



February 25, 2022

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Mr. Jeffrey Zients
COVID-19 Response Team Coordinator
The White House
1600 Pennsylvania Ave., NW
Washington, DC 20500

Submitted via email

Re: Immediate Action Needed to Maintain Uninterrupted Access to COVID-19 Vaccinations, Testing, and Therapeutics at the Nation's Pharmacies

Dear Secretary Becerra,

The National Association of Chain Drug Stores (NACDS) commends your steadfast leadership in responding to the ongoing COVID-19 pandemic. In partnership with the federal government, pharmacies remain committed to serving the American people throughout this dynamic crisis. Given the impending potential for the Public Health Emergency (PHE) to conclude, coupled with the ongoing critical need for Americans to access COVID-19 testing, vaccinations, and therapeutics, NACDS urges your clarification on, or amendment to, the current Public Readiness and Emergency Preparedness (PREP) Act declaration regarding the expiration date for pharmacy personnel actions taken thereunder. These flexibilities granted to pharmacy personnel continue to be instrumental in providing the nation with reliable, equitable and broad sweeping access to needed care during the pandemic. Pharmacies have been a central access point for the nation to receive care amid the ongoing pandemic and have steadfastly supported the Administration's equitable access, response, and recovery priorities. The loss of pharmacy-related PREP Act declaration allowances would impede the equitable access to care that Americans have received from pharmacy during the pandemic. **To help maintain critical public access:**

- 1. We ask the Secretary to clarify that actions conducted by pharmacy personnel pursuant to the PREP Act declaration remain in place and will not be impacted by the lifting of the COVID-19 PHE; or**
- 2. If the current PREP Act declaration does not ensure continued pharmacy access for patients seeking vaccination, testing, and COVID-19 therapeutic services from pharmacies, we ask the Secretary to leverage his authority to issue extensions to the PREP Act declaration based on a credible risk of a PHE, even after the PHE is lifted.**

Since the beginning of the pandemic, pharmacies have risen to bolster the Administration's national response to the pandemic. Specifically, pharmacies remained open and available for patient care while providing key access to COVID-19 testing, COVID-19 and routine vaccinations, COVID-19 therapeutics, and the distribution of free N-95 masks. Together, we have built one of the most effective public-private partnerships in history to fill a vital public health need for the nation, meaningfully fortifying our public health infrastructure in a time of dire crisis. Fully leveraging the existing retail pharmacy network – by which 90 percent of Americans live within 5 miles – has efficiently, equitably, and cost-effectively strengthened important access for Americans, especially those in underserved urban or rural areas, or that may otherwise face healthcare disparities and inequities.

Consider the critical impact of pharmacies during the COVID-19 pandemic:

- Pharmacies have administered more than 229 million COVID-19 vaccinations to date¹
- Today, 2 of every 3 COVID-19 vaccine doses are provided at a pharmacy²
- More than 40% of those vaccinated at pharmacies were from racial and ethnic minority groups³
- About a third of children ages 5 to 11 who received a COVID-19 vaccination did so at a pharmacy⁴
- Half of pharmacy COVID-19 vaccination sites are located in areas with high social vulnerability⁵
- Pharmacies have provided more than 11,000 mobile COVID-19 vaccination clinics across the country⁶
- Pharmacies provide more than 20,000 COVID-19 testing sites nationwide
- Pharmacies provide access to COVID-19 antivirals at thousands of locations nationwide
- 70% of pharmacy testing sites are in areas with moderate to severe social vulnerability⁷

Federal Authorities for Public Access to Pandemic-Related Care Remain Paramount

Without the emergency allowances for pharmacy personnel provided under the current PREP Act declaration – and subsequent amendments – much of the important work outlined above would not have been possible on such a wide scale. Specifically, these flexibilities provided pharmacists the ability to order and administer – and appropriate pharmacy staff to administer – COVID-19 tests, COVID-19 vaccinations, COVID-19 therapeutics, ACIP-recommended childhood vaccinations, and flu vaccinations for adults.⁸ We cannot overstate how paramount these flexibilities have been in supporting pandemic-related care access at pharmacies.

Furthermore, as COVID-19 cases currently trend downward, following a significant spike earlier this year as a result of the Omicron variant,⁹ some experts are optimistic about the potential transition from pandemic to endemic in 2022. Keeping the emergence of new variants at bay may strengthen that possibility; however, there are still many unknowns given the oscillating ebb and flow of the pandemic observed to date. In any case, comprehensive, equitable access to vaccinations, testing, and antiviral treatment remain at the forefront as essential elements of recovery plans.

Importantly, current authorizations under the PREP Act declaration continue to be tremendously impactful and necessary in allowing retail pharmacies nationwide to meet Americans' various, evolving needs across vaccinations, testing, and treatment. However, it is well understood that these authorities will expire eventually, and under the

¹ <https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html>

² White House, available at <https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/02/fact-sheet-president-biden-announces-new-actions-to-protect-americans-against-the-delta-and-omicron-variants-as-we-battle-covid-19-this-winter/>

³ <https://www.gao.gov/assets/gao-22-105079.pdf>

⁴ Biden Administration, COVID-19 Vaccine for Children 6 Months – 4 Years Old Preliminary Considerations for Pediatric Planning, February 2022, available at <https://www.aha.org/system/files/media/file/2022/02/covid-19-vaccine-for-children-6-months-4-years-old-preliminary-considerations-for-pediatric-planning.pdf>

⁵ <https://www.gao.gov/assets/gao-22-105079.pdf>

⁶ <https://www.gao.gov/assets/gao-22-105079.pdf>

⁷ White House, [FACT SHEET: Biden Administration Announces Historic \\$10 Billion Investment to Expand Access to COVID-19 Vaccines and Build Vaccine Confidence in Hardest-Hit and Highest-Risk Communities](#)

⁸ Thousands of pharmacies are currently providing important access to COVID-19 therapeutics, including providing patient and prescriber education, coordinating with prescribers on appropriate use, initiation within the 5-day symptom window, dosing adjustments, infection control procedures, and more. However, the federal government had also granted pharmacists federal authority via the PREP Act declaration to prescribe COVID-19 therapeutics back in September as a planning step to allow for a seamless patient experience where someone, if they chose to, could receive testing, evaluation/prescribing, and get their medication all in one place – at their local pharmacy. However, unexpectedly, the emergency use authorizations (EUAs) issued by FDA for the two COVID-19 oral antiviral medications needlessly omitted this important planning step. This omission can lead to access barriers for patients who now often visit one setting for testing, potentially another for evaluation/prescribing, and then finally visit the pharmacy to receive their treatment, rather than allowing patients to receive this care more conveniently, all in one place at their local pharmacies. NACDS continues to advocate against this needless barrier and for pharmacists to be leveraged in the full end-to-end patient journey to help ensure those who need access, have it in a timely manner, to these vital medications.

current declaration text, **that the expiration timeline for pharmacy personnel is unclear.** This uncertainty makes it extremely difficult for pharmacies to plan for future testing, vaccination, and antiviral efforts when such authorities could expire unexpectedly, potentially in correspondence with the impending conclusion of the PHE. Understandably, pharmacies will need to begin planning several months ahead of any expiration to gradually ramp down activities that have largely been made possible because of the actions taken under the current PREP Act declaration. This means Americans could experience decreased access to COVID-19 vaccinations, testing, and therapeutics, months in advance of any expiration date.

While optimism is mounting, and may be warranted, for a potential end of the currently declared PHE, it is important that the access to care Americans have come to rely on and expect at pharmacies is maintained. Pharmacies have demonstrated their importance as an access point, and remain vital to continue meeting Americans' needs and protecting health and wellness, especially as the nation navigates the potential transition from pandemic to endemic. Importantly, long-term solutions are needed as lessons learned from this pandemic demand the nation establish flexible, scalable, and sustainable access to vaccinations, testing, and other pandemic-related care for Americans at pharmacies now and permanently for future public health crises.

Purpose of Request for Clarification and Suggested Pathway for Continuation

Pursuant to the Eighth Amendment to the PREP Act declaration issued in August 2021, the Secretary made significant changes to the expiration dates for liability immunity for various persons, items, and activities.¹⁰ Significantly, the declaration prescribes that liability immunity for certain persons extends until October 2024. For example, healthcare professionals under section (V)(f) of the declaration – who hold an active license or certification to prescribe, dispense, or administer vaccines under a state law and are conducting such activities in a different state – enjoy liability immunity until October 1, 2024.¹¹ Similarly, members of a uniform service performing under section (V)(g) enjoy liability immunity until October 1, 2024.

Yet, this expiration date does not appear to also apply to pharmacy personnel in any capacity conducting any action authorized under the current PREP Act declaration. Indeed, the only mention of pharmacy personnel in the expiration section states, “[l]iability protections for Qualified Persons under section V(d) of the Declaration who are qualified pharmacy technicians and interns to administer seasonal influenza vaccine to persons aged 19 and older begin on August 4, 2021.” Notably, this provision has no corresponding expiration date. Even if this provision had a corresponding expiration date, however, the expiration would appear to only apply to pharmacists, interns, and technicians conducting certain types of vaccinations under (V)(d). We seek clarification on the expiration date for all pharmacy personnel conducting all activities authorized under the PREP Act declaration during this pandemic, in alignment for the expiration afforded to others in 2024, irrespective of the COVID-19 PHE declaration.¹² We ask that the authorities granted to pharmacy personnel not expire until October 1, 2024. In the alternative, we ask the Secretary to leverage his authority to extend pharmacy personnel authorities pursuant to “a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency.”¹³ Using this pathway, the Secretary may ensure the provisions under the existing PREP Act declaration are maintained beyond the end of the declared PHE.

¹⁰ See <https://www.federalregister.gov/documents/2021/08/04/2021-16681/eighth-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for>

¹¹ Under this subsection, pharmacists or interns authorized under (V)(d) of the declaration who prescribe, dispense, or administer COVID-19 vaccines are included. Yet, it is unclear if that inclusion is meant to avail those pharmacists/interns operating under reciprocity to the October 1, 2024 expiration date.

¹² Even before the Eighth Amendment, the expiration dates for pharmacy personnel activities such as COVID-19 testing and vaccination were unclear. Indeed, in previous iterations of the PREP Act declaration, the Secretary outlined two expiration dates: 1) for those engaged in federal contracts, immunity ended at the end of the PHE or October 1, 2024, whichever occurs first; or 2) for activities outside of federal contracts, immunity ended when the PHE ends. Interpretation of these provisions varied, with some arguing that those activities conducted by pharmacy personnel under federal contracts, like the Federal Retail Pharmacy Program (FRPP), would enjoy immunity until October 2024. This read, however, has not been verified by the federal government.

¹³ 42 U.S.C. § 247d-6d(b)(1).

Conclusion

In conclusion, the value and importance of public access to care at pharmacies has been prominently underscored during the COVID-19 pandemic. It is now critical to maintain public access granted by flexibilities within the current PREP Act declaration and permanent solutions. Failure to do so will undoubtedly result in a loss of equitable access for patients. Now, more than ever, as optimism grows and the future looks bright, the Administration must maintain their proactive, all-hands-on-deck strategy to realize pandemic recovery for the American people.

For questions or further discussion, please contact NACDS' Sara Roszak, Senior Vice President, Health and Wellness Strategy and Policy at sroszak@nacds.org or 703-837-4251. We will reach out early next week to schedule a meeting.

Sincerely,



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

Cc: Director Walensky, CDC; AJ Pearlman, HHS; Nikki Jo Romanik, CDC; Natalie Quillian, White House; Sonya Sackner-Bernstein, White House; Sujeet Rao, White House; Anita Patel, CDC

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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 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. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit NACDS.org.