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Sent via e-mail to chiquita.brooks-lasure@cms.hhs.gov

February 27, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Re: Community Pharmacy Concerns with CMS' Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency Final Rule

Administrator Brooks-LaSure:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to CMS on ongoing concerns regarding implementation of CMS' *Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency Final Rule*.

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care settings. Together, our members represent a $94 billion healthcare marketplace, employ 230,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

Ongoing Independent Pharmacy Cash Flow Concerns

NCPA is thankful to CMS for its letter in December 2023 to insurers and pharmacy benefit managers (PBMs) stating that pharmacies are continuing to have cash flow concerns in Medicare Part D and encouraging Part D plans sponsors and their PBMs to make necessary cash flow arrangements with network pharmacies in preparation for DIR changes in effect Jan. 1, 2024. NCPA is also thankful that the memo encouraged PBMs to engage in fair practices with all pharmacies (not just those owned by PBMs) and stated that CMS is closely monitoring plan compliance with CMS network adequacy standards and other requirements.

However, CMS' memo has done very little to change PBM practices. Cash flow for many pharmacies remains in a precarious state, leading to dire concerns for beneficiary access. Our members continue to experience significant harm from egregious Medicare Part D PBM practices. NCPA fielded a member survey from Friday, Feb. 16 to Monday, Feb. 26, to assess the impact of DIR changes within the Medicare program. Over 800 pharmacy owners responded. We have attached the survey results to this letter.

According to our new survey, *32 percent of all respondents say they are considering closing their doors in 2024 because of the cash crunch in Medicare.* Ninety-three percent say they may drop out of Medicare Part D in 2025 if this years' experience continues, which would decimate patient access across the country, especially for senior citizens. More than half of all respondents say Medicare Part D prescriptions account for 40 percent or more of their business. According to the survey, 99 percent of respondents say their prescription reimbursements have gone down since the rule took effect on Jan. 1. *More than half say that insurance plans and their PBMs are reimbursing pharmacies less than the cost to purchase the drug for at least 3 of every 10 prescriptions they fill.* Over half of pharmacy owners say they are losing money on over 60 percent of the Part D prescriptions they fill when the other costs of running a pharmacy, like rent, taxes, utilities and payroll, are added in. When asked which PBM is causing the most financial stress in the Medicare Part D program, almost half identified Express Scripts, with CVS/Caremark coming in at 35 percent.

Additionally, pharmacy "deserts" are proliferating in the country, especially in urban and rural areas. In 2023, there were over 300 independent pharmacy net closures — almost one less pharmacy open for patients a day — and there are approximately 2,200 fewer retail pharmacies than there were four years ago. Increased vertical and horizontal consolidation of PBMs and health plans has caused severe inequities to pharmacies and Medicare Part D beneficiaries alike. These are startling developments. Action is needed to ensure independent pharmacies can continue to serve their patients.

CMS Enforcement is Required

CMS not only has an obligation to enforce applicable laws, but CMS also has clear authority to act regarding the Any Willing Pharmacy Law. The "non-interference clause" does not prevent CMS from establishing guidelines on the assessment or calculation of reimbursement rates, nor does it restrict CMS from mandating that reimbursements be "reasonable."

According to CMS itself, "since the statute requires [CMS] to regulate many aspects of how drug costs are made available and displayed to beneficiaries and treated in Part D bidding and payment processes, it is clear that [CMS has] an important role to play in establishing rules for consistent treatment of drug costs in the program."[1] CMS has also stated that "[i]t is within [CMS'] authority and appropriate for CMS to provide additional clarification of these regulatory

[1] 79 FR 1918 at 1972.

requirements when necessary to help ensure they are being effectuated in accordance with the statutory requirement."[2]

CMS is authorized to take these additional and necessary steps to address egregious contract abuses by PBMs and plan sponsors, in line with the statutory mandate that CMS ensure PBMs and plan sponsors offer a standard contract with "reasonable and relevant" terms and conditions of participation whereby any willing pharmacy may participate.[3]

CMS has not provided significant clarification and enforcement around the concept of "reasonableness and relevance" of terms and conditions for participation in PDP networks. However, the Secretary of Health and Human Services (the "Secretary") possesses the authority to regulate and enforce Medicare and Medicaid rules.[4] Furthermore, the Medicare Act empowers CMS to establish rules and regulations necessary for the effective administration of insurance programs.[5] This distinct authority vested in the Secretary by 42 USCS § 1395hh(a) compels the agency to uphold the specific directives of 42 CFR 423.505(b)(18), thereby underscoring CMS' obligation to enforce these regulations to ensure that PDP sponsors, including PBMs, provide "reasonable and relevant" terms and conditions in their contracts.

Accordingly, NCPA implores CMS to thoroughly investigate PBM reimbursement practices, which impose rates on community pharmacy providers that contravene the principles of reasonableness.[6] Given the authority vested in the Secretary by 42 U.S.C.S. § 1395hh(a) to regulate and enforce Medicare and Medicaid laws, it is imperative that CMS act to ensure PBMs' reimbursement terms are in compliance with the specific requirements of 42 CFR 423.505(b)(18).

NCPA urges CMS not to depend solely on network adequacy assessments but to proactively ensure that reimbursements are "reasonable and relevant." Despite CMS' recent recognition of issues with low reimbursement rates in its Dec. 14, 2023, communication to PDPs and PBMs, the guidance provided has not resulted in any meaningful change in PBM practices or reimbursements. More decisive and direct action is required from CMS, which is responsible for enforcing program rules. This should involve clear directives that close the gaps that allow PBMs and plans to impose unreasonable terms and conditions. This focused approach is essential to maintain equitable healthcare, especially in determining reimbursements. Unless CMS acts quickly, NCPA fears beneficiary access to pharmacy services will be increasingly threatened, with independent pharmacies being forced to close.

[2] 83 FR at 16590.
[3] See 42 C.F.R. § 423.505(b)(18).
[4] 42 U.S.C.S. § 1395hh(a).
[5] § 1395hh(a)(1).
[6] See 42 U.S.C.S. § 1395w-104(b), et seq.

We have attached our membership survey results to this letter. NCPA appreciates the opportunity to share with CMS our comments and suggestions. Should you have any questions or concerns, please feel free to contact me at doug.hoey@ncpa.org or my colleague Ronna Hauser at ronna.hauser@ncpa.org.

Sincerely,

B. Douglas Hoey
Chief Executive Officer
National Community Pharmacists Association

Cc: The Honorable Cathy McMorris Rodgers, Chair, House Energy and Commerce Committee
The Honorable Frank Pallone, Ranking Member, House Energy and Commerce Committee
The Honorable Jason Smith, Chair, House Ways & Means Committee
The Honorable Richard Neal, Ranking Member, House Ways & Means Committee
The Honorable James Comer, Chair, House Oversight & Accountability Committee
The Honorable Jamie Raskin, Ranking Member, House Oversight & Accountability Committee
The Honorable Ron Wyden, Chair, Senate Finance Committee
The Honorable Mike Crapo, Ranking Member, Senate Finance Committee

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Report for February 2024 Survey of Independent Pharmacy Owners/Managers

Executive summary:

The National Community Pharmacists Association surveyed roughly 10,000 independent pharmacy owners and managers between Feb. 16-26, 2024. The survey produced approximately 815 responses. Questions focused on independent pharmacy's financial status related to the Jan. 1, 2024, implementation of the CMS DIR rule, requiring all pharmacy price concessions (aka DIR fees) to be assessed at point of sale. NCPA has been educating members to prepare for a possible "DIR hangover" period, where lower point-of-sale Part D payments coupled with 2023 DIR fees could lead to financial stress for independent pharmacies.

Key findings:

- The reimbursement strategies of government programs significantly affect the financial viability of independent community pharmacies.
  - More than half of all respondents (51 percent) say Medicare Part D prescriptions account for 40 percent or more of their business.
  - For 45 percent of respondents, Medicare Part D comprises 20-40 percent of their business and for 4 percent, it accounts for up to 20 percent.
- Since the CMS DIR rule took effect on Jan. 1, 2024:
  - Nearly 70 percent of respondents say they now know at the point of sale the amount of pharmacy price concessions (aka DIR fees, therefore their lowest possible reimbursement) they are being charged.
  - Almost all (99 percent) have experienced a reduction in the reimbursed dollar amount of prescribed medications at the point of sale.
  - More than half say that insurance plans and their PBMs are reimbursing pharmacies less than the cost to purchase the drug for at least 3 of every 10 prescriptions they fill.
  - Over half of pharmacy owners say they are losing money on more than 60 percent of the Part D prescriptions they fill when other costs of running a pharmacy, like rent, taxes, utilities and payroll, are added in.
- 85 percent confirm that the DIR hangover has threatened the viability of their business.
- 32 percent say they are considering closing their business within this calendar year.
- 93 percent say they will be less willing to participate in Medicare Part D pharmacy networks next year if their 2024 experience in Medicare Part D continues.
- To attempt to address the DIR hangover:
  - 42 percent of respondents say they secured a line of credit to assist with the DIR hangover. 57 percent of them have had to tap into it.
  - 92 percent are taking steps to protect their business against insolvency. Large numbers report minimizing on-hand inventory of high-dollar drugs, cutting staff, dipping into pharmacy savings, and dipping into personal savings.
- When asked which PBMs are causing the most Medicare Part D financial stress, Express Scripts and CVS/Caremark were the top two.

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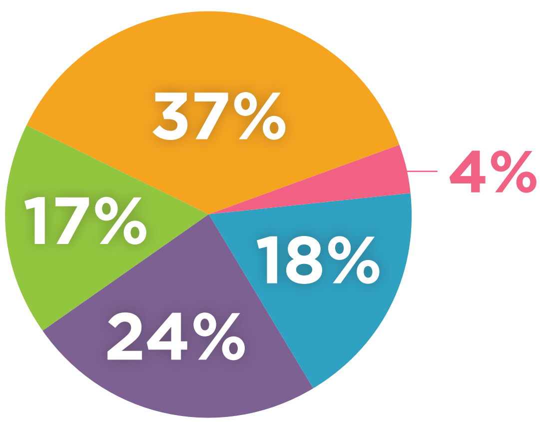
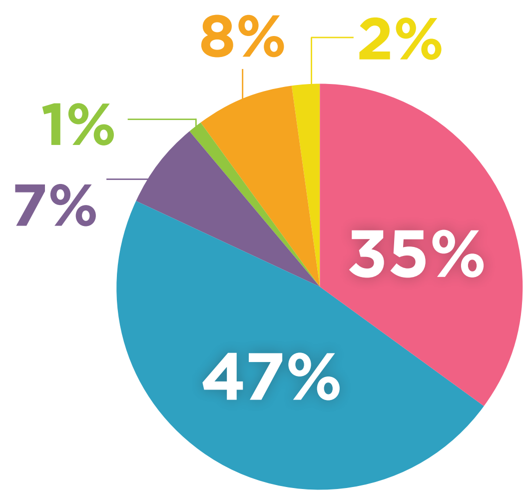
1. What percentage of your Part D prescriptions are being paid below the National Average Drug Acquisition Cost (NADAC)?

- 0-10%
- 10-20%
- 20-30%
- 30-40%
- 40%+

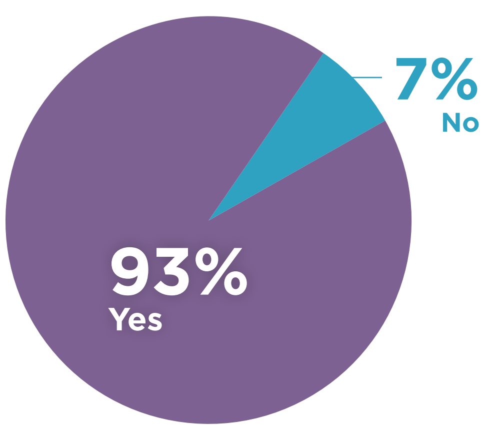


2. Which PBM is causing you the most Medicare Part D financial stress?

- CVS/Caremark
- Express Scripts
- Humana
- MedImpact Healthcare Systems
- OptumRx
- Prime Therapeutics



3. If your 2024 experience in Medicare Part D continues, will you be less willing to participate in Medicare Part D pharmacy networks in 2025?



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