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January 27, 2025

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS–4208–P

Mail Stop C4–26–05

7500 Security Boulevard

Baltimore, MD 21244–1850

Re: 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

Dear CMS Staff:

The Independent Pharmacy Cooperative (IPC) appreciates the opportunity to provide comments to CMS on its *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* (CMS-4208-P).

IPC is the nation's largest group purchasing organization and trade group representing the interests of pharmacist owners, managers, and employees of more than 2000 independent community pharmacies in all 50 states and the District of Columbia. IPC also owns and operates a drug wholesale warehouse that services a total of 7000 independent pharmacies across the country.

IPC submits these comments on behalf of our stores that serve Medicare Part D patients, many of whom are the most vulnerable patients in medically underserved areas and a sizeable number serving Medicare dual-eligible patients.

While this proposed rule for Medicare Part D Plan Year 2026 offers many changes to the regulations on the operation of the Part D Prescription Drug program, IPC's comments focus on the most troubling and threatening to our independent pharmacy members and their ability to continue to provide prescription drug services to their patients for these 10 negotiated price drugs. Without significant changes to the proposed rule including ensuring pharmacies receive full payments for the drug acquisition cost and a cost to dispense there will be beneficiary access challenges.

IPC had pharmacy store owners participate in NCPA's analysis of 5,200 community pharmacies to determine the effect of the Medicare Drug Price Negotiation (MDPN) Program which found that the average pharmacy will have to float over $27,000 every month waiting to be made whole for the MFP refunds from manufacturers of their claims for these 10 negotiated high-cost drugs. 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. That monthly dollar "float" amount will be even higher for approximately 43% of IPC member pharmacies. That is because these pharmacy's patient profiles are disproportionately derived from Medicare/Medicaid dual-eligible prescriptions claims. While this monthly "float" is a huge number it is only for year one of the MDPN Program and will grow larger and larger as more drugs are added each year. That is clear from CMS' just released list of the next 15 drug selected for the 2027 Plan year MDPN, including behavioral health drugs. These compounding MDPN "float" amounts will result in devastating, irreparable impact on IPC members and all U.S. independent pharmacies being able to continue serving their most vulnerable and at-risk patients - especially long-term care facilities and community based dual-eligible patients. IPC has raised these concerns in past listening sessions by CMS's MDPN staff and our deep concern remains based on this proposed regulation.

IPC is asking CMS to provide the following in its final rule:

- Require that Plan D sponsors provide network ID and group ID to pharmacies regarding in-network status, or if not feasible, require BIN and PCN numbers;
- In its provision allowing pharmacies to terminate contracts without cause, eliminate the requirement that this is allowable only if network pharmacy contract allows terminations without cause by the sponsor, and to require commercially reasonable notice of termination;
- For CMS to eliminate pharmacies' mandatory participation in the MDPN Program via PBM/plan contracts;
- Include that plans/PBMs are not allowed to "bundle" or "tie" participation in one network to another non-Medicare Part D network, a practice currently engaged in by some plans/PBMs;
- Require Part D PBM pharmacy network contracts pay every Part D network pharmacy the MDPN NFP as reimbursement for claims for these 10 negotiated drugs along with a cost to dispense fee with clear language of this being a statutory exemption under the Inflation Reduction Act to the Medicaid Modernization Act's non-interference clause;
- Additionally, we strongly encourage CMS in the final rule 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.
- Ensure that pharmacies can easily access information on a Part D enrollee's OOP costs for the Medicare Prescription Payment Plan for prescriptions processed under the program at POS.

- That CMS should 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:

    - To expedite payment to pharmacies, CMS should prefund the Medicare Transaction Facilitator (MTF). The current proposal essentially places an unfunded mandate on the pharmacy to prefund the MDPN Program;
    - In the alternative, should CMS not agree with us that it has the authority to pre-fund the MDPN Program or to require manufacturers to pre-fund the Program, then IPC urges 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 daily.

- That pharmacies need to be paid amounts owed for the Maximum Fair Price (MFP) within 14 days of adjudicating the claim;
- Ensure beneficiary access to LTC pharmacy services in their homes, leveraging the agency's existing authority under the Medicare statute.

Medicare Transaction Facilitator Requirements for Network Pharmacy Agreements

CMS proposes to amend § 423.505 by adding paragraph (q) to require that Part D sponsors' network contracts with pharmacies require such pharmacies to be enrolled in the Medicare Drug Price Negotiation (MDPN) Program's Medicare Transaction Facilitator Data Module (''MTF DM''). IPC joins other pharmacy industry organizations in opposing mandatory participation in the MDPN Program via PBM/plan contracts. IPC believes that CMS is ignoring the fact that, by statute, the Medicare Prescription Drug Program is an optional health care program, and that CMS lacks the statutory authority from Congress to tie participation in Part D as a whole with participation in the MPDN Program. IPC also joins other pharmacy organizations in asking CMS to include in the final rule that plans/PBMs are not allowed to "bundle" or "tie" participation in one network to another non-Medicare Part D network, a practice currently engaged in by some plans/PBMs.

IPC Opposition to CMS's planned Implementation of the MDPN Program

IPC opposes the approach of pharmacy upfront "float" of MFP differential in the proposed MDPN program due to inevitable late manufacturer refund payments. Under CMS's proposed regulation, manufacturers will need to make pharmacies whole with a manufacturer refund by paying pharmacies the difference between wholesale acquisition cost (or another benchmark the manufacturer chooses) and the MFP. This proposed rule will lead to pharmacies waiting over 30 days for the manufacturer refund payments. The best-case scenario is 21 days, which is still unsustainable when most pharmacies have to pay their wholesalers twice every month. Likely, the delay in manufacturer payments to pharmacies will stretch out further than 30 days as the manufacturers will use this reconciliation period to determine any duplicative 340B claims for these MDPN identified prescriptions. Without a coordinated prompt payment deadline of the MMA 14-day prompt pay requirement also applying to the MDPN manufacturer refund, the manufacturers will see every reason to delay the reconciliation process to avoid paying these refunds as long as possible. All pharmacy organizations, including IPC have made our concerns regarding the impossibility of pharmacies implementing the MDPN very clear, yet CMS did not address these concerns in any of the CMS MDPN guidance in 2024.

IPC joins all other pharmacy organizations in opposing CMS' position in this proposed rule to not require fair reimbursement or reasonable terms from PBMs;

- Along with other pharmacy organizations, IPC is asking CMS for clarification - which the agency has not done - that in order to comply with the 14-day prompt MFP payment statutory mandate, the Primary Manufacturer must transmit an MFP refund amount no later than 14 days of adjudication of the MFP drug;
- As with every other pharmacy organization, IPC remains disappointed that CMS refuses to propose having manufacturers, or PDPs prefund the Medicare Transaction Facilitator (MTF) to expedite payment to pharmacies. IPC request that CMS include such a pre-funding requirement;
- IPC joins the call of all pharmacy organizations for CMS to include in the final rule that the standard default refund amount (SDRA) of WAC-maximum fair price (MFP) be required.

Further, IPC contends that CMS is being inconsistent in this proposed rule with its willingness to mandate contract requirements to implement the MDPN, while not protecting pharmacies from Part D PBMs' below cost reimbursements due to CMS's unwillingness to "interfere" with PBM/pharmacy contracts. At the same time, CMS is interfering 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).

IPC believes that if CMS does not adopt the pharmacy industry's requests for revisions to the MFT DM, MFT PM and the NFP and pharmacies are required to "float" the rebate and see payments below the NFP for each drug, patients will see their prescription drug access curtailed by pharmacies not being able to afford to carry these drugs.

Additionally, we strongly encourage CMS in the final rule 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.

Lack of Requirement that Part D PDP's Pharmacy Network Negotiated Price for MDPN Covered Drugs Equal the NFP

IPC is very concerned that the proposed rule does not mandate that Part D PBMs in their pharmacy network contracts must reimburse network pharmacies for every claim at a reimbursement rate no lower than the NFP along with a reasonable and adequate cost to dispense fee. IPC contends that Congress' creation of the MDPN Program is an express written statutory exemption for the drug selected for price negotiation from the rest of the MMA's non-interference clause. While the statutory language places the burden on the drug manufacturer to pay pharmacies for this difference without a cost to the Part D program, Congress also created a statutory exemption in the Part D law that PDP's need to pay pharmacies the negotiated price for these 10 drug prescription claims at the MDPN NFP at a minimum. For CMS to allow Part D PDP to reimburse pharmacies for these 10 drugs below the MDPN NFP rate means that CMS is allowing PDPs to create an unintended and undisclosed Direct and Indirect Renumeration (DIR) price concession below what CMS is paying for the drug. This type of DIR will only enrich the Part D PBMs at a financial cost to the Federal Government, the Part D beneficiary and most certainly the Part D patient's pharmacy provider.

This approach violates Congress' statutory program in creating the MDPN Program. And with clear language of this being a statutory exemption under the Inflation Reduction Act to the Medicaid Modernization Act's non-interference clause, the proposed rules' lack of application of the MDPN NFP to Part D plan MFP opens CMS to potential legal challenges that it is creating a statutorily unauthorized DIR.

IPC Requests that in Adopting the Part D 2026 Final Rule the Agency Include Language Requiring Part D PBM Pharmacy Network Contracts Pay Network Pharmacies the MDPN NFP as Reimbursement for Claims for these Negotiated Drugs Along with a Reasonable and Adequate Cost to Dispense.

Codification of Guidance Specific to Long-Term Care Pharmacies regarding the Medicare Prescription Payment Plan Program

On July 16, 2024, CMS released its "Medicare Prescription Payment Plan: Final Part Two Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Response to Relevant Comments." In response to comments from pharmacy organizations, CMS accurately states, "[l]ong-term care pharmacies typically do not have a POS encounter between the pharmacy and the enrollee (long-term care resident)." IPC joins other pharmacy organizations in appreciating that the agency understands the current mechanism of interaction between long-term care (LTC) pharmacies and the patients under their care.

To address this operational reality, CMS provided guidance, in section 50.3.1, stating, "[a]s such, when the POS notification is received by a long-term care pharmacy, the plan sponsor should not require that the long-term care pharmacy provides the "Medicare Prescription Payment Plan Likely to Benefit Notice" prior to dispensing the medication. Instead, the plan sponsor should require the long-term care pharmacy to provide the notice to the Part D enrollee (or their authorized representative) at the time of its typical enrollee cost-sharing billing process." IPC appreciates CMS providing this guidance.

Failure to recognize and address the operational realities of LTC pharmacies within regulation creates unnecessary uncertainty within the Medicare Prescription Payment Plan Program for LTC residents, facilities, plans and pharmacies. **IPC requests that CMS codify the above referenced July 2024 guidance in its final rule.**

Timely Submission Requirements for Prescription Drug Event (PDE) Records (§ 423.325)
In this rule, CMS proposes to codify the general PDE submission timeliness guidance that currently applies and that addresses three types of PDE submissions: initial PDE records submitted after a pharmacy claim is received by the Part D sponsor (hereinafter referred to as ''initial PDE records''), adjustment and deletion PDE records that update previously submitted records that have been accepted by CMS, and records to resolve PDE records that were rejected by CMS. Further, CMS proposes to codify a specific PDE submission timeliness requirement for initial PDE records when those PDE records are for selected drugs. The proposed submission timelines are as follows:

FIGURE 1. PROPOSED PDE SUBMISSION TIMELINES FOR NON-SELECTED AND SELECTED DRUG CLAIMS

Submission Timeframe	Non-Selected Drug	Selected Drugs
Initial PDE	30 calendar days following date claim received by Part D plan sponsor or its contracted first tier, downstream, or related entity	7 calendar days following date claim received by Part D plan sponsor or its contracted first tier, downstream, or related entity
Resolution of Rejected Records	90 calendar days following receipt of rejected record status from CMS	
Adjustment and Deletion	90 calendar days following discovery of issue requiring change	

IPC along with all other pharmacy organizations believes that in the final rule CMS must 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:

1. To expedite payment to pharmacies, CMS should prefund the Medicare Transaction Facilitator (MTF). At the same time, CMS has no authority to require pharmacies to effectively prefund the MTF. The current proposal essentially places an unfunded mandate on the pharmacy to prefund the MDPN Program;

2. However, in the alternative, should CMS not agree with us that it has the authority to pre-fund the MDPN Program or to require manufacturers to pre-fund the Program, then **IPC urges 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 daily.**

14-Day Prompt Payment. IPC 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 in 2006 and before this provision was put in place at the end of 2008, 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 a net rate of approximately 1 per day, decreasing beneficiary access to care in their local communities. While IPC and others in the pharmacy industry appreciate 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. Manufacturers may also view the data transmission as incomplete if it does not also include information on whether the claim is an 340B program eligible prescription. IPC 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. 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 at a minimum shorten the current 30-day window to 7-days,** however this would only equate to a minimum of 21-days for manufacturer refund payments to reach independent pharmacies**.**

[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.

As stated above, 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 its final guidance, CMS stated that the 14-day prompt MFP payment window begins when the MTF DM sends the claim-level data elements to the Primary Manufacturer, and that it may result in MFP refund payments more than 14-days from time of claim submission by the dispensing entity[3]

Given the 7-day window 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. Manufacturer refund 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 do this, in addition to requiring DDPS to submit PDE claims quicker, potentially once to twice a day at the very least. 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 entire MFP program.

In the alternative, should CMS not agree with us that it has the authority to pre-fund the MDPN Program or to require manufacturers or PDPs to pre-fund the Program (see below), then we join other groups in urging 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.

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.

Impact on Small Businesses— Regulatory Flexibility Analysis (RFA)

The Regulatory Flexibility Act (RFA) states that both initial and final regulatory flexibility analyses do not apply "…to any proposed or final rule if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities."[2] In the proposed rule, CMS certifies that the rule will not have a significant impact on a substantial number of small entities, and defines "substantial" as "3 to 5 percent or more of the affected entities' costs."[3] The certification frees CMS from having to analyze the impacts of the rule on covered small entities. However, the RFA also requires that any certification be accompanied by "the factual basis for such certification."[4]

A proper RFA certification is met when a rule will not have a significant impact on a substantial number of small entities. CMS' certification is incomplete as it only analyzes the impact on the rule using the definition of "substantial" and does not provide any information on the "significance" of the rule's impact on small pharmacies. Usually HHS defines "a significant impact" as being greater than 3-5% of covered small businesses revenue.

IPC joins others in arguing that the rule was inappropriately certified because the factual basis is flawed, and that CMS should have analyzed the rule's impact on small pharmacies by performing an Initial Regulatory Flexibility Analysis per section 603 of the RFA.

Additionally, the MDPN Program specifically will have a significant economic impact on pharmacies. As stated above, IPC had pharmacy store owners participate NCPA's analysis of 5,200 community pharmacies to determine the effect of the Medicare Drug Price Negotiation (MDPN) Program which found that the **average pharmacy will have to float over $27,000 every month waiting to be made whole for the MFP refunds from manufacturers of their claims for these 10 negotiated high-cost drugs.** 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.

Further, CMS is requiring pharmacies to participate in the MDPN Program as a condition for participating in Medicare Part D generally. **IPC reiterates that we do not believe that CMS has the authority to tie participation in Part D with participation in the MDPN Program. IPC request that if CMS will not remove this provision from the final rule, it explains why it believes it has such authority.** Since CMS is currently proposing that pharmacies be required to be enrolled in the MDPN Program in order to be in Medicare Part D, CMS should have analyzed the economic impact of pharmacies' participation in the MPDPN Program. If CMS did this, they would find that the MDPN Program has a significant financial impact on pharmacies. Since there is a proposal in this rule to force small pharmacies to participate in the MDPN Program, via PBM contract terms, CMS must perform an Initial Regulatory Flexibility Analysis.

[2] See RFA § 605(b), available at: The Regulatory Flexibility Act – Office of Advocacy.
[3] Federal Register Vol. 89, No. 237, at 99514-99515. Available at: 2024-27939.pdf.
[4] See RFA § 605(b), available at: The Regulatory Flexibility Act – Office of Advocacy.

In summation, without CMS adopting the revisions to the 2026 Part D proposed regulation as outlined in the comments by IPC, and other pharmacy organizations, senior and dual-eligible patients will find their access to the Medicare Part D drug benefit severely curtailed and CMS will have created an unintended DIR windfall for the PDP's at the expense of federal taxpayers, Part D beneficiaries and especially their pharmacy care providers.

Given the rapid rate at which the IRA implementation is occurring, IPC feels compelled to join other pharmacy organizations in submitting written comments outlining our objections to these specific provisions of the Medicare Part D Plan Year 2026 proposed regulations and our requests for revisions in the final rule to ensure the program meets its Congressional intent to have drug price negotiations save costs for beneficiaries, taxpayers and the Part D program. We urge CMS to freeze the MDPN Program until it can meet with all pharmacy industry organization stakeholders and share our concerns in depth and work collaboratively to identify a method that will ensure the program is workable for pharmacies and patients.

IPC thanks CMS for the opportunity to provide feedback, and we stand ready to work with the agency to offer possible solutions. If you have any questions or need any additional information, please feel free to contact me by either email (mark.kinney@ipcrx.com or by phone (608-628-7311).

Respectfully submitted,

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