

Submitted electronically to: IRAREbateandNegotiation@cms.hhs.gov

November 13, 2023

Benjamin Stidham
Contracting Officer
Department of Health and Human Services
Centers for Medicare and Medicaid Services
Office of Acquisition and Grants Management
7500 Security Boulevard
Baltimore, MD 21244

Re: Request for Information Medicare Transaction Facilitator (MTF) for the Medicare Drug Price Negotiation Program

Dear Mr. Stidham:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to CMS on its [Request for Information Medicare Transaction Facilitator \(MTF\) for the Medicare Drug Price Negotiation Program](#).

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.

Section I. – General Vendor Information:

General Vendor Information to include the following:

- Organization Name: National Community Pharmacists Association
- Mailing address: 100 Daingerfield Rd. Alexandria, VA 22314
- Name, phone number and e-mail address of designated point of contact: Steve Postal, Director of Policy and Regulatory Affairs; 703) 600-1178; steve.postal@ncpa.org
- Business type (large business, small business, small disadvantaged business, 8(a)- certified small disadvantaged business, HUBZone small business, woman-owned small business, very small business, veteran-owned small business, service-disabled veteran-owned small business): N/A

- Organization type (practice, association, third party payer, consumer organization, healthcare-related company etc.): association representing community pharmacy
 - It is requested that Respondents provide a summary of their experience related to 5 prescription drug-related transaction services. Organizations that currently support healthcare claim transactions in some way must identify themselves and provide a description of any licenses, specific expertise, General Services Administration (GSA) credentials and information that is relevant to this RFI: N/A, NCPA does not furnish drug-related transaction services.
- Any current or previous federal contracts in the GSA, Governmentwide Acquisition Contracts (GWAC), or any other relevant federal contracts held by your organization. Section II. The name and contact information of the organization whose views are represented in the submission, if different from the information provided in Section I. N/A

Section III. Respondents are encouraged to provide complete but concise responses to the questions listed below. Please note that a response to every question is not required. Responses will be no more than 2,000 characters per question.

NCPA submits the following responses in Section III:

A. Medicare Transaction Facilitator

1. What functionalities would constitute an MTF minimum viable product?

NCPA response: At a minimum, the MTF must quickly and accurately report to a manufacturer when a pharmacy was reimbursed based on MFP for a covered drug dispensed to a Medicare beneficiary. Additionally, an MTF with the capability of functioning as a clearinghouse for manufacturer payments to pharmacies may reduce paperwork/contracting for manufacturers and tens of thousands of pharmacies dispensing drugs reimbursed at MFP.

2. What minimum payment functionality is needed to minimize burden on pharmacies and other dispensers in accessing the MFP?

NCPA response: NCPA advises that there should be only one MTF. The MTF should reimburse pharmacies and other dispensers in the manner they currently receive payment via an electronic payment within 14 days of receiving payable and verifiable claim information and by providing an X12 835 remittance file. The 835 remittance file should contain the same claim-level identification information (such as Rx number, fill number, date of service, claim authorization number, BIN number, and PCN number) as they received on the initial payment of the claim.

The MTF should have a back-end process with 340B covered entities or their contracted 340B third-party administrator (TPA) to prevent duplicate discount payments by manufacturers. Due to the multiple factors that go into determining that a drug dispensed is eligible for 340B pricing, it is not common for a pharmacy to know at the point of sale that a prescription could be dispensed with a 340B-priced drug. Pharmacies submitting a 340B identifier involves high

administrative burden and financial risk for frontline health care providers. Despite some PBMs requiring 340B claims identifiers, NCPA opposes this practice as it causes further burden to pharmacies. For those reasons, NCPA opposes proactive identification of 340B units by pharmacies. NCPA also opposes retroactive identification of 340B units by pharmacies, as it is unduly burdensome for pharmacies to be able to comprehensively make these identifications. NCPA has found that the N1 transaction is not feasible as it is not adopted by pharmacy information systems. For the reasons above, NCPA opposes CMS requiring pharmacies to identify 340B units, as this would result in a significant, unfunded administrative burden for pharmacies. NCPA supports an alternative solution where 340B TPAs provide 340B data to CMS.

3. What MTF functions should be prioritized in a phased development and implementation process for immediate impact and burden reduction?

NCPA response: The MTF should reimburse pharmacies and other dispensers in the manner they currently receive payment via an electronic payment within 14 days of receiving payable and verifiable claim information and by providing an X12 835 remittance file. The 835 remittance file should contain the same claim level identification information as they received on the initial payment of the claim from the Part D plan sponsor. The X12 835 remittance file should match up with what the system says the pharmacy should be paid, consistent with the coordination of benefits. Pharmacies should not be charged any administrative or transaction fees. Immediate burden reduction might include a per-claim fee paid to the pharmacy that is front-loaded and capped. Such a fee would cover costs of dispensing MFP drugs such as interest, lost prompt-pay discounts, and higher technology costs.

5. What should CMS consider in the design of the MTF to effectively incorporate health information technology standards and functionality, including interoperability as a supplement to existing CMS operating systems, to better support the aims of the MTF?

NCPA response: The MTF should be able to send and receive data using NCPDP standards and X12 standards appropriate for the exchange partner. We recommend that something like an electronic voucher program, which currently exists in the commercial plan marketplace for manufacturer copay discounts. These programs are offered by pharmacy claims switching companies leveraging the NCPDP Telecommunication standard and could be used to identify claims paid on the MFP basis of reimbursement determination to trigger manufacturer reimbursement to the pharmacy within 14 days. This proposed electronic voucher program would need cooperation from the switch(s) and manufacturers.

6. What additional security needs should CMS consider to ensure adequate protection of data exchanges?

NCPA response: NCPA advises that entities cannot sell data gathered from this relationship. If CMS cannot or will not stipulate that de-identified data may not be sold for financial gain of the MTF, NCPA requests that CMS stipulate that entities use these funds to fund the “MFP relief fee” as requested above.

7. How can CMS structure the MTF to receive paid MFP claims data for Part D (and Part B) in a systematic fashion that is least disruptive to the industry?

NCPA response: The MTF should be able to accept NCPDP and X12 standard transactions from the Part D and Part B plan sponsors or their intermediaries that are already in use in the industry.

8. How can CMS structure the MTF functionality to send data to pharmacies (and Part B entities) for booking an accounts receivable for paid MFP drug claims?

NCPA response: The MTF should produce files electronically leveraged in already existing claims data elements from existing NCPDP and X12 standards. The X12 835 remittance file should contain the same claim level information as they received on the initial payment of the claim from the Part D plan sponsor. NCPA also requests flexibility for the MTF to send remittance to the pharmacy or their PSAO or third-party reconciliation service, or to the pharmacy directly if they self-contract.

11. How will Part B functions differ from Part D functions to facilitate retrospective manufacturer reimbursements, and can there be a single facilitator that can perform pass through for both Part D and Part B, or must there be two different systems?

NCPA response: Pharmacy will likely experience a longer revenue cycle with Part B claims as the MTF cannot send data to the manufacturer until the claim is paid (which is not a real-time adjudication like in Part D). NCPDP expects the reimbursements to come from the same MTF for Part D and Part B claims using the existing X12 835 remittance standard. The mapping to the 835 remittance file is the responsibility of the MTF, but NCPA defers to NCPDP to answer questions. The 837 claims file should also be sent to the MTF to determine what to charge the manufacturer.

12. What other considerations and transaction components should CMS take into account in considering transaction flows for data exchange and payment processes in building the MTF?

NCPA response: As discussed above, the MTF should produce files electronically leveraging claims data elements from existing NCPDP and X12 standards. The MTF should reimburse pharmacies and other dispensers in the manner they currently receive payment via an electronic payment within 14 days of receiving payable and verifiable claim information and by providing an X12 835 remittance file. There should be only one MTF that uses existing NCPDP and X12 transactions using the same data exchanges that are used today in the industry.

Payment should be made as required in the Part D regulation within 14 days of receipt of claims data. NCPA requests clarity from CMS that the 14 days starts accruing from when the plan gets the information to the manufacturers, meaning that pharmacists need to ensure that information exchange to be instantaneous to not impede prompt pay to pharmacy. Community pharmacies operate with very tight cashflows and cannot afford to float and loan money to supply chain entities. NCPA asks CMS to elaborate on the 14-day timeframe to ensure prompt payment to pharmacies, consistent with current Part D policy. Furthermore, wholesalers should

take into consideration prompt payment requirements in their contracts for supplies and payment schedules, to ensure that prompt payment is met.

The MTF should reimburse pharmacy with a transaction fee that compensates pharmacy for participating in this program. An additional fee paid by the MTF to the pharmacy should reflect technology costs passed on to the pharmacy by system vendors that will have to undertake coding with a tight deadline and the additional work of tracking the additional receivable and issues that arise from reconciliation discrepancies.

B. Current Experience with similar MTF functionality needs

17. What experience does your organization have with communicating with pharmacy switches that route claims between pharmacies and payers?

NCPA response: CMS should ensure that the MFP follows NCPDP guidelines, is HIPAA compliant, can promptly adjudicate claims, and has a compliant platform like existing switches.

18. What experience does your organization have with managing account balances and tracking amounts paid and owed?

NCPA response: NCPA is an Accreditation Council for Pharmacy Education accredited provider of pharmacist and pharmacy technician continuing education. In that capacity, NCPA strives to provide education offerings to our member pharmacy owners and members of their staff that ensures the success of the pharmacy. This means we tailor education to improve their clinical knowledge and skills as well as their business knowledge and skills. We are familiar with claims processing and reconciling workflow and recommend that the MTF be designed to minimize disruption to service providers in this space. If an NCPDP solution is adopted, a claim response will come back with a basis of reimbursement determination code specific to MFP which could, once development timelines allow, cue pharmacy system to book an account receivable for the manufacturer payment with the pharmacy receiving an 835 remittance file for it from the MTF. Wholesalers and PSAsOs that require central pay should also provide accounts receivable. Pharmacies should not incur any additional administrative or transaction fees for exchange of data or payments from the MTF.

To improve pharmacies' abilities to manage account balances and tracking amounts paid and owed, plans and PBMs should not charge DIR fees to pharmacies for negotiated drugs. We have concerns that pharmacies will be reimbursed below MFP, especially if DIR fees are assessed on these drugs. Additionally, pharmacy reimbursement should be reasonable and cover acquisition cost plus margin plus include a commensurate professional dispensing fee (currently, PBMs pay retail pharmacies dispensing fees far below the actual cost to dispense, as low as \$0). Long-term care (LTC) pharmacies should be safeguarded from being disproportionately affected, given LTC pharmacy's higher dispensing costs compared to the retail setting, based on following CMS' ten criteria for LTC pharmacy. Additionally, NCPA opposes any reporting of acquisition cost to the MTF given anti-competitive concerns.

20. What experience does your organization have with creating Electronic Remittance Advice (ERA) 835 transactions?

NCPA response: Payers must provide 835 remittance files that are complete and accurate, and contain sufficient information to match with the claims on given data.

21. What experience does your organization have with exchanging data with 340B covered entity Third Party Administrators (TPAs)?

NCPA response: Correctly identifying 100% of claims eligible for 340B pricing at the time of dispensing/prescription claim submission is impractical in the current implementation of the 340B program. Pharmacies submitting a 340B identifier involves high administrative burden and financial risk. Due to the multiple factors that go into determining that a drug dispensed is eligible for 340B pricing, it is not common for a pharmacy to know at the point of sale that a prescription could be dispensed with a 340B-priced drug. For those reasons, NCPA opposes proactive identification of 340B units by pharmacies. NCPA also opposes retroactive identification of 340B units by pharmacies, as it is unduly burdensome for pharmacies to be able to comprehensively make these identifications. NCPA has found that the N1 transaction is not feasible as it is not adopted by pharmacy information systems. For the reasons above, NCPA opposes CMS requiring pharmacies to retroactively identify 340B units, as this would result in a significant, unfunded administrative burden for pharmacies. NCPA supports an alternative solution where Third-Party Administrators provide 340B data to CMS. The most reliable entity that would have 340B data would be the Third-Party Administrator (TPA).

NCPA appreciates the opportunity to share with CMS our comments and suggestions on the *Request for Information Medicare Transaction Facilitator (MTF) for the Medicare Drug Price Negotiation Program*. Should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

A handwritten signature in black ink, appearing to read 'Steve Postal', with a stylized flourish at the end.

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