon any change to the information in this section, the information in this form should be updated via the MTF DM user interface. Failure to promptly update information may cause delays or interruptions in processing of MFP refunds.

NCPA opposes this provision due to the significant administrative burden this would cause pharmacies. Alternatively, our third-party support entities could be responsible for this.

Page 10

On page 10, Section 4, Question 2A reads the following:

Section 4, Question 2A. If "Yes" was selected in response to Question 2, please provide the name of the dispensing entity's third-party support entity and the MTF-related services that the third-party support entity is authorized to provide to the dispensing entity for purposes of the MTF. Please add a new row to enter more than one third-party support entity .

Third-party Support Entity	**Third-party Support Entity Service**	**Third-Party Support Entity Service Effective Dates**	**NCPDP Payment Center ID**	**NCPDP Remit and Reconciliation ID**
Text	[Service: Drop-down menu]	Text	Text or Enter "Not Applicable"	Text or Enter "Not Applicable"

Drop-down Menu Options

1	Central payment(i.e., receive MFP refunds on behalf of a dispensing entity)
2	Remittance (i.e., receive ERAs or remittance advice on behalf of dispensing entity)
3	Reconciliation (i.e., submit complaints/disputes on behalf of a dispensing entity)
4	Audit assistance (i.e., assist a dispensing entity or produce records during an investigation or audit)
5	Other

NCPA requests clarification if the dispenser selects option 1 (central payment), does this include electronic remittance advice as well? Can a dispenser choose more than one option in this drop-down menu? How do independent pharmacies know which function to select?

Section 4, Question 2C states "If applicable, please confirm the third-party support entity that will receive MFP refunds on the dispensing entity's behalf by entering the name of the third-party support entity in the text box." **NCPA asks if this can be more than one entity.**

Page 11

On page 11, CMS states:

> Note: With respect to payments passed through the MTF PM, the MTF PM's transfer of the Primary Manufacturer's authorized MFP refund payment to a dispensing entity shall not in any way indicate or imply that CMS or its MTF Contractors have evaluated or determined that the amount paid by the Primary Manufacturer is sufficient to make the MFP available to the dispensing entity and shall not otherwise discharge the Primary Manufacturer's statutory obligation to make the MFP available. Neither CMS nor its MTF Contractors will assert independent control over the disposition of deposited payment amounts or direct payment transfers; instead, the MTF Contractors will perform a ministerial

> function at the behest and direction of the participating Primary Manufacturer with respect to the pass through of the Primary Manufacturer's funds in the amounts and to the dispensing entities identified by the Primary Manufacturer in its claim-level payment elements.

NCPA opposes this, as CMS is not protecting pharmacies from making sure that they are paid sufficiently to make the MFP available.

Additionally, CMS has stated that it will not pay for this program nor will it assume any responsibility for payment:

> Because the MTF PM will only pass payments between Primary Manufacturers and dispensing entities, **under no circumstances will federal funds be used for these transactions or to resolve or make payment related to disputes that may arise between parties when the MTF PM is utilized, including with respect to nonpayment or insufficient payment by a particular party**. **Neither CMS nor the MTF Contractors will be responsible for funding or paying the refund amounts owed by the Primary Manufacturer in instances where the Primary Manufacturer does not pay an MFP refund owed to a dispensing entity**, including in cases where the Primary Manufacturer may be unable to pay (e.g., bankruptcy, insolvency, etc.). Neither CMS nor its MTF Contractors will accrue any interest on funds held by the MTF PM during the period before the funds are transferred to the dispensing entity (or returned to the Primary Manufacturer in the event of unclaimed funds). The MTF PM will serve only as a mechanism to transfer funds of the Primary Manufacturer to dispensing entities as directed by the Primary Manufacturer in the amounts authorized by the claim-level payment elements transmitted by the Primary Manufacturer and will not collect funds for any other use. [NCPA emphasis]

NCPA re-iterates that 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.

<u>EDI 835 Remittance Advice</u>

As CMS works with the X12 standard to develop its specific implementation of the remittance advice to be used by the payment module, we would like to make two key points.

The first is that the implementation layout be made available early in 2025 so that industry stakeholders who offer reconciliation services can initiate development efforts and be ready for the January 2026 kickoff. Sample data should also be made available to assist in the testing process.

The second is that the layout should include one or more fields that can be used for cross-reference. For example, if a manufacturer claws back a previously paid refund because it has subsequently been identified as a 340B claim, the 835 could contain the HRSA identifier for the covered entity, as many pharmacies serve as contract pharmacies for multiple covered entities. Another example might be an invoice number where the discount was prospectively paid.

Page 14

On page 14, for the instruction in Section 6, CMS states:

> An individual eligible to certify this submission on behalf of the dispensing entity must be one of the following: (1) the chief executive officer (CEO) of the organization, (2) the chief financial officer (CFO) of the organization, (3) an individual other than a CEO or CFO, **who has authority equivalent to a CEO or CFO of the organization**, or (4) **an individual with the directly delegated authority to perform the certification** on behalf of one of the individuals mentioned in (1) through (3). [NCPA emphasis]

NCPA is seeking clarification as to if CMS needs proof of the person having authority equivalent to CEO or CFO of the organization, or an individual with the directly delegated authority to perform the certification. NCPA is also wondering how CMS seeks to prevent fraudulent filing, especially bad actors who are not pharmacies who are filling out forms with fake accounts to fraudulently get money.

Page 15

For the third-party support questionnaire, NCPA seeks clarification that for PSAOs enrolling pharmacies, if the pharmacies are designating a PSAO, does the PSAO just need to fill out one form? We reiterate that the MTF should rely on the NCPDP Registry as the authoritative source for pharmacy-to-PSAO relationships, which would help eliminate redundant forms and reduce administrative burdens for both pharmacies and PSAOs.

Page 16

Regarding the NCPDP "Payment Center ID" and NCPDP "Remit and Reconciliation ID" fields, is this a chain code? Will the third-party support entities have to enter every dispensing entity's information? This would be a significant administrative burden for PSAOs. We reiterate that the MTF should rely on the NCPDP Registry as the authoritative source for pharmacy profiles. This would eliminate redundant forms and reduce administrative burdens. As noted earlier in our comments, we request that the new system allow pharmacies the option to opt out of having payments directed to their PSAO.

Page 17

On Page 17, the last column of the chart – this information is a significant burden for PSAOs, as effective dates are different, as pharmacies are joining and leaving PSAOs at all times. This could also impact manufacturer payments going to the wrong PSAOs. We reiterate that the MTF should rely on the NCPDP Registry as the authoritative source for pharmacy-to-PSAO relationships,

which would help eliminate redundant forms and reduce administrative burdens for both pharmacies and PSAOs.

Additional comments

No fees. CMS stated in the final guidance that "…Primary Manufacturers and dispensing entities will not have to pay any fees to enroll in the MTF DM, and Primary Manufacturers will not have to pay any fees to participate in the MTF PM, including but not limited to user fees or transaction fees, as CMS will bear the cost of operationalizing the MTF. In addition, and regardless of whether the MFP refund is passed through the MTF PM or made outside of the MTF PM, neither Primary Manufacturers nor their third-party vendors shall charge dispensing entities any transaction or other fees for the pass through of the MFP refund to the dispensing entity." We support CMS' re-iteration in the final guidance that pharmacies cannot be charged any fees to participate as CMS would bear the cost of operationalizing the MTF. **CMS must ensure that plans, PBMs, manufacturers, wholesalers, CMS nor any other entity be allowed to assess any fee on pharmacies to effectuate the MTF or any aspect of the Medicare Drug Price Negotiation Program whatsoever. Any EFT fees should be borne by the manufacturer and not the pharmacy.**

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

Submitted electronically to: www.regulations.gov

December 20, 2024

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS–10912
Room C4–26–05
7500 Security Boulevard
Baltimore, Maryland 21244–1850

Re: Agency Information Collection Activities: Proposed Collection; Comment Request [Docket No. CMS–10912] - CMS–10912 Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request- Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form

Docket Management Staff,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) to its docket: Agency Information Collection Activities: Proposed Collection; Comment Request [Docket No. CMS–10912] regarding the Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA). Our comments are limited to the Appendix B: Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form.

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.

Overview

CMS has imposed an unreasonable requirement on manufacturers to establish individual Maximum Fair Price (MFP) Effectuation Plans for each medication with an MFP negotiated under the Inflation Reduction Act. CMS has provided very little guidance to manufacturers regarding this process, nor sample Effectuation Plans.

On January 1st, 2026, ten MFP Effectuation Plans will enter effect. On January 1st, 2027, there will be twenty-five different Effectuation Plans with that number growing in future years of the program. **We believe that Manufacturers, whenever possible, should coalesce around unified Effectuation Plans to reduce the burden on pharmacies and Manufacturers**.

While CMS requires Manufacturers to submit their Effectuation Plans by September 1st of the year before the negotiated MFP takes effect, pharmacies and technology providers need more than 122 days to establish systems, procedures and protocols to effectively participate in the Effectuation Plan. **Manufacturers should publish their Effectuation Plans, in whole or in part, as early as feasible.**

Pharmacies and Manufacturers do not currently have established financial relationships as the U.S. drug supply chain leverages wholesalers and other mechanisms to ensure access to needed medications. Despite what CMS has communicated to pharmacy groups, pharmacies are not clients of manufacturers. For the most part, independent pharmacies do not have established direct relationships with manufacturers for purposes of procuring drugs.

Specific Comments/Concerns

We have the following concerns with Appendix B: Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form:

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Q3. "Describe the Primary Manufacturer's process for contacting, receiving, and responding to communications from dispensing entities regarding MFP effectuation. The response should indicate the extent to which the Primary Manufacturer's approach includes any proactive outreach to dispensing entities related to the Primary Manufacturer's MFP Effectuation Plan and its related policies and procedures, plans for disseminating or publishing key information, and the approach the Primary Manufacturer intends to establish for intaking and responding to communications initiated by dispensing entities."

NCPA emphasizes that the high degree of discretion and variability allowed for manufacturers in this model creates an insurmountable administrative burden for pharmacies, which could potentially be facing 25 separate effectuation plans by 2027.

Q4. "Describe the Primary Manufacturer's process for nonduplication of claims that are 340B eligible and not subject to MFP availability."

NCPA supports CMS not requiring pharmacies to identify 340B claims, as CMS stated in October 2024 ***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*****. NCPA re-emphasizes the infeasibility of pharmacies identifying those claims either proactively or retroactively. NCPA has found that the N1 transaction is not feasible as it is not adopted by pharmacy information systems. For NCPA's full comments on this matter, see our March 2023 feedback on CMS'** ***Medicare Part D***

***Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments*.**

We recognize that it is not always possible for pharmacies to identify 340B eligible patients at the point-of-sale; therefore, we believe only claims with a paid response from a Part D Plan – a signal of MFP-eligibility – should be forwarded to manufacturers for Maximum Fair Price (MFP) refund. Additionally, we encourage pharmacies and manufacturers to use the dispute resolution mechanism proposed below to address disagreements over specific claims.

Finally, we want to note that individuals may become eligible to the MFP after the product has been dispensed so retroactive payments may be necessary. As discussed above, we believe the paid response from a Part D Plan should be transmitted with any request for MFP refund and we ask Manufacturers to refrain from establishing policies that limit MFP refund based on the dispensed date of the product. We hope to work with Manufacturers to provide greater education on examples of situations, such as an individual becoming dual-eligible, when retroactive MFP refund payments may be necessary.

Page 4

"**Q5.** As described in the final guidance, Primary Manufacturers are required to transmit their claim-level payment-elements within 14-days of receiving claim-level data elements from the MTF DM." **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.[1] **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 over 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.**

We highly encourage CMS to continue searching for ways to reduce the cycle until it is within 14 days from the dispense date. To help achieve this, CMS could require Part D plans to deliver data daily rather than weekly, delivering claims earlier to the MTF DM and the manufacturers. Additionally, perhaps manufacturers could be incentivized or rewarded in some manner paying refunds within 14 days of the dispense date.

We encourage CMS to explore these and other ideas until pharmacies are receiving their refunds within 14 days of the dispense date.

[1]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.

Q6. "The Primary Manufacturer generally plans to use the Standard Default Refund Amount (SDRA) set forth in the final guidance to calculate and make the retrospective MFP refund payments to a dispensing entity. OR The Primary Manufacturer generally plans to use actual acquisition cost to calculate the MFP refund. OR The Primary Manufacturer generally plans to use a proxy for acquisition cost other than WAC to calculate and make the retrospective MFP refund payments to a dispensing entity. OR The Primary Manufacturer does not intend to use one of the methods listed above as its primary approach and instead intends to use a variety of approaches (e.g., using the SDRA for some dispensing entities while using actual acquisition costs for others) to calculate MFP refunds."

It is strongly recommended that manufacturers use WAC to calculate the Maximum Fair Price (MFP) refund amount; as an equation: WAC – negotiated MFP = MFP Refund.

NCPA believes that pharmacies need protection from manufacturers arbitrarily imposing refund amounts other than the Standard Default Refund Amount (WAC minus MFP) that do not appropriately effectuate the MFP. NCPA thanks CMS for stipulating in the guidance that the claim-level data elements that the Primary Manufacturer will receive from the MTF will include a Standard Default Refund Amount that will reflect the difference between the WAC and the MFP of the selected drug at time of dispensing based on the quantity dispensed. NCPA prefers using WAC as the standardized metric. The WAC price should reflect the date of adjudication, not the date of the refund.

We have concerns that it is voluntary for manufacturers to adopt WAC, given that manufacturers and dispensing entities can "agree to make the MFP available via a retrospective refund that is calculated based on a reasonable proxy for the dispensing entity's acquisition cost," and therefore agree to a different benchmark. In other words, the MTF sends the amount as part of the minimum data elements to the manufacturer, which is WAC-MFP. If the pharmacy and the manufacturer have agreed on a different amount other than WAC, then when the manufacturer sends the data elements back to the MTF, the MTF would send a different amount because that is the indicator that the standardized refund was paid. **NCPA strongly urges 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. The WAC price should reflect the date of adjudication, not the date of the refund.**

The voluntary nature of WAC as a benchmark is especially concerning for dispensers, considering that pharmacies need to be reasonably compensated for these MFP drugs. NCPA advises CMS to require that the manufacturer provide the MFP using the Standard Default Refund Amount and that dispensers have sufficient protections for reasonable reimbursement.

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Q7. "Describe the Primary Manufacturer's methodology for determining the amounts it will reimburse dispensing entities when the Primary Manufacturer is not calculating an MFP refund using the Standard Default Refund Amount. **NCPA asks that manufacturers include a description**

of the documentation the manufacturer intends to retain to support any MFP refund calculations that do not use the Standard Default Refund Amount. [NCPA emphasis]

NCPA supports that CMS requires the manufacturer to include a description of the documentation the manufacturer intends to retain to support any MFP refund calculations that do not use the Standard Default Refund Amount.

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"**Q19.** Respond to the following regarding the use of the MTF PM. The Primary Manufacturer will use the MTF PM to provide retrospective reimbursements to dispensing entities. Selecting 'Yes' indicates that the Primary Manufacturer intends to use the MTF PM to pass through MFP refunds as part of its approach to MFP access for any of its MFP-eligible claims; **selecting 'Yes' does not preclude the Primary Manufacturer from also engaging in alternative arrangements to process MFP refunds without the MTF PM as described in Q9 – Q13 of this Form.**" [NCPA emphasis]

NCPA emphasizes that the high degree of discretion and variability allowed for manufacturers in this model creates an insurmountable administrative burden for pharmacies, which could potentially be facing 25 separate effectuation plans by 2027.

Making use of an **MTF payment facilitation functionality voluntary for Primary Manufacturers could result in many manufacturers electing not to use the MTF PM, which could impact access to certain drugs for pharmacies that do not have a direct relationship with that drug's manufacturer. NCPA is concerned that if payment does not flow through the MTF for everyone, some manufacturers will stop selling drugs to certain pharmacies that they do not have a direct contract/financial relationship with to avoid having to set up MFP payment mechanisms.**

NCPA is disappointed that CMS has chosen to allow manufacturers to voluntarily effectuate the MFP via the MTF PM. This leads to greater uncertainty and potential administrative burden on independent pharmacies. **NCPA requests clarity from CMS as to what other options would there be for independent pharmacies to continue to dispense these drugs if manufactures do not opt-in.**

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"**Q21D.** Describe any additional mechanisms the Primary Manufacturer intends to implement to effectuate the MFP to each dispensing entity within the 14-day prompt MFP payment window, if applicable.

Q21F. Describe the Primary Manufacturer's process for ensuring the 14-day prompt payment window is met for both its electronic and paper options."

Please see our above comments regarding the 14-day window.

Q21I & Q22B/C: Cash Flow Mitigation

To mitigate cashflow for pharmacies, we provide ideas for alternative mechanisms to mitigate pharmacy cashflow issues and to support continued, efficient pharmacy operations.

Preferred Option: Advanced Payment of Expected Maximum Fair Price (MFP) Refund to Pharmacies at the Beginning of the Month

Using claims-level data, pharmacies will communicate to manufacturers the expected number of price-negotiated medications likely to be dispensed to MFP-eligible individuals during a specific month. At the start of the month, the manufacturer would issue a payment for all expected MFP refunds and any additional fees for the given month to the pharmacy.

To ensure manufacturers are not over or underpaying refunds, we recommend use of the credit-debt ledger, through the MFP DM, on a quarterly basis to review payments and adjust for overpayment and underpayment in preceding months and to adjust monthly payments for the forthcoming quarter.

Early Access to Cashflow Mitigation Mechanism

Given the nature of the pharmaceutical supply chain and necessity for many pharmacies to stock medications for immediate dispensing, we believe Manufacturers should initiate their material cashflow mitigation plans by at least October 31 of the year before the negotiated Maximum Fair Price (MFP) takes effect as many products that will be dispensed at the MFP beginning in January will be purchased by pharmacies in the fourth quarter of the preceding year.

Generally, we argue that all pharmacies, not just the types that CMS has stated, have "material cashflow concerns" under the Medicare Drug Price Negotiation Program. Under this model, each community pharmacy would need to float on average $27,000 per month, so all pharmacies should qualify as having "material cashflow concerns" by default, or should be exempt from the MDPN program. Additionally, CMS' category of "pharmacies who predominantly rely on prescription revenue to maintain business operations" encompasses most pharmacies: according to the 2024 NCPA Digest, nearly all revenue (90 percent) of our membership comes from behind the counter. Additionally, pharmacies need to pay wholesalers at least twice per month, with some paying wholesalers every seven days. Pharmacies are critically strapped in their abilities to pay wholesalers, and often wholesalers are unwilling to allow for flexibility of payment from pharmacies.

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Q23: Establishment of a Reasonable "Handling Fee" Associated with Dispensing Products at the Maximum Fair Price (MFP)

The current models that ensure access to needed medications for individuals covered by Medicare Part D have been dependent on revenue from branded medications, especially for long-term care (LTC) pharmacies. While CMS has pledged to monitor program implementation and potentially take immediate corrective action, pharmacies are deeply concerned by CMS' "hands off approach" to addressing the worst behaviors of insurers/PBM's and how delays in federal action will undermine patient access to needed medications.

We recommend that manufacturers, as part of the Effectuation Plans, provide a handling fee as part of the Maximum Fair Price (MFP) refund provided to a pharmacy or other dispensing entity. We believe this professional fee should be a percentage of the MFP refund instead of a flat fee for each dispensed prescription. We believe in cases for very expensive medications with a large difference between WAC and MFP, it would be reasonable for the Manufacturer to cap this handling fee at a specific dollar amount or restrict it to the set number of dispensed prescriptions.

Q25: Amendments to Effectuation Plans

While CMS allows 90-days for the Manufacturer to submit copies of any new agreements that memorialize any substantive changes to alternative arrangements with dispensing entities within 90 days of the change, we strongly encourage manufacturers to refrain from making amendments to their effectuation plans until the start of a new calendar year and that plan changes be submitted through the annualized process of submitting plans to CMS on September 1st for the forthcoming year. Additionally, we strongly encourage CMS to require Manufacturers to make their effectuation plans available prior to September 1 each year as pharmacies need to make decisions on PBM/plan contracts earlier.

Miscellaneous Comments

Trade Association Access to MTF Effectuation Plans

We also request from CMS that pharmacy trade associations such as NCPA can access the MTF effectuation plans in addition to the pharmacies themselves.

Dispute Resolution

As disputes will arise, we recommend that both parties submit any disputes using the specific X12 835 claim number. To facilitate continued pharmacy operation and access to medications by patients, we recommend that manufacturers do not interrupt payments to pharmacies during a dispute and that all claims be paid as the credit/debt ledger exists as a mechanism for manufacturers to recoup any over or incorrect payments. To ensure disputes are rapidly addressed, we believe manufacturers and pharmacies should agree to binding arbitration if they are unable or unwilling to resolve the dispute within 30 days on the initial complaint by one party. Finally, we recommend that both parties identify a singular point of contact for all disputes.

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

PCMA

December 20, 2024

Filed electronically via www.reginfo.gov/public/do/PRAMain
Dr. Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1859

Re: Information Collection Request (ICR); Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act [Document Identifier: CMS-10912]

Dear Dr. Seshamani:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments on the U.S. Centers for Medicare & Medicaid Services' (CMS) information collection request (ICR) for the initial price applicability year (IPAY) 2027 of the Medicare Drug Price Negotiation Program ("Negotiation Program")[1], specifically Appendix C: Medicare Drug Price Negotiation Program Primary Manufacturer Payment Elements Form.

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 275 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and plans offered for sale on the Exchanges established by the Affordable Care Act. PBMs negotiate price concessions with manufacturers on their brand medications to improve the value of the Part D program. These price concessions reduce premiums for all beneficiaries and provide access to preferred drugs with reduced cost sharing.

Negotiated drugs under the Inflation Reduction Act (IRA) will be priced no higher than the prices PBMs are already able to negotiate on average, and in some cases may be priced higher than an individual Part D plan is already paying. We have an interest in ensuring that manufacturers do not find loopholes in the CMS program, so that Part D plans and their contracted PBMs have certainty as we continue to negotiate on behalf of the program for both these drugs and those not selected by CMS.

Below are our comments on Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act.

Background: The Medicare Transaction Facilitator (MTF) was created by CMS under the Inflation Reduction Act (IRA) of 2022 to facilitate the exchange of claims and payment data between and dispensing entities, and drug Primary Manufacturers to facilitate the effectuation of the Maximum Fair Price (MFP). PCMA has previously raised significant concerns about the

[1] https://www.regulations.gov/docket/CMS-2024-0198/document.

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

design of the MTF and its financial impact on dispensing entities, particularly independent and rural pharmacies, as well as the negative impacts on payment delays and pharmacy financial health.

For IPAY 2026 and 2027, CMS has proposed new forms and reporting requirements to effectuate the MFP. While these forms aim to standardize and streamline the MFP effectuation process, PCMA has several concerns about the impact on dispensing entities, especially on independent and rural pharmacies. We have specific comments on Appendix A, Section: Dispensing Entity Identification Information, below.

The proposed forms place significant reporting obligations on pharmacies and other dispensing entities requiring detailed data submissions to support price adjustments and payments. Pharmacies are already concerned about potential delays in payment, and the complexity and the likely errors in these forms could further exacerbate payment delays, leaving pharmacies vulnerable to cashflow issues. There is a legitimate concern that these forms will shift the financial risk from Primary Manufacturers to dispensing entities.

CMS is proposing to include one form question (Section 3, Question 3A) for dispensing entities to self-identify as having material cashflow concerns at the start of the IPAY due to the shift from payment by the Part D sponsor to a combination of Part D sponsor payment plus a potentially lagged MFP refund from Primary Manufacturers. CMS expects certain types of dispensing entities, such as sole proprietor rural and urban pharmacies, long-term care pharmacies, 340B covered entities with in-house pharmacy, and Indian Health Services and Urban Indian (I/T/U) pharmacies, may have material concerns about cash flow.

While the dispensing entity will make the self-identification, CMS proposes to allow Primary Manufacturers to make the unilateral determination as to whether a dispensing entity actually has material cashflow concerns under the new IRA framework and, thus, whether the dispensing entity will have access to the yet-to-be-defined Primary Manufacturer mitigation process. This approach is highly problematic for several reasons. First, permitting Primary Manufacturers to determine whether a dispensing entity has material cashflow concerns is a direct conflict of interest as Primary Manufacturers have a direct financial stake in minimizing their costs, including avoiding making available any alternative mitigation process that is likely to be more burdensome on the Primary Manufacturer. Allowing Primary Manufacturers to assess a pharmacy's cashflow concerns could lead to biased decisions aimed at protecting their own interests rather than supporting the pharmacy's stability when effectuating the MFP. In addition, independent pharmacies are already operating at low margins, and granting Primary Manufacturers the authority to determine whether a pharmacy faces material cashflow problems leaves pharmacies vulnerable to exploitation and/or arbitrary decisions.

The proposed forms do not guarantee that Primary Manufacturers will use consistent or transparent criteria to evaluate dispensing entity cashflow issues. This will create uncertainty and potential inequities in how a dispensing entity is assessed, further undermining trust in the program MFP effectuation process. There is also concern that dispensing entities that challenge Primary Manufacturers and/or report problems to CMS could face retaliatory actions, such as delayed payments or unfavorable terms. These risks will be particularly acute for small, rural, or independent pharmacies that lack the bargaining power larger pharmacy chains enjoy.

Lastly, CMS has not provided any guidance on what mitigation processes will be approved as part of its review of Primary Manufacturers' MFP effectuation plans. Even if Primary Manufacturers choose to exercise the discretion of permitting a dispensing entity to participate in such a mitigation process, CMS has provided no clarity on what type of process will be deemed acceptable to accommodate the needs of pharmacies facing cashflow concerns.

Dispensing entities serve as the frontline providers of Medicare Part D medications to beneficiaries. If Primary Manufacturers make arbitrary and incorrect decisions about the financial stability of dispensing entities or fail to make a meaningful mitigation process available, many pharmacies could struggle to maintain inventory, particularly for expensive MFP-selected drugs. This will lead to medication shortages and reduced beneficiary access to medically necessary prescription medications, undermining the goals of the Medicare Drug Negotiation Program.

While policymakers and stakeholders have recognized these potential problems, CMS released proposed forms for the MTF under IPAY 2026 and 2027 that could create significant cashflow problems for dispensing entities, especially rural and independent pharmacies.

PCMA Recommendations: To alleviate these issues, PCMA recommends certain considerations to address these concerns and ensure a transparent, fair, and functional program.

- **CMS should maintain oversight and develop standards** for dispensing entity cashflow determinations. Primary Manufacturers should not have a role in arbitrarily assessing dispensing entity cashflow concerns.
- **CMS should develop standards for appropriate mitigation processes** so that dispensing entities that avail themselves of this process are materially protected.
- **Prompt payment protections** should be codified, including an enforceable payment timeline and mechanisms to resolve disputes quickly.
- **Independent audits** should be conducted regularly to monitor compliance and ensure fair treatment of dispensing entities.
- **Technical and financial support** should be provided to independent and rural pharmacies to assist them in navigating the new MTF reporting and payment system.

Conclusion

We thank CMS for the opportunity to comment on these important concerns. If you have any questions, please contact Emilia Clements at eclements@pcmanet.org.

Sincerely,

Timothy Dube

Timothy Dube, Senior Vice President, Policy & Regulatory Insights, PCMA

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

December 20, 2024

VIA Electronic Filing – http://www.regulations.gov

William N. Parham, III
Director
Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS-10912, OMB 0938-NEW

Re: Information Collection Request: Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)

Dear Director Parham:

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 Information Collection Request (ICR) for the *Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)*, which CMS released on October 28, 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 for clarity across the Supporting Statement, Appendix A (the Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Entity Enrollment Form), Appendix B (the Primary Manufacturer MFP Effectuation Plan Form), Appendix C (the Drug Price Negotiation Program Primary Manufacturer Payment Elements Form), and Appendix D (the Drug Price Negotiation Program Complaint and Dispute Intake Form). 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 selected manufacturers develop MFP effectuation plans and for the smooth effectuation of Maximum Fair Prices under the IRA.

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 Maximum Fair

[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

Price (MFP) would be for CMS to utilize an approach similar to the Part D Coverage Gap Discount Program (CGDP), including pass-through of 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 DM and the need for manufacturers to develop cash flow mitigation plans. While PhRMA supports ensuring prompt payment to pharmacies, we have significant concerns on how stakeholders did not have opportunity to provide comment on the cashflow mitigation plan requirement.

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I. MTF ICR Supporting Statement

PhRMA believes that CMS is significantly underestimating the burden for Primary Manufacturers to complete the applicable ICR forms and strongly disagrees with the total annual burden estimates published in the Supporting Statement. The MFP Effectuation Plan Form will require input from many different divisions within each Primary Manufacturer, including *multiple* staff from groups identified by CMS in the ICR, not just sole employee representatives, along with outside legal counsel and outside consultants. Similarly, given the volume of claims data selected drug manufacturers will be receiving on a near daily basis,[2] the Agency's estimate of only two staff dedicated to sampling and analyzing data for the MTF DM payment elements form is woefully inadequate.[3]

Moreover, the ICR notes that "CMS also anticipates some Primary Manufacturers will need to develop novel internal processes to establish their approach to MFP effectuation and engage with the [Medicare Transaction Facilitator (MTF)] system." However, the total annual burden estimates do not adequately reflect the necessary staff resources and expertise to develop and implement the significant internal processes within the companies that are necessary to develop these novel approaches for MFP effectuation. CMS also does not include adequate burden estimates of the necessary time that Primary Manufacturers will need to fully integrate internal systems with the MTF system in order to gain an adequate understanding of MTF processes and to successfully complete the MFP Effectuation Plan Form.

We would highly recommend that CMS talk with Primary Manufacturers to develop more realistic estimates of time and burden costs.

II. Appendix A: Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Entity Enrollment Form

PhRMA recommends that CMS make dispenser information reported on the enrollment form available to manufacturers of selected drugs through the MTF DM portal. This would be similar to how CMS plans to make manufacturer MFP effectuation plans available to dispensers through the MTF DM portal and would ensure critical information from both dispensers and manufacturers is available to all parties involved in MFP effectuation.

[2] Based on the 2022 Part D dashboard, daily claims for one of the 10 drugs selected for Initial Price Applicability Year (IPAY) 2026 averaged nearly 52,000. *See* https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug

[3] In addition, on a technical basis, CMS will require manufacturers to authorize payment of MFP refunds seven days a week, but the burden estimate only contemplates staff working five days per week to sample and analyze data.

III. Appendix B: Drug Price Negotiation Program MTF DM Primary Manufacturer MFP Effectuation Plan Form

Q4: Details on Primary Manufacturers' processes for 340B nonduplication.

PhRMA remains highly concerned about the continued lack of a role for CMS in identifying and deduplicating 340B claims, with CMS stating in the Final Guidance for the Medicare Drug Price Negotiation Program[4] (Final Guidance) that the Agency "will not, at this time, assume responsibility for deduplicating discounts between the 340B ceiling price and MFP."[5]

Manufacturers have in many cases very limited insight into which Part D units are subject to 340B pricing. While PhRMA appreciates the addition of the Prescriber ID data field to the data elements that will be shared with Primary Manufacturers through the MTF Data Module (DM), CMS noted in the Final Guidance that "…[National Provider Identifier (NPI)] alone (whether a prescriber NPI or a hospital/provider NPI) generally will not constitute sufficient evidence that a claim was 340B-eligible…." Without some requirement from CMS and/or the Health Resources and Services Administration (HRSA) for covered entities to identify 340B units and share appropriate information with manufacturers, manufacturers face virtually certain risk of paying duplicate MFP and 340B discounts in direct contradiction to the prohibition under the IRA.[6]

Furthermore, in the Final Guidance, CMS stated that it "strongly encourages manufacturers to work with dispensing entities, covered entities and their 340B [third party administrators], and other prescription drug supply chain stakeholders (e.g., wholesalers) to facilitate access to the lower of the MFP and 340B ceiling price…. CMS anticipates this will include utilizing data available from covered entities and their 340B TPAs, and other prescription drug supply chain stakeholders…."[7] However, as CMS should be aware, one state has passed a law expressly prohibiting manufacturers from requiring 340B claim-level data from covered entities (or contract pharmacies acting on their behalf) in certain circumstances, with more states expected to consider similar legislation next year. And, to date, HRSA has rejected reasonable business solutions that could help manufacturers address 340B and MFP duplicate discount risks through 340B rebate models.[8] The Agency's expectation that manufacturers will be able to rely on claims data submission processes for 340B identification is infeasible given certain state laws and actions by HRSA.

We urge CMS and HRSA to implement a coordinated, comprehensive approach to achieve the IRA's statutory command of no duplicate 340B/MFP discounts. One component of such an approach would be to utilize the claims data repository CMS described in the CY 2025 Medicare Physician Fee Schedule Final Rule[9] for use in the Part D inflation rebate program. In all cases, implementation

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[4] 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. *See* https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf

[5] Final Guidance, p. 55.

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

[7] Final Guidance, p. 232.

[8] *See, e.g.*, *Eli Lilly and Co. v. Becerra*, No. 1:24-cv-03220 (D.D.C. Nov. 14, 2024); *Johnson & Johnson Health Care Sys. Inc. v. Becerra*, No. 1:24-cv-03188 (D.D.C. Nov. 12, 2024); *Kalderos v. United States*, No. 1:21-cv-02608 (D.D.C. Oct. 6, 2021).

[9] *See* https://public-inspection.federalregister.gov/2024-25382.pdf

of a repository should be accompanied by clear requirements for covered entities to timely and accurately report claims data with HHS oversight and enforcement.

Q6 – Q7: Primary Manufacturers' plans for calculating the MFP Refund amount.

CMS should clarify that Questions 6 and 7 are only applicable for manufacturers choosing to provide access to the MFP retrospectively. Manufacturers choosing to provide access prospectively would not need to answer these questions.

More broadly, PhRMA has significant concerns with the Agency's statement in the Final Guidance that "SDRA may not be universally appropriate or sufficient to effectuate the MFP."[10] Based on conversations with supply chain experts, we believe the extra charges above WAC are not due to manufacturer prices, but instead additional charges by other supply chain entities (such as wholesalers). In other words, manufacturers have very limited control of pricing in the supply chain beyond WAC. We believe the Final Guidance as written could undermine the integrity of the Drug Price Negotiation Program (DPNP) by creating perverse incentives for dispensers and others in the pharmaceutical supply chain to improperly increase profits through arrangements that artificially increase MFP refund amounts.[11]

Concerns with potential manipulation of prices and profits are not hypothetical, as instances of stakeholders artificially increasing costs to others in the supply chain are abundant. For example, until CMS prohibited the practice beginning in January 2024, Part D plan sponsors could enter into arrangements with pharmacies (or, in some cases, unilaterally impose arrangements) that resulted in the Part D negotiated price being higher than the final payment from the Part D plan sponsor to the pharmacy.[12] The resulting inflated negotiated price increased costs to the federal government in the form of higher low-income subsidies, to manufacturers in the form of higher Part D coverage gap discounts, and to beneficiaries with coinsurance in the form of higher cost sharing, as all of these figures are calculated based on the Part D negotiated price.[13] Similarly, recent work by the Brookings Institution has observed that vertical integration "permits [Medicare Advantage (MA)] plans to circumvent regulations aimed at constraining the profits that can be earned from the MA program." Specifically, "a vertically integrated MA plan can move profits from the MA plan to the

[10] Final Guidance, p. 69.

[11] For example, consider an illustrative selected drug with a WAC of $100 and an MFP of $40. Wholesaler A typically purchases the selected drug from the Primary Manufacturer at a price of $96, and Dispenser B typically purchases the selected drug from Wholesaler A at a price of $98. Utilizing the SDRA, the Primary Manufacturer would owe an MFP refund of $60, giving Dispenser B a margin of $2 on the transaction (excluding dispensing fees) and Wholesaler A likewise a margin of $2. However, consider that Dispenser B could enter into an arrangement with Wholesaler A to acquire the selected drug at a cost of $120. The Primary Manufacturer would then owe an MFP refund of $80. If Wholesaler A agrees to retrospectively refund $10 of the acquisition price to Dispenser B, Wholesaler A would earn a margin of $14 and Dispenser B could earn a margin of $10 (excluding dispensing fees), substantially higher than before.

[12] CMS. Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency. Final Rule. May 9, 2022. Available at: https://public-inspection.federalregister.gov/2022-09375.pdf

[13] Ibid.

related business. This increases the MA plan's [medical loss ratio] without reducing the parent company's profits, weakening the MLR constraint."[14]

In addition, basing manufacturer refund obligations on acquisition costs that ostensibly exceed WAC would be a unique approach differing from other federal programs that require customer-specific pricing for drugs. For example, in the 340B program, wholesaler chargebacks for 340B-eligible units of covered outpatient drugs are typically calculated using the difference between WAC (regardless of the CE's acquisition cost for the drug) and the applicable 340B price.

Finally, CMS should not be assessing whether a Primary Manufacturer is providing access to the MFP by relying on prices set by an entity other than the Primary Manufacturer (e.g., the price a wholesaler charges a dispenser to acquire a drug). Manufacturers do not control the price at which dispensers purchase drugs from supply chain intermediaries such as wholesalers. PhRMA is highly skeptical that Congress could have intended to obligate Primary Manufacturers to pay an MFP refund based on an unbounded acquisition cost over which Primary Manufacturers have no control given the perverse supply chain incentives.

Thus, PhRMA continues to strongly urge CMS to specify in future guidance that MFP refunds can be no larger than the SDRA (i.e., WAC minus the MFP).

We also recommend that CMS monitor how SDRA MFP refund payments impact dispenser reimbursement in Part D. According to the National Average Drug Acquisition Cost (NADAC) survey, on average, pharmacies acquire single source brand drugs for prices that are about 4% below WAC.[15] Thus, on average, an SRDA MFP refund value results in small overpayment to dispensers. CMS should closely track pharmacy reimbursement by Part D plan sponsors and pharmacy benefit managers (PBMs) acting on their behalf to ensure that Part D plans are not clawing back pharmacy payment.

Q10 – Q11: Alternative Arrangements to Provide Access to the MFP Outside the MTF PM.

While PhRMA appreciates the need to provide CMS with information on alternative arrangements to provide access to the MFP, we urge the Agency to simplify Question 10. For example, if a manufacturer is adopting an alternative arrangement outside of the MTF PM that will apply to all dispensers or a large group of dispensers, CMS should make clear that manufacturers could indicate "all dispensers" or the types of dispensers covered by the alternative arrangement as opposed to uploading the NPIs of over 60,000 pharmacies. Requiring the uploading of individual NPIs is extremely burdensome and of questionable value to CMS in evaluating manufacturer plans.

PhRMA also 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

[14] Frank RG, Milhaupt C. Related businesses and preservation of Medicare's Medical Loss Ratio Rules. *Brookings*, June 2023. https://www.brookings.edu/articles/related-businesses-and-preservation-of-medicares-medical-loss-ratio-rules/
[15] Myers and Stauffer. NADAC Equivalency Metrics. Last Updated September 20, 2024. Available at: https://www.medicaid.gov/medicaid/prescription-drugs/downloads/retail-price-survey/nadac-equiv-metrics.pdf

credit/debit record system. While we understand 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.

More broadly, PhRMA remains concerned with the Agency's interpretation of the IRA as placing "sole responsibility" to provide access to the MFP on manufacturers, yet at the same time, placing strict requirements on manufacturers if they choose to use an approach outside the MTF PM. For example, CMS is maintaining the requirement for manufacturers to transmit payment to dispensers within 14 days from receipt of MTF DM claim data even if a pharmacy and manufacturer have agreed to a different timeline under an alternative arrangement. And in Question 11, CMS notes that it may request copies of private pharmacy-manufacturer contracts without limitation. Given the Agency's repeated statements that it is "sole responsibility" of manufacturers to provide access, then for arrangements outside of the MTF PM, CMS should defer to terms governing pharmacy and manufacturer agreements.

Q14 – Q18: Information on MFP effectuation for selected drugs with Secondary Manufacturers.

PhRMA continues to maintain significant concerns regarding the Agency's establishment of separate categories of "Primary" and "Secondary" manufacturers and the Agency holding Primary Manufacturers responsible for other distinct corporate entities ("Secondary" manufacturers) to make discounts available on behalf of separate entities. This liability is unworkable and not supported by statute.

Nothing in the IRA authorizes CMS to impose requirements or liability on a legal actor who maintains a distinct corporate identity. The Agency's approach also exceeds its authority, as imposing such requirements is not "necessary for purposes of administering the program and monitoring compliance with the program."[16] In fact, CMS could more easily monitor a manufacturer's compliance if it required separate effectuation plans from Primary and Secondary Manufacturers and entered into separate agreements with such manufacturers. PhRMA has repeatedly explained why CMS' continued stance runs afoul of fundamental corporate law principles. We refer the agency to our comments on the IPAY 2026 guidance, particularly on section 40 of such guidance,[17] as well as Appendix B to our comments on the IPAY 2027 guidance.[18]

[16] SSA § 1193(a)(5)

[17] PhRMA comments are 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

[18] In those comments we noted that "PhRMA continues to object to CMS' unfounded 'Primary Manufacturer/Secondary Manufacturer' construct, including making Primary Manufacturers liable for Secondary Manufacturers' conduct (e.g., failure to make the MFP available) and imposing civil monetary penalties for violations by Secondary Manufacturers. Secondary Manufacturers are distinct corporate entities, and CMS' policy appears likely to result in unforeseen, unworkable scenarios, including situations where a Primary Manufacturer may need to provide or receive proprietary data from the Secondary Manufacturer in order to comply with CMS' policy, conflicting with fundamental corporate law principles, such as that independent corporations are distinct legal entities with limited liability. *See, e.g.*, Fletcher, *Fletcher Cyclopedia of the Law of Corporations*, §§ 28-29; Phillip I. Blumberg, *Limited Liability and Corporate Groups*, 11 J. Corp. L. 573, 591–592 (1986); Franklin A. Gevurtz, *The Globalization of Corporate Law: The End of History or A Never-Ending Story?*, 86 Wash. L. Rev. 475, 487 (2011); Douglas G. Smith, *A Federalism-Based Rationale for Limited Liability*, 60 Ala. L. Rev. 649, 667 (2009)"

We continue to urge CMS to abandon the Primary and Secondary Manufacturer construct in future guidance.

Q21: Primary Manufacturers' processes for effectuating the MFP outside of the MTF PM.

PhRMA urges CMS to clarify that Primary Manufacturers can respond to Question 21 by providing information that is aggregated across dispensers or types of dispensers. We believe reporting at the aggregate level will still provide CMS with the information required from manufacturers choosing not to participate in the MTF PM but will help to minimize the burden on Primary Manufacturers.

Q22: Interactions with dispensing entities with material cashflow concerns.

PhRMA is opposed to the requirement to develop mitigation plans for dispensers with material cashflow concerns. While we share the Agency's goal of ensuring dispensers are paid promptly, we continue 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 CGDP, including pass-through of CMS pre-funded MFP refund amounts to dispensers on behalf of Primary Manufacturers at the time of claim adjudication with manufacturers invoiced at a later date. This should be paired with a claims data repository to deduplicate 340B and MFP claims, as noted above, with required reporting by covered entities and HHS oversight and enforcement.

In addition, PhRMA has significant concerns with the fact that the mitigation plan requirement was not included in the draft guidance for MFP effectuation in 2026 and 2027.[19] By introducing this new concept solely in the Final Guidance, CMS deprived stakeholders, including manufacturers, of the opportunity to provide comment and input.

If the Agency continues to decline to adopt an MFP effectuation model similar to the CGDP with pre-funded MFP refunds, then we would strongly encourage CMS to provide more transparency about the types of mitigation plans the Agency is expecting. While we appreciate the ability of Primary Manufacturers to develop qualifying criteria for their mitigation plans under Question 22C, the lack of clarity from CMS on what types of qualifying criteria and types of mitigation plans the Agency would consider acceptable presents significant uncertainty and compliance burden on Primary Manufacturers.[20] CMS should also affirmatively acknowledge that Primary Manufacturers are permitted to require that any pharmacies claiming material cashflow concerns provide documentation to support such claims.

We also ask that CMS monitor Part D plan sponsor and dispenser actions surrounding the mitigation plans. PhRMA is concerned about unintended outcomes in response to different manufacturers developing different mitigation plans.

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[19] *See* https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf

[20] *See* Final Guidance, p. 287: "CMS will consider the information provided by a Primary Manufacturer in its mitigation process when conducting a risk assessment of the Primary Manufacturer's MFP effectuation plan."

Other topics for comment in Appendix B.

Confidentiality of manufacturer effectuation plans.

PhRMA appreciates the change made by CMS in the Final Guidance to limit distribution of the MFP effectuation plans to dispensers through the MTF DM. However, we remain concerned about protecting the confidentiality of proprietary information that may be included in the MFP effectuation plans. We recommend that CMS add a field to the MFP effectuation plan form that would enable Primary Manufacturers to indicate which information is proprietary and would need to be redacted upon distribution to dispensers through the MTF DM.

In addition, prior to effectuation plans being distributed, CMS must ensure that Primary Manufacturers are provided an opportunity to object to the distribution of any confidential commercial information, as required by HHS' FOIA procedures in 45 C.F.R. Part 5, Subpart D.

Document uploads.

PhRMA recommends that CMS allow Primary Manufacturers to upload documents for a broader number of questions, including Questions 4, 10, 15, 16, 17, 21, and 22. This would give Primary Manufacturers the option to include a schematic or other visual that may help to clarify written explanations. Alternatively, CMS could also provide the option to upload documents at the end of the form, and Primary Manufacturers could reference those attachments in their answers to individual questions.

IV. Appendix C: Medicare Drug Price Negotiation Program Primary Manufacturer Payment Elements Form

General comments.

PhRMA urges CMS to provide mathematical or numerical examples for the payment element fields as the Agency continues to work to implement the MTF PM. This would be similar to the mathematical examples CMS provided as part of the Medicare Prescription Payment Plan guidance and materials. Providing these examples in advance will allow CMS and the MTF PM contractor to pressure test the payment field formats and provide time for field adjustments if necessary.

In addition, PhRMA continues to urge CMS to add a de-identified beneficiary ID field to the MTF DM data elements. We agree with the Agency that this field would not be useful to manufacturers for verifying beneficiaries' Medicare eligibility.[21] Rather, this field is necessary to help avoid erroneous duplicate claims for the same Medicare beneficiary. PhRMA appreciates that both Part D plan sponsors and the DDPS will be verifying Medicare eligibility, but neither entity appears to be

[21] *See* Final Guidance, pp. 205 – 206: "The provision of additional patient information (such as an encrypted "Medicare Beneficiary Identifier") by the MTF DM will not help the Primary Manufacturer to verify the selected drug was dispensed to an MFP-eligible individual because the Primary Manufacturer would also need access to the individual's Medicare eligibility status to verify eligibility."

scrubbing claims data for duplicates or other types of claim errors. By providing manufacturers with a randomized, de-identified ID field that is unique to each Medicare beneficiary, CMS can protect patient privacy while making it easier and faster for manufacturers to verify that no claim records received from the MTF DM are duplicates, improving efficiency and lessening disputes.

Quantity of Selected Drug field.

We encourage CMS to clarify how manufacturers should report the "Quantity of Selected Drug" field. For example, should manufacturers use the same quantity included in the "Quantity Dispensed" data field included in the elements shared by the MTF DM?

V. Appendix D: Drug Price Negotiation Program Complaint and Dispute Intake Form

To lessen the burden on all stakeholders in the supply chain, PhRMA recommends that CMS aggregate or batch disputes for dispensers by parent organization or by Pharmacy Services Administrative Organization (PSAO) for dispensers participating in a PSAO. This would lessen the volume of separate disputes and improve efficiency.

VI. General Comments Across Appendices

In Appendices B, C, and D the ICR notes that both questions about the ICR and technical assistance questions should be sent to "XXX@xxx.xxx". This appears to be a placeholder email address, which one is not able to utilize to ask questions of the Agency. For example, in Appendix B the ICR notes, "For technical assistance related to the submission of information in the MTF DM, questions should be sent to XXX@xxx.xxx. Questions about MTF DM user access should be sent to XXX@xxx.xxx."

Moreover, the ICR directs users to several placeholder URLs noted as [SYSTEM URL]. For example, in Appendix B the ICR notes, "Primary Manufacturers will submit the information for Sections 1 through 6 via the MTF DM, which can be accessed here: [SYSTEM URL]."

Primary manufacturers need usable email addresses and URLs in order to direct their questions and gain the necessary information to complete required information as outlined in this ICR. We urge CMS to include working email and URL addresses in the next iteration of the ICR.

* * *

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

799 9th Street NW
Suite 210
Washington, DC 20001

T (202) 354-2600
vizientinc.com

December 20, 2024

Submitted electronically via: www.regulations.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Agency Information Collection Activities: Proposed Collection; Comment Request (Docket No.: CMS-2024-0323; Form CMS-10912; OMB Control Number: 0938-New)

Dear Administrator Brooks-LaSure,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Information Collection Request ("ICR"), which includes several forms[1], as implementation of the Medicare Drug Price Negotiation Program ("MDPNP") has a significant impact on our healthcare provider members and the patients they serve. Vizient continues to express concerns about implementation of the MDPNP from the provider perspective, particularly given the administrative burden, financial challenges and anticipated lack of transparency from manufacturers, as described in prior comments.

Background

Vizient, Inc., the nation's largest provider-driven healthcare performance improvement company, serves more than 65% of the nation's acute care providers, including 97% of the nation's academic medical centers, and more than 35% of the non-acute market. The Vizient contract portfolio represents $140 billion in annual purchasing volume enabling the delivery of cost-effective, high-value care. With its acquisition of Kaufman Hall in 2024, Vizient expanded its advisory services to help providers achieve financial, strategic, clinical and operational excellence. Headquartered in Irving, Texas, Vizient has offices throughout the United States. Learn more at www.vizientinc.com.

Recommendations

Vizient is responding to elements of the forms included in the appendix of the ICR that may pose challenges to providers. We continue to urge CMS to better address concerns providers have raised related to the MDPNP, particularly related to additional financial strain and administrative burden given the significant variation that may exist within effectuation plans, including harmful retrospective rebate models, and challenges associated with a dispute resolution process. Vizient offers suggestions for the agency's consideration regarding several forms included in the ICR, including certain questions, and we urge the agency to work more

[1] The ICR includes the following forms: Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Enrollment Form (Appendix A); Drug Price Negotiation Program MTF DM Primary Manufacturer Maximum Fair Price (MFP) Effectuation Plan Form (Appendix B); Drug Price Negotiation Program MTF DM Primary Manufacturer Payment Elements Form (Appendix C); and Drug Price Negotiation Program Complaint and Dispute Intake Form (Appendix D).

closely with providers to better ensure the MDPNP does not cause them harm and, indirectly, harm the patients they serve.

Comments regarding Appendix B: Drug Price Negotiation Program Medicare Transaction Facilitator (MTF) Data Module (DM) Primary Manufacturer MFP Effectuation Plan Form

According to the ICR, the MDPNP MTF DM Primary Manufacturer Maximum Fair Price (MFP) Effectuation Plan Form is designed to collect the necessary information from Primary Manufacturers related to the MFP Effectuation Plan. As currently drafted, there are no questions about steps manufacturers have taken to inform their effectuation plans to ensure they are reasonable to providers, no clear CMS approval process and it is unclear how incomplete or blank answers in the response section of the form would be treated. As a result, Vizient is concerned that this form may be too lenient, risking that this form would effectively be viewed as optional for manufacturers, and that the form does not provide adequate insight to the effectuation process. Vizient urges CMS to consider opportunities to enhance this form to better ensure that manufacturers are transparent, have tested and vetted detailed effectuation plans with providers and the forms are completed. Further, CMS should clarify its review and approval process for this form, particularly if coordination with other stakeholders or government agencies is needed to validate any information, to support smoother implementation.

Regarding Question 4, CMS asks the Primary Manufacturer to include their process for nonduplication of claims that are 340B eligible and not subject to MFP availability, and requests that certain additional information be included. As noted above, we are concerned that there may be too much flexibility in how these forms are completed by manufacturers and that CMS review and oversight is unclear. Further, Vizient notes that the form does not request that the Primary Manufacturer demonstrate how 340B program requirements would be followed under the effectuation plan, a point which was included in the Final Guidance.[2] We suggest the form be modified to ask this information of manufacturers, and that a more stringent review be provided by CMS, which would help ensure the form is more thoughtfully completed.

In Question 6, manufacturers are to choose one of four methods to calculate MFP refunds, but there is limited additional information asking how manufacturers will ensure transparency throughout the refund process. As CMS is aware, reconciling payments between pharmacies and pharmacy benefit managers (PBMs) has been a longstanding challenge which the agency should avoid duplicating through the MDPNP. Transparency is lacking in multiple ways, including that there is no indication on the forms whether providers (or what proportion of providers) were consulted regarding alternative refund amounts as considered in the Final Guidance[3] or how providers can seamlessly access and validate information manufacturers rely upon when providing MFP refunds. Also, in the form, there is no acknowledgement of whether a manufacturer has communicated with a provider to determine that an alternative amount is appropriate. While Vizient does not believe specific agreements between providers and manufacturers need to be disclosed for this purpose, we encourage CMS to add fields to

[2] In the Final Guidance (pg. 55), CMS provides, "CMS also notes that nothing in this guidance modifies a manufacturer's statutory obligations under section 340B(a)(1) of the PHS Act, including the obligation to provide the 340B ceiling price to eligible entities. Nothing in this guidance alters a manufacturer's liability under section 340B of the PHS Act for an overcharge violation and sanctions for failure to provide the 340B ceiling price to eligible entities pursuant to section 340B(d)(1)(B)(vi) of the PHS Act and 42 C.F.R. § 10.11."

[3] In the Final Guidance (pg. 69), CMS notes that "CMS encourages 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."

enhance transparency, such as asking whether manufacturers have reached agreements with providers for alternative amounts or whether they plan on imposing alternative amounts unilaterally. Should the latter be permitted, which Vizient opposes, Vizient suggests that CMS consider more closely monitoring these manufacturers' behaviors to ensure providers are not harmed, as the dispute resolution process may pose a host of challenges to providers, particularly in these circumstances.

In Question 7, CMS notes that Primary Manufacturers should "Include a description of the documentation the manufacturer intends to retain to support any MFP refund calculations that do not use the Standard Default Refund Amount." Vizient is concerned that manufacturers may use this as an opportunity to request additional information be reported from providers, which would be burdensome for providers. While, at the same time, the manufacturer would not have to disclose or justify the specific need for the data. Vizient suggests that CMS clarify in the question that manufacturers may not request additional documentation from providers.

Regarding Questions 9-13, CMS requests information regarding alternative purchasing arrangements and notes that CMS may request copies of these contracts. Contracts may take a range of forms, such as having multiple products or purchasing circumstances considered and including other terms and conditions, such as confidentiality requirements, posing challenges for disclosure. Vizient encourages CMS to consider more targeted and flexible approaches to requesting information regarding alternative purchasing agreements given such agreements may not solely include products negotiated under the MDPNP.

Lastly, regarding Question 22, which relates to manufacturers assisting entities (e.g., pharmacies) with material cashflow concerns, CMS permits manufacturers to include additional qualifying criteria. Vizient suggests that CMS revise this section to remove 22c to clarify that manufacturers do not have discretion to determine whether a material cashflow concern exists. A determination of whether a material cashflow concern exists should be based on the entity's determination, not a manufacturer's decision.

Comments regarding Appendix D: Drug Price Negotiation Program Complaint and Dispute Intake Form

Vizient appreciates the establishment of a complaint and dispute process but recommends enhancements to make it more accessible and feasible for providers, who often have fewer resources than manufacturers. For example, more detailed guidance regarding the distinction between a complaint and dispute would be helpful, particularly as diverse scenarios arise. In addition, Vizient suggests that CMS give providers more flexibility regarding supporting documentation needs, as the examples noted on the form may be excessively burdensome to obtain and there could be a range of challenges in sharing certain information (e.g., confidential information, information containing patient information, sensitive information).

Further, Vizient notes that it is unclear how CMS will use or share this information once submitted. As a result, Vizient suggests that CMS provide significant deference to providers' detailed description of issues and for providers, not require additional supporting documentation. As a less burdensome alternative for providers, CMS could accept an attestation regarding the accuracy of the information shared rather than requiring supporting documentation to be uploaded in the initial complaint or dispute process.

Conclusion

Vizient thanks CMS for considering feedback related to the ICR and we continue to encourage the agency to consider provider perspectives as it works to implement the MDPNP.

Vizient membership includes a wide variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. Additionally, many are specialized, including academic medical centers and pediatric facilities. Individually, our members are integral partners in their local communities, and many are ranked among the nation's top health care providers. In closing, on behalf of Vizient, I would like to thank CMS for providing the opportunity to comment on the ICR. Please feel free to contact me, or Jenna Stern at jenna.stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these recommendations.

Respectfully submitted,

Shoshana Krilow
Senior Vice President of Public Policy and Government Relations
Vizient, Inc.