



March 27, 2023

Stephen Cha, MD
Counselor to Secretary
U.S. Department of Health and Human Services (HHS)
200 Independence Ave SW
Washington, DC 20201

Dear Dr. Cha:

On behalf of the American Pharmacists Association (APhA), we would like to thank HHS Secretary Becerra and you for the opportunity to participate in the pharmacy roundtable on March 20, 2023. As a follow-up to this meeting, we are providing additional information about the potential for access to vaccinations to decline in a total of 46 states and the District of Columbia in 45 days and a potential decrease in access to COVID-19 tests and therapeutics. Due to the widespread impact this will have across the country and the already prevalent confusion amongst the pharmacy and state government community, we urge the Secretary's office to issue clear and unambiguous policy that liability protections originally authorized in the Declaration Under the Public Readiness and Emergency Preparedness (PREP) Act for Medical Countermeasures Against COVID-19¹ and the Third,² Fourth,³ Eighth,⁴ Ninth,⁵ and Tenth⁶ Amendments will remain in effect until October 1, 2024, or beyond.

Founded in 1852, APhA is the largest association of pharmacists in the United States representing the entire pharmacy profession. APhA members practice in community

¹ U.S. Department of Health and Human Services. Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19. Published March 17, 2020. Available at: <https://www.govinfo.gov/content/pkg/FR-2020-03-17/pdf/2020-05484.pdf>.

² U.S. Department of Health and Human Services. Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19. Published August 24, 2020. Available at: <https://www.govinfo.gov/content/pkg/FR-2020-08-24/pdf/2020-18542.pdf>.

³ U.S. Department of Health and Human Services. Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration. Published 12/9/2020. Available at: <https://www.govinfo.gov/content/pkg/FR-2020-12-09/pdf/2020-26977.pdf>.

⁴ U.S. Department of Health and Human Services. Eighth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19. Published August 4, 2021. Available at: <https://www.govinfo.gov/content/pkg/FR-2021-08-04/pdf/2021-16681.pdf>.

⁵ U.S. Department of Health and Human Services. Ninth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19. Published 9/14/2021. Available at: <https://www.govinfo.gov/content/pkg/FR-2021-09-14/pdf/2021-19790.pdf>.

⁶ U.S. Department of Health and Human Services. Tenth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19. Published January 7, 2022. Available at: <https://www.govinfo.gov/content/pkg/FR-2022-01-07/pdf/2022-00151.pdf>.

pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

The need for greater clarity is due in part to conflicting interpretations of this language included in *Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap*⁷:

“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.”

And this language in the Administration for Strategic Preparedness & Response’s (ASPR’s) *PREP Act Questions and Answers*⁸:

“For all activities related to a federal agreement through October 1, 2024 (for example, a federal contract for procurement and distribution of vaccines or treatments, provider agreement; memorandum of understanding, etc.);”

*“For all activities not related to a federal agreement (e.g., countermeasures distributed entirely through the commercial sector or as part of a state emergency response) **through October 1, 2024**, or the end of any federal, regional, state, or local declared emergency, whichever is first;”*

“Thus, under the terms of the current PREP Act declaration for COVID -19 countermeasures, PREP Act coverage will end if the PHE and all other emergency declarations end, and there is no federal agreement relevant to the activity.”

It has been made clear that liability immunity for pharmacy personnel to provide various countermeasures related to a federal agreement will remain in effect until October 1, 2024. However, there remains conflicting interpretations for countermeasures and activities related to a non-federal agreement, which is resulting in divergent decisions by both public and private decision-makers. On the call with the HHS Secretary, it was conveyed that at least currently,

⁷ U.S. Department of Health and Human Services. Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap. Published February 9, 2023. Available at: <https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html>.

⁸ U.S. Administration for Strategic Preparedness & Response. PREP Act Questions and Answers. Accessed March 21, 2023. Available at: <https://aspr.hhs.gov/legal/PREPAct/Pages/PREP-Act-Question-and-Answers.aspx>.

PREP Act coverage for countermeasures and pharmacist and pharmacy personnel activities will remain when the PHE expires on May 11, 2023, particularly related to vaccines and therapeutics, because they are not entirely commercially available. This should be made explicitly clear by HHS publicly.

Examples of conflicting and confused decisions include:

- a national pharmacy chain sending out the following message on March 22, 2023, “Technician Immunizers in the following 27 states, Washington, D.C., and Puerto Rico **CANNOT administer vaccinations after 5/11*: AK, AZ, CA, CT, DC, GA, HI, IL, IN, KS, ME, MD, MA, MN, MS, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, VT, WV, Puerto Rico**”
- a state Board of Pharmacy ruled that pharmacists will lose the ability to provide any immunization to patients down to age 3 years old and pharmacists’ immunization scope of practice will defer back to state scope of practice after May 11, 2023.

There is an urgency for clarity because the interpretation of when liability immunity for pharmacists to order or administer and pharmacy personnel to administer vaccines will impact 46 states and the District of Columbia. Additionally, the interpretation of when liability immunity for pharmacists to order and administer and pharmacy interns or pharmacy technicians under the supervision of a pharmacist to administer FDA-authorized, approved, or licensed COVID-19 therapeutics will impact 44 states and the District of Columbia.

Here are some questions from APhA and others that we urge the Secretary’s office to provide answers to, in addition to clear and unambiguous guidance:

- The HHS Transition Roadmap Fact Sheet states that “*unless another federal, state, or local emergency declaration is in place for area where countermeasures are administered,*” making coverage dependent on a specific “area.” However, the HHS Question and Answer document does not mention area and instead states that immunity ends “if the PHE *and all other emergency declarations* end, and there is no federal agreement relevant to the activity.” With the emphasis in the latter FAQ, it can be interpreted to mean that in the totality of emergency declarations, if one is in place, then coverage remains, independent of area where administered, since area was not mentioned. What is the scope of “all other emergency declarations?”
- If a product is approved, licensed, or cleared and in the commercial sector but an indication or use is authorized under an emergency use authorization (EUA), does that mean the product is not “entirely in the commercial sector?” Several vaccines have authorizations for administration to certain ages that are not fully licensed or approved. If this means the product is not entirely in the commercial sector, this should also be clarified by HHS. Many are interpreting that since the product is commercialized, there is no coverage. Some are interpreting this to mean that administration to only those authorized age groups, and not all administration or use related to that product, is covered.

- Does liability immunity for ordering (pharmacists) and administering (pharmacist, pharmacy intern, pharmacy technician) all ACIP-recommended childhood vaccines (ages 3-18) and influenza vaccines (ages 3 and up) that are entirely in the commercial sector or solely a state or local activity end on October 1, 2024? If not, what is the date liability immunity ends? If there is an end of any “*regional, state, or local declared emergency*” after May 11, 2023, but prior to October 1, 2024, will this impact federal PREP Act liability immunity coverage?

With the end of the federal PHE set to expire in 45 days, and the lack of clarity as to whether the end of the federal PHE will impact the liability immunity granted under PREP Act Declarations for pharmacy personnel ordering and administering vaccines and COVID-19 therapeutics, we are concerned about patient and health care professional confusion, and delays in providing needed vaccines and therapeutics.

We ask HHS to urgently provide clear and unambiguous guidance as to when liability immunity provided under PREP Act Declaration Amendments will be ending for all activities that are related to a federal agreement and activities not related to a federal agreement. Furthermore, to avoid the inevitable confusion and complications in the marketplace, APhA urges HHS to maintain the liability immunity for all current activities related to the PREP Act until October 1, 2024, regardless of whether they are related to a federal agreement.

We appreciate our recent meeting and your focus on these important and urgent issues. Please contact Michael Baxter, APhA Acting Head of Government Affairs at mbaxter@aphanet.org with any additional questions or to arrange a meeting with us.

Sincerely,



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

cc: The Honorable Xavier Becerra, HHS Secretary