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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.

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"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