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Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair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.

Deputy Administrator Seshamani,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to CMS on its *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair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*.

NCPA represents America's community pharmacists, including 19,400 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 represent a $94 billion healthcare marketplace, employ 230,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers. NCPA submits these comments on behalf of both community and LTC independent pharmacies.

NCPA urges CMS to implement the Medicare Drug Price Negotiation Program in a way that does not harm independent pharmacies and patient access alike. NCPA hopes to avoid a similar shock to independent pharmacy that occurred in January 2006 with the launch of the Medicare Part D program, which had significant negative effects on independent retail and LTC pharmacies, who had to float the program, and where states had to intervene with assistance.

NCPA's analysis of 5,200 community pharmacies to determine the effect of MFP drugs on community pharmacies found that if the MFP rebate reaches 60 percent of the acquisition cost, then the average pharmacy will have to float over $26,000 every month waiting to be made whole for the MFP rebates. The impact on the cash flow on the roughly 20,000 independent pharmacies in the country will be a collective half a billion dollars every month. This huge number

is only for year one of the MFP program, and will grow larger and larger as more drugs are added each year, resulting in devastating, irreparable impact on pharmacies serving most vulnerable and at-risk patients, especially those serving long-term care facilities.

In order to preserve patient access to MFP drugs under this program, and to insure that pharmacies are paid timely and are not floating this program, NCPA urges CMS to ensure and verify the following, among other asks in these comments:

1. That the MFP is the ingredient cost for a selected MFP drug, and that CMS has the authority to ensure that pharmacies are paid at that specific price;
2. That the IRA equates MFP with ingredient cost, because manufacturers have to make selected drugs available for purchase by pharmacies at MFP;
3. That under the IRA, pharmacies are to be reimbursed by PDP sponsors at MFP for their ingredient costs, plus a dispensing fee, with no extraction of further concessions;
4. That PBMs and plans should not be able to impose any pharmacy price concessions that would ultimately reduce patient access to MFP drugs;
5. That pharmacy reimbursement will incorporate a negotiated price that is no lower than the maximum fair price and; 2) cover acquisition cost plus commensurate professional dispensing fee in line with Medicaid fee-for-service and should be paid within Medicare prompt pay requirements;
6. That pharmacies will be paid timely within Medicare prompt pay requirements, within 14 days of adjudicating the claim;
7. That CMS will shorten the current 30-day window of the time that Part D plan sponsors have to submit complete Part D Prescription Drug Event (PDE) records to CMS' Drug Data Processing System (DDPS), to 7 days;
    a. To expedite payment to pharmacies, NCPA suggests that CMS prefund the Medicare Transaction Facilitator (MTF);
    b. However, in the alternative, should CMS not agree with us that it has the authority to pre-fund the Negotiation Program or to require manufacturers to pre-fund the Program, then we urge CMS to shorten the PDE reporting period from 30 days to 1 day, and to require MTFs to provide the requisite data to the Primary Manufacturers on a daily basis.
8. That the MTF generate an Electronic Remittance Advice (ERA), or 835, to the pharmacy for purposes of reconciling manufacturer retrospective MFP refunds; and
9. That neither plans, PBMs, manufacturers, wholesalers, CMS nor any other entity assess any fee on pharmacies to effectuate the MTF or any aspect of the Medicare Drug Price Negotiation Program whatsoever, and that any EFT fees should be borne by the manufacturer and not the pharmacy.

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

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

Under the Inflation Reduction Act, there is a process by which the Secretary selects MFP drugs. Once a drug is selected, the Secretary is required to enter into agreements with manufacturers to set the MFP for particular drugs. The manufacturer is then required to "provide access to such price . . . to maximum fair price eligible individuals who . . . are dispensed such drug (and to pharmacies, mail order serves, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs)."[1] In addition, the basic definition of "maximum fair price" means the amount negotiated between the Secretary and a manufacturer for a selected drug—that is, for the ingredient cost of that drug.[2] **Given the above, NCPA believes that the IRA equates MFP with ingredient cost, because manufacturers have to make selected drugs available for purchase by pharmacies at MFP.**

NCPA submits that the Inflation Reduction Act means that pharmacies are to be reimbursed by PDP sponsors at MFP for their ingredient costs, plus a dispensing fee, with no extraction of further concessions. There are a few reasons that CMS should arrive at this conclusion. First, as discussed above, the IRA is constructed around treating MFP as the ingredient cost, and it uses a single definition for MFP throughout. Second, the amended definition of "negotiated prices" supports this conclusion. For non-MFP drugs, the total amount of the negotiated price for a non-MFP drug includes (1) the ingredient cost, (2) any "price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs," and (3) "any dispensing fees for such drug[ ]."[3] *In contrast, for MFP drugs* [emphasis added], the "negotiated price" is simply a payment (1) "no greater than the maximum fair price" for the drug and (2) "any dispending fees."[4] Thus, unlike non-MFP drugs, where Congress acknowledged the existence of "concessions" in addition to ingredient costs, Congress did not provide PDP sponsors explicit authorization to extract "concessions" for MFP drugs. Therefore, PDP sponsors should reimburse pharmacies at ingredient cost plus a dispensing fee.

To be sure, Congress provided that the PDP sponsors should make payments to pharmacies at an amount "no greater than the maximum fair price,"[5] which implies that PDP sponsors could reimburse less than MFP, but that is not the best reading of the statute. For one thing, the IRA consistently treats MFP at the ingredient cost, and the fact that manufacturers must provide pharmacies with access to MFP when those pharmacies dispense to an MFP eligible individual

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

strongly implies that the pharmacies will then be reimbursed by PDP sponsors at MFP plus any dispensing fee. For another, as noted above, if Congress had wished to allow PDP sponsors to extract additional concessions, it could have said so when it came to defining "negotiated prices" for MFP drugs. But it deliberately excluded concessions from that definition.

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

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

40.4 Providing Access to the MFP in 2026 and 2027

40.4.1 Medicare Transaction Facilitator Data Facilitation

Privacy. The draft guidance states that each Primary Manufacturer will be required to sign privacy and security agreements with CMS and comply with privacy and security requirements to protect the data elements received from and transmitted to the Medicare Transaction Facilitator (MTF), and that CMS is evaluating the data privacy and security implications of collecting, holding, and, if applicable, sharing interested parties' financial and securities information for purposes of MTF payment facilitation. **CMS should require that each Primary Manufacturer ensure the privacy and security of data provided to them by pharmacies, which shall not exceed the information under Table 2: MTF Claim-Level Data Elements (see chart below) and the "information disclosures" under 40.4.4 of these comments.**

Table 2: MTF Claim-Level Data Elements

MTF Data Elements List	Purpose	Data Source
Record ID	Used to identify the type of record, such as new claim, adjustment, reversal, etc.	MTF
MTF Internal Claim Number (ICN)	Used to identify the internal unique MTF ID to support claim adjustments	MTF
MTF XRef ICN	Used to link an adjustment to original MTF ICN	MTF
Process Date	Used to identify MTF processed date	MTF
Transaction Code	Used to indicate original claim, adjustment, reversal, etc.	MTF
Medicare Source of Coverage	Used to identify coverage under Medicare Part B or Part D	MTF
Date of Service	Used to verify MFP eligibility	PDE Record
Service Provider Identifier Qualifier	Used to verify MFP eligibility	PDE Record
Service Provider Identifier	Used to verify MFP eligibility	PDE Record
Prescription/Service Reference Number	Used to verify MFP eligibility	PDE Record
Fill Number	Used to verify MFP eligibility	PDE Record
Product /Service Identifier	Used to verify MFP eligibility	PDE Record
Quantity Dispensed	Used to assist the manufacturer in calculating a refund	PDE Record
Days' Supply	Used to verify MFP eligibility	PDE Record
340B Claim Indicator (as voluntarily reported by dispensing entity)	Used to verify MFP eligibility	PDE Record
Contract Number	Used to verify MFP eligibility	PDE Record
Wholesale Acquisition Cost (WAC) at time of dispensing	Used to calculate the Standard Default Refund Amount	MTF
Maximum Fair Price (MFP) at time of dispensing	Used to assist the manufacturer in calculating a refund	MTF
Standard Default Refund Amount (WAC-MFP)	Used to assist the manufacturer in calculating a refund	MTF
Service Provider MTF Enrollment Status	Used to indicate if dispensing entity opted in to MTF payment facilitation	MTF

340B claims identification. NCPA notes that in the draft guidance, the 340B Claim Indicator in Table 2 of the MTF claim-level data elements is labelled "as voluntarily reported by [the] dispensing entity." **NCPA supports CMS not requiring pharmacies to identify 340B claims, and 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*.

Manufacturer calculating and paying dispensing entity. According to the draft guidance, "[r]egardless of whether the Primary Manufacturer uses the potential MTF payment facilitation functionality, the Primary Manufacturer bears responsibility for calculating and paying an appropriate amount to the dispensing entity to effectuate the MFP." **CMS should require that the manufacturer pay the difference between Wholesale Acquisition Cost (WAC) and MFP.**

14 days prompt pay. **NCPA stresses that pharmacies need to be paid timely, within 14 days of adjudicating the claim.** As CMS acknowledges, under 42 C.F.R. § 423.520 (Prompt Payment by Part D Sponsors), Part D sponsors are required to pay pharmacies within 14 days after receiving an electronic Part D claim that is a clean claim.[6] **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.**

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

Even if the 7-day window for submitting PDE records is implemented, pharmacies will still be waiting longer than 14-days to receive MFP related payments. In the draft guidance, CMS stated that the MFP must be passed through to the dispensing entity within 14 days of the MTF sending claim-level data elements that verify that the selected drug was dispensed to an MFP-eligible individual. **Given the 7-day window that NCPA recommends that CMS should implement to submit PDE records, plus the 14-day manufacturer prompt pay window, this means pharmacies will be waiting at a minimum of 21 days for payment. This is unsustainable for independent pharmacies. Pharmacies need to be made whole within 14 days of adjudicating the claim at the pharmacy, period. Pharmacies must pay their wholesalers on an approximate two-week payment cycle, and cannot float the MFP program. Payment to pharmacies should in no circumstances exceed the 14-day prompt pay requirement under Medicare Part D.**

Manufacturer prefunding MTF. **To expedite payment to pharmacies, CMS should prefund the MTF.** CMS has the authority to direct manufacturers to prefund the MTF, in addition to requiring DDPS to submit PDE claims quicker, potentially once to twice a day at the very least. Furthermore, CMS has the authority to prefund the MTF and to require the manufacturer to

[6]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.

prefund the MTF. At the same time, CMS has no authority to require pharmacies to effectively prefund the MTF, and pharmacies should not be prefunding the MFP. **The current proposal essentially places an unfunded mandate on the pharmacy to prefund the MFP program.**

Electronic remittance advice. **NCPA strongly supports CMS's proposal to require electronic remittance advices be provided to dispensing entities showing MTF reconciliation and suggest that CMS mandate a provision of requiring that the MTF generate an Electronic Remittance Advice (ERA), or 835, to the pharmacy for purposes of reconciling manufacturer retrospective MFP refunds.** Additionally, NCPA asks that CMS mandate standardization of 835s. While the 835 is a standard, there are multiple variations in use today by PBMs which complicates the work of reconciliation vendors. Manufacturers could use a standard implementation of the 835 for MFP payments that could be fleshed out in an NCPDP task group. Further, CMS must collect the delivery address for the 835s. Additionally, CMS should ensure that the MTF should be responsible for generating the EDI 820 document that relates to banking financial standards. This information should be made available in the MTF portal for each pharmacy.

40.4.2 Nonduplication with 340B Ceiling Price

In the draft guidance, CMS states that

> If it is subsequently determined that the individual who is dispensed a selected drug was a 340B-eligible patient and received access to the MFP, and the 340B ceiling price for the selected drug is determined to be lower than the MFP, then the Primary Manufacturer will need to promptly provide to the 340B covered entity dispensing the 340B drug the difference between the MFP (which was already provided by the Primary Manufacturer to the dispensing entity) and the 340B ceiling price.

CMS has encouraged wholesalers, along with other drug supply chain stakeholders, to collaborate with manufacturers and covered entities to address this issue with potential industry solutions. It is important to note that duplicate discounts will occur at contract pharmacies if the Covered Entity (or its contracted administrator) follows the current practice of shipping replacement products to the contract pharmacy after retrospectively designating a Medicare claim as 340B eligible.

We believe all affected parties are motivated to prevent duplicate discounts up front to eliminate the need for retrospective de-duplication and complex audits. This can be accomplished by patterning the processes in place today to ensure Medicaid claims are not dispensed using product purchased at the 340B price.

NCPA understands from the Revised Guidance that the Medicare Transaction Facilitator will not perform the deduplication of 340B claims and is encouraging industry stakeholders to develop a process. Many of our members serve as 340B contract pharmacies and should not bear the brunt

of this complex process, especially given their critical role in expanding access to medications for underserved populations.

While NCPA acknowledges the need for the deduplication of claims, the current lack of system integration between pharmacy claim receivable systems and 340B systems poses a significant challenge. For instance, if a pharmacy were to have a previously paid MFP payment clawed back due to a duplicate 340B discount, it would be highly difficult to reconcile that transaction against the current 340B accounting systems. The administrative burden and financial strain of such clawbacks could jeopardize the operational viability of many contract pharmacies. Therefore, NCPA urges CMS to influence the industry design by prohibiting the clawback of previously paid MFP refunds for 340B deduplication purposes. Preventing clawbacks will push covered entities and manufacturers to develop effective means to make covered entities whole without involving contract pharmacies. This approach ensures that the responsibility for resolving duplication issues rests with the parties best equipped to manage them, thereby protecting contract pharmacies from undue administrative and financial burdens.

40.4.3 Retrospective Refund Amount to Effectuate the MFP

WAC as benchmark. In this draft guidance, while CMS stated that it "intends" for the MTF to use WAC as the standardized pricing metric to calculate the Standard Default Refund Amount, it does not expressly require the Primary Manufacturer to use WAC for reconciliation purposes. The MTF will provide the Primary Manufacturer with the Standard Default Refund Amount (i.e., WAC minus MFP) as part of the transmitted data elements. The Primary Manufacturer may elect to use the Standard Default Refund Amount, as appropriate, to calculate and make the retrospective MFP refund payment to dispensing entities. WAC, as defined by section 1847A(c)(6)(B) of the Act, is the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including any non-guaranteed purchasing incentives, such as prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data. WAC is a widely available pricing metric, published and regularly updated in large pharmaceutical pricing database compendia that would be accessible and transparent to interested parties in the MFP effectuation process, and that does not require the sharing of confidential, proprietary data, such as contracted pricing, discounts, and rebates between parties. **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.**

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.**

Pricing for drugs based on WAC is wildly variable, and WAC discounts quoted by wholesalers are not guarantees, but instead are non-guaranteed purchasing incentives that are often contingent on volume, payment terms, generic brand ratio, and many other factors. Manufacturers are unlikely to provide discounts to wholesalers on MFP drugs, and pharmacies in turn are unlikely to receive any discounts downstream.

When WAC is higher than acquisition costs. The draft guidance states that the Primary Manufacturer can choose to refund an amount different than the Standard Default Refund Amount if the Primary Manufacturer determines some other amount is appropriate to make the MFP available**.** For example, CMS states that the Standard Default Refund Amount may not be appropriate when the acquisition cost of a dispensing entity is greater than the WAC of a selected drug. In this case, payment of the Standard Default Refund Amount would not be sufficient to make the MFP available to the dispensing entity. CMS suggests that the Primary Manufacturer could address these circumstances by making MFP refund payments that reflect the dispensing entity's higher acquisition costs for the claims. **NCPA's members occasionally will have acquisition costs higher than WAC in instances of major shortages, and when they are buying from secondary wholesalers.**

Beneficiary access to Community and LTC pharmacy will suffer if pharmacies are not reasonably reimbursed for MFP drugs. NCPA, in conjunction with industry partners, conducted an analysis of 5,200 community pharmacies to determine the effect of MFP drugs on community pharmacies. The analysis reviewed actual dispensing trends from January 1, 2024 – May 31, 2024, and contained several enlightening data points that reveal the true nature and scale of the impact of MFP.

The average community pharmacy dispenses 58 prescriptions for MFP drugs each month for Medicare recipients, which represents 30 percent of the brand name medicines that they fill for Part D recipients. These 58 medications represent $44,000 each month in drug acquisition cost. If the MFP rebate reaches 60 percent of the acquisition cost, then the average pharmacy will have to float over $26,000 every month waiting to be made whole for the MFP rebates. The impact on the cash flow on the roughly 20,000 independent pharmacies in the country will be a collective half a billion dollars every month. This huge number is only for year one of the MFP program, and will grow larger and larger as more drugs are added each year to the program.

The most vulnerable and at-risk patients are in Medicare Part D, and if there is no viable margin on these drugs, pharmacies have no business incentive to stock these drugs. The most at-risk

patients will subsequently lose access to the most needed drugs in Medicare Part D. Independent and LTC pharmacies will be at the greatest risk for decreased access to these drugs. Because so many pharmacies are combination shops (both LTC and retail locations combined), the negative effects on the MFP program on both LTC and retail pharmacy will in turn continually negatively impact each other.

LTC pharmacies that service long-term care facilities have a regulatory obligation to dispense drugs for their patients. While 42 CFR 483.45 requires that these facilities provide or obtain routine and emergency medications and biologicals in order to meet the needs of each resident,[7] most LTC pharmacies interpret this to mean that the pharmacies should dispense within 4 hours for an emergency medication and within 24 hours for a maintenance medication. Therefore, floating the MFP program would put LTC pharmacies at significant risk for not being able to continue to service their long-term facility patients, and in turn threaten the viability of LTC pharmacy itself. Further, it is unlikely that long-term care facilities will be able to find other pharmacies for their patients.

The decrease in availability of these drugs could also create situations where elderly patients will need to travel long distances and go to multiple pharmacies to find them. If these patients ultimately are able to obtain them at another pharmacy, it is likely that the original dispensing pharmacies will be greater removed from the care of the patient, and thus not be able to check for drug interactions or duplicity, creating greater risks of adverse events and hospitalizations. These concerns demonstrate the infeasibility of pharmacy floating the MFP program given zero or extremely small margins for pharmacy under this program, and the necessity that manufacturers must use WAC as a benchmark for payment.

Reimbursement from Part D Plan Sponsors/PBMs for MFP drugs must be reasonable to ensure beneficiary access. Part D plans are required to provide "reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy." According to Medicare Part D regulations:

> To agree to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy including all of the following:
>
> (i) Making standard contracts available upon request from interested pharmacies no later than September 15 of each year for contracts effective January 1 of the following year.
>
> (ii) Providing a copy of a standard contract to a requesting pharmacy within 7 business days after receiving such a request from the pharmacy.[8]

[7] 42 CFR 483.45 -- Pharmacy services.

[8] 42 CFR §423.505(b)(18). Available at: https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423/subpart-K/section-423.505.

CMS must ensure that payment for MFP drugs be reasonable and relevant. For MFP drugs, Part D plan sponsor/PBM pharmacy reimbursement should be no lower than the maximum fair price and include a commensurate professional dispensing fee in line with Medicaid fee-for-service. Additionally, PBMs and plans should not be able to impose any pharmacy price concessions on MFP drugs that would ultimately reduce patient access to MFP drugs or reduce pharmacy reimbursement. Price concessions are commonly assessed on Part D drugs today by PBMs on a per claim basis and serve no other function than to enrich the PBMs. Since HHS is negotiating the price of MFP drugs, PBMs have no role in their pricing, and therefore, should not be able to extract any monetary value from the dispensing of MFP drugs.

40.4.4 Options for Medicare Transaction Facilitator Payment Facilitation

No fees. CMS stated in the draft guidance that "…any potential payment facilitation functionality of the MTF would be voluntary for dispensing entities and Primary Manufacturers, and neither party would have to pay any fees to participate as CMS would bear the cost of operationalizing the MTF." We support CMS' re-iteration in the draft 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.**

"Option 1" and "Option 2". CMS is seeking comment on the two MTF payment facilitation functionality options it is considering. Under "Option 1," the MTF would not transfer funds between parties directly. Instead, the MTF would collect and share participating dispensing entities' bank account information with participating Primary Manufacturers as part of the data elements transmitted by the MTF to facilitate the Primary Manufacturer's direct transfer of funds itself (or through a contracted third-party) to participating dispensing entities. Dispensing entities would only be required to provide bank account information, such as account numbers and bank routing information, to the MTF if they elected to opt-in to the MTF payment facilitation.

NCPA does not prefer Option 1. Under this option, both CMS and the MTF do not have as much control of the process, as the MTF is just giving banking information to manufacturers who transfer funds directly to pharmacies.

Under "Option 2," CMS would receive aggregated MFP refund amount payments from participating Primary Manufacturers and pass through such payments to participating dispensing entities utilizing bank account information collected by the MTF. CMS states that this option is intended to address concerns that manufacturers typically do not interface directly with dispensing entities, and to create a single platform for transmitting refund payments to create greater efficiency, standardization, and predictability in the execution of a high volume of continuous payments.

NCPA favors Option #2, as this option gives CMS more control and standardization. **That being said, NCPA recommends that CMS maintain flexibility to receive pharmacy banking information from a variety of sources, including PSAOs, GPOs, or directly from the pharmacies. Additionally, CMS should be aware that some pharmacies have multiple NCPDP/NPI numbers, especially LTC pharmacies, so CMS and the MTF should be prepared to accommodate these when compiling pharmacy banking information.**

Regardless of the mechanism for distributing payments, NCPA again emphasizes its position that the Standard Default Refund Amount must be paid automatically.

Voluntary MTF facilitation. While NCPA supports CMS' proposed Option 2, as stated above, it is concerned with CMS' suggestion that any potential MTF payment functionality will be voluntary. Making use of an **MTF payment facilitation functionality voluntary for Primary Manufacturers voluntary could result in many manufacturers electing not to use the MTF, 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.**

CMS also discusses that "the Primary Manufacturer would also need to indicate whether it would participate in the MTF payment facilitation functionality in its written plan for making the MFP available." **NCPA is disappointed that CMS has chosen to allow manufacturers to voluntarily effectuate the MFP via the MTF.** This leads to greater uncertainty and potential administrative burden on independent pharmacies. We have grave concerns that manufacturers may not utilize Option 2. **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?**

Information disclosures. CMS states that information collected from the participating dispensing entity in order to facilitate payment between the Primary Manufacturer and the dispensing entity could include but would not be limited to: (1) legal business name and address; (2) Tax Identification Number (TIN) and/or National Provider Identifier (NPI); (3) financial institution details, including address and contact information; (4) financial institution routing number; (5) depositor account number with financial institution; and (6) type of registered financial account. Participating dispensing entities would need to certify that information provided is accurate and up to date. **NCPA members do not see any issues with sharing the listed data to facilitate payment. However, we are concerned by the breadth of the language "would not be limited to," and request that CMS explain what additional data Primary Manufacturers could require from dispensing entities. NCPA believes that the enumerated data set above is sufficient, and that Primary Manufacturers should not require dispensing entities to disclose more information than what is enumerated in this list, as data minimization, in light of the UGH/Change cybersecurity incident, should be paramount.**

90.2.2 Negotiation Program Complaints and Disputes

CMS states that one type of complaint may include operational issues with the MTF system originating from interested parties participating in MTF data or potential payment facilitation functionality. For this type of complaint, CMS expects that the MTF contractor would provide helpdesk functions and resolve these types of issues promptly to ensure that the system operates smoothly without input or further evaluation from CMS, including communicating the solution to the submitting party. CMS envisions that the MTF helpdesk would be a way for the MTF contractor to quickly provide answers to Primary Manufacturers and dispensing entities regarding daily operations of the MTF. **NCPA is concerned that the MTF contractor "helpdesk" is suggested and not required. CMS should mandate that the MTF contractor has a non-automated helpdesk and that it be responsive to any concerns from dispensing entities during normal business hours accounting for all U.S. time zones.**

Under the guidance, CMS further states that Complaints related to a lack of MFP availability would not necessarily 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 believes that CMS's stipulation that a lack of MFP availability does not necessarily require restitution and investigation to be troubling. 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 and that dispensers have sufficient protections for reasonable reimbursement and to make complaints.**

Additionally, CMS states that it is still exploring the limits on the scope of disputes and complaints that the agency may remediate in the context of an otherwise private transaction between the Primary Manufacturer and dispensing entity. In addition, CMS is currently exploring the most efficient way to receive reports of complaints and disputes and welcomes comment.

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 GPOs and 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 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 if option 2 is selected.

<u>RFQ Process Not Transparent</u>

NCPA is also concerned that the RFQ process to select the MTF is not transparent. The RFQ is posted on the GSA MAS schedule, but only those with user access to that schedule can access the RFQ. This precludes many stakeholders, including NCPA and its membership, from reviewing and/or commenting on the RFQ. Further, we need to understand how the RFQ works in tandem with this draft guidance. **We ask that CMS open the RFQ process to be more transparent moving forward.**

Conclusion

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 Ronna Hauser, Senior Vice President, Policy & Pharmacy Affairs, at ronna.hauser@ncpa.org or (703) 838-2691, and Steve Postal, Director of Policy and Regulatory Affairs, at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

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