Submitted electronically to: chiquita.brooks-lasure@cms.hhs.gov and meena.seshamani@cms.hhs.gov

Sept. 4, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
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Meena Seshamani, MD, PhD
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Re: Regulating fair and common-sense contracting guardrails between Part D plans/PBMs, and pharmacies

Administrator Chiquita Brooks-LaSure and Deputy Administrator Seshamani,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to CMS asking it to regulate fair and common-sense contracting guardrails between Part D plans/PBMs and pharmacies.

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

Medicare Part D makes up 36 percent of the average independent pharmacy's business. Thus, contractual terms that reimburse pharmacies less than the pharmacy's costs to acquire medications, dispense prescriptions, and earn a reasonable profit are having a disproportionately negative effect on the solvency of pharmacies. Pharmacy deserts are proliferating in the country, especially in some of the areas where our country's most socially vulnerable populations reside. In 2023, there were over 300 independent pharmacy *net* closures — in other words, *every day*

patients have one less independent pharmacy from which to choose. Additionally, there are approximately 2,200 fewer retail pharmacies than there were four years ago — an overall 4 percent decrease of pharmacy choices for patients — and that pattern of pharmacy closures is increasing. Based on the most recent month available, April 2024, independent pharmacy net closures continue at approximately 1.8 stores per day. Increased vertical consolidation of PBMs and health plans has caused severe inequities to pharmacies and Medicare Part D beneficiaries alike. These are startling developments.

In fact, one alarming result from a recent survey we conducted of our members was that *32 percent of all respondents say they are considering closing their doors in 2024 because of the cash crunch in Medicare.* **And, perhaps, most disturbing of all, 93 percent of respondents said they may drop out of Medicare Part D in 2025 if this year's experience continues, which would decimate patient access across the country, especially for senior citizens.**

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"[1] [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.[2] 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.

Therefore, NCPA requests 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**

[1] 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.
[2] See https://www.songlyrics.com/the-eagles/hotel-california-lyrics/.

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 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[3] 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:

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

    - 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.
    - 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.

Conclusion

NCPA thanks CMS for the opportunity to provide feedback to preserve the integrity of the Medicare Part D program, and we stand ready to work with the agency to offer possible solutions and ideas. Please let us know how we can assist further. Should you have any questions or concerns, please feel free to contact Ronna Hauser, senior vice president of policy and pharmacy affairs, at ronna.hauser@ncpa.org or (703) 838-2691, and Steve Postal, senior director of policy and regulatory affairs, at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

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