

February 13, 2022

The Honorable Xavier Becerra  
Secretary  
U.S. Department of Health & Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dr. Ashish Jha  
The White House  
Washington, DC 20500

**RE: Clarify PREP Act coverage for pharmacists, pharmacy interns and pharmacy technicians will continue until October 2024**

Dear Secretary Becerra and Dr. Jha,

The American Pharmacists Association (APhA) writes to express strong concerns on behalf of our nation's pharmacists and our patients in response to information contained in the February 9, 2023 [Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap](#)). HHS's discussion in the Fact Sheet of liability immunity is not clear and will result in confusion, patient delays, and reduced access to essential COVID-19 and related tests, immunizations, and therapeutics. We question HHS's interpretation based on information contained in the Public Readiness and Emergency Preparedness (PREP) Act, COVID-19 Declaration, Amendments, and other documentation and urge you to provide clarity and ensure that the PREP Act coverage of these activities will not end on May 11, 2023.

The Fact Sheet states:

*"Public Readiness and Emergency Preparedness (PREP) Act liability protections for may be impacted. Currently, the amended PREP Act declaration provides liability immunity to manufacturers, distributors, public and private organizations conducting countermeasure programs, and providers for COVID-19 countermeasure activities related to a USG agreement (e.g., manufacturing, distribution, or administration of the countermeasures subject to a federal contract, provider agreement, or memorandum of understanding). That coverage*

*will not be affected by the end of the PHE. However, PREP Act liability protections for countermeasure activities that are not related to any USG agreement (e.g., products entirely in the commercial sector or solely a state or local activity) will end unless another federal, state, or local emergency declaration is in place for area where countermeasures are administered. HHS is currently reviewing whether to continue to provide this coverage going forward.”*

Ending coverage on May 11, 2023, compromises the federal government’s commitment to public health response and promoting health equity. As you know, The HHS General Counsel’s Office has already [determined](#) the PREP Act authorities for our nation’s pharmacists, preempts state laws that restrict the ability of pharmacists to order and administer tests, treatments and immunizations that underserved communities have come to rely upon. Many states have updated their laws to authorize pharmacists, interns, and pharmacy technicians to perform the services authorized under the PREP Act, however, it is not consistent and is a work-in-progress, at best, across the nation.

The PREP Act liability coverage and authorities include pharmacists, pharmacy interns, and pharmacy technicians ability to:

- Order (pharmacists) and administer COVID-19 tests;
- Order (pharmacists) and administer COVID-19 and flu vaccinations (ages 3 years and older);
- Order (pharmacists) and administer all ACIP-recommended childhood vaccines (ages 3-18);
- Pharmacists dispense, order, or administer COVID-19 therapeutics.

We know from the [data](#) that both the federal and state governments rely upon pharmacists as a key part of our nation’s public health infrastructure, including providing:

- More than 50% of the COVID-19 vaccinations nationwide,
- 12 million more influenza vaccinations to adults in 2020-21 compared to the previous season, and
- 42 million tests and over 300 million vaccinations during the COVID-19 pandemic.

Even using [conservative estimates](#), pandemic interventions by pharmacists and teammates averted >1 million deaths, >8 million hospitalizations, and \$450 billion in healthcare costs. Patients have come to expect that they can access these vital healthcare services at their local pharmacy, particularly in [minority and underserved communities](#), where the neighborhood pharmacy may be the only healthcare provider for miles. The next variant, strain, or public health crisis could happen at any moment and the federal

government needs to provide certainty to its citizens that pharmacists and their team's roles are a permanent part of our nation's health care infrastructure on the frontlines that will be there for them.

This abrupt change will also create chaos and confusion at the pharmacy counter when pharmacists are deciding which vaccine to administer if they receive products pursuant to different agreements. Oftentimes, product is received from the same wholesaler regardless of whether it is from a federal or other source or agreement. Pharmacies typically do not segregate products on shelves by what source the product was received (federal, state, commercial).

Again, APhA urges you to continue to provide this coverage going forward and provide a more detailed explanation of the coverage description in the Fact Sheet. If you have any questions or require additional information, please contact Michael Baxter, Acting Head of Government Affairs, at [mbaxter@aphanet.org](mailto:mbaxter@aphanet.org).

Sincerely,

A handwritten signature in black ink, reading "Ilisa BG Bernstein". The signature is fluid and cursive, with the first name "Ilisa" being more prominent and the last name "Bernstein" written in a standard cursive script.

Ilisa BG Bernstein, PharmD, JD, FAPhA  
Interim Executive Vice President and CEO

CC: Dr. Thomas Tsai, Senior Policy Advisor for the COVID-19 Response, Testing and Treatment Coordinator White House COVID-19 Response Team  
The Honorable Dawn O'Connell, JD, Assistant Secretary for Preparedness and Response (ASPR)