NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

October 18, 2024

The Honorable Paul Friedrichs, MD
Director of the Office of Pandemic Preparedness and Response Policy
Executive Office of the President of the United States
1600 Pennsylvania Avenue N.W.
Washington D.C., 20500

Submitted via Paul.A.Friedrichs@oppr.eop.gov

Re: The Essential Role of the Nation's Pharmacies in the COVID-19 Response & Key Actions for Future Preparedness

Dear Dr. Friedrichs,

The National Association of Chain Drug Stores (NACDS) applauds your work to advance the nation's preparedness and effectively combat existing and emerging health threats. NACDS greatly appreciates your consideration of the critical role of the nation's pharmacies in strengthening future response efforts, and we appreciated the opportunity to recently meet in person to discuss key issues related to preparedness and public health amid the current respiratory season.

As demonstrated during the 2009-2010 H1N1 response, and particularly during the COVID-19 response, the nation's pharmacies offer unique scale, efficiency, and clinical expertise in providing essential access to medical countermeasures for the American people, in partnership with federal and state governments. In fact, between February 2020 and September 2022, pharmacy COVID-19 interventions averted more than 1 million deaths, prevented more than 8 million hospitalizations, and saved $450 billion in healthcare costs, using conservative estimates.[1]

In planning for future response efforts, consider that 90% of Americans live within just 5 miles of a community pharmacy, and 97% of Americans live within 10 miles. [2] Importantly, 86% of adults report that pharmacies are easy to access – the most accessible of any healthcare setting tested.[3] Plus, pharmacies are open extended hours – including nights and weekends – when other healthcare providers are unavailable. Across populations, people visit pharmacies far more often than other healthcare settings, and this difference is even more pronounced in rural communities. For example, Medicare beneficiaries visit pharmacies 14 times per year compared to just 5 visits yearly with their primary care provider in rural areas.[4]

Snapshot of Pharmacies' Impact in Preparedness & Response

- 90% of Americans live within 5 miles of a pharmacy.
- Pharmacy interventions during the COVID-19 pandemic averted more than 1 million deaths, prevented more than 8 million hospitalizations, and saved $450 billion in healthcare costs.
- Last season, CDC reported pharmacies were the most common settings for adult flu (48.0%), updated COVID-19 (71.5%), and RSV vaccinations (81.7%).
- 81% of adults believe it's important to permanently ensure the same access to pharmacy vaccination, testing, and treatment services that were available during the COVID-19 pandemic.

[1] https://www.japha.org/article/S1544-3191(22)00279-5/fulltext
[2] https://www.japha.org/article/S1544-3191(22)00233-3/fulltext
[3] https://accessagenda.nacds.org/dashboard/
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7364370/

Pharmacies' integration into the fabric of communities and the daily lives of Americans not only strengthens access to clinical interventions during a response effort, but also cultivates trust – a key ingredient to an effective public health response.

As pharmacies demonstrated their unequivocal ability to meaningfully expand critical access to care during the recent pandemic, the American people have certainly taken notice. According to a poll conducted by Morning Consult and commissioned by NACDS in October of 2023, 81% of adults in the United States believe it is important to update policies to ensure that people permanently have the same access to pharmacy vaccination, testing, and treatment services that were available during the COVID-19 pandemic.[5] Similarly, over 70% of Americans support pharmacists performing more healthcare services.

Key Recommendations to Advance Preparedness Leveraging the Nation's Pharmacies

Pharmacies' accessibility, paired with the clinical expertise of pharmacy teams, positions them well to engage and support robust responses to current and future public health threats, in collaboration with the White House and other key partners. **However, several critical policy changes have yet to be implemented that would accelerate the ability of pharmacies to engage in protecting the American people during routine and emergency response efforts moving forward, including:**

1. **Comprehensive Pharmacy Benefit Manager (PBM) Reform**: To maintain the robust footprint and accessibility of the nation's pharmacies to respond to current and future public health threats, PBM reform is sorely needed now. PBMs have been highly unregulated as an industry. Also, a new poll indicates that more than two-thirds (69%) of registered voters agree that Congress should consider legislation to reform PBMs' role and actions in healthcare to be "must-pass legislation" before concluding its work in 2024. Also, 69% of registered voters agree that their member of Congress "should do whatever it takes" to ensure Congress enacts such legislation in 2024.[6]

   As is well recognized at this point, PBMs claim to reduce prescription drug costs, but their business practices are key components of skyrocketing healthcare spending. PBM activities include unfair and opaque dealings with pharmacies with respect to reimbursement, network design, audit practices, constructing artificial barriers that limit patient choice and competition, self-referring patients to their own mail-order and/or retail operations, switching patients to more expensive medications to benefit the PBM, and questionable use and disclosure of sensitive patient information. On June 23, 2024, the House Committee on Oversight and Accountability 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. Similarly, in their July 9, 2024, Interim Staff Report on Prescription Drug Middlemen, the Federal Trade Commission (FTC) found – consistent with the findings of many other entities on a bipartisan basis – that "PBMs wield enormous power over patients' ability to access and afford their prescription drugs, allowing PBMs to significantly influence what drugs are available and at what price." The FTC also described PBM tactics as "imposing unfair, arbitrary, and harmful contractual terms on pharmacies."

   PBMs claim their ability to negotiate with drug manufacturers and pharmacies reduces overall prescription drug costs. However, despite their claims, PBMs regularly inflate the prices patients pay for medications, resulting in overall prescription drug spending and patient out-of-pocket costs continuing to steadily increase, and frequently forcing pharmacies to operate at a loss. Simply put, without meaningful PBM reform, more dollars are flowing to PBMs instead of reducing Americans' prescription drug costs and safeguarding access to their trusted and convenient pharmacies. While more than 130 new PBM reform laws were enacted throughout the

[5] https://accessagenda.nacds.org/dashboard/

[6] This poll was conducted by Morning Consult and commissioned by NACDS between October 1-October 3, 2024, among a sample of 1,778 Registered Voters. The interviews were conducted online and the data were weighted to approximate a target sample of Registered Voters based on gender by age, educational attainment, race, marital status, home ownership, race by educational attainment, 2020 presidential vote, and region. Results from the full survey have a margin of error of plus or minus 2 percentage points.

states from 2021 to 2023, comprehensive federal PBM reforms and enforcement of existing reform laws are urgently needed.

Pharmacies provide comprehensive and reliable care access points and patient-centered services, in addition to traditional dispensing roles, to advance the health and wellness of communities across the nation. Pharmacies' value was underscored during the recent public health emergency, and pharmacy access is especially critical for vulnerable and underserved populations. Despite this value added to the healthcare system, this access is at risk. The burden of compounding financial pressures on pharmacies is quickly becoming insurmountable. An alarming and ever-increasing number of pharmacies have closed permanently as a result of payers increasingly reducing reimbursement – in many cases to unconscionable levels that force pharmacies to dispense prescription drugs below cost. Stopping the egregious practices of market-dominant PBMs is foundational to pharmacies' future ability to respond to public health threats.

The current situation is untenable and is putting patient access and pharmacies in jeopardy. To maintain the ability of the nation's pharmacies to effectively respond to current and future public health emergencies, PBM reform is urgently needed and long overdue. Given the intolerable nature of market-dominant PBMs' practices and their far-reaching negative effects, the reforms that now enjoy bipartisan and bicameral consensus, as evidenced by the Modernizing and Ensuring PBM Accountability (MEPA) Act and the Better Mental Health Care, Lower Drug Cost, and Extenders Act which passed out of the Senate Committee on Finance, as well as the Lower Cost, More Transparency Act which passed the House – all either unanimously or by stunning margins – simply have to be considered "must-pass" legislation in the 118th Congress.

2. **Passage of the Equitable Community Access to Pharmacist Services Act (H.R. 1770/S. 2477):** This critical legislation builds on pharmacies' proven success delivering care during the COVID-19 pandemic, and would help support Medicare beneficiaries with the option to seek routine care for common health threats like influenza and COVID-19 from their local pharmacies, in instances where their respective state scope of practice authorizes pharmacists to perform such services. This legislation would accelerate the ability for pharmacies to provide key services during an emergency response, and enhance the nation's capacity and resilience to address both routine and emerging infectious disease threats by creating a direct reimbursement mechanism to pay for important pharmacist services provided to Medicare Part B beneficiaries, such as testing, treatment access, and vaccinations for COVID-19, flu and other common infectious diseases. During the COVID-19 pandemic, without this legislation in place, temporary workarounds had to be built and delays in access resulted. For example, CDC data from April 2022 – September 2023 indicates underutilization of Paxlovid for high-risk groups, and pharmacies were limited in their ability to help improve access and uptake. This can be prevented in future response efforts with the passage of this bill. More information on this critical legislation is available from the Future of Pharmacy Care Coalition here.

Gaps in Access to COVID-19 Countermeasures Post-PREP Act

- Pharmacist authority to autonomously order and administer both COVID-19 and flu shots for people 3 years and older will decrease in 31 states.
- Pharmacist authority to autonomously initiate antivirals after testing for COVID-19 has decreased in 33 states and D.C.
- Pharmacy technician authority to administer COVID-19 and flu shots will be eliminated in 5 states – including New York and Texas, which together account for approximately 15% of the total population.
- Pharmacy technician authority to perform COVID-19 tests will decrease in 31 states and D.C.

3. **Swiftly Extend the Current PREP Act Declaration Amendment for Pharmacies to Continue Providing COVID-19 Vaccines & Other Services:** Importantly, during the COVID-19 pandemic, HHS issued amendments and guidance under the COVID-19 PREP Act Declaration to authorize pharmacists to order and administer, and pharmacy technicians and pharmacy interns to administer: COVID-19 tests, vaccinations, therapeutics, flu vaccines, and other routine vaccinations for children.[7] These actions were critical in

[7] https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx

preempting state-by-state variations in pharmacy personnel's authorities to perform these activities, underpinning the coordinated and robust national response effort by pharmacies, which ultimately saved lives and contributed to reopening the country.

Without swift action, the remaining authorities granted to pharmacies via the PREP Act Declaration and related amendments will expire at the end of this year.[8] While significant progress has been made across states to permanently authorize pharmacy teams to order and administer COVID-19 tests, vaccines, and therapeutics in alignment with pandemic authorities, significant access gaps have and will continue to result from the PREP Act authorities expiring. Diminished access and capacity to provide important services, especially vaccinations and testing, can be avoided by extending the remaining PREP Act authorities now. Other response efforts have been supported by longer timelines. For example, the current mpox PREP Act Declaration is in place through 2032.

4. **Encourage States to Modernize Scope of Practice & Payment Policies that Support Pharmacies' Role in Responding to Public Health Threats:** Because state scope of practice for pharmacy personnel varies from state to state, modernizing state laws broadly provides major opportunity to promote efficient emergency responses by instantaneously boosting the workforce available to assist in taking care of the public when emergencies strike. While the PREP Act will continue to be an important tool for novel threats and in the short-term for COVID, states should permanently allow pharmacy teams to provide all FDA-approved or authorized vaccinations and CLIA-waived tests, in addition to the initiation of therapeutics based on test results and current clinical guidelines and recommendations. These services have been proven safe and effective, especially during the COVID-19 pandemic, and state scope of practice changes informed by these lessons learned will help speed future response efforts.

5. **Continue to Leverage the PREP Act to Support Pharmacies' Role in Future Responses:** Even with modernizations in state scope of practice authority for pharmacy teams, the PREP Act will remain a critical tool to effectively leverage pharmacy teams in future response efforts. NACDS appreciates HHS' work to utilize the PREP Act to support pharmacy engagement throughout the COVID-19 pandemic in a timely and proactive manner. Additionally, we appreciate the authorities related to mpox in effect for pharmacy personnel under the PREP Act. Because pharmacy teams need ramp up time to prepare for deploying new countermeasures, proactive amendments and guidance under the PREP Act are essential in laying the groundwork for pharmacies to plan operationalizing countermeasure access across thousands of pharmacy sites, as demonstrated during the COVID-19 pandemic. Continued partnership and proactive coordination between the nation's pharmacies and the federal government - to promote harmonized and effective response efforts and to promote clear messaging for the American people about countermeasure access - are essential.

6. **Advance Modernizations in the Vaccines for Children (VFC) Program & Design a Vaccines for Adults Program to Support Pharmacy Participation**: Given the longstanding barriers to pharmacy participation in the VFC program, NACDS and other vaccination advocates have long urged for needed modernizations that support the participation of pharmacies. Challenges include administrative barriers, burdensome stocking requirements, low reimbursement, and other hurdles, which have largely impeded more pharmacies from being able to participate. In fact, less than 1% of all VFC providers are pharmacies, despite the significant volume of vaccinations pharmacies provide today. For example, pharmacies provided more than 40% of COVID-19 vaccines for children during the pandemic. Changes to the VFC program that support pharmacy engagement are important to meaningfully improving access and uptake of childhood and adolescent vaccinations, building on existing success of the program. NACDS also recommends the federal government help ensure pharmacies are part of the design and planning for a prospective Vaccines for Adults (VFA) Program to advance vaccination access and uptake among vulnerable adults to promote broader health and preparedness of the nation, and to prevent challenges for pharmacies in the VFC program from being applied to a future VFA program. Draft concepts of a potential VFA program have failed to consider some of the existing challenges for pharmacies in VFC, and further collaboration is needed to design a VFA program that best supports pharmacy engagement.

[8] https://www.hhs.gov/about/news/2023/04/14/factsheet-hhs-announces-amend-declaration-prep-act-medical-countermeasures-against-covid19.html

Examining Pharmacies' High Impact Across COVID-19 Vaccinations, Testing & Therapeutics

A. Federal Retail Pharmacy Program for COVID-19 Vaccination: Pharmacies Persisted in Administering 340 Million Shots

For more than a decade, the effectiveness of pharmacies to meaningfully improve vaccine access and uptake across diverse populations has been well documented.[9,10] The COVID-19 pandemic further underscored the critical importance of leveraging pharmacies in efficiently getting vaccinations to the American people nationwide. Pharmacies were instrumental in pushing to achieve the nation's COVID-19 vaccination goals and success across key metrics from sheer volume of vaccinations administered, reaching underserved and vulnerable communities, pediatric and adolescent vaccine access, and improved health outcomes and lives saved.

The COVID-19 vaccination campaign began in December 2020 with a focus on priority populations like healthcare workers and long-term care residents, and the Federal Retail Pharmacy Program for COVID-19 Vaccination accelerated in February of 2021 with the goal to "expand access to vaccines for people living in socially vulnerable areas."[11,12] The Federal Retail Pharmacy Program included 41,000 vaccine locations across the country, representing 21 pharmacy organizations. While the bulk of initial vaccination supply was allocated to states and jurisdictions, and a relatively small amount of vaccine was initially provided to the retail pharmacy program, by August 2021, the majority of vaccine doses were being distributed nationwide through pharmacies.[13] Specifically, between April and July 2021, the proportion of vaccine doses distributed through the retail pharmacy program increased from just 29% to a whopping 92% according to a GAO report.[14]

Extensive & Sweeping Impact of Pharmacies on Vaccine Uptake

- Pharmacies provided about 340 million COVID-19 vaccines through March 2024.
- Last season, CDC reported that pharmacies were the most common settings for adult flu (48.0%), updated COVID-19 (71.5%), and RSV vaccinations (81.7%).
- 43% of people vaccinated through the Federal Retail Pharmacy Program were from racial and ethnic minority groups, exceeding CDC's goal of 40%.
- Pharmacies administered 46.4% of COVID-19 vaccine doses to children 5-11 years old, including 48.7% of doses in high SVI areas.

In total, pharmacies provided about 340 million COVID-19 vaccines since the start of the vaccination campaign through the first quarter of 2024. Specifically, during the 2022-2023 season, more than two-thirds of adult COVID-19 vaccinations were administered at pharmacies,[15] and compared to medical offices during the 2023-2024 season, pharmacies provided more than 90% of COVID-19 vaccines.[16] Also last season, CDC reported that pharmacies were the most common settings for adult flu (48.0%), updated COVID-19 (71.5%), and RSV vaccinations (81.7%).[17] Additionally, with respect to bivalent COVID-19 vaccinations, pharmacies administered 81.6% and 60.0% of bivalent vaccine doses in urban and rural areas, respectively.[18] Similar trends have persisted for influenza vaccinations with pharmacies providing about 60% of flu shots compared to medical offices in both the 2022-23 season and 2023-24 seasons.[19] Also, data indicates a 60% co-administration rate of flu and COVID-19 vaccines at chain pharmacies.[20]

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[9] https://www.sciencedirect.com/science/article/pii/S0149291817307713

[10] Le LM, Veettil SK, Donaldson D, Kategeaw W, Hutubessy R, Lambach P, Chaiyakunapruk N. The impact of pharmacist involvement on immunization uptake and other outcomes: An updated systematic review and meta-analysis. J Am Pharm Assoc (2003). 2022 Sep-Oct;62(5):1499-1513.e16. doi: 10.1016/j.japh.2022.06.008. Epub 2022 Jun 24. PMID: 35961937; PMCID: PMC9448680.

[11] https://www.gao.gov/assets/720/718907.pdf

[12] https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/02/fact-sheet-president-biden-announces-increased-vaccine-supply-initial-launch-of-the-federal-retail-pharmacy-program-and-expansion-of-fema-reimbursement-to-states/

[13] Ibid.

[14] https://www.gao.gov/assets/720/718907.pdf#page=13&zoom=100,298,856

[15] https://www.liebertpub.com/doi/10.1089/hs.2023.0085

[16] https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive/adult-vaccinations-administered.html

[17] https://www.cdc.gov/vaccines/imz-managers/coverage/national-state-vaccination-estimates.html#print

[18] https://www.cdc.gov/mmwr/volumes/73/wr/mm7313a2.htm?s_cid=mm7313a2_e&ACSTrackingID=USCDC_921-DM125690&ACSTrackingLabel=%20This%20Week%20in%20MMWR%3A%20Vol.%2073%2C%20April%204%2C%202024&deliveryName=USCDC_921-DM125690

[19] https://www.cdc.gov/flu/fluvaxview/dashboard/vaccination-administered.html

[20] Presentation at NACDS Total Store Expo. IQVIA, 2023.

Further, within the Federal Retail Pharmacy Program, pharmacies prioritized vaccine access in areas with high social vulnerability, focused on reaching harder to reach populations, to support better access in communities that needed it most. In fact, approximately 50% of retail pharmacy program sites were located in areas with high social vulnerability as of September 8, 2021.[21] According to a GAO report, CDC officials stated that pharmacies prioritized outreach to community and national organizations, faith groups, and community centers to promote vaccine administration to racial and ethnic minority groups. Pharmacy partners also provided on-site vaccinations in places such as churches to help increase access and convenience. As of August 22, 2021, participating pharmacies had cumulatively administered more than 3 million vaccine doses at more than 11,000 mobile clinics across the country. Pharmacies also extended their appointment times after 6 p.m. and over weekends, and established walk-in hours to improve vaccine accessibility. Pharmacy partners also translated materials into multiple languages to help provide educational information about COVID-19 vaccines to persons with limited English proficiency. Ultimately, 43% of people vaccinated through the Federal Retail Pharmacy Program were from racial and ethnic minority groups, exceeding CDC's goal of 40% — the approximate percent of the U.S. population comprised of racial and ethnic groups other than non-Hispanic White.[22]

Separately, because of existing state scope of practice barriers, in addition to challenges for pharmacies in the Vaccines for Children Program, pharmacies historically have had limited opportunities to expand access to childhood and adolescent vaccinations. However, during the COVID-19 response when these barriers were mitigated, pharmacies administered 46.4% of COVID-19 vaccine doses to children 5-11 years old, including 48.7% of doses in high SVI areas, in addition to 12% of seasonal influenza vaccines .[23] Unfortunately, pharmacies once again face longstanding barriers to participation in the Vaccines for Children program.[24] The VFC program was developed three decades ago, at a time when childhood vaccines were administered primarily in pediatrician offices and in public health clinic settings. Since that time, and especially in recent years, retail pharmacies have become a common vaccine destination for the public. Yet, 0.5% of VFC providers are pharmacies.

Modernizing VFC to support pharmacy participation and engagement is an important strategy to promote further vaccination uptake and coverage, leveraging lessons learned during the pandemic where pharmacies successfully provided COVID-19 vaccines to VFC-eligible children, smoothing access barriers for those children and their families to gain needed protection against COVID-19. NACDS has participated in a number of recent efforts to discuss key VFC changes necessary to support pharmacy participation, in order to build on the success of the VFC program to date. For example, NACDS helped inform the National Alliance of State Pharmacy Associations' comprehensive set of recommendations to increase the engagement of pharmacies within the VFC Program. These recommendations were informed and developed by a diverse group of pharmacy professionals and stakeholders over nine months to address the unique challenges and opportunities, including increased access, associated with integrating pharmacies into the VFC program.[25] Similarly, future efforts to implement a Vaccines for Adults program to provide no-cost vaccine access for uninsured and underinsured adults should consider and prioritize the inclusion of pharmacies as a key provider of adult vaccines. NACDS has developed recommendations to support the design of a VFA program available here to help inform the creation of any future VFA program to help ensure the program is implemented a way that is workable for pharmacies to maximize public access and convenience.

Additionally, when the PREP Act authorities for COVID-19 expire, based on NACDS research, pharmacist authority to autonomously order and administer both COVID-19 and flu shots for people 3 years and older will decrease in 31 states; and pharmacy technician authority to administer COVID-19 and flu shots will be eliminated in 5 states – including New York and Texas, which together account for approximately 15% of the total population. Aligning permanent state pharmacy laws with the services that were proven safe and effective during the pandemic, including vaccination for individuals 3 years and older, is a critical step to strengthening future response efforts and preparedness. In the interim, extending pharmacy authorities under the current COVID-19 PREP Act is important to safeguard access to care for the

[21] https://www.gao.gov/assets/720/718907.pdf
[22] Ibid.
[23] https://www.cdc.gov/mmwr/volumes/71/wr/mm7110a4.htm
[24] https://www.mysocietysource.org/sites/HPV/ResourcesandEducation/Lists/Clearinghouse/Attachments/516/ASTHO%20VFC%20Pharmacy%20Report_Executive%20Summary.pdf
[25] https://naspa.us/blog/2024/07/25/naspa-releases-recommendations-to-enhance-pharmacy-engagement-in-vaccines-for-children-vfc-program/

public in the short-term. To advance further refinements for the nation's public health and preparedness, additional policy changes are needed, as outlined beginning on page 2 of this letter.

B. Increasing Community Access to COVID-19 Testing Program: Pharmacies Spearheaded New Partnerships & Innovative Testing Models

For more than a decade, pharmacists in the United States have increasingly provided screening and testing services.[26,27] In fact, the use of CLIA-waived tests in pharmacies has grown by 140% since 2019, given the essential need for more accessible testing services during the COVID-19 pandemic where pharmacies provided more than 42 million COVID-19 tests.[28,29] Throughout the pandemic, pharmacies broadly supported better access to testing by leveraging point-of-care testing, providing over-the-counter COVID-19 tests, and partnering with labs to create new partnerships that provided more testing options for the American people.[30]

The Increasing Community Access to Testing (ICATT) Program, originally part of the Community-Based Testing Sites (CBTS) program, was created by a White House Joint Task Force, co-led by HHS and FEMA in March 2020, with a distinct element of the program being "Pharmacies+ Testing," through a federal government collaboration with commercial partners, including retail pharmacies and other contract service providers.[31] In April 2021, the CBTS "Pharmacies+ Testing" and "Surge Testing" programs were expanded into the ICATT program, and as of November 2021, the testing programs included about 10,000 active testing sites. Pharmacies provided 87% of tests within the ICATT program, prioritizing 70% of testing sites in areas of need based on SVI.

In addition to COVID-19 testing, a wide array of pharmacy-based "testing and treatment" and "screen and intervene" services have been proven safe and effective, including for influenza, strep throat, blood glucose, A1c, HIV, hepatitis C, and more.[32,33,34,35] Earlier detection and treatment or referral improves health outcomes and leveraging the convenience and accessibility of community pharmacies helps encourage patients to seek testing on their own schedule and without long wait times for an appointment at another healthcare provider. Leveraging pharmacies for testing and screening to better address current and emerging public health threats should be an important consideration for future response planning and preparedness.

Additionally, during the pandemic, CMS authorized temporary flexibilities to support pharmacies enrolling and billing as labs, in addition to the opportunity for pharmacies to support no-cost access to OTC COVID-19 tests for Medicare beneficiaries. CMS flexibilities also allowed pharmacists to order COVID-19 tests for Medicare beneficiaries, as authorized under the PREP Act. However, all CMS flexibilities ended with the conclusion of the national Public Health Emergency in May 2023, diminishing pharmacy-based COVID-19 testing access for the public, despite the PREP Act authorities for testing that remain in effect. Importantly, the passage of the Equitable Community Access to Pharmacist Services Act (H.R. 1770/S. 2477) would help address some of these barriers, including by allowing pharmacists to bill for ordering and administering tests for routine illnesses, like COVID and flu, for Medicare beneficiaries, in states that authorize pharmacists to perform these services.

In tandem with important payment policy changes, including the legislation described above, it is critically important

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[26] Klepser ME, Klepser DG, Dering-Anderson AM, Morse JA, Smith JK, Klepser SA. Effectiveness of a pharmacist-physician collaborative program to manage influenza-like illness. Journal of the American Pharmacists Association (2003). 2016 Jan;56(1):14-21. doi: 10.1016/j.japh.2015.11.008. PMID: 26802915.
[27] Grabenstein JD. Essential services: Quantifying the contributions of America's pharmacists in COVID-19 clinical interventions. Journal of the American Pharmacists Association. 2022;62(6):1929-1945.e1. doi:https://doi.org/10.1016/j.japh.2022.08.010
[28] Zalupski B, Elroumi Z, Klepser DG, Klepser NS, Adams AJ, Klepser ME. Pharmacy-based CLIA-waived testing in the United States: Trends, impact, and the road ahead. Res Social Adm Pharm. 2024;20(6):146-151. doi:10.1016/j.sapharm.2024.03.003.
[29] Grabenstein JD. Essential services: Quantifying the contributions of America's pharmacists in COVID-19 clinical interventions. Journal of the American Pharmacists Association. 2022;62(6):1929-1945.e1. doi:https://doi.org/10.1016/j.japh.2022.08.010
[30] https://www.cms.gov/COVIDOTCtestsProvider
[31] https://www.cdc.gov/mmwr/volumes/70/wr/mm7049a3.htm?s_cid=mm7049a3_w
[32] Buss VH, Deeks LS, Shield A, Kosari S, Naunton M. Analytical quality and effectiveness of point-of-care testing in community pharmacies: A systematic literature review. Research in Social and Administrative Pharmacy. 2019;15(5):483-495. doi:10.1016/j.sapharm.2018.07.013
[33] Kugelmas M, Pedicone LD, Lio I, Simon S, Pietrandoni G. Hepatitis C Point-of-Care Screening in Retail Pharmacies in the United States. Gastroenterol Hepatol (N Y). 2017;13(2):98-104.
[34] Jakeman B, Gross B, Fortune D, Babb S, Tinker D, Bachyrycz A. Evaluation of a pharmacist-performed tuberculosis testing initiative in New Mexico. Journal of the American Pharmacists Association. 2015;55(3):307-312. doi:https://doi.org/10.1331/japha.2015.14141
[35] Klepser DG, Klepser ME, Smith JK, Dering-Anderson AM, Nelson M, Pohren LE. Utilization of influenza and streptococcal pharyngitis point-of-care testing in the community pharmacy practice setting. Research in Social and Administrative Pharmacy. 2018;14(4):356-359. doi:10.1016/j.sapharm.2017.04.012

that states modernize their scope of practice laws to support continued public access to testing services at pharmacies that were available during the pandemic to support public health and preparedness for the future. For example, some states unduly limit the point-of-care tests that pharmacists and technicians can provide, while other states have implemented cumbersome requirements, such as pharmacies needing to have a laboratory director with certain credentials.[36] Unfortunately, based on NACDS research, pharmacist authority to autonomously initiate antivirals after testing for COVID-19 has decreased in 33 states and DC, given that prescribing authorities were not fully extended under the PREP Act extension. Also, pharmacy technician authority to perform COVID-19 tests will decrease in 31 states and DC at the end of this year without swift action from HHS to extend the remaining pharmacy authorities. Aligning permanent state pharmacy laws with the services that were proven safe and effective during the pandemic is a critical step to strengthening future response efforts and preparedness. In the interim, extending the remaining pharmacy authorities under the current COVID-19 PREP Act is important to safeguard access to care for the public in the short-term. To advance further refinements for the nation's public health and preparedness, additional policy changes are needed, as outlined beginning on page 2 of this letter.

C. Pharmacies Led COVID-19 Antiviral Dispensing, Yet Full Impact Blunted by Lacking Payment Pathways

Pharmacies have provided testing and treatment services for more than a decade for conditions such as influenza and strep throat. In March 2022, the federal government launched a nationwide "Test to Treat" initiative for COVID-19, and HHS began distributing oral antivirals directly to participating "Test to Treat" pharmacy-based clinics, in addition to antivirals for dispensing outside a "Test to Treat" model. In fact, 87.5% of antiviral dispensing sites were pharmacies (35,000 of the 40,000 sites), and some pharmacies did implement "Test to Treat" via their clinics, in addition to leveraging telehealth, for example.

However, gaps in payment policies limited pharmacies' ability to scale "Test to Treat" for COVID-19 more broadly, and undermines the ability for pharmacies to efficiently and effectively respond to future threats. Pharmacists were unable to broadly provide Paxlovid prescribing services in their communities – despite authorization from HHS under the PREP Act Declaration and subsequent authorization from FDA within the revised Paxlovid EUA. The reason for this is because there was not – and still is not – a reimbursement mechanism for pharmacists to perform a patient assessment to inform whether or not Paxlovid is clinically appropriate. This challenge persists especially in Medicare, but is also a problem across Medicaid and commercial plans as well. Pharmacists cannot initiate Paxlovid without first performing a basic patient assessment – and they cannot bill health insurance plans for performing such an assessment. This created a challenging situation for pharmacists who wanted to help their patients and for the patients who were sick and could have benefited from access to lifesaving Paxlovid through their local pharmacist. Ultimately, this barrier significantly undermined the ability for pharmacists to provide Paxlovid assessments and prescribing at the scale they provided other countermeasures like vaccines and testing. Data from April 2022 – September 2023 published by CDC in October 2024 indicates that fewer than one half of people 65 years and older with an outpatient COVID-19 diagnosis received a recommended COVID-19 antiviral medication, including 48% among adults aged 65–74 years, 44% among those aged 75–89 years, and 35% among those over 90 years.[37] The authors conclude, "lower prevalence of outpatient antiviral treatment in the oldest age groups highlights the continued need to improve COVID-19 antiviral use by increasing awareness and testing, and facilitating early treatment in these groups."

Beyond COVID-19, other pharmacy-based testing and treatment models have proven to be safe and effective, and the public has become even more accustomed to receiving clinical care from their local pharmacist in recent years. In fact, 58% of Americans are likely to visit a pharmacy first when faced with a non-emergency medical issue and 81% say they trust a pharmacist to diagnose minor illnesses and prescribe medications to treat them.[38] In a study of people who received testing and treatment services from a pharmacist, 98% were satisfied with the care provided and stated they would use it again.[39] Also, research indicates that when pharmacists offer testing and treatment, over a third of people

[36] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9401373/
[37] https://www.cdc.gov/mmwr/volumes/73/wr/mm7339a3.htm?s_cid=mm7339a3_w
[38] Rebelo A. Wolters Kluwer's Pharmacy Next survey shows 58% of Americans likely to first seek non-emergency healthcare at pharmacies. www.wolterskluwer.com. Published May 17, 2023. https://www.wolterskluwer.com/en/news/survey-shows-americans-seek-non-emergency-healthcare-at-pharmacies
[39] Kirby J, Mousa N. Evaluating the impact of influenza and streptococcus point-of-care testing and collaborative practice prescribing in a community pharmacy setting. *Journal of the American Pharmacists Association:* JAPhA. 2020;60(3S):S70-S75. doi:https://doi.org/10.1016/j.japh.2020.03.003

who utilize the service may not have access to a primary care provider, and almost 40% visit the pharmacy outside of usual medical office hours.[40] Additionally, point-of-care tests are often used in both medical offices and pharmacies, and these tests, by definition, are so simple that there is little risk of error.[41] In initiating any treatments based on test results, pharmacists strictly adhere to evidence-based protocols that reflect the latest clinical guidelines, and as medication experts, are well prepared to manage drug therapy, including any drug interactions.

For example, a study analyzed community pharmacist testing and treatment services including 273 patients tested for strep throat, of which 46 tested positive and received the appropriate treatment. At follow-up, almost 94% of patients that tested positive reported feeling better, and patients that reported feeling worse were referred to additional care. Of those tested, more than 43% did not have a primary care provider.[42] Also, in a study of 55 community pharmacies providing testing and treatment for flu, pharmacists performed 75 tests and among them, 8 people (11%) tested positive and were provided appropriate treatment. At the initial visit, 4 patients were instructed to seek additional care based on the pharmacist's assessment. These patients were successfully reached at follow-up and reported the following: one diagnosis of pneumonia, one diagnosis of bronchitis, and two antiviral prescriptions for flu. The patients reported feeling better due to the pharmacist's referral. In addition, pharmacists successfully followed up with 79% of all tested patients within 48 hours of the initial visit and 78% of those reached reported feeling better.

Despite consistent evidence on the effectiveness and value of pharmacist-provided care, including testing and treatment services, unfortunately, pharmacists have limited ability to bill Medicare for the services they provide. This puts pharmacists in an untenable position. Although they are clinically trained to provide clinical care, and these services are needed by their communities, they cannot realistically offer this care to their patients without a payment mechanism to sustain these services. This is a lose-lose-lose situation for pharmacists who want to help their patients, for the public who needs better access to care, and for the preparedness of the nation. These barriers proved harmful during the COVID-19 pandemic, and are undercutting the effectiveness and efficiency of our healthcare system still today.

The successful passage of the Equitable Community Access to Pharmacist Services Act (H.R. 1770/S. 2477) would help address this challenge in Medicare. The legislation would create a direct reimbursement mechanism to pay for important pharmacist services provided to Medicare Part B beneficiaries, such as testing, treatment, and vaccinations for COVID-19, flu and other routine infectious diseases, in instances where state scope of practices authorizes pharmacists to perform such services. This critical legislation builds on pharmacies' proven success delivering care for decades, as underscored during the COVID-19 pandemic, and would help support Medicare beneficiaries with the option to seek routine care for common illnesses from their local pharmacies. More information on this critical legislation is available from the Future of Pharmacy Care Coalition here.

Also, as described above, unfortunately, pharmacist authority to autonomously initiate antivirals after testing for COVID-19 has decreased in 33 states and DC, given that prescribing authorities were not fully extended under the PREP Act extension. Aligning permanent state pharmacy laws with the services that were proven safe and effective during the pandemic is a critical step to strengthening future response efforts and preparedness. In the interim, extending the remaining pharmacy authorities under the current COVID-19 PREP Act is important to safeguard access to care for the public in the short-term. To advance further refinements for the nation's public health and preparedness, additional policy changes are needed, as outlined beginning on page 2 of this letter.

Next Steps

Thank you for your continued engagement and partnership. NACDS looks forward to continuing to work together to strengthen the nation's public health and preparedness, including through the recommendations outlined in this letter.

[40] Klepser DG, Klepser ME, Smith JK, Dering-Anderson AM, Nelson M, Pohren LE. Utilization of influenza and streptococcal pharyngitis point-of-care testing in the community pharmacy practice setting. Research in Social and Administrative Pharmacy. 2018;14(4):356-359. doi:10.1016/j.sapharm.2017.04.012

[41] Clinical Laboratory Improvement Amendments (CLIA) How to Obtain a CLIA Certificate of Waiver. https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/howobtaincertificateofwaiver.pdf

[42] Klepser DG, Klepser ME, Dering-Anderson AM, Morse JA, Smith JK, Klepser SA. Community pharmacist–physician collaborative streptococcal pharyngitis management program. Journal of the American Pharmacists Association. 2016;56(3):323-329.e1. doi:https://doi.org/10.1016/j.japh.2015.11.013

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Sincerely,

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