

June 7, 2022

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

Re: Request for Clarifications to Maintain Public Access to Pandemic-Related Services at the Nation's Pharmacies

Dear Secretary Becerra:

The undersigned organizations represent patients, public health advocates, pharmacists, pharmacy staff, and pharmacies. Given the essential role pharmacists, pharmacy staff, and pharmacies have played in the nation's ongoing COVID-19 response, we seek formal clarification from the U.S. Department of Health and Human Services (HHS) on potential expiration of pharmacy personnel flexibilities granted during the pandemic. These authorizations, enabled through numerous Public Readiness and Emergency Preparedness (PREP) Act declaration amendments and advisory opinions, support vaccination, testing, and therapeutics access at more than 41,000 pharmacies across the country. In particular, the authorities continue to support the cultivation of strong public health and pharmacy collaborations, synergistically leveraging the strengths of all community partners to better serve the American people.

In fact, a poll conducted by Morning Consult and commissioned by the National Association of Chain Drug Stores (NACDS) shows that 70% of Americans support extending these policies and 68% support making them permanent. Those who received a COVID-19 vaccination from a pharmacist or pharmacy staff in a pharmacy are even more supportive: 85% support extending these policies and 84% support making them permanent. These data emphasize that the reach and accessibility of pharmacists, pharmacy staff, and pharmacies have been invaluable to supporting a more equitable and robust pandemic response in lockstep with the efforts of public health and other community partners. For example:

- Pharmacists and pharmacy staff have administered more than 248 million COVID-19 vaccinations to date¹
- Approximately 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
- More than 40% 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

¹ CDC, Federal Retail Pharmacy Program, *available at* <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 GAO, Federal Efforts to Provide Vaccines to Racial and Ethnic Groups, *available at* <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*, Feb. 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 GAO, Federal Efforts to Provide Vaccines to Racial and Ethnic Groups, *available at* <https://www.gao.gov/assets/gao-22-105079.pdf>.

- Pharmacists and pharmacy staff have provided more than 11,000 mobile COVID-19 vaccination clinics across the country⁶
- Pharmacies have provided more than 45 million COVID-19 tests, across more than 20,000 testing sites nationwide, and 70% of such sites are in areas with moderate to severe social vulnerability⁷
- Pharmacies and retail health clinics provide access to COVID-19 antivirals at thousands of locations nationwide⁸

The authorities granted have been instrumental to supporting the role of pharmacists, pharmacy staff, and pharmacies to expand access and foster equity throughout the pandemic. Considering that the Public Health Emergency (PHE) may conclude in the future, the expiration of these important pharmacy personnel authorizations requires clarification. **Clarification from HHS that pharmacy personnel flexibilities granted through the PREP Act will remain in place through October 1, 2024, as established for other healthcare providers, is essential for effective, proactive community planning and to support certainty for public access.**

Current and ongoing ambiguities leave pharmacy personnel, their community and public health partners, and the American people they serve in an untenable position. Therefore, we respectfully request a technical correction to make clear that the end date for PREP Act coverage for all pharmacy personnel, including pharmacists and technicians, is no different than the end date for other professions as indicated and will continue through October 1, 2024.

Requested Action

We request HHS take immediate action to provide greater clarity for pharmacies. Please consider the following:

1. We request that the Secretary issue a declaration under the PREP Act clarifying that the relevant pharmacists, pharmacy staff, and pharmacy authorities granted in various amendments to the Secretary's existing declaration extend through October 1, 2024, even in the event the emergency declaration is rescinded because a credible risk of such an emergency remains, including:
 - **All of those outlined in section V(d) of the Declaration under the PREP Act for medical countermeasures against COVID-19:**
 - **Ordering and administration of COVID-19, flu, and pediatric vaccines;**
 - **Ordering and administration of COVID-19 testing and therapeutics; and,**
 - **That qualified persons include all pharmacy personnel: pharmacists, technicians, and interns;**
 - **As well as pharmacists and interns acting pursuant to V(j) with respect to reciprocity across state lines.**

⁶ GAO, Federal Efforts to Provide Vaccines to Racial and Ethnic Groups, available at <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, available at <https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/25/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/>
https://content.govdelivery.com/attachments/USDHSEMA/2021/03/09/file_attachments/1717220/By%20the%20Numbers.COVID.FINAL.Mar.%208.2021.pdf
<https://www.cdc.gov/icatt/index.html>

⁸ Also, the Administration recently announced a pharmacy-based Test-to-Treat initiative to help enhance access to COVID-19 antivirals through hundreds of pharmacy-based co-located clinics. While this program is a step in the right direction to promote a more seamless patient journey and better access to care, opportunity exists to further leverage the full force of pharmacies to address access and equity through pharmacist assessment and initiation of COVID-19 antivirals as authorized in September 2021 via the Ninth Amendment to the current PREP Act declaration. Unexpectedly, the emergency use authorizations (EUAs) issued by FDA for the two COVID-19 oral antiviral medications needlessly omitted pharmacists as authorized prescribers. In addition to those pharmacy locations able to participate in the Test-to-Treat initiative, thousands of pharmacies are also providing important access to COVID-19 therapeutics by providing a dispensing access point, and are also 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.

2. **We request that the Administration clearly state that all relevant countermeasures, personnel, and activities/authorizations⁹ outlined above are covered through October 1, 2024, irrespective of regional, state, or local declarations.** Connecting PREP Act declaration authorizations to states' declared emergencies, for example, undercuts the effectiveness of these flexibilities to mount an equitable, comprehensive, nationwide response. Consider, for example, that COVID-19 emergency orders have expired in the majority of states.

3. **Since the HHS Secretary had issued a letter indicating that the Administration would not end the PHE without providing sufficient advance notice, we urge the Administration similarly to provide an assurance that any expiration date of activities authorized under the PREP Act declaration would not be shortened prior to, or extended beyond the October 1, 2024, expiration date without at least 90 days' notice.** Advance notice of any expiration is critical given the extensive operational changes and considerations that would need to be untangled and ramped down.

Conclusion

Pharmacists, pharmacy staff, and pharmacies have demonstrated their tremendous value, importance, and collaboration in helping to maintain reliable access to needed countermeasures throughout the pandemic. Access granted by authorizations within the current PREP Act declaration must be maintained and clarified to support an ongoing, effective, and robust response for the American people.

We thank you for your consideration of our requests.

Signed,

Academy of Managed Care Pharmacy
Accreditation Council for Pharmacy Education
Alabama Pharmacy Association
Alabama Society of Health-system Pharmacists
Alaska Pharmacists Association
Alliance for Pharmacy Compounding
American Association of Colleges of Pharmacy
American College of Apothecaries
American College of Clinical Pharmacy
American Disease Prevention Coalition (ADPC)
American Pharmacists Association
American Society of Consultant Pharmacists
American Society of Health-System Pharmacists
Arizona Pharmacy Association
Arkansas Pharmacists Association
Association of Immunization Managers
California Pharmacists Association
California Society of Health-System Pharmacists
Colegio de Farmaceuticos of Puerto Rico

⁹ <https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx>.

Colorado Pharmacists Society
Connecticut Pharmacists Association
Connecticut Society of Health-System Pharmacists
Delaware Pharmacists Society
Florida Pharmacy Association
Florida Society of Health-System Pharmacists
FMI—The Food Industry Association
Georgia Pharmacy Association
Georgia Society of Health-System Pharmacists
Global Healthy Living Foundation
Hawai'i Pharmacists Association
Hematology/Oncology Pharmacy Association
Idaho Society of Health-System Pharmacists
Idaho State Pharmacy Association
Illinois Council of Health-System Pharmacists
Illinois Pharmacists Association
Indiana Pharmacists Association
Iowa Pharmacy Association
Kansas Pharmacists Association
Kentucky Pharmacists Association
Kentucky Society of Health-System Pharmacists
Louisiana Society of Health-System Pharmacists
Maine Pharmacy Association
Maine Society of Health System Pharmacists
Maryland Pharmacists Association
Massachusetts Society of Health System Pharmacists
Michigan Pharmacists Association
Minnesota Society of Health-System Pharmacists
Mississippi Pharmacists Association
Mississippi Society of Health-System Pharmacists
Missouri Pharmacy Association
Montana Pharmacy Association
National Alliance of State Pharmacy Associations
National Association of Chain Drug Stores
National Association of Specialty Pharmacy
National Community Pharmacists Association
National Consumers League
National Grocers Association
National Pharmaceutical Association
National Rural Health Association
Nebraska Pharmacists Association
Nevada Pharmacy Alliance
New Jersey Pharmacists Association
New Mexico Pharmacists Association
New Mexico Society of Health-System Pharmacists
New York State Council of Health-system Pharmacists
North Carolina Association of Pharmacists
North Dakota Pharmacists Association

North Dakota Society of Health-System Pharmacists
Ohio Pharmacists Association
Ohio Society of Health-System Pharmacy
Oklahoma Pharmacists Association
Oklahoma Society of Health-System Pharmacists
Oregon Society of Health-System Pharmacists
Oregon State Pharmacy Association
Pennsylvania Society of Health System Pharmacists
Pharmaceutical Care Management Association
Pharmacy Society of Wisconsin
RetireSafe
Rhode Island Pharmacists Association
Society of Infectious Diseases Pharmacists (SIDP)
South Dakota Pharmacists Association
South Dakota Society of Health System Pharmacists
Tennessee Pharmacists Association
Texas Pharmacy Association
Texas Society of Health-System Pharmacists
Utah Pharmacy Association
Vermont Pharmacists Association
Vermont Society of Health-System Pharmacists
Virginia Pharmacists Association
Virginia Society of Health-System Pharmacists
Washington Metropolitan Society of Health-System Pharmacists
Washington State Pharmacy Association
West Virginia Pharmacists Association