NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Statement

Of

The National Association of Chain Drug Stores

For

United States Senate
Committee on Finance

On

The President's Fiscal Year 2020 Budget

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Introduction

The National Association of Chain Drug Stores (NACDS) thanks Chairman Grassley, Ranking Member Wyden, and the Members of the United States Committee on Finance for the opportunity to submit a statement on "The President's Fiscal Year 2020 Budget."

NACDS and the chain pharmacy industry are committed to partnering with Congress, HHS, patients, and other healthcare providers to 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 this Committee examines the President's Fiscal Year 2020 Budget, we offer the following for your consideration, with a specific focus on the FY2020 Department of Health and Human Services (HHS) Budget Request.

Lowering Costs Through Pharmacy DIR Reform

The FY2020 HHS Budget Request notes steps the Department took in the past year aimed at lowering the cost of prescription drugs, including ensuring beneficiaries are benefiting from price concessions at the pharmacy counter. We urge HHS to continue these actions in FY2020 by finalizing provisions in the November 2018 Centers for Medicare and Medicaid Services (CMS) proposed rule "Modernizing Part D and Medicare Advantage to Lower Prices and Reduce Out-of-Pocket Expenses" 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. CMS has proposed to reform pharmacy DIR by requiring that pharmacy price concessions are passed on to patients.[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 as the first step toward the development of Medicare Part D pharmacy quality incentive program**. HHS needs to develop a pharmacy quality incentive program to align incentives between plans, pharmacies and beneficiaries. Pharmacy incentive payments

[1] 83 Fed. Reg. 62152, 62190-92 (Nov. 30, 2018).

would support higher quality and health outcomes. Examples are medication optimization and improved medication adherence, which would improve patient outcomes and reduce downstream healthcare costs.

The use of pharmacy DIR fees grew an astonishing 45,000 percent between 2010 and 2017.[2] Because of this, Medicare beneficiaries are paying more out-of-pocket, 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."

As CMS has thoroughly documented, pharmacy DIR fees increase beneficiary drug costs and increase taxpayer costs for catastrophic coverage and low-income cost-sharing subsidies.[3] CMS also recognizes that pharmacy DIR fees harm pharmacies by reducing transparency and predictability of reimbursement.[4] More broadly, pharmacy DIR fees undermine drug price transparency, which is necessary for efficient market competition that would reduce prescription drug costs.[5] CMS has recognized the harms caused by pharmacy DIR fees for years.[6]

Pharmacy DIR fees obfuscate true drug prices, thus undermining the transparency needed 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."[7]

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

Better Medication Adherence and Medication Optimization Reduce Healthcare Costs

Finalizing pharmacy DIR reform needs to be coupled with the development of standardized 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. As a result, there is not an effective means for consumers to compare plans and pharmacies within the Part D program, undercutting market competition.

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[2] *Id.* at 62147.
[3] *Id. at* 62190-92
[4] *Id.* at 62191.
[5] *Id*. at 62176.
[6] *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.
[7] Id. at 62176

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, which will encourage a more systematic investment in pharmacy quality programs 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.[8]

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.[9,10,11] 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.[12] Specifically, the study estimated that avoidable costs from medication nonadherence of four chronic conditions is $28.9 billion, representing 8 percent

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[8] 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 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

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

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

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

[12] 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.

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.[13] And a 2016 cost-benefit analysis concluded that between one and two thirds of medication-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.[14] Multiple, credible sources have drawn the same conclusion: medication non-adherence is a costly, preventable problem that dramatically affects total cost of care.

Value of Pharmacy

NACDS urges Congress and HHS to explore opportunities to utilize pharmacists to their fullest extent in improving access to high-quality, affordable healthcare and improving overall health outcomes. For generations, Americans have relied on their local, community pharmacists to meet their healthcare needs—trusted, highly accessible healthcare providers deeply committed to providing accurate prescriptions and helping patients take medications as prescribed.

Pharmacist Provider Status

The full value of pharmacy is broader in scope, however. Pharmacies and pharmacists are being recognized for their abilities to provide high-quality healthcare services at an overall lower cost.

Millions of Medicare beneficiaries lack adequate access to primary healthcare services, and this is only expected to increase as the number of enrollees grows. According to the American Association of Medical Colleges (AAMC), by 2030, we will face a shortage of more than 120,000 doctors.[15] Pharmacists are uniquely positioned to help address this anticipated shortage by playing a greater role in the delivery of healthcare services in collaboration with other healthcare team providers.

NACDS' member chain community pharmacies are accessible, patient-centered healthcare destinations. One study of a high-risk Medicaid population found that patients visited their pharmacies 35 times per year, compared to seeing their primary care doctors 4 times per year, and specialists 9 times per year.[16] Voters agree:

- 83% of voters say that pharmacies are easy to access[17]
- 80% of voters have visited a pharmacy in the past twelve months[18]

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[13] "A Treatable Problem: Addressing Medication Nonadherence by Reforming Government Barriers to Care Coordination;" *Prescriptions for a Healthy America*; October 2017.
[14] Patterson JA, et al; "Cost-Benefit of Appointment-based Medication Synchronization in Community Pharmacies;" *American Journal of Managed Care*; 2016.
[15] HIS Markit, LTD; "The Complexities of Physician Supply and Demand: Projections from 2016 to 2030;" Prepared for Association of American Medical Colleges, March 2018
[16] Moose, J and Branham, A; "Pharmacists as Influencers of Patient Adherence;" Pharmacy Times, August 21, 2014
[17] Poll conducted by Morning Consult from January 04-06, 2019, among a national sample of 1995 Registered Voters
[18] *Id.*

Community pharmacists are among the advanced healthcare professionals with doctorate-level education and years of clinical training. Pharmacists' education and training equips them to provide many services in addition to dispensing and educating patients on their medications. Such services include health tests and screenings, management of chronic conditions and related medications, point of care testing (e.g. flu, strep) and immunization screening and administration. Pharmacists have been recognized by numerous states through their scope of practice laws to provide these and other services to patient populations. However, while physicians and certain other providers are already reimbursed under Medicare Part B for providing similar services, pharmacists are not.

Community pharmacists reduce the costs of health care by improving patient care and collaboration among providers, optimizing medication use for improved patient outcomes, contributing to medication error prevention, and preventing hospital readmissions cost-avoidance, which cost Medicare $26 billion annually.[19]

Pharmacists can also be better utilized to respond to immediate public health needs. For example, in the battle against the opioid crisis pharmacists can help identify and treat those with opioid addiction or who may be prone to addiction. This includes providing services such opioid antagonist counseling or opioid risk factor intervention services.

We urge members of the Committee to support soon-to-be introduced legislation that will recognize pharmacists as Medicare providers, allowing them to offer a greater role in the delivery of healthcare services and work in collaboration with other providers in addressing opioid abuse and misuse.

Addressing the Opioid Epidemic

In addition to recognizing pharmacists as key providers in the battle against the opioid epidemic, NACDS supports additional policy solutions to reduce the incidence of opioid addiction and abuse, including:

- Requiring that all prescriptions be issued electronically with limited exceptions;
- Legislate a 7-day supply limit for the prescribers of initial opioid prescriptions issued for acute pain;
- Collaboration with stakeholders on a nationwide prescription drug monitoring program (PDMP) database; and
- Providing manufacturer-funded mail-back envelopes for unused opioid drugs, available to patients at pharmacies upon request.

NACDS seeks to partner with lawmakers to advance these key policy initiatives. NACDS seeks the support of members of the 116th Congress to enact legislation establishing a 7-day supply limit for initial opioid prescriptions written for acute pain.

[19] Agency for Healthcare Research and Quality. Statistical Brief #172, April 2014 Available from: http://www.hcup-us.ahrq.gov/reports/statbriefs/sb172-Conditions-Readmissions-Payer.pdf (Accessed December 9, 2014)

Per the Centers for Disease Control and Prevention (CDC), a greater amount of opioid exposure increases the risk of long-term use and addiction. Notably, the average day supply per opioid prescription has increased in recent years, from 13.3 to 18.1 days per prescription between 2006 and 2016. Considering this trend and the risk of exposure to higher amounts of opioids, lawmakers must adopt policies to promote careful prescribing practices for prescription opioids.

Enactment of 7-day supply limits for acute opioid prescriptions is supported by the CDC prescribing guidelines, as it helps reduce the incidence of misuse, abuse, and overdose of these drugs. So far, over 30 states have adopted laws or other policies limiting the maximum day supply that can be authorized on an initial opioid prescription for acute pain.

NACDS encourages members of the Committee to support legislation that is standardized nationwide to promote consistent patient care and implementation that limits initial opioid prescriptions for acute pain to no more than a 7-day supply. If pain continues, the prescriber may issue any appropriate new prescription.

When addressing our nation's opioid epidemic, voters are most likely to understand that pharmacists are part of the solution, rather than the problem. This is a distinction that pharmacists share with law enforcement. For example:

- 65% of voters support allowing pharmacists to work with Medicare patients to help prevent, detect or treat potential opioid abuse (17% oppose; 28% don't know/no opinion)[20]
- 61% of voters support requiring that all prescriptions be issued and handled electronically to reduce fraud and abuse (19% oppose; 20% don't know/no opinion)[21]
- 58% of voters support limiting the initial fill of certain opioid prescriptions to a seven-day supply to reduce the incidence of addition and abuse (24% oppose; 28% don't know/no opinion)[22]

Pharmacies and pharmacists are integral to our nation's healthcare system. They are among the most accessible healthcare providers and provide high-quality healthcare services that are not only lower cost, but also prevent more costly downstream healthcare services.

Specific Medicare Part D Concerns

Beyond our concerns that HHS address DIR reform, we also ask the Committee to raise the following issues with HHS:

[20] Poll conducted by Morning Consult from January 04-06, 2019, among a national sample of 1995 Registered Voters
[21] *Id.*
[22] *Id.*

Broader Use of Prior Authorization and Step Therapy, New Formulation and Drug Price Increases Exceptions

In the November 2018 Part D Rule, CMS proposed providing Part D plans with a number of utilization management tools designed to drive the utilization of lower cost drugs.[23] Specifically, CMS is proposing to allow plans: (1) to use prior authorization for protected class drugs or to determine use for protected class indications or both, (2) to exclude from their formularies a protected class single-source drug or biological product for which the manufacturer introduces a new formulation with the same active ingredient or moiety that does not provide a unique route of administration, and (3) to exclude from their formularies any single-source drug or biological product that is a protected class drug whose price increases, relative to the price in a baseline month and year, beyond the rate of inflation.

NACDS supports efforts to curb the rising costs of prescription drugs but cautions that any action that HHS takes must be balanced with ensuring access to needed prescriptions drugs for Medicare beneficiaries. Plans should only be allowed flexibility to make changes to the treatment of protected class drugs and manage drugs through exception processes to the extent that doing so does not reduce drug coverage. Limiting access to prescription drugs can have unintended consequences, including decreased medication adherence, which further leads to poorer health and increased costs down the road.

In order to ensure beneficiary access and adherence is not jeopardized, NACDS recommends that any policies making changes in utilization management of protected classes be based on clinical parameters focused on the best treatment for the patient. Specifically, we recommend the following parameters be considered in allowing plans more flexibility with respect to utilization management tools:

- Only apply to new starts *and* only if guided by drug-selection assay criteria (e.g. genotypic assay),
- Not apply to products that show improved adherence, convenience, or tolerability profile, and
- Apply only to non-protected class indications.

We believe implementing such protections will help ensure beneficiaries will continue to have access to the treatments they need to best address their healthcare needs.

Ensuring access to needed medications is particularly crucial for the most vulnerable beneficiaries, such as those being treated with antiretrovirals (ARVs) and antineoplastics. The treatment of those with HIV and cancer involves unique challenges not present with other patients and therapies within the Part D program. For example, patients with HIV are now living longer than ever before due to advances in clinically superior treatment options, however, challenges such as evolving HIV population demographics and increases in costs for HIV treatment contribute to suboptimal adherence to drug regimens and risk of ARV resistance.

Similarly, the use of individualized and targeted therapy, tumor-agnostic therapy, CAR T-cell,

[23] 83 Fed. Reg. 62152 (Nov. 30, 2018).

gene and other therapies for cancer patients have greatly improved the specificity of treatment as well as long-term outcomes and survival. This has only increased the importance of immediate access to a wide array of therapies, as any delay can have catastrophic effects. Traditional utilization management tools are of limited usefulness due to the individualized and targeted nature of modern cancer treatments that do not have other clinically interchangeable options.

The unique challenges that patients living with HIV/AIDS and cancer face must be balanced with traditional utilization management tools and approached in a manner that ensures access to a broad array of treatment options. These challenges require that effective treatment options be available among the six protected drug classes. We ask that the Committee members communicate to HHS that the agency must ensure that any changes to drug management or drug formularies do not come at the cost of patient access and medication adherence, and especially so for vulnerable patient populations.

Prohibition Against Gag Clauses in Pharmacy Contracts

NACDS applauds Congress for passing the "Know the Lowest Price Act of 2018" (P.L. 115-262) that prohibits plans from restricting their network pharmacies from informing their plan enrollees of the availability of prescription drugs at a cash price that is below what that the enrollee would be charged (either the cost sharing amount or the negotiated price when it is less than the enrollee's cost sharing amount) for the same drug under the enrollee's plan. We are encouraged that CMS states that the measure will become effective with the plan year starting January 1, 2020. The prohibition of gag clauses in contracts among plans, Medicare Advantage plans, PBMs, and pharmacies will enhance patient access to medications, enable pharmacists to have improved relationships with patients, and keep healthcare costs for patients to a minimum. We look forward to working with you to implement this important requirement.

Part D Explanation of Benefits

CMS also proposed to require that plans include the cumulative percentage change in the negotiated price since the first day of the current benefit year for each prescription drug claim in the explanation of benefits (EOB). NACDS agrees that providing beneficiaries with necessary information to make informed choices about their health care, including making determinations about whether a prescription is covered under their plan is a valuable goal and could help reduce costs and lead to better health. However, the usefulness of the information is time sensitive and providing this information after a prescription has been filled, such as through the EOB or through an end-of-the-year annual statement, may allow a beneficiary to make a more informed choice going forward, but misses the opportunity to make an immediate change, as could be done if the information were provided at the point of prescribing.

To this end, we ask members of the Committee to communicate to HHS that the agency should adopt provisions that allow the prescriber to make a coverage determination and access cost information at the point of prescribing. Providing information at the point of prescribing will allow the beneficiary to work with his or her prescriber to find alternative or lower cost solutions and avoid unnecessary delay and potential lapses in therapy.

Electronic Prescribing and the Part D Prescription Drug Plan

NACDS strongly supports patient-centered policies and legislation that lower patient costs, including 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."[24]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.

While appreciating CMS' efforts to improve access to clinically appropriate and cost information, NACDS cautions policies utilizing RTBTs must be designed to provide information in a manner that allows the prescriber to make a determination about 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 sufficient information to the prescriber and pharmacy to facilitate clinical decision making that will inform prescribers and pharmacists to assist in determining optimal patient medication regimens.

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, therapeutically alternatives that are subject to high rebate arrangements between PBMs and manufacturers. Such results would needlessly drive up the overall spending of 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. Not allow commercial messaging within RTBT transmissions; and
5. Ensure information integrity, fairness and accuracy among others.

Again, we ask members of the Committee 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.

[24] *Id.* at 62165

Conclusion

NACDS thanks the Committee for your consideration of our comments. We urge members of the Committee to ask 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. Additionally, we encourage the Committee to support policy solutions that recognize the value pharmacy provides in helping combat the opioid epidemic and helping reduce patient costs while improving overall health.