NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

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President Donald J. Trump
Health and Human Services Secretary Nominee Robert F. Kennedy, Jr.
Trump-Vance Transition
Washington, DC 20500

RE: Four Wins to Make America Healthy Again

The nation's pharmacies stand ready to advance the Trump Administration's priorities to improve health across all communities in America, and make prescription drugs affordable and readily accessible. NACDS appreciates your consideration of the following recommendations, which align top priorities of pharmacies with your Administration's.

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. The nation's community pharmacies play a key role in providing critical healthcare access for Americans, including rural areas.

Pharmacies are the trusted and local healthcare access point for neighborhoods across America, integrated into the fabric of communities and the daily lives of Americans as the most accessible healthcare provider. Compelling and longstanding evidence demonstrates that pharmacist-provided care is a fundamental component of communities' vitality and sustainability.[5]

Essential Role of Pharmacies in Community Healthcare

- 90% of Americans live within 5 miles of a pharmacy, and 97% live within 10 miles.[1]
- Americans visit pharmacies 10 times more often than other healthcare settings.[2]
- 85% of adults in the U.S. say pharmacists are easy to access, the highest percentage of the tested options.[3]
- Pharmacies are often open during evenings and weekends, and are especially more accessible in rural America.
- Americans want to access more healthcare services at pharmacies.[4]
- Pharmacist-provided healthcare services promote better health outcomes, better access, and lower costs.

[1] https://www.japha.org/article/S1544-3191(22)00233-3/fulltext
[2] Gaskins RE. Innovating Medicaid: the North Carolina Experience, NC Med J. 2017, *available at* https://www.ncbi.nlm.nih.gov/pubmed/28115558.
[3] https://accessagenda.nacds.org/dashboard/
[4] https://accessagenda.nacds.org/dashboard/
[5] Dalton K, Byrne S., Role of the pharmacist in reducing healthcare costs: current insight,. Integr Pharm Res Pract. 2017;6:37–46, Published 2017 Jan 25 doi:10.2147/IPRP.S108047, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5774321/;
Newman TV, Hernandez I, et al., Optimizing the Role of Community Pharmacists in Managing the Health of Populations: Barriers, Facilitators, and Policy Recommendations, J Manag Care Spec Pharm. 2019 Sep;25(9):995-1000, doi: 10.18553/jmcp.2019.25.9.995, *available at* https://www.ncbi.nlm.nih.gov/pubmed/31456493.

NACDS is sharing **Four Wins to Make America Healthy Again**, which are designed to drive down the costs of prescription drugs, expand access to care, and improve the nation's health. These policies are important for all Americans and for pharmacies serving them in neighborhoods throughout America.

NACDS Recommendations – Four Wins to Make America Healthy Again:

1. **Stop the rip-off: enact PBM middleman reform to lower Americans' costs and ensure pharmacy choice.** It is time to stop the pharmacy benefit manager (PBM) middlemen from inflating Americans' drug prices, from barring access to Americans' pharmacy of choice, and from forcing pharmacies out of business. This win is ready to go in Congress and it is long overdue.

2. **Partner with pharmacies to address the chronic disease crisis.** The goal to "Make America Healthy Again" is a tall order. Chronic disease is up. Health costs are out of control. Healthcare is more out-of-reach – certainly in rural America. The system has capacity issues. The United States still focuses more on "sick care" than "healthcare." Pharmacies are vital to the prevention and management of chronic disease. It is time to rely on pharmacies as a healthcare destination – starting with baseline screening for blood sugar, blood pressure and cholesterol and continuing with a plan to reduce and manage risk. It is time to rely on pharmacies for Food is Medicine programs and for nutrition education like the NACDS Nourish My Health campaign.

3. **Stop the system from cheating seniors out of access to pharmacy care services.** Even when states give Americans more access to pharmacy-based healthcare, Medicare says no. The bureaucracy ignores pharmacists as providers. A broad array of other providers can bill Medicare for services that seniors need – but not pharmacists, the trusted and most accessible health professionals. It is time for a law to fix this, which one-third of the Congress sponsored in the 118th Congress.

4. **Remove unnecessary regulatory burdens standing between consumers and pharmacy care.** The Trump Administration has made clear it wants to hear how government gets in the way. NACDS has stories. In one example, Congress said pharmacies should not be harmed by Medicare price-negotiation, but the government is relying on pharmacies to float the finances for the program. In another example, the government has mandated country-of-origin labeling for prescription bottles, but this information is useless to Americans. If the goal is medication independence, then real solutions are needed. In a third example among many more, the government also needs to get to the bottom of wild fluctuations in pharmacy reimbursement resulting from dramatic changes in a key drug-price benchmark, National Average Drug Acquisition Cost (NADAC). Progress has been made, but this problem needs to be fixed for good.

Discussion

1. Stop the rip-off: enact PBM middleman reform to lower Americans' costs and ensure pharmacy choice. Take immediate action to work with Congress to enact long-overdue reforms that will prevent PBMs from continuing to harm Americans and their pharmacies.

Given the intolerable nature of market-dominant pharmacy benefit manager (PBM) practices and their far-reaching negative effects for Americans, it is imperative that the Trump administration consider the critical PBM reforms, that now enjoy bipartisan and bicameral consensus, as "must-pass" legislation in the 119th Congress. Comprehensive and meaningful PBM reform will be invaluable to the American people – driving down overall healthcare costs through improved patient health outcomes and access to medically necessary prescription drugs. NACDS implores the incoming Trump administration to work with their colleagues in Congress to ensure these reforms become law immediately. **NACDS has been gratified to see your comments, President Trump, about the need to address the middlemen's tactics – as stated in two national media appearances in one week's time last December.**

For over a decade, NACDS has warned of the increasing threats posed by market-dominant PBMs to Americans, pharmacies, and others. Unfortunately, the effects of pharmacy benefit manipulation have become increasingly dire. Every day that is allowed to pass without comprehensive PBM reform is another day that market-dominant PBMs are allowed to sustain and worsen their tactics. The situation has deteriorated further. Pharmacies are experiencing rapidly decreasing Medicare Part D pharmacy reimbursements, taking many pharmacies even further below the acquisition cost of the prescriptions they fill daily. This untenable situation of decreasing reimbursement, combined with lingering pharmacy direct and indirect remuneration (DIR) fees, jeopardizes patient access and pharmacies.

The perils faced by Americans, pharmacies, and others continue to draw the attention of a broad array of observers. *The Wall Street Journal* has consistently and repeatedly reported on its front page the harmful and costly impact of PBM middlemen and their ever-evolving business practices designed to outrun federal and state regulators and hide invaluable data. Recent reporting showed that the complex negotiations between PBMs and Medicare Part D plans resulted in a single drug having 2,200 different price points with a spread of thousands of dollars depending on the location of the beneficiary.

Moreover, on June 21, 2024, *The New York Times* published the first article in an anticipated series of articles that exposed PBM tactics. *The New York Times* presented compelling examples that acted as a tipping point for shedding light on growing concerns surrounding PBM practices. In their work on the article, the reporters said they conducted more than 300 interviews with current and former PBM employees, patients, physicians, pharmacists, and other industry experts. The article, titled "The Opaque Industry Secretly Inflating Prices for Prescription Drugs," provides stunning examples of PBMs' harmful tactics. One example describes that a PBM required a patient in rural Middleport, N.Y., to pay for a more expensive brand-name inhaler instead of the generic option the patient usually obtained at their pharmacy. The patient could not afford the extra $60 and decided to leave the pharmacy without the needed asthma medication. On October 19, 2024, *The New York Times* focused on PBM tactics that force pharmacies out of business. The article stated: "PBMs frequently pay the pharmacies at rates that do not cover the costs of the drugs, according to more than 100 pharmacists around the country and dozens of examples of insurance paperwork and legal documents."

On July 23, 2024, the House Committee on Oversight and Accountability – chaired by U.S. Rep. James Comer (R-KY) – published a report titled *The Role of Pharmacy Benefit Managers in Prescription Drug Markets.* The report found the largest PBMs force drug manufacturers to pay rebates in exchange for the manufacturers' drugs to be placed in a favorable tier on a PBM's formulary, making it difficult for competing, lower-priced prescriptions (often generics or biosimilars) to get on formularies. The report highlighted that as many states and the federal government weigh and implement PBM reforms, the three largest PBMs have begun creating foreign corporate entities and moving certain operations abroad to avoid transparency and proposed reforms – with these anti-competitive policies of the largest PBMs costing taxpayers and reducing patient choice.

Shortly before, on July 9, 2024, the Federal Trade Commission (FTC) released its interim report, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*. The report found that PBMs hold significant power over patients' access to affordable prescription drugs, enabling them to influence which drugs are available and at what prices. The FTC also condemned PBM practices as "imposing unfair, arbitrary, and harmful contractual terms" on pharmacies.

The FTC – on a unanimous 5-0 vote – went on to release a second interim report on January 14, 2025, *Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers.* **This second**

report focuses on PBMs' markups by thousands or hundreds of percent of cancer, HIV, a other critical drugs. The FTC said: **"Such significant markups allowed the Big 3 PBMs and their affiliated specialty pharmacies to generate more than $7.3 billion in revenue from dispensing drugs in excess of the drugs' estimated acquisition costs from 2017-2022. The Big 3 PBMs netted such significant revenues all while patient, employer, and other healthcare plan sponsor payments for drugs steadily increased annually, according to the staff report."**

The *Wall Street Journal*, *New York Times,* House Committee on Oversight and Accountability, and FTC all provide poignant examples of the harm inflicted by PBM practices, further increasing and amplifying awareness and momentum for reform. With the increased momentum, there is enough evidence to prove that PBMs jeopardize the health and well-being of Americans who depend on medications and on pharmacies – and jeopardize Americans' access to the pharmacies themselves. In the worst cases, these actions result in tragic human costs and, at minimum, higher healthcare options (e.g., hospitalizations).

More specifically, in the commercial prescription insurance market, employers are increasingly choosing PBM alternatives to reduce costs. Recently, a major employer in the Fortune 100 announced its plans to drop its PBM for its 175,000 employees to reduce costs. Additionally, a recent 3 Axis Advisors study evaluated roughly 20,000 pharmacy claims in Washington State and found that the average plan sponsor (employer) costs were approximately $165,000 higher (roughly 80 percent more) than the reimbursement provided to pharmacies (approximately $8 more per prescription). This is yet another case study of how PBMs drive up costs throughout the system through their tactics, such as spread pricing.

It is extremely important to note that all of this is happening to Americans, communities, employers, taxpayers, and pharmacies of all sizes. At the same time, estimates project that PBMs more than doubled their revenue over the course of the last decade and that they will do so again in the current decade. In this environment, pharmacies of all sizes struggle to operate and provide quality care that patients deserve and need. Immediate enactment of real PBM reforms in Medicare and Medicaid is desperately needed.

Pharmacies and pharmacists are firmly united across all practice settings on next steps for bipartisan and bicameral PBM reform to help curb the middlemen's pharmaceutical benefit manipulation. It is past time for action. NACDS and collaborating pharmacy organizations have worked together to call attention to needed reforms. It is vitally important for the incoming Trump administration and Congress to hear consistently what is needed and expected to protect Americans and their pharmacies.

Pharmacy organizations have spoken with one voice and clearly articulated pharmacies' legislative priorities that are necessary to confront the harms that are ravaging Americans and their pharmacies. **The following aspects of reform are absolutely necessary to ensure that a reform package is effective and that it can be supported by pharmacies:**

- Medicaid managed care pharmacy payment reform and a ban on spread pricing by requiring 100% pass-through to the pharmacy of the ingredient cost and of the professional dispensing fee, which could allow the federal government and states to save billions of dollars.

    - Ensuring fair and adequate Medicaid managed care pharmacy reimbursement from PBMs to cover the cost of acquiring and dispensing prescription drugs.

- Requiring National Average Drug Acquisition Cost (NADAC) survey participation to help establish benchmarks for Medicaid reimbursement to pharmacies, which can be used to ensure fair reimbursement to pharmacies in Medicaid managed care and in the commercial markets.

- Requiring the Centers for Medicare and Medicaid Services (CMS) to define and enforce "reasonable and relevant" Medicare Part D contract terms, including information about reimbursement and dispensing fees, and establishing in Medicare Part D an approach by which "any willing pharmacy" can truly participate and serve patients.

- Establishing relevant, standardized, and transparent pharmacy quality measurements in Medicare Part D.

These, along with additional policies, have been the subject of bipartisan and bicameral work across key committees of jurisdiction, creating a robust package of Medicare, Medicaid, and commercial market reforms that also include:

- Promoting transparency of insurer claims and reimbursement information to the pharmacy, including independent audits and enforcement measures in Medicare Part D.

- Prohibiting PBM compensation in Medicare Part D from being tied to the manufacturer's list price of a drug.

- Prohibiting spread pricing in the commercial market by requiring 100% rebate pass-through of rebates and payments from drug manufacturers to commercial health plans to lower beneficiary cost and ensure adequate reimbursement for pharmacy acquisition and dispensing costs.

To reiterate, the intolerable nature of market-dominant PBMs' practices has far-reaching negative effects on prescription drug costs and access for Americans. **The reforms that now enjoy bipartisan and bicameral consensus should be considered "must-pass" legislation in the 119th Congress and NACDS encourages the Trump administration to work with Congress to ensure these reforms become law without further delay.**

2. Partner with pharmacies to address the chronic disease crisis. Leverage the reach and clinical expertise of pharmacies to help tackle the chronic disease epidemic through access to affordable prescription drugs, healthcare services, and nutritious food.

NACDS urges the Trump Administration to leverage pharmacies to fill gaps in healthcare capacity as part of your strategy to reverse America's chronic disease epidemic. For example, **through Executive Orders or other measures, in coordination with CMS and the States, the Administration can empower pharmacies to expand nationwide access to chronic disease prevention and management services, in addition to advancing access to nutritious foods through food is medicine care at pharmacies, aligned with food prescription programs or other efforts.**

The chronic disease burden is rising, and life expectancy has decreased in recent years. Preventable diseases like type II diabetes and cardiovascular disease are plaguing the country, and the situation is even worse for people in rural areas. In the United States, 129 million people live with a chronic disease, 42% live with 2 or more, and spending on chronic diseases continues to drive rising healthcare spending.

In fact, the U.S. spends the most on healthcare compared to peer countries. **In 2022, U.S. healthcare expenditures reached $4.4 trillion, largely driven by spending on chronic diseases.** Nationally, four in 10 adults have obesity, and people living in rural communities tend to have some of the highest rates of obesity.[6] The chronic disease crisis is also weakening our national security as 11% of people aged 17-24 do not qualify for military service as they fail to meet current weight and fitness standards.[7] Without quick action, chronic disease rates will continue to rise, placing mounting pressures on the nation's already vulnerable and dysfunctional healthcare infrastructure.

Pharmacies, as the most accessible healthcare settings, can help change the abysmal trajectory of chronic diseases across the country. Pharmacists receive six years of advanced education and are clinically trained in chronic disease management, including support of lifestyle changes (e.g. nutrition and exercise), in addition to optimizing medication use to yield better health outcomes. Current pharmacy school standards include anatomy and physiology, medical microbiology, pathology, medicinal chemistry, medication prescribing and administration, patient assessments, patient safety, and clinical experiential learning through real-world experience taking care of patients.

Today, pharmacies offer screenings like blood sugar, blood pressure, and cholesterol to help identify people who are at-risk of chronic diseases, and to help link them to follow up care for further evaluation and treatment. Pharmacists can help better identify at-risk people and support linkage to follow-up care to help prevent and manage early stages of chronic diseases before late stages of disease require more expensive, potentially life-long treatments.

Pharmacists also provide chronic disease management programs that help manage and treat people who have already been diagnosed with chronic diseases. People who receive chronic disease care from pharmacists have better health outcomes. Pharmacist-led chronic disease care also helps reduce strain and burden on primary care providers who are being asked to care for an unmanageable number of people who require support to prevent and treat chronic diseases. In rural areas specifically, the patient-to-primary care physician ratio is only 39.8 physicians per 100,000 people, compared to 53.3 physicians per 100,000 in urban areas.[8] This is clearly an unworkable system, and pharmacists can help promote solutions in the short-term.

In addition to pharmacy services, many pharmacies also have food offerings within their broader retail stores and some grocery stores with pharmacies also offer dietician services. Promoting access to nutritious foods and encouraging uptake of healthcare services to better prevent and manage chronic diseases are core to the value pharmacies provide in communities nationwide.

[6] State of Obesity 2024: Better Policies for a Healthier America. Trust for America's Health, September 2024.
[7] 2020 Qualified Military Available Study. Department of Defense.
[8] About Rural Health Care. National Rural Health Association, 2024.

Milken Institute 2024 Report on the Role of Pharmacies in Food is Medicine

- Describes the value of pharmacies to better address chronic diseases, including improving access to Food is Medicine care.
- Underscores the importance of recognizing pharmacists as eligible providers under Medicare Part B, state Medicaid programs, and private insurance.

The Milken Institute recently highlighted the value of pharmacies in addressing chronic diseases and "Food is Medicine" care in a June 2024 report, "Catalyzing Action for Pharmacist-Provided Food Is Medicine Care." The Milken Institute's analysis of a literature review, 33 semi-structured interviews, and a 40-person roundtable found that pharmacists are particularly well-positioned to facilitate Food is Medicine care for patients with chronic conditions.

Among other recommendations, the report highlights the importance of fostering sustainable opportunities for pharmacies to expand access and uptake of Food is Medicine and chronic disease care across Medicare, Medicaid, and private insurance.

Members of the Trump administration have acknowledged the role of poor nutrition correlated with certain diseases and, conversely, the potential of nutritious foods to support overall health and wellbeing. Poor nutrition is the number one cause of poor health outcomes in the United States, with lives disrupted and billions of dollars spent annually as a result of preventable, diet-related diseases.

To that end, NACDS is pleased to share an overview of NACDS' Nourish My Health. **A public education campaign, Nourish My Health was created by NACDS in 2023 as part of our health and wellness innovation platform that leverages pharmacies and retail health services from NACDS members to help build healthy communities.** NACDS invited leading health organizations to collaborate on Nourish My Health, including the Alzheimer's Association®, the American Cancer Society, the American Diabetes Association® (ADA), the Food is

Medicine Institute at the Friedman School of Nutrition Science and Policy at Tufts University, and March of Dimes. For the past year, this ambitious public health initiative has been dedicated to educating Americans on the critical role that nutrition plays in preventing and managing chronic diseases.

#NourishMyHealth℠

Pharmacies are supporting the Nourish My Health Campaign's 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.

NACDS "Nourish My Health" Campaign 1-Year Highlights

- Achieved more than **400 million** impressions, reach Americans all over the country
- Delivered more than **60,000** biometric baseline screenings at Higi screening stations
- Garnered support from 6 leading healthcare organizations
- Participation from pharmacy partners representing **25,000** locations across all 50 states
- Conducted a national nutrition survey among more than **17,000** Americans

Looking ahead to the remainder of 2025, the six national partners and 23 NACDS members and associate members are excited to introduce the campaign to new communities across the country, leveraging our current portfolio of printed and digital campaign assets, and developing new ones to extend its reach. **NACDS implores the Trump Administration to leverage the commitment, reach, and clinical expertise of the nation's pharmacies to help tackle the chronic disease epidemic. Improving access and uptake of proven chronic disease prevention and management strategies, in tandem with nutritious foods, can meaningfully support the movement to Make America Healthy Again.**

3. Stop the system from cheating seniors out of access to pharmacy care services. Support legislation in the 119th Congress to finally secure seniors' access to cost-effective pharmacist services by reducing Medicare's red tape.

NACDS urges the Trump Administration's strong support of legislation in the 119th Congress that would secure better access for Medicare beneficiaries to receive healthcare services provided by pharmacists - to promote choice, competition, better health, and lower overall costs.

Pharmacies offer cost-effective healthcare access options for the American people to receive routine healthcare services. The majority of states allow pharmacists to provide various healthcare services in their respective states, yet Medicare unduly restricts beneficiaries' access to pharmacist care because pharmacists

are overlooked as eligible providers in the Social Security Act. This undue restriction and resulting red tape currently limits seniors' choice to access clinical care from their pharmacists, despite strong evidence on the proven benefits. All 50 states and Washington D.C. have authorized state-licensed pharmacists to provide a variety of healthcare services, yet without billing authorities in Medicare, this option is unfairly limited for seniors.

Eliminating unnecessary restrictions in Medicare to leverage pharmacists in taking care of seniors is critical to supporting the nation's health, especially for rural communities given the detrimental void in healthcare options in those areas. **Unfortunately, data indicates people in rural communities suffer from more chronic diseases, have less access to healthcare, and higher poverty rates. They are also more likely to die early because of preventable diseases compared to people who live in urban areas. To achieve better health, the American people need more healthcare access options.**

While other providers are able to bill Medicare for the valuable care they provide to beneficiaries – including physicians, nurse practitioners, physician assistants, clinical psychologists, clinical social workers, marriage and family therapists, mental health counselors, occupational therapists, and physical therapists – pharmacists are among the only healthcare providers that have yet to be leveraged to improve care for seniors. Supporting beneficiary choice to access care at pharmacies will help foster competition across healthcare providers and various settings, which is important to achieving higher quality and more affordable healthcare for Americans, including in Medicare.

The Equitable Community Access to Pharmacist Services Act (ECAPS) was important legislation introduced in the 118th Congress to amend the Social Security Act to help support seniors' access to routine pharmacist-provided healthcare services, promoting more cost-effective options for routine care. **This legislation garnered strong bipartisan support from 145 cosponsors, one-third of the Congress. This bill remains a priority for improving access to health and wellness services, and is especially critical for working Americans and people in rural areas where primary care providers and hospitals may be out of reach and too expensive, especially for routine healthcare needs. NACDS anticipates that new legislation will be introduced in the current Congress.**

At the same time, fixing the methods of calculating the true financial implications of health policies is important to driving bold and forward-looking approaches to making America healthy. **To move the nation from a sick-care system to a true healthcare system, Congress must move beyond antiquated bean counting and bureaucracy in scoring legislation. This past year, the Congressional Budget Office made progress in recognizing the downstream savings that preventive services can provide, and the House Energy and Commerce Committee majority has been focused on enhanced use of dynamic scoring.[9] NACDS urges for the Trump Administration's support in promoting dynamic scoring methodologies that better capture the true costs and benefits of innovative healthcare solutions.**

The nation's nearly 60,000 pharmacies are well-situated across the country to help address a wide range of healthcare needs by filling gaps in access to primary care providers and other healthcare personnel. There are 15% more pharmacy locations compared to physician practices in low-income communities, and rural residents disproportionately are living below the poverty line. Pharmacies are often open on evenings and weekends when other healthcare providers are closed. Pharmacy-based healthcare access is critical for working Americans with busy schedules and for those with limited access to healthcare who are being asked to travel long distances for basic healthcare needs. Research proves that pharmacist-provided healthcare services promote

[9] https://freopp.org/oppblog/the-case-for-dynamic-scoring/

better health outcomes, better access, and lower costs. Other countries, in addition to the U.S. Department of Veteran Affairs, have recognized the significant value of pharmacists in improving healthcare.

- In Nova Scotia, Canada, pharmacists have had prescribing authorities since 2011. Pharmacists can assess patients and prescribe for minor ailments, such as urinary tract infections, acid reflux, nausea, sore throat, sleep disorders, and more. Pharmacists can also renew prescriptions for many medications for up to 180 days, perform a variety of screenings and tests, and help patients manage their chronic diseases, such as diabetes, COPD, and high blood pressure.[10,11] Pharmacist prescribing in Canada has resulted in increased access, more appropriate referrals, better medication adherence, and cost savings.[12,13]

- If pharmacists in the United States were leveraged to help manage high blood pressure like they are in Canada, the U.S could save approximately $37.9 billion per year.[14]

- In the United Kingdom, pharmacists have been prescribing since 2006.[15] Within their "Pharmacy First" program, pharmacists can manage ear infections, infected insect bites, shingles, sinus infections, sore throat, and urinary tract infections.[16] This program gives people quicker and more convenient access to safe and high quality healthcare. A survey found that over 90% of patients who sought guidance from a community pharmacy within the past year reported receiving good advice.[17] Pharmacies have also been leveraged to help address key health challenges including smoking and high blood pressure.[18,19]

- The Department of Veterans Affairs looks beyond traditional roles to give pharmacists more influence on the course of patient care. VA pharmacists have unique responsibilities, and can write prescriptions directly based on their clinical knowledge and in light of patients' unique needs.[20]

Clear evidence from research in the United States and abroad recognizes the unequivocal value of pharmacists to improve health and reduce downstream healthcare spending. This value has been untapped for American seniors for too long, as sickness rises and healthcare costs soar, and NACDS urges your support in eliminating this archaic restriction by supporting corresponding legislation in the 119th Congress.

[10] https://www.sciencedirect.com/science/article/pii/S2667276623000021
[11] https://pans.ns.ca/pharmacist-will-see-you-now#:~:text=What%20is%20the%20Role%20of,any%20queries%20they%20may%20have.&text=What%20goes%20on%20behind%20the%20counter%20at%20your%20pharmacy?&text=If%20playback%20doesn't%20begin%20shortly%2C%20try%20restarting%20your%20device.
[12] https://pmc.ncbi.nlm.nih.gov/articles/PMC11556606/
[13] https://pubmed.ncbi.nlm.nih.gov/33778880/
[14] Dixon DL, Johnston K, Patterson J, Marra CA, Tsuyuki RT. Cost-Effectiveness of Pharmacist Prescribing for Managing Hypertension in the United States. JAMA Netw Open. 2023;6(11). https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2811317
[15] https://www.england.nhs.uk/primary-care/pharmacy/pharmacy-integration-fund/independent-prescribing/
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[17] https://www.england.nhs.uk/primary-care/pharmacy/pharmacy-services/pharmacy-first/
[18] https://www.england.nhs.uk/primary-care/pharmacy/pharmacy-services/nhs-community-pharmacy-blood-pressure-check-service/
[19] https://www.england.nhs.uk/primary-care/pharmacy/pharmacy-services/nhs-community-pharmacy-smoking-cessation-service/
[20] https://news.va.gov/101462/va-pharmacists-prescribe-wellness-for-veterans/#:~:text=On%20our%20team%2C%20pharmacists%20have,history%20and%20their%20own%20knowledge.

4. Remove unnecessary regulatory burdens standing between consumers and pharmacy care.

4a. Help ensure that the implementation of the Inflation Reduction Act's Medicare Drug Price Negotiation Program maximum fair price does not require pharmacies to pre-fund or float the program.

NACDS urges the Trump Administration to implement the *Inflation Reduction Act* (IRA) Medicare Drug Price Negotiation Program ("Negotiation Program") in the same manner as CMS has implemented and operates the Medicare Part D Coverage Gap Discount Program (CGDP).

Even though Congress has made clear that manufacturers are responsible for implementing the Negotiation Program, and that pharmacies should not be impacted negatively, CMS is planning to implement the Negotiation Program in a manner that requires pharmacies to pre-fund the very refund they will receive. In other words, pharmacies will have to provide a financial float in order to make the program work. The IRA does not provide CMS with the authority to require this of pharmacies.

This is yet another example of CMS action and inaction that are harming pharmacies. CMS continues to allow PBMs in the Medicare D program to under-reimburse pharmacies for prescription medications. This is occurring at the same time as pharmacies continue to suffer from PBM tactics in Medicare and also commercial plans, as outlined above. NACDS fears that this CMS requirement could further accelerate the closing of pharmacies nationwide.

Pharmacy closures are leading to patient harm as patients find it more and more difficult to access their life-saving prescription medications and pharmacy services. Pharmacies are among the most accessible health care providers—and they are the most convenient health care providers, especially in rural areas. Pharmacies are the closest heathcare providers for a majority of Americans, and have the greatest ability to positively impact patient health and to feel and share their burdens. It is unfortunate that the healthcare providers that are closest to the American people continue to struggle from costs and burdens being shifted downstream to them, such as this latest CMS requirement.

NACDS has four main concerns, outlined below, about CMS' current implementation plans that would be resolved if the Negotiation Program were to operate in the same manner as the CGDP.

First, the implementation plan does not ensure that pharmacies will be reimbursed for the full medication cost and dispensing fee. Consequently, Part D plan sponsors and their PBMs could exploit this program by keeping for themselves funds that should be provided to pharmacies.

Second, CMS' implementation plan would lead to pharmacies not being fully reimbursed for the affected medications for up to a month due to how CMS has structured the program. CMS's approach shifts the obligation to effectuate the maximum fair price (MFP) to pharmacies, contrary to the statute.

By allowing manufacturers to provide access to the MFP by retrospectively reimbursing pharmacies, CMS would in effect, be requiring pharmacies to pre-fund the MFP refund that those pharmacies would receive, as mentioned above. Imposing such a mandate on pharmacies is misaligned with statutory intent and exceeds CMS's authority, as mentioned above.

Pharmacies continue to suffer from inadequate reimbursement, Part D plan, and PBM clawbacks in the Part D program. Pharmacies do not have the financial ability to pre-fund the Negotiation Program. Pharmacies are so often reimbursed below cost for medications dispensed to Part D beneficiaries that pharmacies in some cases must consider whether they can even stay financially afloat. Pharmacies should not be responsible for pre-funding or floating the Negotiation Program as pharmacies and pharmacists have the immediate responsibility to assure optimal outcomes for all patients and sustain pharmacy clinical services despite the underwater reimbursement challenges from PBMs.

Third, there is no standardization in how pharmacies will be reimbursed. CMS plans to establish a Medicare Transaction Facilitator (MTF) payment module (PM) to provide a clearinghouse that manufacturers may use to provide the MFP to pharmacies. However, CMS is not requiring manufacturers to utilize the MTF PM, it is purely voluntary. Without requiring manufacturers to use the MTF PM, pharmacies could potentially have to set up reimbursement relationships with every manufacturer of a selected drug. This is administratively unworkable and untenable for pharmacies.

Fourth, CMS will ask pharmacies to self-identify whether they anticipate having material cashflow concerns due to the reliance on retrospective MFP refunds. CMS will provide this information to manufacturers to assist in the development of their MFP effectuation plans. CMS will require manufacturers to include their approach to mitigating material cashflow concerns in their MFP effectuation plans.

Although NACDS appreciates CMS' providing the opportunity for pharmacies to self-identify whether the program will impose material cashflow concerns, NACDS strongly believe that this is woefully inadequate to ensure that pharmacies are properly reimbursed in a timely manner. CMS is not requiring manufacturers to do anything with the information about pharmacy cashflow concerns nor does CMS have any requirements for how manufacturers should respond, should they decide to do so.

To address NACDS' numerous concerns, the Trump administration should require CMS to design the Negotiation Program to operate in the same manner as the CGDP. A critical feature of the CGDP is that CMS pre-funds the program to ensure that it operates smoothly and that pharmacies are promptly and accurately reimbursed. CMS has clear authority to pre-fund the Negotiation Program. This authority hinges on whether it has both statutory authority and an appropriation to do so. NACDS believes that CMS's $3 billion IRA appropriation may cover its prospective funding of the MTF.

4b. Reverse the Customs and Border Patrol's (CBP) recent interpretive ruling regarding Country of Origin (COO) marking for prescription medication bottles that pharmacies dispense to patients and withdraw a recently issued CBP fact sheet on the topic.

NACDS urges the Trump administration to reverse a recent U.S. Customs and Border Protection (CBP) interpretive ruling regarding country of origin (COO) marking for prescription medication bottles that pharmacies dispense to patients, as well as withdraw a recently issued CBP Fact Sheet, both indicating that medication bottles that pharmacies dispense to patients must be marked with the COO on the packaging that the patient receives.

This misguided CBP policy will not foster American prescription medication independence, and will only serve to increase costs and burdens upon pharmacies. As thoroughly described above, pharmacies are already

struggling to stay open because of harmful PBM tactics that are causing underwater reimbursement and because of CMS' misdirected implementation of the Negotiation Program of the IRA. This CBP policy places another heavy burden on pharmacies, further challenging pharmacies' ability to survive. **Moreover, this is a heavy burden with no useful purpose, as the COO information provides patients with information that they have no ability to act upon.**

Importantly, NACDS believes CBP's interpretive ruling and Fact Sheet misinterpret the relevant statutory law; and that CBP should revert to its previous interpretation that pharmacies and medical service providers are the ultimate purchasers of prescription medications.

CBP's Ruling Letter determined that the "ultimate purchaser" of prescription medication is the customer/patient who buys the medication at retail and not the retail pharmacy that purchased the medication from an importer. Retail pharmacies have operated for decades under the premise that they are the ultimate purchasers for purposes of COO labeling requirements and that such requirements were met so long as a drug's COO appeared on the packaging received by the pharmacy. Notably, hospital pharmacies and physicians that dispense medications are considered by CBP to be the ultimate purchasers because these entities perform a service when dispensing medications.

Similar to hospital pharmacies and dispensing physicians, retail pharmacies perform a professional service when they receive the prescription and dispense the medication to the patient accordingly. Dispensing the medication to provide correct quantities, strengths, indications, instructions, and warnings is an important service that can only be performed by licensed professionals.

Retail pharmacists review all prescriptions for accuracy, perform medication reconciliation, resolve medication-related issues, such as contraindications and interactions, verify that the correct drug products are dispensed and with the correct instructions, counsel patients if requested, respond to customer concerns, and respond to provider medication questions.

In sum, retail pharmacies do much more than merely repackage drugs into separate containers. They dispense the drugs to patients as part of a valuable professional service and should therefore be considered the ultimate purchaser for purposes of COO marking.

The Trump administration should reverse the CBP interpretive ruling regarding COO marking for prescription medication bottles and the associated Fact Sheet because they incorrectly interpret the law and fail to recognize the professional services that retail pharmacies perform when dispensing medication. Retail pharmacies are the ultimate purchasers, just as physicians and hospital pharmacies are, because they dispense medication as part of a professional service.

NACDS understands that a priority of the Trump Administration is to foster American security in a number of policy areas. To be clear, CBP's policy will do nothing to help secure the American prescription drug supply. Rather, it is unnecessary and ineffective bureaucracy that is an example of over-regulation with no purpose. Ultimately, it is a pointless burden on pharmacies that could lead to further pharmacy closings and increased prescription drug costs.

4c. Get to the bottom of wild fluctuations in pharmacy reimbursement resulting from dramatic changes in a key drug-price benchmark, National Average Drug Acquisition Cost (NADAC).

NACDS appreciates efforts underway now in the government to at least mitigate wild fluctuations in pharmacy reimbursement resulting from dramatic changes in a key drug-price benchmark, NADAC. **While efforts to "smooth" these fluctuations – if effective – are welcome and necessary, it also remains essential to get to the bottom of the causes of this completely unworkable situation.**

While this current situation is harmful in its own right, it is magnified amid lingering issues – described in this document – which harm Americans and their pharmacies. NACDS looks forward to working with you to resolve this specific issue, as well as the full complement of policies that jeopardize cost-effective and high-quality healthcare.

Conclusion

NACDS looks forward to forging ongoing dialogue and collaboration with you on these and other issues of mutual interest to Americans, to the Trump Administration, and to America's pharmacies. With any questions about these recommendations, and moving forward, please contact Sara Roszak, DrPH, MPH, Senior Vice President, Health & Wellness Strategy & Policy, at sroszak@nacds.org or Christie Boutte, Pharm.D., Senior Vice President, Reimbursement, Innovation & Advocacy, at cboutte@nacds.org.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer