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May 29, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4207–NC
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Medicare Program; Request for Information on Medicare Advantage Data [CMS–4207–NC]

Dear Administrator Brooks-LaSure:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to CMS on its *Request for Information on Medicare Advantage Data*.

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 (LTC) 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. NCPA submits these comments on behalf of both community and LTC independent pharmacies.

NCPA appreciates the opportunity to comment on this timely RFI as vertical integration, under-cost pharmacy reimbursement, increased pharmacy fees and other behaviors of the larger payers and pharmacy benefit managers (PBMs) are in full effect and continue to jeopardize patient access to total pharmacy care as well as inflate and manipulate costs for patients, taxpayers, and providers and pharmacies throughout the care delivery supply chain. Multiple horizontal[1] and vertical[2] mergers by and between payors, PBMs and pharmacies over the past 20 years have resulted in a highly concentrated market structure that allows PBMs to "exercise

[1] "PBM Mergers – Acquisitions – Contracts Timeline." NCPA. Accessed May 15, 2024. https://ncpa.org/sites/default/files/2023-03/pbm-mergertimeline-2023.pdf.

[2] "Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, Retail Pharmacies, Mail-Order Pharmacies and Providers, 2024." NCPA. Accessed May 15, 2024. https://ncpa.org/sites/default/files/2024-05/VerticalBusiness_2024_040324.pdf.

undue market power."[3] Three vertically integrated companies[4] now control access to approximately 80%[5] of all prescriptions filled in the United States. Each PBM is vertically integrated upstream with insurers and downstream with their own pharmacies. These transactions resulted in national and local monopolies that the PBMs exploit to their advantage.

Consolidation harms small businesses, competition, and consumers alike. Working with researchers at the University of Southern California's Schaeffer School of Pharmacy, NCPA and USC found that in 2020, 25% of all neighborhoods in the U.S. are pharmacy shortage areas (approx. 81 million people), accounting for 36.7% of the low-income population. In the first 20 years of the 21st Century, neither the FTC nor the DOJ challenged a single transaction in this market with anything more substantial than targeted divestitures of retail stores. Many transactions did not even receive a Second Request. Too often, merger reviews were constrained by a narrow template that resulted in regulators clearing mergers despite those mergers substantially lessening competition, raising prices at the point of sale to consumers, and diminishing access and innovation.

In the PBM-pharmacy industry, "concentration" reflects the number and relative size of PBMs competing to offer access to insured lives, while simultaneously competing with independent pharmacies to fill and dispense prescriptions to those same beneficiaries. Retail pharmacy suffers from bad actors that create closed-loop or "walled gardens," where the dominant actors establish a market and control access to the market of insured lives that are managed by their vertically integrated PBM through rules and fees that disadvantage competitors. PBMs create and exploit these walled gardens through their pharmacy networks. The PBMs also further consolidate control of the market with take it or leave it network contracts with unconscionable terms that offer below cost reimbursement, are wrought with junk fees, and leave access to dispute resolution unattainable to most.

Through vertical consolidation, PBMs and their affiliated pharmacies control access to customers and have a tremendous ability and a number of incentives to weaken and exclude its rivals, who are our members. That consolidation has also hurt consumers.

From a consumer perspective, we have seen PBMs control market access using competitively sensitive information that they extract from their network pharmacies and through their consolidated entities. While there has been a tremendous amount of horizontal consolidation in the PBM industry, the vertical consolidation is equally troubling due to the data the consolidated entities now have access to, which further enables the ability of the vertically integrated entity to foreclose competitors. For example, UnitedHealth Group's acquisition of Change Healthcare gave UnitedHealth Group access to Change's eRx network (which is a "switch" in pharmacy parlance). It is now part of OptumInsight. The switch contains an inordinate amount of data that

[3] Council of Economic Advisors, Reforming Bio Pharmaceutical Pricing at Home and Abroad (February 2018) at 10.
[4] Aetna-CVS-Caremark; UHG-Optum; Cigna-ESI.
[5] Fein, Adam. "The Top Pharmacy Benefit Managers of 2023: Market Share and Trends for the Biggest Companies—And What's Ahead." Drug Channels. April 9, 2024. https://www.drugchannels.net/2024/04/the-top-pharmacy-benefit-managers-of.html.

has both medical and pharmaceutical implications for insurability and healthcare utilization.[6] It also contains sensitive information of UnitedHealth Group's competitors. A switch possesses data that gives a comprehensive view of patients' claims, bills, payments, and pharmacy interactions across nearly all insurers. It also contains competitive information on pharmacy benefit managers, insurers, patients, and pharmacies that compete at various levels with the UnitedHealth Group vertical which includes OptumRx – UnitedHealth Group's mail order pharmacy. UnitedHealth Group can now use that data to surveil patient habits like which patients are most adherent, which patients are on the most lucrative drug regime, which patients are on a competitor's insurance plan or use a competitor PBM, and which patients are the most profitable. UnitedHealth Group can then use that data to steer the most lucrative patients to their own insurance plans, PBM, and pharmacy thereby harming competition along each vertical.

The PBMs do not operate in a competitive environment and do not seek to attract pharmacies into their networks by offering competitive contract terms. Because PBMs control access to beneficiaries, PBMs instead impose non-negotiable terms on pharmacies that include below cost reimbursement, junk fees, unattainable dispute resolution, and unilateral one-sided no notice contract changes. These terms are driving independent pharmacies out of business – and their customers are steered to the PBM-affiliated pharmacies, further consolidating market power into the vertical entity. Importantly, consumers do not receive any benefits from these terms that squeeze independent pharmacies.

Pharmacies are in a crisis, and they have been struggling with escalating reimbursement challenges for decades, especially in Medicare. These challenges are largely due to 1) below-cost reimbursement (meaning reimbursement is below the pharmacy's cost to acquire and dispense the prescribed drug to the beneficiary) from market-dominant insurer-PBMs, 2) effects of insurer-PBM consolidation and patient steering to affiliated pharmacies, and 3) emerging egregious PBM transaction schemes (e.g., quality measures, bonus pool programs) that have created additional financial woes for the pharmacy community. Insurer and PBM opaque and self-serving business practices such as unfair and unreasonable reimbursement to pharmacies and their abuse of pharmacy performance measures in the Medicare program leads to inflationary effects on drug prices, restrictions on patients' access to medications, higher healthcare costs for patients and prescription abandonment, less competition in healthcare and an extinction of community pharmacies. **With that said, NCPA supports CMS' efforts to ensure greater quality and transparency in the MA program and urge CMS to take a comprehensive approach when renovating the MA program that successfully incorporates the pharmacy's voice and reimbursement concerns.**

Community pharmacies need reasonable reimbursement in Medicare and comprehensive PBM reform. We strongly believe that vertical integration of plans and PBMs are notably harming patient and pharmacy provider relationships across the quality-of-care continuum and need to be proactively addressed in the MA program.

NCPA asks that CMS prioritize the issue of PBM reform, and urges CMS to work with NCPA to help identify existing and new MA data points relevant to pharmacy that will help save millions of healthcare dollars, secure access to pharmacy services for millions of Americans and achieve our below priorities:

1. **NCPA urges CMS to help ensure reasonable and relevant reimbursement for pharmacies in Medicare, to support enforcement of "Any Willing Pharmacy" regulations, and to ensure that pharmacy payment will cover acquisition cost plus a commensurate professional dispensing fee in line with Medicaid fee-for-service.**

Congress established Medicare Part D "Any Willing Pharmacy" protections over 20 years ago with overwhelming bipartisan support (Medicare Modernization Act, 2003) to ensure Medicare patients have the freedom to receive medications and care from the pharmacy of their choice. Unfortunately, for years some Part D plans and their PBMs have undermined this law and the patients and pharmacies the law is meant to protect by imposing contract terms on pharmacies that are not reasonable or relevant, in direct contradiction of the "Any Willing Pharmacy" law. A continual downward push on pharmacy reimbursement could lead to negative impacts (e.g., pharmacy closures, delayed or insufficient pandemic response, lower adherence rates, fewer pharmacy providers) on beneficiary access to pharmacy services and health outcomes.

CMS has acknowledged that pharmacy DIR pharmacy price concessions or DIR fees, net of all pharmacy incentive payments, growing more than 107,400 percent between 2010 and 2020.[7] These increases are in part due to the expanded market leverage and consolidation of PBM and insurers and a non-transparent pharmaceutical supply chain. PBMs' DIR or retroactive, clawback fees often occur weeks or months after a transaction closes, when the PBM decides to recoup a portion of the pharmacy's reimbursement. These fees and clawbacks have made the economic viability of community pharmacies increasingly difficult. While *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* (Final Rule)[8] has made these DIR fees transparent to pharmacies at point of sale, the DIR fees themselves remain.

Under today's MA and Part D program, all types of pharmacies have reported instances where pharmacy reimbursement is below a pharmacy's costs to acquire and dispense drugs to the beneficiary. Specifically, it is also important to note that major PBMs compensate pharmacies far below the actual cost to dispense, as low as $0 or lower. NCPA fielded a member survey from February 16 to 26, 2024 to assess the impact of DIR changes within the Medicare program. Over 800 pharmacy owners responded. According to our survey, in 2024, 25 percent of all Medicare Part D claims are paid under acquisition cost, while 75 percent of all Medicare Part D claims are paid under cost plus $10.[9] This structure puts pharmacies in an untenable situation for providing

[7] 87 Fed. Reg. 1842, 1916 (Jan. 12, 2022).
[8] See https://www.govinfo.gov/content/pkg/FR-2022-05-09/pdf/2022-09375.pdf.
[9] See Feb2024-DIRsurvey.Exec Summary.pdf (ncpa.org).

needed care to the patients and communities they serve.

Medicare Part D makes up 36 percent of the average independent pharmacy's business. Thus, contractual terms that pay pharmacies less than they pay for medications are having a disproportionately negative effect on the solvency of pharmacies. As a result of 2024 Medicare Part D contract terms, 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 data through February 29, 2024, independent pharmacy net closures continue at approximately one store per day. These closures are expected to escalate. 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. **Immediate action must be taken to help ensure patients continue to have readily available access to pharmacy care services.**

Under the Medicare Part D statute and regulations, "Any Willing Pharmacy" that meets a Part D Plan sponsor's standard terms and conditions must be allowed to participate in a Part D plan's pharmacy network. CMS has made clear that this requirement means that Part D network terms are to be "reasonable and relevant."[10] However, CMS has also noted that the PBM's applicable standard terms and conditions have effectively "circumvented" these any willing pharmacy requirements and inappropriately excluded pharmacies from network participation.[11] CMS has not gone as far as to set specifics on what would be considered "reasonable and relevant" terms and conditions. Instead, CMS stated the requirement is meant "to minimize barriers to pharmacy network participation" and that terms and conditions must be relevant "in light of the changes and innovations in pharmacy practice and business models."[12]

It is notable that in the *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* (Final Rule)[13], CMS recognizes concerns raised by pharmacies that the lowest Part D drug price applied at the point of sale as determined by insurer-PBMs could have market consequences for "already struggling pharmacies to decrease services or medication availability, and/or be unable to remain in business, which may impact pharmacy networks," stating that this will be considered for future rulemaking.[14] As such, CMS has the authority to address standards for fair reimbursement through the "Any Willing Pharmacy" statute to provide pharmacies across the country some much-

[10] 42 C.F.R. § 423.505(b)(18).
[11] 83 Fed. Reg. 16,440 (Apr. 16, 2018).
[12] *Id.*
[13] See https://www.govinfo.gov/content/pkg/FR-2022-05-09/pdf/2022-09375.pdf.
[14] *Id.,* at 27843.

needed relief, the ability to afford to participate in PBM networks, and to deliver care to patients in both the MA and Part D programs.

CMS should keep in mind that the lowest possible reimbursement could result in instances where the terms and conditions of a network may forcibly preclude too many pharmacies from being able to participate.[15] **CMS must not allow plans and PBMs to circumvent the any willing pharmacy statute, through below cost-reimbursement, to erect barriers to pharmacy network participation.** The any willing pharmacy statute is critical to help protect patients' access to pharmacies. Enforcement of the any willing provider statute to address reasonable and relevant contract terms will help to ensure that pharmacies are no longer reimbursed at financial toxic levels that limit network participation or result in rapid pharmacy market consolidation, closures, and reduced beneficiary access to life-saving medications and preventive services. This regulatory enforcement would also help to ensure total reimbursement paid by PDP sponsors and MA-PD plans, net of all price concessions, fees, incentive payments, and any other form of remuneration, protects a pharmacy from being paid below the cost to acquire and dispense drugs.

2. **NCPA urges CMS to use its current authority to implement standardized pharmacy measures that are long overdue, including the evaluation and reporting of plan performance data that CMS has finalized in rulemaking.**

CMS has authority under the Medicare statute and regulations to develop a standard set of applicable pharmacy performance measures. Standardized measures are critical to help stop abusive PBM tactics where pharmacy reimbursement transactions are typically tied to these arbitrary and unreasonable pharmacy performance measures. We believe standardized pharmacy measures will provide improved MA-PD data points to help accurately assess the pharmacy's role and interventions in the patient care continuum and help improve beneficiary health outcomes across the board. This approach would also align with ongoing CMS efforts to ensure high-quality care for Medicare beneficiaries and protect the Medicare Trust Fund.

CMS' authority to administer the Medicare program includes oversight of plan access, quality, and beneficiary protections. The relevant statutory text provides CMS with the authority to use performance programs and measures to ensure compliance, noting: "performance measures established by the Secretary pursuant to subparagraph A(ii) shall include at least measures for cost, quality programs, customer service, and benefit administration, and claims adjudication."[16] This language provides CMS authority to establish additional measures beyond those specifically listed in the statute.

NCPA has repeatedly weighed in with CMS regarding our concerns with direct and indirect remuneration (DIR) and pharmacy price concessions in the Medicare Part D program and the

[15] 42 U.S.C. § 1395w-104(b)(1)(A).
[16] 42 U.S.C. § 1395w–111(g)(5)(b).

need for the development of standard pharmacy quality measures. Community pharmacists should be rewarded for efforts to drive performance and not solely penalized, especially when plan sponsors are receiving bonus payments.

Plan sponsors are receiving significant bonus payments for their performance, yet bonus payments are not being passed down to providers to drive performance.

On January 15, 2021, CMS finalized a rule requiring Part D plans to disclose pharmacy performance measures and how they are applied to pharmacies to CMS. CMS will be able to make those measures publicly available to increase transparency in the Part D space and use the information to begin development of standardized pharmacy performance measures. The requirement became effective on January 1, 2022.

In CMS' Medicare Part D final rule issued in May 2022, CMS encouraged the industry to continue to work together on developing a set of pharmacy performance measures through a consensus process and Part D sponsors to adopt such measures to ensure standardization, transparency and fairness. CMS also stated that the authority to establish a reporting requirement is effective January 2022; however, CMS stated that the actual data elements must be proposed through the Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) process in a future package.

The Paperwork Reduction Act (PRA) requires federal agencies (1) to seek public comment on proposed information collections and (2) to obtain approval from the Office of Management and Budget (OMB) before collecting information from the public. **NCPA requests an update on this future package, as we request that plans start reporting this information now.**

NPCA urges CMS to use a wide scope under their authority to collect information related to how pharmacy "performance" is measured, regardless of whether a plan or PBM utilizes the term "pharmacy performance measures" in contractual language.

NCPA recommends for each pharmacy performance metric being used by a plan/PBM to measure a pharmacy, CMS shall collect:

- The measure developer or entity responsible for development of the measure;
- How the measure was validated and tested;
- How often the measure is updated;
- If the plan/PBM is using the measure in accordance with published measure specifications which have been validated and tested;
- If the plan/PBM is using the measure according to licensing agreements with measure stewards;
- Adjustments or modifications to measure steward specifications;
- Source of data used to calculate the measure;

- The minimum number of patients required in the denominator to reliably calculate the measure;
- The platform, e.g., EQuIPP, and measurement period used in calculating the measure;
- Thresholds for incentives or other cut points related to pharmacy performance;
- Level of attribution, e.g., individual pharmacy vs. Pharmacy Services Administration Organization (PSAO), and attribution criteria;
- Risk adjustment or stratification included in the measure to account for clinical or socioeconomic variables;
- Whether the measure is being used to calculate reimbursement, either through recoupment, credit to a deduction in payment or bonus payments, or a combination thereof;
- Claim ID for payor, prescription number, pharmacy NCPCP number, transaction number, or Generic Product Identifier, and fill date to identify the claim(s) being used to determine the measure; and
- Where the measure should apply i.e., community pharmacy-based claims, specialty pharmacy-based claims, LTC pharmacy-based claims and if the quality measures are different based on where the patient lives.

It is imperative that such level of detail outlined above be provided to CMS via Medicare Part D reporting requirements. This is because the measures often being applied by plans/PBMs to pharmacies were developed for use in population health measurement at a health plan level, not developed for use in pharmacies with smaller numbers of patients.

There is wide variance and lack of standardization among PBMs and plans with respect to terminology, metrics, timing, and calculation methods. PBMs and plans regularly deviate from the measure specifications when using endorsed measures to determine pharmacy level quality.

PBMs and plans will oftentimes alter the list of drugs used to capture a metric during the evaluation period. There is a lack of transparency as to how PBMs and health plans are implementing their own and/or altering endorsed measure specifications. Moreover, the frequency of changes makes it challenging for pharmacies to consistently track their performance. There is a lack of consistency in attribution methods or number of patients required to capture a metric. PBMs and plans may use a measure to determine the entire pharmacy's quality based on as few as one patient.

Community pharmacists oftentimes have no insight into their individual pharmacy's quality standing in any given PBM network. A pharmacy may not be given access to a dashboard or data/metrics showing where it stands in relation to other pharmacies in the PBM "quality" network. **For these reasons, NCPA strongly urges CMS to require the greatest level of detail when requiring plans/PBMs to report pharmacy performance measures.** It is important for community pharmacy that plans and PBMs make all aspects of these measures fully transparent, and CMS ensures plans/PBMs are held accountable for the measures being used. As CMS begins to collect data from the plans/PBMs, NCPA recommends CMS identify potential misuses and unfair applications of pharmacy performance measures, particularly focused on independent

pharmacies arbitrarily grouped together within a particular network.

NCPA also suggests CMS make all the information on pharmacy performance measures collected publicly available as soon as possible so pharmacies can make decisions on their Part D contracts, increase transparency, and benefit patients. It is important that participating pharmacies are aware of the measures for which they are being held accountable.

Furthermore, NCPA requests CMS develop a system where pharmacies can validate the data submitted by the plans/PBMs. CMS accords plans and PBMs to reconcile, validate, dispute, and review submitted data. Since pharmacies are being judged on similar criteria, they should have the same opportunity to audit the submitted data to correct for mistakes and inaccuracies.

NCPA requests CMS require the use of pharmacy level measures and develop a verification process to ensure the data being used to measure pharmacy performance is correct and statistically meaningful.

Under the Part D program, plans/PBMs have clear and consistent quality measurement rules that are not suitable for pharmacies. Community pharmacies have no such rules. As pharmacies serve patients from multiple health plans and PBMs, there is an inconsistent and untenable application of the definition of "quality" applied to pharmacies among the various payors. This lack of consistency has led to the extraction of billions of dollars in pharmacy DIR fees, and we greatly appreciate CMS taking this first important step to address the problems our members are facing in serving Part D patients. NCPA looks forward to continuing to work with CMS and other interested stakeholders to develop universal pharmacy performance measures as well as responsible and practicable ratings for pharmacy.

Conclusion

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
Director, Policy & Regulatory Affairs
National Community Pharmacists Association