Submitted electronically to: www.regulations.gov

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 [CMS–4208–P]

Docket Management Staff,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) proposed rule: 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]

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.

NCPA's analysis of 5,200 community pharmacies to determine the effect of the Medicare Drug Price Negotiation (MDPN) Program 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. 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 MDPN 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. NCPA will be releasing a study showing updated IRA MDPN Program impacts on community pharmacy in the near future and will share that study with CMS once available. NCPA continues to be vocal about our concerns and has attached updated NCPA member survey results on the impact of the MDPN Program, and underwater Medicare Part D reimbursement generally, on our members.

A survey conducted of our members in January 2025 highlighted some disturbing trends of the viability of Medicare Part D for independent pharmacy:

- **96.5 percent** of independent pharmacists said PBM and plan reimbursement for Medicare Part D threatened the viability of their business;
- **40.8 percent** of independent pharmacists said they were paid below the National Average Drug Acquisition Cost (NADAC) on more than 40 percent of the prescriptions they filled for Medicare Part D patients;
- **29.2 percent** of independent pharmacists said they were paid below NADAC on 50 percent or more of the prescriptions they filled for Medicare Part D patients;
- **80.3 percent** of independent pharmacists said the financial health of their business declined in 2024;
- **48.6 percent** of independent pharmacists said the financial health of their business declined significantly in 2024; and
- **30.3 percent** of independent pharmacists said they are considering closing their business in Calendar Year 2025.

Perhaps most importantly, of those surveyed 60.4 percent are strongly not considering stocking one or more drugs with prices negotiated under Medicare Part D, while an additional 32.8 percent have already decided not to stock one or more of the drugs, which would all but guarantee that CMS' attempt to reduce prescription drug prices will fail. NCPA has attached the full survey results to this comment letter.

In sum, NCPA asks that CMS 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;
- CMS must 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;
- 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.
- For the proposal of requirements for Part D sponsors to 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 the POS:

    - These costs should be provided in the paid claim billing response on the Medicare Prescription Payment Plan COB transaction. In addition, Part D sponsors must ensure that pharmacies are prepared to provide this information to a participant at the POS;
- 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 provide the notice to the Part D enrollee (or their authorized representative) at the time of its typical enrollee cost-sharing billing process;
- 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) or require the manufacturers to prefund the 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;
    - 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 NCPA 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 on a daily basis.
- Pharmacies need to be paid amounts owed for the maximum fair price (MFP) within 14 days of adjudicating the claim;
- To expedite payment to pharmacies, CMS should prefund the MTF;
- For Medication Therapy Management;
    - CMS should be more inclusive and add "neurodegenerative diseases," which is inclusive of dementias, like Alzheimer's disease, as well as other conditions that can drive polypharmacy and therefore reduced patient outcomes while living with devastating conditions that rob individuals of their mental facilities;
    - CMS should not further broaden coverage of MTM services without increasing payment to pharmacies, as doing otherwise will create an "unfunded mandate" on pharmacy;
    - MTM payments should be commensurate with the care and expertise provided to the patient, not based on generating additional revenue for the plans and the PBMs;
- To provide regulations outlining Part D pharmacy contracting guardrails to ensure fair and common-sense contracting between Part D plans/PBMs and pharmacies.
- To require PBMs to ensure network parity between affiliated and unaffiliated pharmacies;
- To require that the final reimbursement to pharmacies after any reconciliation for a prescription drug is no less than NADAC plus a commensurate professional dispensing fee;

- To confirm that under the Inflation Reduction Act (IRA), 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;
- To clarify 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;
- A revision to the Retail Pharmacy Access Standards, to use "within 1 mile" for urban areas, "within 2 miles" for suburban areas, and "within 10 miles" for rural areas. But for census tracts where there is a high percentage of low vehicle ownership, regardless of if urban, suburban, or rural, NCPA advises that CMS use "within 0.5 miles."
- Ensure beneficiary access to LTC pharmacy services in their homes, leveraging the agency's existing authority under the Medicare statute.

Promoting Transparency for Pharmacies and Protecting Beneficiaries From Disruptions

1. Plan Notification to Pharmacies of In-Network Status

CMS is proposing to require Part D sponsors (or first tier, downstream, or related entities (FDRs), such as pharmacy benefit managers (PBMs), on the sponsors' behalf) to notify network pharmacies which plans the pharmacies will be in-network for in a given plan year by October 1 of the year prior to that plan year and to require sponsors to provide a list of these plans to network pharmacies on request after October 1. **NCPA requests that CMS require that sponsors provide a list of these plans to network pharmacies automatically after October 1 but prior to the first day available for beneficiaries to enroll in a plan, not on request. Additionally, NCPA supports the following redline to the proposed regulatory language:**

> (i) For every Part D PBP that the pharmacy participates in pursuant to the contract, the list must include all of the following:
>
> (A) The Part D contract number assigned by CMS.
>
> (B) The plan ID assigned by CMS for the PBP.
>
> (C) The network ID assigned by the sponsor or the first tier, downstream, or related entity
>
> (D) The group ID assigned by the sponsor or the first tier, downstream, or related entity
>
> ~~(C)~~ (E) The marketing name of the PBP.

In previous conversations between NCPA and CMS, CMS has stated that it is unable to make this proposed redline because network and group ID are not defined in regulation. NCPA requests clarity on this point in the final rule and also asks if CMS can add BIN (and when The

NCPDP Telecommunication Standard Implementation Guide Version F6, January 2020 and equivalent NCPDP Batch Standard Implementation Guide, Version 15, October 2017, goes into effect in February 11, 2028, IIN) and PCN numbers to the above requirements instead.

2. Termination of Contracts Without Cause

At § 423.505(i), CMS proposes to require Part D sponsors to allow pharmacies to terminate their network contracts without cause after the same notice period that the sponsor is allowed to terminate network pharmacy contracts without cause. CMS maintains that this provision would only apply if the network pharmacy contract allows terminations without cause by the sponsor; if the contract does not allow terminations without cause by the sponsor, it would not be required to allow such terminations by the pharmacy. CMS maintains that this change would prohibit the current practice CMS has observed by some sponsors to only allow pharmacies to terminate their network contracts without cause after giving a relatively long period of notice (sometimes exceeding one year), while preserving their right to terminate without cause on much shorter notice.

NCPA asks that CMS incorporate the following redline changes to its proposed regulatory language in its final rule:

> **§ 423.505 Contract provisions. * * * * ***
>
> (8) Any contract between the sponsor and a pharmacy, or between a first tier, downstream, or related entity and a pharmacy on the sponsor's behalf, for participation in one or more of the Part D sponsor's networks ~~that allows the sponsor or the first tier, downstream, or related entity to terminate the contract or the pharmacy's participation in a particular network without cause~~ must allow the pharmacy to terminate the contract or its participation in a particular network without cause after providing commercially reasonable (e.g., sixty (60) days) ~~the same~~ notice of ~~that the contract requires the Part D sponsor or the first tier, downstream, or related entity to provide for a~~ termination without cause.

NCPA believes that CMS must recognize the outsized market power of the PBMs and their unwillingness to negotiate many, if not all, aspects of their network agreements, provider manuals, and similar agreement documents. The PBMs have all taken a position that they can, and do, unilaterally change the terms of the agreements between the PBMs and network participating pharmacies. Often those changes are untenable and the pharmacy gets stuck in agreements that can, and often do, put them out of business. Therefore, there is little benefit to the PBM to have a right of termination without cause dictated by CMS. Rather, the need is a unilateral one and the need is for the network pharmacy to have that right given the market power of the PBMs and their affiliated insurance companies and pharmacies.

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''). **NCPA opposes mandatory participation in the MDPN Program via PBM/plan contracts via this mandatory requirement. NCPA does not believe that CMS has the authority to tie participation in Part D as a whole with participation in the MDPN Program, and NCPA requests formal explanation as to why CMS believes it has such authority. Additionally, NCPA asks that CMS 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.**

NCPA opposes the way that CMS plans to implement the MDPN Program:

- NCPA opposes CMS requiring pharmacies to float this program because this is a financially unviable solution. NCPA's analysis of 5,200 community pharmacies to determine the effect of the MDPN Program 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. 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 MDPN 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. NCPA will be releasing a study showing updated IRA MDPN Program impacts on community pharmacy in the near future and will share that study with CMS once available. NCPA continues to be vocal about our concerns and has attached updated NCPA member survey results on the impact of the MDPN Program on our members. Our survey, conducted in January 2025, indicated that approximately 61 percent of independent pharmacists are strongly not considering stocking one or more drugs with prices negotiated under Medicare Part D, while an additional approximately 33 percent have already decided not to stock one or more of the drugs, which would all but guarantee that CMS' attempt to reduce prescription drug prices will fail.

- NCPA opposes this program due to anticipated late manufacturer refund payments. Under the program, 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. As it stands now, pharmacies will likely be waiting over 30 days for the manufacturer refund payments. The best-case scenario is 21 days, which is still unsustainable when pharmacies have to pay their wholesalers twice every month. NCPA has made our concerns regarding the impossibility of pharmacies implementing the MDPN very clear, yet CMS did not address our concerns. Looking at our comments to CMS' draft guidance on the MDPN guidance in July 2024 versus CMS's final guidance in October 2024:

- NCPA opposed CMS requiring fair reimbursement for MPF drugs from PBMs, including dispensing fees to pharmacy under this program, yet CMS choses to continue to not require fair reimbursement and dispensing fees;
- NCPA asked for clarification from CMS regarding the Primary Manufacturer transmitting an MFP refund amount within 14 days of adjudication of the MFP drug, as opposed to ensuring the dispensing entity has received the MFP reimbursement within 14 days, to comply with the 14-day prompt MFP payment window, yet CMS did not clarify this;
- NCPA asked that CMS prefund the Medicare Transaction Facilitator (MTF) to expedite payment to pharmacies, yet CMS did not require a prefund from either CMS or manufacturers;
- NCPA asked that the standard default refund amount (SDRA) of WAC-maximum fair price (MFP) be required, yet CMS did not mandate this; and
- NCPA expressed concern that CMS has chosen to allow manufacturers to voluntarily effectuate the MFP via the MTF Payment Module (MTF PM), yet CMS made manufacturer participation in the MTF PM optional, causing pharmacies to worry that they will have to have multiple systems and software programs to reconcile these payments.

Further, CMS is unwilling to protect pharmacies from PBMs' underwater 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). So, while CMS is willing to interfere with contracts concerning the data module, it is not willing to interfere in contracts that make certain pharmacies are paid fairly. For those reasons, NCPA thinks this program has a high likelihood of failure and opens CMS up to potential legal claims that it can -- in fact -- interfere in PBM/pharmacy contracts but chooses not to do so.

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.

<u>Medicare Prescription Payment Plan Pharmacy Claims Processing</u>

In this proposed rule, CMS proposes to codify the requirements established in the final part one and final part two guidance for 2026 and subsequent years at § 423.137(j). CMS proposes to codify that Part D sponsors and pharmacies must use a BIN/PCN electronic claims processing methodology for Medicare Prescription Payment Plan transactions at paragraph (j)(1). CMS proposes to codify the requirement for handling of higher final patient pay amounts from supplemental payers at paragraph (j)(2). CMS proposes to codify that the claims processing methodology have no impact on PDE reporting at paragraph (j)(3). CMS proposes to codify that program participation and the associated claims processing methodology have no impact on the cost-sharing information displayed in real-time benefit tools at paragraph (j)(4). CMS proposes to establish standards for exclusion of retroactive or ''paper'' claims at paragraph (j)(5). CMS proposes to codify requirements for the readjudication of certain covered Part D claims for

program participants at (j)(6). Finally, CMS proposes to codify new requirements for Part D sponsors to enhance OOP cost transparency at the POS at (j)(7).

At § 423.137(j)(7), CMS proposes requirements related to transparency around OOP costs for the Medicare Prescription Payment Plan at the pharmacy POS. Once an enrollee is a participant in the Medicare Prescription Payment Plan, they will pay $0 at the pharmacy POS. Part D sponsors then correctly calculate the monthly caps based on the statutory formulas, determine the amount to be billed, and send monthly bills to program participants. CMS has heard concerns about the potential lack of participant visibility into their OOP costs for the Medicare Prescription Payment Plan at the POS, given the $0 final claim response from the Part D sponsor to the pharmacy. As noted in the final part two guidance, CMS strongly encourages Part D sponsors to educate program participants on the options for assessing OOP costs for the Medicare Prescription Payment Plan prior to the pharmacy POS (such as utilizing interactive prescription drug cost tools available on the Part D sponsor's website or calling the plan's customer service line).

However, to provide additional support for out-of-pocket (OOP) cost transparency for Medicare Prescription Payment Plan participants, **CMS is proposing requirements for Part D sponsors to 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 the POS. These costs should be provided in the paid claim billing response on the Medicare Prescription Payment Plan COB transaction. In addition, Part D sponsors must ensure that pharmacies are prepared to provide this information to a participant at the POS**. CMS seeks comment on the proposal, including suggested processes for how Part D sponsors can provide this information to pharmacies in a manner that conforms with existing standards.

NCPA believes that Part D enrollees could benefit from additional OOP cost transparency if it addresses enrollees' demand and is implemented appropriately. This proposal was published less than one month into the program which is too early to assess whether this is an actual or merely anticipated need. The learning curve will be steep and there is no way at this point to measure dissatisfaction with OOP transparency at POS or default on payments to the Part D sponsor's Medicare Prescription Payment Plan. **NCPA recommends that any requirement to print the patient pay amount submitted to the Medicare Prescription Payment Plan take effect with the HIPAA NCPDP final rule[1] implementing the updated version of the retail pharmacy drug claim standard, The NCPDP Telecommunication Standard Implementation Guide Version F6, January 2020 and equivalent NCPDP Batch Standard Implementation Guide, Version 15, October 2017, in February 11, 2028.** It may be beyond the capability of the standard to convey any amount other than the patient pay amount submitted to the Medicare Prescription Payment Plan in real-time claims adjudication.

[1] See Administrative Simplification: Modifications of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) Retail Pharmacy Standards; and Modification of the Medicaid Pharmacy Subrogation Standard. Fed Reg Vol 89, No 240, 13 Dec 2024.

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 NCPA and other 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)." NCPA appreciates 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." Likewise, NCPA appreciates CMS providing this guidance. However, NCPA is disappointed that CMS did not seek to codify this guidance in the proposed regulation.

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. **NCPA encourages CMS to 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	

NCPA continues to call on CMS to 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 NCPA 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 on a daily basis.

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.[2] **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 a net rate of approximately 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. 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 pharmacies which is not workable for independent pharmacies**. 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 (see below), then NCPA 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 on a daily basis.**

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

[2]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.

sends the claim-level data elements to the Primary Manufacturer, and that it may result in MFP refund payments in excess of 14 days from time of claim submission by the dispensing entity[34]

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 MFP program.**

Further, 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.

Medication Therapy Management (MTM) in Part D

As medication experts, community pharmacists are critical to helping patients stick with and get the most out of their prescription drugs. Yet so much more can be done to improve medication adherence and achieve better health outcomes at lower overall costs. That is where medication therapy management, or MTM, services can play a vital role. NCPA believes that prevention is

[4] Medicare Drug Price Negotiation Program: Final 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 in 2026 and 2027, page 50.

the best medicine, and whether it is catching a medication error before it leads to a hospitalization or effective chronic disease management, MTM services present an opportunity to improve patient care while providing greater efficiencies within the healthcare system.

NCPA supports CMS proposal to expand the list of chronic conditions eligible for the Medication Therapy Management (MTM) Program to include all forms of dementia and not solely Alzheimer's Disease. **While the proposal list expansion is an important and good step, NCPA believes CMS should be more inclusive and add "neurodegenerative diseases," which is inclusive of dementias, like Alzheimer's disease, as well as other conditions that can drive polypharmacy and therefore reduced patient outcomes while living with devastating conditions that rob individuals of their mental facilities.**

NCPA supports the intent of these changes in that they will increase the number of beneficiaries eligible for MTM services. NCPA provides the additional comments below.

NCPA opposes further broadening coverage of MTM services without increasing payment to pharmacies, as doing otherwise will create an "unfunded mandate" on pharmacy. It is crucial that Part D plans increase payment for these services, as the existing payment rates are insufficient for pharmacies. If low payments continue, pharmacists will not invest the time in providing MTM services. Part D plans should recognize the role and value of the pharmacist and what they provide for MTM services and compensate them accordingly.

Furthermore, MTM payments should be commensurate with the care and expertise provided to the patient, not based on generating additional revenue for the plans and the PBMs. NCPA opposes Part D plans utilizing MTM to generate cost savings, such as formulary management tools that arbitrarily seek to move patients to the PBM's preferred formulary medication or transitioning to an extended-day supply of medication. Often patients that qualify for MTM are not ideal candidates for extended-day supplies, such as 90-day fills. Additionally, extended day supply can often lead to less clinically appropriate in-person, pharmacy-patient contact. MTM payments should emphasize the professional services and relationships that pharmacists provide to patients. MTM should not arbitrarily limit time and engagement with patients.

Additionally, NCPA supports CMS requiring Part D contracts to contain "any willing pharmacy" language to allow pharmacies to participate in MTM services. Such participation in MTM should be based on pharmacies' capacities and willingness to handle MTM cases. Plans should not be allowed to have performance scores, fees or payment withholds contingent on the number of MTM beneficiaries a pharmacy has.

REQUEST FOR INFORMATION ON ACCESS TO PHARMACY SERVICES AND PRESCRIPTION DRUGS
CMS seeks comment on what additional data or information to consider—such as reimbursement rates, underlying costs, steering, contracting terms, and other elements which may affect pharmacies' ability to continue providing Part D drugs to beneficiaries—to improve CMS' ability to protect beneficiaries' convenient access to Part D drugs consistent with current access standards at § 423.120.

NCPA provides the following comments on contracting terms, reimbursement, that CMS must address Part D plan sponsor/PBM payments to pharmacies for MFP drugs to ensure beneficiary access to MFP drugs, and Medicare retail pharmacy access standards:

Contracting terms

To alleviate the crisis that pharmacies are facing in Medicare Part D, NCPA asks CMS to provide regulations outlining Part D pharmacy contracting guardrails to ensure fair and common-sense contracting between Part D plans/PBMs and pharmacies. This is essential to eliminate abuses in contracting practices and processes from Part D plans and PBMs, and to ensure patient access to accurate information to select their pharmacy of choice.

Currently, some contracts between PBMs and Part D plans and pharmacies are opt-out contracts. Current PBM contract practices, as an example, require pharmacies to opt out of 2025 contracts as early as the end of 2023, creating confusion and uncertainty for pharmacies. **NCPA opposes opt-out contracts.**

First, under current CMS regulations, the Part D plans/PBMs are required to "[m]ak[e] 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"[5] [NCPA emphasis]. Interpreting existing regulation, it is logical that pharmacies should be offered contracts **each year**, pursuant to each contract year, no later than Sept. 15. If contracts are for more than one year, pharmacies find themselves in a relationship with plans/PBMs similar to the Eagles' "Hotel California," which they can never leave.[6] We believe that plans/PBMs are attempting to lock our members into multiple year contracts to game CMS' pharmacy access standards in Medicare Part D. We also believe that the Sept. 15 timeframe is insufficient for pharmacies to make decisions on which Part D pharmacy networks to join.

NCPA advises that CMS**:**

- **Revise the above regulation to state that plans/PBMs should make their standard contracts available upon request from interested pharmacies "no later than the first week of June of each year when Part D bids are due" to give pharmacies and their contracting entities (PSAOs) enough time to adequately analyze and negotiate a PBM contract (from the first week of June to Oct. 1 of each year).**
    - This will allow contracts to be finalized prior to Open Enrollment, which is from Oct. 15 through Dec. 7. This will ensure that pharmacy network status is correct in Medicare Plan Finder prior to the start of Open Enrollment.
- **Establish a regulation that on Oct. 1 of each year, Part D plans/PBMs must notify pharmacies or their contracting entities (PSAOs) of the pharmacies' network status for**

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

[6] See https://www.songlyrics.com/the-eagles/hotel-california-lyrics/.

the upcoming plan year, and the contracts themselves must be signed and finalized prior to Oct. 1 each year.

- **Include in the regulation that contracts must be offered anew every year, with payments and networks that cannot be changed without further negotiation and consent of all parties to the contracts.**
- **Include in the regulation 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**.**

CMS should also require that:

- Part D plans and PBMs must offer contracts[7] that:
    - Are opt-in contracts with at least 30 days to respond and that require the signatures of pharmacies or their contracting entities (PSAOs).
    - Are sent through certified mail or some trackable means, other than fax, with clear and reasonable deadlines for response.
    - Provide Bin/PCN/Group numbers, and network IDs to pharmacies or their representatives to identify:
        - Which networks will be used to serve specific beneficiary populations (i.e., MA, LIS, duals);
        - Which pharmacies are in network versus out of network; and
        - Which pharmacies are preferred so that pharmacies can evaluate and make an informed decision about the probable impact of each network on current business.
    - Do not move beneficiary lives from one network to another in the middle of a contract term (i.e., after the terms of a contract are agreed upon, or after the renewal of the contract).
- Plans/PBMs must not provide contracts that allow for unilateral changes by the plans/PBMs without the option for the pharmacies to have a minimum of 30 days before the changes go into effect to reject the changes.
- Part D plans and PBMs must:
    - Have accurate pharmacy network information loaded to Plan Finder prior to the beginning of Open Enrollment on Oct. 15.
        - In order to ensure that pharmacy networks are not being constantly adjusted and to provide beneficiaries with an acceptable degree of certainty that they are relying on credible information, it is imperative that there is a "hard stop" to when network information can be changed.
    - Offer an expedited remediation process to correct Plan Finder errors when pharmacies are inaccurately listed.

7 The term "contracts" consist of numerous documents, including a provider agreement, a provider manual, the Medicare Network Enrollment forms, and numerous addenda.

    - Explicitly state in Plan Finder if the pharmacy network information contains retail pharmacy, LTC pharmacy, or both.
- Part D plans and PBMs must be required to assign patients to a separate group identifier. The plan's unique group should correspond to a network the pharmacy belongs to and which is identified in a claim response using the NCPDP Telecommunication field 545-2F Network Reimbursement ID, and NCPDP 835 Pharmacy Remittance Template. Requiring this additional level of detail will provide greater clarity to the pharmacy provider as to network participation, and ensure that claims reconciliation and performance measure tracking and other offsets are correct.
- Part D plans and PBMs must only tie one group number to one contract, and may not assign one group number to many contracts. This would increase transparency for pharmacies and distinguish different plans.
- Part D plans and PBM contracts must not have unlimited revocation policies that:
    - Allow termination from a network without requiring a materiality standard, and pharmacies must be allowed to undergo an attainable independent appeal process prior to termination. For example, there should be no requirement to put in escrow $50,000 to arbitrate an issue, or pay for a PBM counsel's time if the pharmacy loses on the appeal.
    - Do not clearly communicate the reason for termination.
- Part D plans and PBM contracts must have resolution terms that have due process rights that make it possible for a pharmacy to dispute the actions of the PBM without undue costs and hardships associated with the dispute resolution terms.
- Part D plans and PBM contracts must have standard turnaround times of 24-48 hours on claim disputes, especially in cases where pharmacy participation has been established and the claim is being processed correctly.
- Part D plans and PBM contracts must have a simple process to allow and enable a change of ownership, and without disrupting patient access to that pharmacy.
    - Note: PBMs give themselves the right to terminate an independent pharmacy as a matter of right upon a change of ownership. This devalues a pharmacy and leads to many pharmacies having no choice but to sell to a pharmacy within the PBM's vertically integrated structure, or to close.
    - Change in ownership should not trigger network termination or another change in network status, or require additional recredentialling or other administration fees to transition the pharmacy to the change in ownership.
        - Note: An exception can be made for new owners on the Medicare excluded providers list.
- Part D plans and PBMs must not have the ability to remove a pharmacy from the network due to issues from another pharmacy under common ownership.
    - Note: An exception can be made for new owners on the Medicare excluded providers list.

Reimbursement

Currently, PBM reimbursement does not cover a pharmacy's costs (including acquisition, dispensing, and other related care services) and puts pharmacies under immense financial pressure and in unpredictable financial situations with disturbing consequences, which may include forcing pharmacies to cut back on staff, operations, and even to shut their doors permanently in some cases. Pharmacies have been, and remain, essential team players across the patient care continuum. However, the current environment where PBMs continue to game the healthcare system at the expense of patients and pharmacies across America has left pharmacies and pharmacies providers in a crisis and on the precipice of becoming non-existent.

The FTC recently published a second interim staff report on the PBM industry's impact on specialty generic drugs in the Medicare and commercial market – citing atrocities such as price hikes on cancer drugs, anticoagulants, and more. The latest findings highlight numerous marked up specialty generic drugs dispensed by the 'Big 3 PBMs' and their affiliated pharmacies by thousands of percent and others by hundreds of percent. As well as significant patient steering of the highly profitable prescriptions to their affiliated pharmacies. For example, of the specialty drugs analyzed that were dispensed at affiliated pharmacies, 63% were reimbursed at rates marked up by more than 100% over the estimated National Average Drug Acquisition Cost (NADAC) and 22% were increased by greater than 1,000%. Additionally, the Big 3 PBMs generated more than $7.3 billion in revenue for dispensing drugs in excess of NADAC on these specialty generic drugs over the 5-year study period (between 2017 and 2022).

NCPA encourages CMS to promulgate rules that would stop these harmful practices by ensuring reasonable and relevant reimbursement for our pharmacies that would in turn result in fewer access barriers for the families that rely on them. Additionally, CMS should consider requiring PBMs to ensure network parity between affiliated and unaffiliated pharmacies and require that the final reimbursement to pharmacies after any reconciliation for a prescription drug is no less than NADAC plus a commensurate professional dispensing fee. By taking on these issues, pharmacies can receive total and fair compensation for their patient care services and a more predictable pharmacy reimbursement rate.

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 CMS 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)."[8] 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.[9] **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[ ]."[10] *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."[11] 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,"[12] 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 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.

[8] 42 U.S.C. § 1320f-2(a)(1) (NCPA emphasis added); *accord id.* § 1320f-2(a)(2), (a)(3).
[9] *Id.* § 1320f(c)(3); *see also id.* § 1320f-3 (describing the negotiating process for the "maximum fair price").
[10] *Id.* § 1320w-102(d)(1)(B).
[11] *Id.* § 1320w-102(d)(1)(D).
[12] *Id.* § 1320w-102(d)(1)(D).

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.

Retail Pharmacy Access Standards

Under the Prescription Drug Benefits Manual, Chapter 5: Benefits and Beneficiary Protections:

> **50.1 - Retail Pharmacy Access (Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)** [13]
>
> Part D sponsors must secure the participation in their pharmacy networks of a sufficient number of pharmacies that dispense drugs directly to patients (other than by mail order) to ensure convenient access to covered Part D drugs by Part D plan enrollees. CMS convenient access rules require Part D sponsors to establish pharmacy networks in which:
>
> • In urban areas, at least 90 percent of Medicare beneficiaries in the Part D sponsor's service area, on average, live **within 2 miles** of a retail pharmacy participating in the sponsor's network;
>
> • In suburban areas, at least 90 percent of Medicare beneficiaries in the Part D sponsor's service areas, on average, live **within 5 miles** of a retail pharmacy participating in the sponsor's network; and
>
> • In rural areas, at least 70 percent of Medicare beneficiaries in the Part D sponsor's service area, on average, live **within 15 miles** of a retail pharmacy participating in the sponsor's network. [NCPA emphasis]

NCPA advises CMS to revise the above Retail Pharmacy Access Standards and instead use "within 1 mile" for urban areas, "within 2 miles" for suburban areas, and "within 10 miles" for rural areas. But for census tracts where there is a high percentage of low vehicle ownership, regardless of if urban, suburban, or rural, NCPA advises that CMS use "within 0.5 miles." Thresholds were determined by industry experts, the USC-NCPA Pharmacy Access Initiative,[14] and align with peer reviewed studies.

[13] See Prescription Drug Benefit Manual Chapter 5: Benefits and Beneficiary Protections. CMS.
[14] See https://ncpa.org/usc-ncpa-pharmacy-access-initiative.

ADDITIONAL COMMENTS TO CMS RELATED TO PART D PLANS AND RECOMMENDATIONS FOR FUTURE RULEMAKING

Access to Pharmacists' LTC Pharmacy Services for Home-Based Patients with an Institutional Level of Care Need

NCPA commends CMS's focus on holding MA and Part D plans more accountable for delivering and ensuring access to high-quality care. However, NCPA is disappointed that long-term care (LTC) pharmacy at home services were not included in this proposed rule, despite being a critical area of care delivery that requires similar support. **To this end, NCPA urges CMS to use the final rule as an opportunity to ensure beneficiary access to LTC pharmacy services in their homes, leveraging the agency's existing authority under the Medicare statute.**

NCPA reminds CMS that such action falls within its statutory authority under the Medicare statute. The convenient access standard established under 42 U.S.C. §1395w-104(b)(1)(C)(i) requires Medicare Part D prescription drug plans (PDPs) to ensure convenient access to LTC pharmacies for Part D enrollees. Importantly, this requirement is not restricted to beneficiaries residing in LTC facilities but encompasses all Part D beneficiaries. NCPA urges CMS to leverage this authority in the final CY 2026 MA and Part D rule by requiring expanded access to LTC pharmacy at-home services.

In recent years, a significant shift, largely driven by patient preferences, toward delivering LTC in home and community-based settings has transformed care for seniors and individuals living with disabilities and multiple chronic conditions. Central to the success of effective home-based care are LTC pharmacies, these specialized pharmacies are uniquely equipped to fill the needs of patients with complex medical conditions living in their homes and communities by being available 24 hours a day, seven days a week, and providing around-the-clock access to support. By being easily accessible and able to assist medically complex patients, LTC pharmacies ensure that people are on the right medications and at the right dose, promote medication adherence, consult with family members and caregivers, offer access to and administration of vaccines, and more.

CMS has previously recognized the vital contributions of LTC pharmacies. In December 2021, the agency issued guidance clarifying that higher dispensing fees for pharmacies providing LTC services in non-institutional settings, including patients' homes, are permissible under Medicare.[15] While this guidance was a meaningful step, its impact has been limited and a significant disparity still exists in the level of support provided to Medicare beneficiaries living in the community in need of LTC pharmacy services. Many Medicare PDPs have not adjusted their reimbursement structures to adequately support LTC pharmacy services delivered in home and community settings. As a result, patients with LTC needs living at home often face barriers accessing these critical services, despite having care needs comparable to those residing in skilled nursing facilities.

[15] See Part D Dispensing Fees and Enrollees with Institutionalized Level of Care Needs. CMS 15 Dec 2021.

As CMS works to strengthen beneficiary protections and access to care through this rule, NCPA urges CMS to explicitly require MA and Part D plans to expand access to LTC pharmacy services in homes. As the trend toward home-based care continues to grow, it is important, now more than ever, that CMS turn its focus to eliminating barriers to LTC pharmacy services for all Medicare beneficiaries with complex medical needs, regardless of where they reside. Given the lack of meaningful response from plans following the 2021 guidance, stronger and more explicit regulatory action is necessary.

Expanding access to LTC pharmacy services at home would not only enhance health outcomes but also generate significant cost savings. Preventable hospitalizations and emergency room visits associated with adverse drug events cost the U.S. roughly $500 billion annually.[16][17] By reducing adverse drug events, improving medication adherence, and ensuring continuity of care, LTC pharmacies play a critical role in mitigating these costs while enabling beneficiaries to receive necessary care outside of a traditional facility setting.

The reductions in pharmacy reimbursement as a result of the MDPN program will likely affect LTC pharmacies even more. For LTC pharmacy especially, very high inflationary costs have made it very difficult to operate and provide services and medications that residents require. When other businesses exhibit this type of increase in costs, they raise their prices to continue to survive. But pharmacies cannot as they are driven by reimbursement that the payer chooses without allowance for increase in pharmacy operational costs. In pharmacy, PBMs determine payment. The LTC facility must be contracted with a pharmacy that is designated as the primary pharmacy provider to supply all physician ordered medications. If the LTC pharmacy elects to not stock the MDPN Program medications, it will drastically reduce accessibility of these medications to the resident and thus severely decrease resident care and outcomes. If additional burdens like this continue to be placed on LTC pharmacies, there will be continued pharmacy closures, ultimately reducing resident/patient care.

Additionally, without action on reforming the MDPN Program, patients, especially seniors and those with disabilities could go without their medication. Given the rapid rate at which the IRA implementation is occurring, we wanted to reach out and share our concerns. We urge CMS to make the above requested changes to the proposed rule in order to identify a method that will ensure the MDPN program is workable for pharmacists and patients.

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."[18] In the proposed rule, CMS certifies that the rule will not have a significant impact on

[16] Medicine Spending and Affordability in the U.S.: Understanding Patients' Costs for Medicines. Iqvia 04 Aug 2020.

[17] Watanabe JH, McInnis T, Hirsch JD. Cost of Prescription Drug–Related Morbidity and Mortality. Annals of Pharmacotherapy. 2018;52(9):829-837. doi:10.1177/1060028018765159.

[18] See RFA § 605(b), available at: The Regulatory Flexibility Act – Office of Advocacy.

a substantial number of small entities, and defines "substantial" as "3 to 5 percent or more of the affected entities' costs."[19] 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."[20]

In the proposed rule, CMS provides the following small entities analysis for pharmacies and other stakeholders:

> We next examine in detail each of the other stakeholders and explain how they can bear cost. Each of the following are providers (inpatient, outpatient, or pharmacy) that furnish plan-covered services to plan enrollees for: (1) Pharmacies and Drug Stores, NAICS 446110; (2) Ambulatory Health Care Services, NAICS 621, including about 2 dozen sub-specialties, including Physician Offices, Dentists, Optometrists, Dialysis Centers, Medical Laboratories, Diagnostic Imaging Centers, and Dialysis Centers, NAICD 621492; (3) Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, and Specialty Hospitals; and (4) SNFs, NAICS 623110.
>
> If these providers are contracted with the plan, their aggregate payment for services is the sum of the enrollee cost sharing and plan payments.

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.

Stakeholders like NCPA cannot determine this information given the limited data given by CMS as compared to the agencies' estimate of small pharmacies' revenue or other reasonable metric. This is the only way to determine if the certification is justifiable. **Therefore, NCPA argues 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.**

NCPA asserts that this is an insufficient factual basis for certification that the proposed rule will not have a significant impact on a substantial number of small entities, in this case, independent pharmacies. According to the 2024 NCPA Digest, nearly all revenue (90 percent) of our membership comes from behind the counter, and 35 percent of prescriptions in independent community pharmacies were covered by Medicare Part D.

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

Additionally, the MDPN Program specifically will have a significant economic impact on pharmacies. As stated above, NCPA's analysis of 5,200 community pharmacies to determine the effect of the MDPN Program 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. 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 MDPN 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. NCPA will be releasing a study showing updated IRA MDPN Program impacts on community pharmacy in the near future and will share that study with CMS once available. NCPA continues to be vocal about our concerns, and has published a survey on the impact of the MDPN Program on our members. Our survey, conducted in January 2025, indicated that approximately 61 percent of independent pharmacists are strongly not considering stocking one or more drugs with prices negotiated under Medicare Part D, while an additional approximately 33 percent have already decided not to stock one or more of the drugs, which would all but guarantee that CMS' attempt to reduce prescription drug prices will fail.

Further, CMS is requiring pharmacies to participate in the MDPN Program as a condition for participating in Medicare Part D generally. **NCPA does not believe that CMS has the authority to tie participation in Part D as a whole with participation in the MDPN Program. NCPA requests formal explanation as to why it believes it has such authority.** That being said, because 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 MDPN 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 withdraw the certification and perform an Initial Regulatory Flexibility Analysis that would theoretically include information on the cost impacts to small pharmacies.** This would allow interested stakeholders like NCPA to determine if the impact assumptions are reasonable and whether small pharmacies can withstand the rule's requirements to not exceed CMS' 3-5% revenue threshold for significance under the RFA.

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

Report for January 2025 Survey of Independent Pharmacy Owners/Managers

Executive summary:

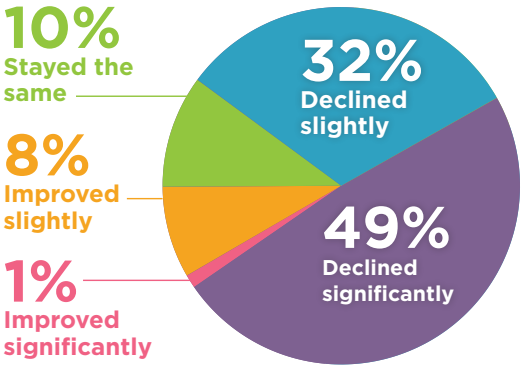
NCPA frequently surveys its members on key issues and market conditions that affect their businesses. The data we collect informs our advocacy and education programs. Between January 14 and January 24, 2025, NCPA surveyed 8,000 pharmacy owners and managers on the Medicare Part D Inflation Reduction Act Medicare Drug Price Negotiation Program.

Below is a summary of key findings:

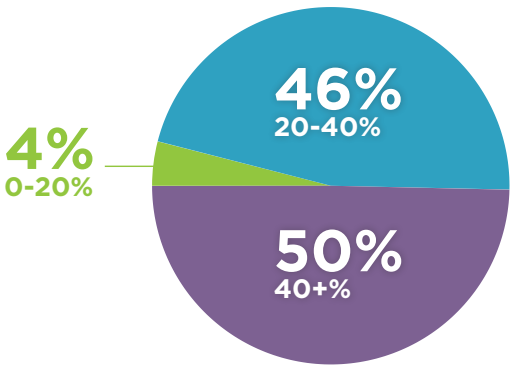
- 93.2 percent of independent pharmacists are considering not stocking, or have already decided not to stock, one or more of the first 10 drugs listed in the Medicare Drug Price Negotiation Program.
- 60.4 percent of independent pharmacists are considering not stocking one or more of the first 10 drugs listed in the Medicare Drug Price Negotiation Program.
- 32.8 percent of independent pharmacists have already decided not to stock one or more of the drugs listed in the Medicare Drug Price Negotiation Program.
- 96.5 percent of independent pharmacists said PBM and plan reimbursement for Medicare Part D threatened the viability of their business.
- 40.8 percent of independent pharmacists said they were paid below the National Average Drug Acquisition Cost (NADAC) on more than 40 percent of the prescriptions they filled for Medicare Part D patients.
- 29.2 percent of independent pharmacists said they were paid below NADAC on 50 percent or more of the prescriptions they filled for Medicare Part D patients.
- 80.3 percent of independent pharmacists said the financial health of their business declined in 2024.
- 48.6 percent of independent pharmacists said the financial health of their business declined significantly in 2024.
- 30.3 percent of independent pharmacists said they are considering closing their business in Calendar Year 2025.

100 Daingerfield Road
Alexandria, VA 22314-2888
703.683.8200 PHONE
703.683.3619 FAX

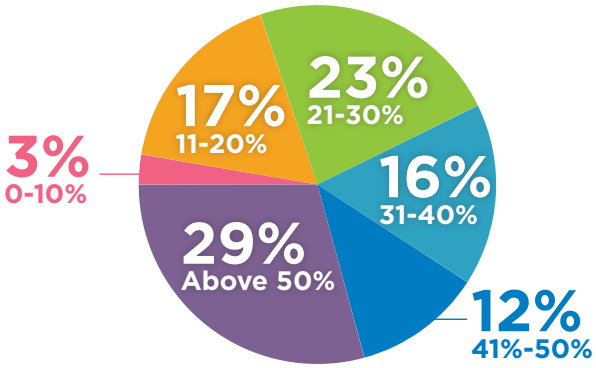
1. In 2024, how did your pharmacy's overall financial health change?



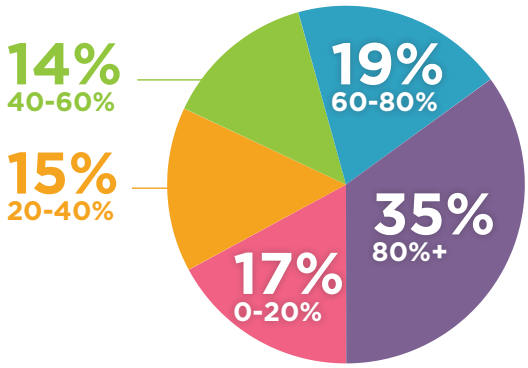
2. In 2024, what percentage of your business was Medicare Part D by prescription volume?



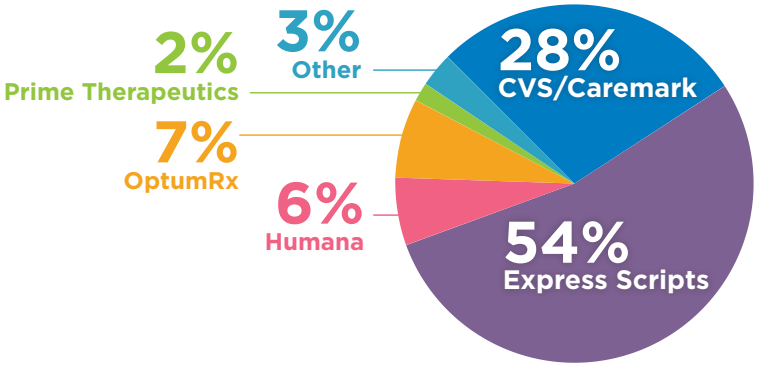
3. In 2024, what percentage of your Part D prescriptions are being paid below the National Average Drug Acquisition Cost (NADAC)?



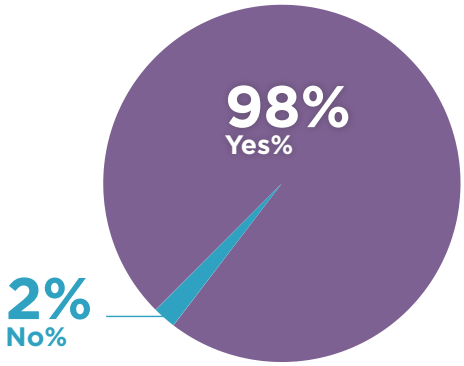
4. In 2024, what percentage of your Part D prescriptions were paid below the National Average Drug Acquisition Cost (NADAC) + $10?



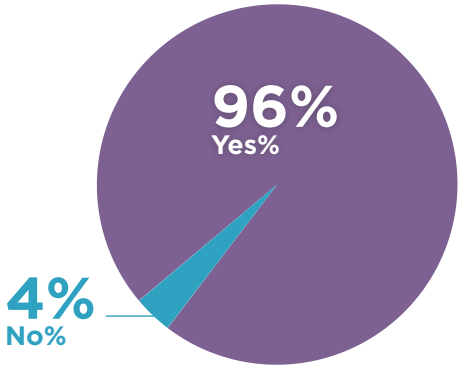
5. In 2024, which PBM caused you the most Medicare Part D financial stress?



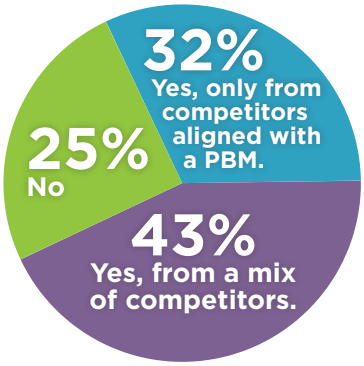
6. In 2024, did patients express confusion or dissatisfaction with PBM-related policies (e.g., restricted formularies, mandatory mail-order)?



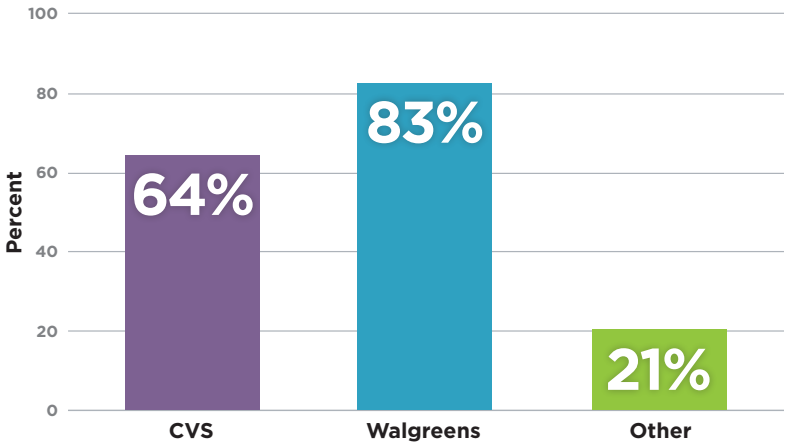
7. In 2024, did PBM and plan reimbursement for Medicare Part D threaten the viability of your business?



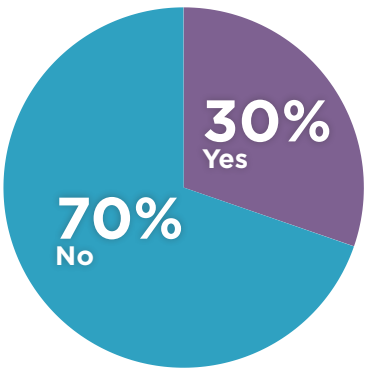
8. In 2024, did you receive letters from competitors asking you to sell your pharmacy?



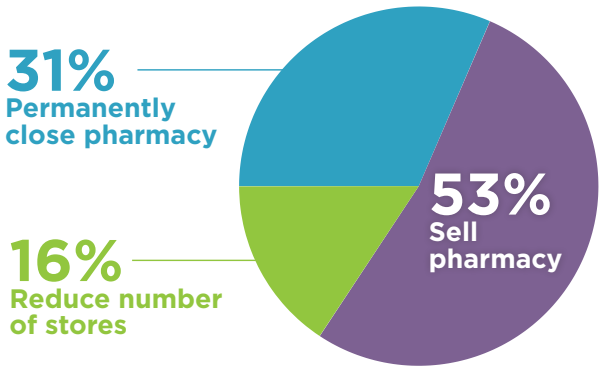
9. If yes, who has sent the letters?



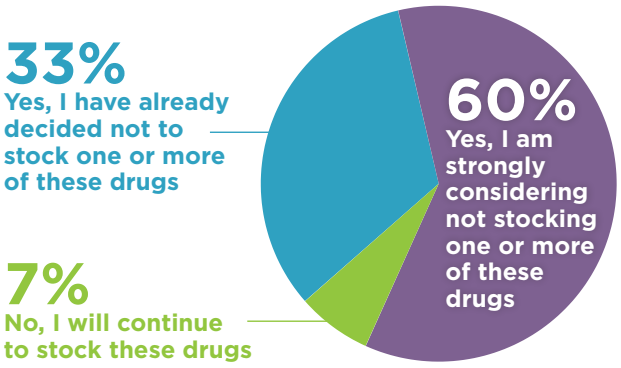
10. Are you considering closing your business within this calendar year?



11. If yes, do you plan to permanently close pharmacy, sell pharmacy, or reduce number of stores?



12. CMS recently released the negotiated prices of the first 10 drugs in the Medicare Drug Price Negotiation Program, which begins Jan. 1, 2026. Under this program, pharmacies will likely be waiting over 30 days for the manufacturer to refund payments, and the average pharmacy will have to float over $27,000 every month waiting to be made whole from manufacturer refund payments. Does this affect your decision to continue to stock these drugs?



13. What is your experience with the rollout of the Medicare Prescription Payment Plan (MPPP)? business?