NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

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U.S. Department of Justice
950 Pennsylvania Ave., N.W., Suite 3337
Washington, DC 20530
Docket No. ATR 102

Submitted Via www.regulations.gov

Re: Department of Justice, Department of Health and Human Services, and Federal Trade Commission Request for Information (RFI) on Consolidation in Health Care Markets

Dear Ms. Lee:

The National Association of Chain Drug Stores (NACDS) immensely appreciates the Department of Justice (DOJ), the Department of Health and Human Services (HHS), and the Federal Trade Commission (FTC) for the Agencies' continued leadership to create a fairer and competitive healthcare marketplace as well as open-mindedness and patience to better understand the grave challenges in community pharmacies across the America. Furthermore, thank you for the opportunity to comment on this timely tri-agency RFI titled, *"Consolidation in Health Care Market,"* as the consolidation and predatory tactics such as arbitrary and new fee transactions, of the larger private payers and pharmacy benefit managers (PBMs), especially the "Big Three" 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 supply chain.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability.

We have heard loud and clear from our members that their pharmacies are in a crisis, and they have been struggling with escalating reimbursement challenges for decades. 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) from market-dominant insurer-PBMs, 2) effects of insurer-PBM consolidation and patient steering to affiliated pharmacies, and 3) other egregious PBM transaction schemes (e.g., quality measures, bonus pool programs) that have created additional financial toxicities for the pharmacy community. These issues have been exacerbated by the absence of legislative and regulatory transparency and oversight guardrails, the cyberattack on Change Healthcare, and the competition – eroding practices of PBMs that impact timely patient access, pharmacy sustainability, overall healthcare costs, and pharmacy's innovative vision to empower patients' total health and wellness. Said differently, consolidated insurer-PBMs' opaque and self-serving business practices such as unfair and unreasonable reimbursement to pharmacies and their abuse of pharmacy performance measures in the Medicare Part D program as a whole leads to inflationary effects on drug prices, restrictions on patients' access to medications, higher healthcare costs for patients and prescription abandonment, and less competition in healthcare.

NACDS' mission is to prevent these negative outcomes, promote accessible and lower healthcare costs, and to

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preserve and uplift the backbone of frontline pharmacy healthcare in America for generations to come, including in the incident of another global public health emergency. However, this mission is impossible to achieve without comprehensive PBM reform this summer in Congress and more support from DOJ, HHS, (including CMS), and the FTC on the matter.

We are hopeful that Congress will continue to work toward a pathway to advance PBM reforms because pharmacies cannot wait until 2025, 2026, or beyond for these issues to be addressed. Despite CMS' attempts to curb these practices with their 2023 letters of support for the pharmacy community by acknowledging our concerns about PBMs' harmful practice and harsh direct and indirect remuneration (DIR) realities, the consolidated insurer-PBM markets continue to manipulate the system and are often cutting reimbursement to negative levels, accordingly to several of our members. As so eloquently illustrated at the White House's Roundtable on Lowering Healthcare Costs on March 5th, PBMs have engineered their own favorable transactions and rules of the road and will abide by those instead of what's best for the patient, the market, and the care delivery supply chain. Additionally, we think it's also critically important to raise the bird's-eye view of the global and unintended consequences of well-intentioned but bifurcated federal and state drug pricing reforms such as the Inflation Reduction Act (IRA), the Center for Medicare and Medicaid Innovation's (Innovation Center) $2 Drug List Model (expected effective date Fall 2024) and states' Prescription Drug Affordability Boards (PDABs) with Upper Payment Limits (UPLs) that may only focus on reducing out-of-pocket costs for patients and not the downstream supply chain and PBM reimbursement effects on providers, pharmacies, and the patients they serve.

Community pharmacies need reasonable reimbursement in Medicare and comprehensive PBM reform to withstand the impact of these bifurcated policies and the daily manipulation from PBMs. We strongly believe that major vertically integrated insurer-PBMs' current and emerging transaction practices are concerning trends that are notably harming patient and pharmacy provider relationships across the quality-of-care continuum and healthcare costs. We urge DOJ, HHS, CMS, and FTC to keep prioritizing the issue of PBM reform until pharmacies and patients have some relief and sustainable solutions. Due to the outlined effects of transactions conducted by private payers (i.e., insurer-PBMs), we propose the below critical measures to help save millions of healthcare dollars and secure access to pharmacy services for millions of Americans:

- **Advance comprehensive PBM reform now to help ensure reasonable and relevant reimbursement for pharmacies in Medicare. Support enforcement of "Any Willing Pharmacy" regulations and comprehensive PBM reform to help ensure PBMs reimburse pharmacies at minimum the cost to acquire and dispense covered prescription drugs and network adequacy.**
- **Urge CMS to use its current authority to implement standardized pharmacy measure data that are long overdue, including the evaluation and reporting of plan performance measure data.**
- **Monitor data related to newly evolving reimbursement models and tactics deployed by PBMs that conflict with CMS' move to promote transparency, resulting in further decreases in pharmacy reimbursement and beneficiary access.**
- **Encourage the inclusion of community pharmacies in innovative healthcare models in Medicare, especially in the design and implementation of value-based care model agreements that seek to explore opportunities to expand healthcare access, advance healthcare outcomes data, and promote healthcare savings.**

I. Advance comprehensive PBM reform now to help ensure reasonable and relevant reimbursement for pharmacies in Medicare. Support enforcement of "Any Willing Pharmacy" regulations and comprehensive PBM reform to help ensure PBMs reimburse pharmacies at minimum the cost to acquire and dispense covered prescription drugs and network adequacy.

Congress established Medicare Part D "Any Willing Pharmacy" protections almost 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 and manipulated 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. Once again, we wish to raise our concern with CMS that the continual downward push on pharmacy reimbursement could lead to negative impacts (e.g., pharmacy closures, lower adherence rates, fewer pharmacy providers) on beneficiary access to pharmacy services and health outcomes.

Over the years CMS has acknowledged that pharmacy DIR data continues to increase significantly, with negative pharmacy price concessions or DIR fees, net of all pharmacy incentive payments, growing more than 107,400 percent between 2010 and 2020.[1] These increases are in part due to the expanded market leverage and consolidation of PBM and insurers and a non-transparent pharmaceutical supply chain. Furthermore, PBMs' DIR or retroactive fees and claw backs often occur weeks or months after a transaction closes, when the PBM arbitrarily decides to recoup a portion of the pharmacy's reimbursement. These fees and claw backs have made the economic viability of community pharmacies increasingly difficult, due to the unpredictability of reimbursement and the increased damage to bottom lines.

Under today's MA and Part D program, all types of pharmacies have reported that at times, DIR fees (or a new fee by another name) can result in 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 presently, major PBMs often compensate pharmacies far below the actual cost to dispense, as low as $0 or lower, by using emerging tactics and new "transaction" fees. *(See section III to learn more.)* Others have reported that such deep concessions have made remaining in preferred pharmacy networks increasingly challenging. This structure puts pharmacies in an untenable situation for providing needed care to the patients and communities they serve. **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."[2] 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."[3] 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."[4]

It is notable that in the final Contract Year 2023 Medicare Part D rule issued in 2022, 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. As such, CMS has the authority to strategically address standards for fair reimbursement through the "Any Willing Pharmacy" statute to provide pharmacies across the country some much-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.

With this backdrop, it is extremely important to keep top-of-mind that the lowest possible reimbursement

[1] 87 Fed. Reg. 1842, 1916 (Jan. 12, 2022).
[2] 42 C.F.R. § 423.505(b)(18).
[3] 83 Fed. Reg. 16,440 (Apr. 16, 2018).
[4] *Id.*

could result in instances where the terms and conditions of a network may forcibly preclude too many pharmacies from being able to participate.[5] Moreover, we agree that the any willing pharmacy statute must not be circumvented to erect barriers to pharmacy network participation. **Said differently, below-cost reimbursement is a monumental barrier 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 financially 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 any and 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 going forward.

II. Urge 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.

As we continue to express to Congress and HHS, 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 the 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."*[6] This language provides CMS authority to establish additional measures beyond those specifically listed in the statute.

Even more specific authority related to pharmacy measures is provided in the statutory and regulatory requirements for Medication Therapy Management Programs (MTMPs) and quality assurance programs.[7] Specifically, when adopting MTMP regulations, CMS contemplated creating specific pharmacy measures along with minimum MTMP requirements to ensure programs are operating effectively for Medicare beneficiaries. CMS stated that, while it did not identify specific MTMP or pharmacy measures in its 2005 final Part D rule, it could do so in future rulemaking:

> *[W]e intend to work with industry and other stakeholders to develop a comprehensive strategy for evaluating plan performance that collectively considers multiple standards and services affecting the cost and quality of drug therapy. As industry practices evolve, including the expected expansion of electronic prescribing, we believe meaningful performance measures can be identified that will validate best practices and provide benchmarks that will spur further program and system improvements. Accordingly, we will work with the industry*

[5] 42 U.S.C. § 1395w-104(b)(1)(A).
[6] 42 U.S.C. § 1395w–111(g)(5)(b) (emphasis added).
[7] *See* 42 U.S.C. § 1395w-104; 42 C.F.R. § 423.125(d).

to identify new standards for quality and performance that could eventually become plan requirements.[8]

[*W*]*e intend to utilize the Medicare Prescription Drug Benefit as a platform for driving the quality improvement of prescription drug therapy. We require plans to report details on their respective MTMPs, and we intend to collaborate further with the industry to develop measures that can be used to evaluate programs and establish relevant standards.*[9]

Given the experience garnered from many years of administering the Part D program, CMS now has the knowledge to reform the program along with the MA-PD program through the adoption of standardized pharmacy performance measures.

- **NACDS continues to strongly urge CMS to implement standardized pharmacy performance measures as part of modernizing the MA program's transparency and data capabilities and reforming consolidated insurer-PBMs.**

    - These measures should include patient-centered, clinically meaningful metrics developed through a neutral third-party facilitator, with experience creating and testing potential pharmacy performance measures based on industry consensus to better align with broader CMS goals on healthcare equity, access, quality, and value.

    - Examples of existing CMS measures ripe for beneficial pharmacy impact on patient health outcomes and key indicators are included below.

CMS clearly underscores that it has the authority to develop a comprehensive strategy for evaluating plan performance data. Although CMS did not finalize other pharmacy standards in 2005, the agency noted that it has the authority to create a platform as well as pharmacy measures in the future.

- **Conversely, today, pharmacy price concessions, including those based on performance and cost containment metrics, remain contingent, variable, and without regard to beneficiary outcomes and care experience. *(Also, see Appendix A for Example Quality Metrics in CMS Programs Suited for Pharmacist Influence.)***

    - In other words, price concessions based on subjective and often irrelevant performance measures (without pharmacies' input) continue to be extracted from pharmacies and may continue to lead to lower and lower reimbursements to pharmacies, without any regard to quality or performance at all. Commonly, these measures vary from health plan to health plan and from pharmacy to pharmacy. This structure undermines the intent of the measures and CMS' goals to best serve the needs of Part D beneficiaries.

    - Consider the following examples published in a 2019 white paper by INMAR available here: Source https://www.nacds.org/pdfs/government/2019/DIR-Whitepaper.pdf

        - **Generic Dispensing Rate (GDR):** As an example of a largely unattainable metric, to qualify for the lowest DIR fee with one PBM, a pharmacy must achieve a GDR of greater than 95%. Traditional community pharmacies generally cannot come close to reaching the 95%

[8] 70 Fed. Reg. 4194, 4277 (Jan. 28, 2005) (emphasis added).
[9] *Id.* at 4280 (emphasis added).

threshold despite best-made efforts due to circumstances beyond their control such as prescriber choice of medication, the disease states of the patient populations they serve, and brand/generic definitions that vary from plan to plan, making the upper metric threshold unachievable and unrealistic.

- **Inconsistent Definitions:** Generic Effective Rate (GER) is a difficult metric to monitor as different PBMs and plans use varying brand/generic definitions and set different targets that pharmacies must reach. Additionally, some PBMs and plans have a DIR fee that is specific to adherence to "specialty medications" but don't provide pharmacies a list of those medications, and don't provide a definition of what qualifies as a specialty medication on which the pharmacy will be measured.
- **Vague Comparison Groups for Measurement:** The vague nature of many contracts often results in an individual pharmacy, or even a pharmacy chain, not knowing the universe of other pharmacies that they are being compared to and measured against.
- **Unpredictable Methodologies:** While 80% on a medication adherence score is a widely accepted target in the industry, most plans do not publish their target scores for pharmacies to see. Targets set by plans for pharmacies usually range from 75%-100%. PBMs are not transparent in terms of what data they utilize, nor do they disclose the measurement calculations. Pharmacies are left to their own devices utilizing their dispensing data and best guesses at calculations. Of course, rarely do the two measures align and the PBMs get to choose whatever they like. Inevitably it's the one that allows them to pay less to the pharmacy.
- **Variable Timelines:** The time period in which performance is measured for DIR assessment is different for every PBM and plan and the recoupment timeline varies by weeks, months, and years.

To date, CMS has not fully implemented these reporting requirements and has requested insight into data points that should be captured. As previously stated, there is a lack of standardization across plans for the types of measures that are being used to assess pharmacy performance. Even with such limited transparency and variations across plans and measures, **NACDS believes that the below suggestions are examples of data points that will raise situational awareness and transparency around the discrepancies in the application of performance measures by insurer-PBMs to pharmacies within the various PBM networks.**

In this regard, CMS should consider the following data points for plan reporting requirements on plan performance measures:

- The measure developer or entity responsible for the development of the measure;
- How the measure was validated and tested;
- How often the measure is updated;
- Whether the measure is evidence-based, feasible, appropriate, and achievable based on industry data, and focus on pharmacy performance and quality of care;
- 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;
- 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;
- 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 and measurement period used in calculating the measure;
- Thresholds for incentives or other cut points related to pharmacy performance;
- Level of attribution and attribution criteria;
- Risk adjustment or stratification included in the measure to account for clinical or socioeconomic variables;
- 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
- Evidence that the measure can be significantly impacted by pharmacy;
- 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.

III. Monitor relevant data related to newly evolving reimbursement models and tactics deployed by PBMs that conflict with CMS' move to instill transparency resulting in further decreases in pharmacy reimbursement.

As DOJ, HHS (including CMS), and FTC continue to work toward lowering prescription drug costs, addressing health care consolidation, PBM reform, and overall transparency in DIR fees, it is essential to keep in mind potential plan responses through evolving tactics that could also negatively impact patient access, cost of care, and pharmacy reimbursement. PBMs have begun and continue to pursue practices that expand opaqueness, complexity, and ambiguity around reimbursement practices through mechanisms like charging pharmacies DIR fees or other remuneration demands or obligations, creating bonus performance pool programs that are in direct conflict with the CMS Part D transparency provisions, and developing modified versions of cost plus reimbursement models that remove flat fees and incorporate negotiations that could drastically decrease reimbursement. Specifically, evolving tactics that pharmacies are experiencing and bracing for include, but are not limited to:

a. Inflation Reduction Act's Maximum Fair Price (MFP)

To help ensure continued beneficiary access to their preferred pharmacy as PBMs get "smarter," DOJ, HHS (including CMS), and FTC must take steps that would minimize financial and operational burdens on pharmacies. Specifically, CMS must ensure that entities dispensing the MFP funds and involved in the MFP supply chain are held accountable and not impose or charge pharmacies any direct or indirect remuneration fees (DIR Fees) or other remuneration demands or obligations on negotiated drugs. NACDS has concerns that pharmacy access will become even more restricted and reimbursement will fall below the MFP without any protection from CMS, especially if DIR Fees are applied to these drugs. Furthermore, and as mentioned above, pharmacy reimbursement should be fair and reasonable –meaning reimbursement should cover the cost to purchase the drug plus margin plus include a professional dispensing fee (PDF) to safeguard patient access. As mentioned earlier, major PBMs often compensate pharmacies far below the acquisition cost and below the actual cost to dispense, as low as $0 or lower, by using emerging tactics and "transaction" fees.

b. Pharmacy Benefit Manager (PBM) Bonus Performance Pool Programs

Another evolving scheme is the PBM Bonus Pool Performance Programs (referred to as "bonus pool programs" hereafter). The bonus pool programs offer financial incentives and deductions to pharmacies based on unstandardized criteria and measures, which often result in arbitrary reimbursement claw backs for pharmacies post point of sale (POS). As we understand these programs, a PBM will withhold a small

amount (e.g., $0.40) from every Medicare Part D claim, which will appear as a transaction fee to the pharmacy. These funds are then placed in a bonus pool, ostensibly to pay higher-performing pharmacies at the end of the performance period (which is unknown), as determined by the PBM. This program may also result in concessions for some pharmacies in states with poorer health outcomes and larger bonuses for pharmacies not located in those states, which can unfairly benefit market-dominant vertically integrated/affiliated pharmacies.

Our primary concern revolves around PBMs' open violation of CMS' recently effective negotiated price rule, which requires that PBMs include all price concessions in the "negotiated price" at POS so that a patient's cost-sharing can be based on the lowest amount a pharmacy can receive. Per CMS' June 2, 2023, memo titled, "*Reminder of Regulatory Requirements for Pharmacy Price Concessions,"* the pharmacy price concessions provisions finalized in the May 9, 2022, final rule, require the application of all pharmacy price concessions at the POS, including pharmacy's contributions to the plan's bonus pool (even when not assessed on a per claim basis). Furthermore, as stated on pg. 27851 of the final rule, for pharmacy price concessions that are not assessed at the claim level, Part D sponsors would have to determine a methodology to attribute such concessions to the claim level to stay in compliance with the final rule's definition of negotiated price. CMS reiterates this position in the November 2023 memorandum titled, *"Application of Pharmacy Price Concessions to the Negotiated Price at the Point of Sale Beginning January 1, 2024 (senate.gov)."*[10]

The resurgence of these bonus pool programs along with its transaction fee appears to violate the final rule and effectively alters the predictability of the agreed-upon negotiated price and overall pharmacy reimbursement. In addition, the programs introduce additional opaqueness, undisclosed financial variables, and eliminate any predictability achieved under the new rule if these concessions are not reflected in the negotiated price. Moreover, pharmacies have no insight or involvement in setting performance measures which typically dictate "bonus" rates, so unless this is addressed the game will continue to be fixed against pharmacies and the patients they serve. The PBMs' effectuation of this program appears to contradict the final rule and does not drive value for the plans, patients, or pharmacies—only for the PBMs.

We urge DOJ, HHS, and FTC to act now and take a closer look at these bonus pool programs, as it appears that PBMs may have created a transaction fee loophole. NACDS strongly believes that a pharmacy's contributions to these bonus pool programs (including concessions post-POS based on performance) should be reflected in the negotiated price at POS so that beneficiaries' cost-sharing is based on the lowest price and pharmacies can regain some degree of predictability.

Furthermore, we ask DOJ, HHS, and FTC to provide more oversight on this issue, require plans to evaluate whether these funds went back to the pharmacy, and urge CMS to be explicit in future rulemaking that any and all pharmacy price concessions must be included in the negotiated price. This is only the tip of the iceberg and without any action, these bonus pool programs along with other measures will further jeopardize the financial viability of community pharmacies and patient access, as well as undermine the final rule and pharmacies' ability to provide quality care, improve health equity, and maintain vital services, particularly for our most vulnerable Americans.

c. Cost-Plus Reimbursement Models

The Cost-Plus Reimbursement Models are new reimbursement methodologies being introduced by some of

[10] Center for Medicare and Medicaid Services. *Application of Pharmacy Price Concessions to the Negotiated Price at the Point of Sale Beginning January 1, 2024*. 6 Nov. 2023, www.grassley.senate.gov/imo/media/doc/pharmacy_price_concessions_hpms_memo_november_2023_final_508.

the larger consolidated insurer-PBM-pharmacy as presumably a lower-risk and lower-return model for pharmacies. From what we surmise, these approaches are modeled after Mark Cuban's cost-based reimbursement model, which is based on a drug's acquisition cost plus a flat 15% margin and a pharmacist fee. Conversely, two of the major PBM models do not include a flat % margin but a markup % that would be negotiated with each payer— like today's reimbursement environment.

NACDS has long advocated for reasonable reimbursement for all pharmacies. Specifically, we have advocated for that at a minimum, PBM reimbursement covers a pharmacy's costs to acquire and dispense each covered drug so that the pharmacy may have the option to participate as a network provider and can provide quality and equitable pharmacy services necessary for dispensing drugs to beneficiaries. Unfortunately, the emerging Cost-Plus models (i.e., cost-based pharmacy reimbursement) are not what they first appear, as their pharmacy reimbursement falls drastically short of this objective; in fact, they often significantly cut reimbursement rates even more for pharmacies, especially the dispensing fees. We fear these Cost-Plus models will continue to evolve and be touted by PBMs as the solution to "help" community pharmacies. As currently designed, these non-transparent models are even more detrimental to pharmacies and result in lower margins, again, resulting in pharmacy viability and access challenges for beneficiaries.

We urge DOJ, HHS, and FTC to investigate these new models to help ensure they provide fair and reasonable reimbursement and network parity. This will help ensure that all Medicare participating pharmacies are not being reimbursed below the cost to acquire, dispense, and serve beneficiaries and meet their health care needs.

IV. Encourage the inclusion of community pharmacies in innovative healthcare models in Medicare, especially in the design and implementation of value-based care model agreements that seek to explore opportunities to expand healthcare access, advance healthcare outcomes data, and promote healthcare savings.

Healthcare payment model reform to reward value-based care, better quality, and improved clinical outcomes can help align incentives toward what really matters - better health, while lowering unnecessary and preventable costs for our healthcare system. However, despite a multitude of research examples and published literature on the value of pharmacies and pharmacists to improve health outcomes through clinical services and save downstream healthcare dollars, pharmacists and pharmacies have yet to be directly engaged as care providers in the existing CMS Innovation Center's value-based care models and further opportunities exist to engage pharmacies in value-based care across commercial payers, as well. NACDS urges DOJ, HHS, and FTC to explore what MA data may be necessary to help support exploring opportunities for Medicare to include pharmacists and pharmacies in innovative healthcare models, including value-based care. More detail on the tremendous value of including pharmacies in the CMS Innovation Center's work, for example, to advance value-based care can be found in a 2021 report available here.

The 2021 report highlights a myriad of evidence supporting the clinical effectiveness of pharmacists to move the needle on healthcare quality, outcomes, and value, including in rural and underserved populations. For example, a CMS Innovation Center-funded, pharmacy-led chronic care management initiative was designed to serve an underserved population. This initiative aimed to optimize patient health and reduce avoidable hospitalizations and emergency visits for high-risk patients by integrating pharmacists into safety net clinics. This collaborative program resulted in reduced rates of uncontrolled blood sugar by nearly a quarter (23%), improvements in LDL with 14% more patients controlled, and improvements in blood pressure with 9% more patients controlled at 6 months in the intervention group (collaborative care model with pharmacists as leads) versus the control group (primary care physicians

only). Through this project, pharmacists identified 67,169 medication-related problems in 5,775 patients, which resulted in a 33% reduction in readmissions per patient per year.

While Medicare Advantage plans offer a number of important, supplemental benefits such as Food is Medicine interventions and transportation benefits, there is limited publicly available information on the depth, breadth, and uptake of these offerings. Given their accessibility and clinical expertise, pharmacies are well positioned to support interventions, such as screening for social determinants of health, linkage to care and other services based on social needs, providing education to support uptake of supplemental benefits, and more. Such activities could be built into value-based care models with pharmacies or other mechanisms to support payment pathways for pharmacist services.

In fact, leveraging the proven ability for pharmacies to make an important impact on chronic disease prevention and management, NACDS has undertaken two recent Food is Medicine projects as commitments to the White House Conference on Hunger, Nutrition, and Health. First, NACDS' Nourish My Health campaign is a nationwide public education campaign aimed at highlighting the connection between eating nutritious foods and reducing the risk of diet-related heart disease, diabetes, and cancer. Campaign messaging highlights the following calls to action: (1) Get a baseline health screening (blood pressure, cholesterol, blood sugar/blood glucose, and body mass index) and learn about your risk for nutrition-related diseases; (2) Improve your baseline numbers by adding healthy foods to your diet to live longer and healthier; and (3) Access important information about healthy foods, lifestyle modifications, and health screenings through the campaign website and related resources. In addition to leading health organizations engaging in the campaign, a dozen pharmacy organizations have also activated in the campaign, sharing key messages and resources with their audiences across communities, and providing important interventions, like baseline health screenings. To date, Nourish My Health has achieved 175 million impressions, reaching Americans across the country, including rural and underserved populations. The campaign has also garnered nearly 8,000 responses to a nutrition security survey developed by the Food is Medicine Institute at the Friedman School of Nutrition Science and Policy at Tufts University. Please visit nourishmyhealth.org for more information.

In addition, the Milken Institute Feeding Change and NACDS are working with multisectoral stakeholders and experts to determine the policy, infrastructure, operational, and programmatic steps necessary to leverage pharmacies in expanding access to Food Is Medicine interventions, especially for communities with high rates of diet-related disease and food insecurity. The learnings of this work, informed by 30 experts, will be available in June, and will be leveraged to inform and promote scalable implementation of accessible and sustainable produce prescriptions across diverse communities. This work is part of a commitment by NACDS and the Milken Institute to the White House's Challenge to End Hunger and Build Healthy Communities. NACDS looks forward to continued opportunities for pharmacies to be leveraged more broadly in promoting access and uptake to Food is Medicine interventions that have demonstrated impact in mitigating harms from chronic diseases.

Additionally, pharmacists as medication experts are positioned to help reverse increased spending attributable to suboptimal medication use and promote better health outcomes. For example, it was estimated that up to $21.9 billion could be saved within the U.S. healthcare system by optimizing medication use. Also, it has been estimated that lack of medication adherence causes 125,000 deaths, at least 10% of hospitalizations, and hundreds of billions of preventable healthcare spending. Healthcare spending on non-optimal medication therapy is estimated at $528.4 billion per year and medication non-adherence is estimated to cost the system $290 billion per year. Importantly for Medicare beneficiaries, it was recently estimated that medication nonadherence for diabetes, heart failure, hyperlipidemia, and hypertension resulted in billions of Medicare fee-for-service expenditures, millions in hospital days, and thousands of emergency department visits that could have been avoided. If the 25% of beneficiaries with

hypertension who were nonadherent became adherent, Medicare could save $13.7 billion annually, with over 100,000 emergency department visits prevented and 7 million inpatient hospital days that could be averted. Pharmacists can help curb these wasteful spending trends and improve health more broadly.

Also, looking across quality measure data used in existing CMS programs, pharmacists are well positioned to help address a wide variety of quality measures by optimizing medication use, improving uptake of preventive care, like screenings and vaccinations, and supporting improvements in chronic disease control. Research continues to support pharmacists' ability to meaningfully impact these priority clinical areas, yet pharmacies and pharmacists have not had the opportunity to directly engage in the CMS Innovation Center's models, and opportunities exist to further leverage pharmacies in innovative healthcare models across private payers, as well.

HHS and CMS should act on opportunities such as MA program enhancements to improve outcomes, advance access, and reduce preventable healthcare spending by leveraging community pharmacies in innovative healthcare models across public and private payers. Doing so would not only strengthen development of innovative care models, but would also support needed advancements in healthcare access, including in rural and underserved areas, in addition to healthcare technology and data interoperability, and lowering healthcare costs.

V. Conclusion

In conclusion, NACDS expresses its gratitude to FTC, HHS, and DOJ for the opportunity to comment on the tri-agency RFI titled, *"Consolidation in Health Care Markets"* and to describe the role the consolidated insurer-PBM industry plays in adversely affecting many communities' access to care, the healthcare market, and the viability of neighborhood pharmacies. It is unacceptable that PBMs continue to profit at the expense of patients, pharmacists, and pharmacies. We see this RFI and the RFI titled, "*Medicare Program; Request for Information on Medicare Advantage,"* as an opportunity for meaningful PBM reform, a fairer health care marketplace and modernization of our Medicare program to ensure affordable and high-quality healthcare for Americans. To learn more about our current advocacy efforts to enact PBM reforms in Medicare and Medicaid, please visit the NACDS Legislative Resource Center. If we can provide any additional information or schedule a future in-person meeting or listening session, please do not hesitate to contact Dr. Christie Boutte, Senior Vice President, Reimbursement, Innovation and Advocacy, at cboutte@nacds.org.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

Appendix A

Quality Metrics in CMS Programs Suited for Pharmacist Influence		
Measure Topic	**Measure Examples**	**CMS Programs**
Chronic Disease Outcomes		
Chronic Disease Assessment and Management	Blood pressure control A1c control Depression remission Osteoarthritis function assessment	**Universal Foundation Measures** Merit-Based Incentive Payment System (MIPS) Program Qualified Health Plan (QHP) Quality Rating System (QRS) Medicaid Medicare Shared Savings Program Million Hearts Medicare Part C Star Rating
Patient Experience	CAHPS: Health Promotion and Education CAHPS: Health Status/Functional Status CAHPS: Getting Timely Care, Appointments and Information	**Universal Foundation Measures** Medicare Shared Savings Program
Medication Adherence and Optimization		
Medication Adherence, Persistence or Optimization	High-risk medications in the elderly Adherence to optimal medications for diabetes, cholesterol, blood pressure, COPD, asthma, schizophrenia, heart failure Concurrent use of benzodiazepines and opioids Improvement in management of oral medication Statin therapy in cardiovascular disease Statin therapy in diabetes	**Universal Foundation Measures** Medicaid, Merit-Based Incentive Payment System (MIPS) Program Medicaid Qualified Health Plan (QHP) Quality Rating System (QRS) Home Health Quality Reporting Home Health Value-Based Purchasing Medicare Part D Star Rating Medicare Shared Savings Program Million Hearts
Transitions of Care		
Reducing Preventable Readmissions	All Cause Readmissions	**Universal Foundation Measures** Hospital Compare Merit-Based Incentive Payment System (MIPS) Program Medicare Part C Star Rating Medicaid Qualified Health Plan (QHP) Quality Rating System (QRS) Hospital Readmission Reduction Program
Medication Review/ Reconciliation	Medication Reconciliation Post-Discharge	Medicare Part C Star Rating Merit-Based Incentive Payment System (MIPS) Program Physician Compare
Preventive Care and Screening		

Immunization Assessment and Delivery	Adult Immunization Status Childhood Immunization Status Immunizations for Adolescents Pneumococcal Vaccination Status for Older Adults Preventive Care and Screening: Influenza Immunization Zoster (Shingles) Vaccination	Universal Foundation Measures Medicare Part C Star Rating Merit-Based Incentive Payment System (MIPS) Program Qualified Health Plan (QHP) Quality Rating System (QRS) Medicaid Home Health Value-Based Purchasing Hospital Inpatient Quality Reporting Inpatient Psychiatric Facility Quality Reporting
Antibiotic Stewardship	Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)	Merit-Based Incentive Payment System (MIPS) Program Qualified Health Plan (QHP) Quality Rating System (QRS)
Screenings and Interventions	BMI, weight, and nutrition assessment Suicide risk assessment Screening and intervention for alcohol use and/or tobacco use DEXA scans Functional status and cognitive assessments Spirometry HIV screening Falls risk assessment/screening Blood pressure and/or diabetes screening Screening for social drivers of health	**Universal Foundation Measures** Medicare Part C Star Rating Medicaid Merit-Based Incentive Payment System (MIPS) Program Medicare Shared Savings Program Hospital Compare Inpatient Psychiatric Facility Quality Reporting End-Stage Renal Disease Quality Incentive Program

Additional NACDS Resources:

a. NACDS Comments Re: CMS Part D Propose4d Rule- Submitted 2024 available at: NACDS Comments to CMS 2025 Medicare Proposed Rule
b. NACDS Comments Re: CMS Part D Proposed Rule – Submitted 2023 available at: https://www.nacds.org/pdfs/CMS-2024-Part-D-Proposed-Rule-NACDS.pdf
c. NACDS Comments Re: CMS Part D Proposed Rule – Submitted 2019 available at: https://www.nacds.org/wp-content/uploads/2019/01/DIR-fee-reform-comments-to-CMS-1-25-2019.pdf