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May 1, 2025

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) 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 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.

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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." While a time limit is required for dispute/complaint submission, there is no agreement in terms of

response time or resolution to submitted disputes/complaints. Pharmacies need to know how quickly disputes will be resolved.

"Question 5: Supporting Documentation"

We thank CMS for increasing the document limitation on the supporting documentation upload from 5 documents to 10 documents. However, we would appreciate greater flexibility for the document limitation. 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 10 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:

<u>Technical and security infrastructure.</u> 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.

<u>Portal</u>. 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. This should include information about any claims that are undergoing further DDPS editing by the plans. 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.

Additionally, NCPA has concerns that the dispute/complaint process seems to limit issues to only transaction data visible to the manufacturer. Other systems in this process use data that could be compromised. For example:

- Plans: Medicare Part D plan or PBM could miscalculate an MFP price (differences in MFP or WAC effective dates and/or price); there could be a lack of MFP identifier on claim response; there could be timing or gaps in processing reversals; claim submissions (transaction date > date of service).
- DDPS: 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)
- Manufacturers: Disputes regarding manufacturer identification of 340B claims;
- New CARC and RARC codes: MFP payment codes (between manufacturer and MTF) will
  need to be mapped to the new 835 CARC and RARC codes and provide pharmacies with
  a payment manual to use for reference. We recommend that CMS create 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. We appreciate CMS adding to its revised version of Appendix D the "MTF Internal Claim Number(s) or Reference ID(s) on X12 835" with an optional text field to Question 3: Selected Drug & Claim Information as information that can be provided if known.

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 <a href="mailto:steve.postal@ncpa.org">steve.postal@ncpa.org</a> or (703) 600-1178.

Sincerely,

Steve Postal, JD

Senior Director, Policy & Regulatory Affairs National Community Pharmacists Association