NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Statement

Of

The National Association of Chain Drug Stores

For

United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

On

Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain

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2322 Rayburn House Office Building

National Association of Chain Drug Stores (NACDS)
1776 Wilson Blvd, Suite 200
Arlington, VA 22209
703-549-3001
www.nacds.org

1) Introduction

The National Association of Chain Drug Stores (NACDS) thanks Chairwoman Eshoo, Ranking Member Burgess, and the Members of the Subcommittee on Health for the opportunity to submit a statement for the hearing on "Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain."

NACDS and the chain pharmacy industry are committed to partnering with Congress, HHS, patients, and other healthcare providers to find solutions to lower the cost of prescription drugs and improve access to quality, affordable healthcare services. NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' over 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 157,000 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. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit nacds.org.

As a key stakeholder in the drug supply chain, community pharmacists have for generations been trusted, highly accessible healthcare providers deeply committed to providing accurate prescriptions and helping patients take medications as prescribed. Community pharmacists provide a critical role in the continuum of care for patients. Importantly, not only do pharmacist interventions improve patient health and outcomes, but also pharmacy care has been shown to save downstream health care dollars.

As the demand for healthcare services continues to grow, pharmacists have expanded their role in healthcare delivery, partnering with physicians, nurses, and other healthcare providers to meet their patients' needs. Through quality-driven, innovative services pharmacists help avoid more costly forms of care and help improve patient quality of life. As the Subcommittee explores policies to lower the cost of prescription drugs, we offer the following recommendations we believe will help achieve that goal while improving patient health.

2) Lowering Costs Through Pharmacy DIR Reform

a) CMS Proposed Rule

On November 30, 2018, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule, "Modernizing Part D and Medicare Advantage to Lower Prices and Reduce Out-of-Pocket Expenses" that included policy reforms that would increase competition in the Medicare Part D program and lower beneficiary out-of-pocket costs by reforming pharmacy direct and indirect remuneration (DIR) fees.[1] Specifically, these reforms include:

- **Redefining the "negotiated price" to include all pharmacy price concessions**. Including all pharmacy price concessions in the negotiated price would reduce its amount and result in lower beneficiary cost sharing;

- **Developing a broad definition of "price concession" to include all forms of discounts, direct or indirect subsidies, or rebates that serve to reduce costs incurred by Part D sponsors**. Again, this would help ensure the lowest negotiated price and thus, lower beneficiary cost-sharing; and

- **Developing standardized pharmacy performance metrics for 2020. NACDS believes such metrics would be a good first step toward the development of Medicare Part D pharmacy quality incentive program**. The Department of Health and Human Services (HHS) needs to develop a pharmacy quality incentive program to align incentives between plans, pharmacies and beneficiaries. Pharmacy incentive payments would drive higher quality health outcomes. Opportunities to increase medication optimization and improve medication adherence would improve patient outcomes and reduce future healthcare costs.

CMS has recognized the harms caused by pharmacy DIR fees.[2] Between 2010 and 2017 the use of pharmacy DIR fees grew 45,000 percent.[3] As a result, Medicare beneficiaries are paying more out-of-pocket costs, the federal government is not fully understanding what it is paying for prescription drugs, and retail pharmacies are conducting business in an environment where they are unsure whether a payment will be clawed back at some later date as DIR.

CMS also recognizes that pharmacy DIR fees harm pharmacies by reducing transparency and predictability of reimbursement.[4] Pharmacy DIR fees undermine drug price transparency, which is necessary for efficient market competition that would reduce

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[1] 83 Fed. Reg. 62152, 62190-92 (Nov. 30, 2018).
[2] *See, e.g.,* 82 Fed. Reg. 56336, 56420-21 (Nov. 28, 2017) (explaining how pharmacy DIR fees increase beneficiary costs and decrease drug price transparency necessary for competition among plans); CMS, Medicare Part D – Direct and Indirect Remuneration (DIR) (Jan. 19, 2017) (noting the negative impact of pharmacy DIR fees on beneficiary drug costs, taxpayer subsidies and plan cost-avoidance); CMS, "Fact Sheet - Medicare Part D – Direct and Indirect Remuneration (DIR)" (January 19, 2017), available at https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir.
[3] *Id.* at 62147.
[4] *Id.* at 62191.

prescription drug costs.[5] Such transparency is vital to allow all stakeholders, notably patients and providers, to make informed decisions about how to best meet healthcare needs. As CMS also points out, "consumers cannot efficiently minimize both their costs and costs to the taxpayers by seeking and finding the lowest-cost drug or a plan that offers them the lowest-cost drug and pharmacy combinations."[6]

Beneficiaries are likely unaware that the increasing use of pharmacy DIR fees has led to inflated drug costs and higher cost-sharing. The impact of higher cost-sharing for beneficiaries negatively impacts medication adherence, leading to increased total cost of care and poorer health outcomes.

Moreover, finalizing pharmacy DIR reform needs to be coupled with the development of standardized achievable pharmacy quality metrics and a pharmacy quality incentive program. Without a standard set of metrics, beneficiaries, pharmacies, and plans are unable to make comparisons of pharmacy quality. Consequently, there is not an effective means for consumers to compare plans and pharmacies within the Part D program, undercutting market competition, which can contribute to higher costs.

b) Better Medication Adherence and Medication Optimization Reduce Healthcare Costs

Pharmacy DIR fee reform and the development of a standardized pharmacy quality incentive program will save taxpayers billions of dollars by aligning incentives for the entire Medicare program. By establishing a pharmacy quality incentive program, HHS will encourage a more systematic investment in pharmacy quality designed to facilitate care coordination, reduce medical errors, advance population health, and empower and motivate beneficiaries to achieve better health outcomes through medication optimization services and improved medication adherence.

Medication optimization services encompass patient-centered activities that improve health outcomes by addressing medication appropriateness, effectiveness, safety, adherence, and access. Medication optimization services delivered by community pharmacies are central to the care of beneficiaries. Nearly all Americans (91.7 percent) live within 5 miles of a community retail pharmacy and in 2017 nearly 73 percent of prescriptions dispensed in the U.S. were filled at retail pharmacies. Face-to-face interactions with beneficiaries at the point-of-dispensing allow the pharmacist to counsel and educate the patient and are critical to achieving national-scale improvements in health outcomes and lowered costs.[7]

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[5] *Id*. at 62176.
[6] Id. at 62176
[7] Patients who participated in brief face-to-face counseling sessions with a community pharmacist at the beginning of statin therapy demonstrated greater medication adherence and persistency than a comparison group who did not receive face-to-face counseling. The intervention group had statistically greater Medication Possession Ratio (MPR) than the control group every month measured. Taitel M, Jiang J, Rudkin K, Ewing S, Duncan I; "The impact of pharmacist face-to-face counseling to improve medication adherence among patients initiating statin therapy;" *Patient Prefer Adherence;* 2012;6:323-9. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3340117/. Likewise, a systematic review was conducted using 51 studies determining the optimal modes of delivery for interventions to improve adherence to

The better use of medicines will also reduce medication non-adherence—that is, patients not taking their medications as prescribed by their healthcare provider. Medication non-adherence contributes to $100-290 billion in unnecessary healthcare expenditures every year as a result of increased hospitalizations and other avoidable, expensive medical services.[8,9,10] Numerous studies have shown that reducing patient drug costs increases medication adherence, which, in turn, reduces overall healthcare costs. For example, a recent study found that medication nonadherence for diabetes, heart failure, hyperlipidemia, and hypertension resulted in billions of dollars in Medicare fee-for-service expenditures, millions of hospital days, and thousands of emergency department visits that could have been avoided.[11] Specifically, the study estimated that avoidable costs from medication nonadherence of four chronic conditions is $28.9 billion, representing 8 percent of the total expenditures. A 2017 white paper found that the direct medical costs and consequences related to not taking medication as prescribed is estimated to be 7 to 13 percent of national health spending annually—approximately $250 billion to $460 billion in 2017, translated to a potential cost to taxpayers of $6 trillion over 10 years.[12] And a 2016 cost-benefit analysis concluded that between one and two thirds of medicine related hospitalizations are caused by poor adherence. Improving adherence could result in annual per-person savings ranging from $1,000 to $7,000, depending on the disease state.[13] Multiple, credible sources have drawn the same conclusion: medication non-adherence is a costly, preventable problem that dramatically affects total cost of care.

c) Subcommittee Support

As detailed above, pharmacy DIR reform as proposed by CMS would lead to lower prescription drug costs for both Medicare Part D beneficiaries and federal taxpayers. In addition, pharmacy DIR reform would lead to better medication adherence among Part D beneficiaries, which would lead to further healthcare cost savings. With these cost saving benefits in mind, we urge the Subcommittee to communicate support to CMS in favor of finalizing pharmacy DIR reform, including the development of standardized pharmacy quality metrics that would lead to a pharmacy quality incentive program.

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cardiovascular medications. Among person-dependent interventions (nonautomated phone calls, in-person interventions), phone calls showed low success rates (38%). In-person pharmacist interventions were effective when held in a pharmacy (83% successful) but were less effective in clinics (38%). Cutrona SL, Choudhry NK, et al; "Modes of Delivery for Interventions to Improve Cardiovascular Medication Adherence;" *AJMC*; December 2010. https://www.ajmc.com/journals/issue/2010/2010-12-vol16-n12/ajmc_10dec_cutrona929to942?p=1

[8] Rosenbaum L, Shrank WH; "Taking Our Medicine - Improving Adherence in the Accountability Era;" *New England Journal of Medicine*; Aug. 22, 2013

[9] Network for Excellence in Health Innovation; "Bend the Curve: A Health Care Leader's Guide to High Value Health care;" 2011.

[10] The NCPIE Coalition; "Enhancing Prescription Medicine Adherence: A National Action Plan;" 2007.

[11] Lloyd, Jennifer T., Maresh, Sha, Powers, Christopher, Shrank, WH, Alley, Dawn E; "How Much Does Medication Nonadherence Cost the Medicare Fee-for-Service Program?"; Medical Care, January 2019.

[12] "A Treatable Problem: Addressing Medication Nonadherence by Reforming Government Barriers to Care Coordination;" *Prescriptions for a Healthy America*; October 2017.

[13] Patterson JA, et al; "Cost-Benefit of Appointment-based Medication Synchronization in Community Pharmacies;" *American Journal of Managed Care*; 2016.

3) Reform to Manufacture Rebates

a) NACDS Supports Goals of Proposed Rule but Changes and Clarifications are Needed

Earlier this year, HHS and the Office of Inspector General (OIG) released a proposed rule with the goal of lowering the cost of prescription drugs by requiring that manufacturer reductions in prescription drug prices to health plans/pharmacy benefit managers (PBMs) be passed on to the patient at the pharmacy counter. We support the goals of the proposed rule and believe the changes could lead to reduced patient out-of-pocket costs and could lower government program costs by improving medication adherence.

However, we believe HHS and OIG must include specific revisions in the final rule, as well as issue other regulatory or sub-regulatory guidance to maximize the impacts of passing manufacturer reductions in price to patients at the point-of-sale, reduce costs for all stakeholders, and increase efficiencies by utilizing and leveraging current capabilities and technologies. Specifically, the following changes and clarifications are needed in the final rule or in concurrent guidance:

- **Timeliness of payments** – Payment of discounts to pharmacies under a new system must follow current prompt payment requirements. Without prompt pay requirements applying to all elements of pharmacy claims, pharmacies would face devastating cash flow challenges resulting from having to wait months after dispensing medications before receiving payment of manufacturer reductions in price.

- **Transparency -** The total reimbursement due to the pharmacy, including the amount of any payment related to manufacturer reductions in price, must be known by the pharmacy at the point-of-sale at the time of dispensing. Failure to account for the manufacturer reductions in price at the point-of-sale claim adjudication would make it nearly impossible for pharmacies to track the collection of open receivables and could put pharmacies at substantial financial risk.

- **Protection from Unnecessary Fees -** Pharmacies should not be responsible for fees or other costs associated with administering manufacturer reductions in price. Specifically, pharmacies should not pay additional transaction, administrative, or other fees either directly, or indirectly through reduced reimbursements. The total and final reimbursement to the pharmacy must consist of the full contracted reimbursement from the plan/PBM, the reduction in price negotiated between the manufacturer and the plan/PBM, and the cost-sharing payment from the beneficiary; and shall not be affected by the reduction in price negotiated between the PBM and the manufacturer.

- **Maximize Efficiency and Minimize Additional Costs –** The final rule should maximize the use of existing technology, standards, systems, and business relationships. A new system potentially requiring the development of new

capacities and technologies for data sharing, processing and auditing of payments to pharmacies, as well as new financial relationships, will only add unnecessary cost and complexity into the healthcare system.

b) HHS Must Address Pharmacy DIR First

HHS must finalize reforms in the use of pharmacy DIR fees in the Medicare Part D program (as discussed in detail above) before moving forward with finalizing changes to the treatment of manufacturer rebates. Moving forward with reforms to manufacturer rebates without reforming the use of pharmacy DIR fees could incentivize even more aggressive use of pharmacy DIR fees, which would increase beneficiary and taxpayer costs, and lead to poorer medication adherence and worsening overall beneficiary health. We ask the Subcommittee to communicate with HHS the importance of finalizing the proposed CMS rule that reforms pharmacy DIR before finalizing manufacturer rebate reform.

4) Electronic Prescribing and the Part D Prescription Drug Plan

NACDS supports the efforts of HHS and CMS in integrating a patient-specific real-time benefit tool (RTBT) into the Part D benefit to drive lower prescription drug spending and minimize beneficiary out-of-pocket costs. Beneficiaries often arrive at the pharmacy counter with little or no insight as to what a medication will cost them, which can lead to overuse of unnecessarily expensive medications and the underuse of essential medications. We strongly agree with CMS that "reducing medication cost also yields benefits in patients' medication adherence" and that "increasing patient cost-share for a medication [is] associated with a significant decrease in medication adherence."[14] The integration of a RTBT into the Part D benefit will give providers and beneficiaries the information needed to make better informed choices on their healthcare treatment.

NACDS cautions that policies utilizing RTBTs must be designed in a manner that allows the prescriber to decide whether a prescribed drug is covered by the beneficiary's insurance plan without fear of "steering" a beneficiary to certain pharmacies or to mail order. This could be accomplished by requiring the beneficiary to select his or her pharmacy of choice prior to the prescriber utilizing the RTBT to access the enrollee cost-sharing information. Moreover, we believe that the RTBT must provide enough information to the prescriber and pharmacy to facilitate clinical decision making and assist in determining optimal patient medication regimens.

[14] 83 Fed. Reg. 62152, 62165 (Nov. 30, 2018).

RTBTs must also be able to take into consideration pharmacy-level cost-containment programs, such as $ 4.00 generic programs, or patient assistance programs. Moreover, absent system safeguards, RTBTs can inadvertently drive physician prescribing of expensive, therapeutic alternatives that are subject to high rebate arrangements between PBMs and manufacturers. Such results would negate the goal of using a RTBT and needlessly drive up overall spending in the Part D program. Policies utilizing RTBTs must:

1. Preserve patient's right to pharmacy selection at the outset;

2. Ensure accurate and complete patient's out-of-pocket costs at formulary and pharmacy levels;

3. Avoid unintended economic costs to taxpayers and beneficiaries associated with steering patients to therapeutic alternatives that are subject to "spread pricing" due to excessive list prices and rebates;

4. Prohibit commercial messaging within RTBT transmissions; and

5. Ensure information integrity, fairness and accuracy.

We ask members of the Subcommittee to communicate to HHS the need for RTBTs to be implemented in a way that serves its goals of providing timely information that would lower prescription drug costs.

5) Conclusion

NACDS thanks the Subcommittee for your consideration of our comments. We urge members of the Subcommittee to voice their thoughts to HHS to use their authority to include pharmacy DIR fee reform, the development of standardized pharmacy quality metrics, and the development of a pharmacy quality incentive program in the Final Part D Rule for FY2020 and to move forward with requiring manufacturer reduction in prices be passed on to patients at the pharmacy counter in a manner that does not harm the supply chain or jeopardize patient health. Finally, we ask members of the Subcommittee to communicate to HHS the benefit of incorporating a RTBT into the Medicare Part D program in a manner that will drive lower spending on prescription drugs while protecting patient choice.