

Fact Sheet: HHS Announces Intent to Amend the Declaration Under the PREP Act for Medical Countermeasures Against COVID-19

Today, Secretary Becerra is announcing that in the coming weeks, he will issue an amendment to the declaration under the *Public Readiness and Emergency Preparedness* (PREP) Act for medical countermeasures against COVID-19. The PREP Act declaration has been a key tool for ensuring that Americans have broad access to critical COVID-19 countermeasures including vaccines, tests, and treatments. The PREP Act declaration has provided flexibilities and protections for those individuals and entities who have been involved in providing these critical tools that have helped the United States get to a better place with COVID-19. For the past three years, much of the health care landscape—including pharmacies—has relied on these flexibilities and liability protections. By issuing this amendment, the Secretary of HHS intends to allow pharmacies to continue their critical roles in our response, even after certain products transition to traditional health care pathways. The end of the COVID-19 public health emergency alone does not automatically terminate PREP Act coverage for countermeasures. This Fact Sheet will explain some of the key planned changes that partners can expect regarding PREP Act coverage as well as some of what will not change.

In the month remaining before the end of the COVID-19 Public Health Emergency (PHE) declared under section 319 of the Public Health Service Act, HHS will continue to work closely with its partners, including Governors, state, local, Tribal, and territorial agencies, industry, and advocates to ensure an orderly transition.

Amendment to the Declaration Under the PREP Act for Medical Countermeasures Against COVID-19:

Over the past three years, the PREP Act declaration has provided liability protection to manufacturers, distributors, and other organizations conducting countermeasure programs and providers administering COVID-19 countermeasures. This coverage includes liability protection for those entities engaged in manufacturing, distribution, or administration of COVID-19 countermeasures (such as tests, treatments, and vaccines) purchased by the Federal government for administration at pharmacies and other locations.

All COVID-19 vaccines and treatments **for which distribution is currently directed by the United States Government** (USG) are covered by PREP Act protections and flexibilities. Additionally, COVID-19 tests that are administered through the USG Increased Community Access to Testing (ICATT) program are covered by PREP Act protections and flexibilities.

Even once vaccines, tests, and treatments move away from being distributed under a USG agreement as they transition to traditional pathways for procurement, distribution, and payment, PREP Act coverage will not automatically terminate in all instances. Rather, the duration of PREP Act coverage for COVID-19 countermeasures will be determined by the terms of the PREP Act declaration in place at the time.

In light of the significant impact of this policy on the health care landscape and in order to provide further clarity, HHS is providing additional information about key elements of our plans for some of the PREP Act flexibilities and protections that will remain in place moving forward.

This Fact Sheet is not exhaustive, and the amended declaration may address additional issues not covered here.

Key changes that Secretary Becerra plans to make under the upcoming amended declaration include:

- **Extending coverage for COVID-19 vaccines, seasonal influenza vaccines, and COVID-19 tests.** PREP Act immunity from liability will be extended through December 2024 to pharmacists, pharmacy interns, and pharmacy technicians to administer COVID-19 and seasonal influenza vaccines (to those individuals three and over, consistent with other requirements), and COVID-19 tests, regardless of any USG agreement or emergency declaration.
- **Extending coverage through December 2024 for Federal agreements.** This includes all activities related to the provision of COVID-19 countermeasures that are 1) provided based on a Federal agreement (including the vaccines and treatments purchased and provided by the USG), or 2) directly conducted by the USG, including by Federal employees, contractors or volunteers.
- **Ending of coverage for certain activities.** Once products are no longer distributed under a USG agreement, PREP Act coverage will no longer extend to the following activities:
 - COVID-19 vaccination by non-traditional providers (e.g., recently retired providers and students); and
 - COVID-19 vaccinations across state lines by licensed providers and pharmacists and pharmacy interns.
- **Ending of coverage for routine childhood vaccinations:** Once there is no emergency in effect, PREP Act coverage will no longer extend to all routine childhood vaccinations by pharmacists, pharmacy interns, and pharmacy technicians.

Some of the key features that will not change under the amended declaration include:

- **No immediate impact on USG distributed COVID-19 countermeasures.** As noted above, the amended PREP Act declaration will not have any immediate impact on COVID-19 vaccines, treatments, and tests currently distributed by the USG—either now or when the COVID-19 PHE ends on May 11.
- **No change to coverage for certain prescribing and dispensing of COVID-19 oral antivirals.** The PREP Act will continue to offer liability immunity for pharmacists, pharmacy technicians, and pharmacy interns dispensing COVID-19 treatments, in accordance with a U.S. Food and Drug Administration (FDA) authorization, such as the oral antiviral treatments Paxlovid and Lagevrio. In the case of Paxlovid, pharmacists are permitted to prescribe the treatment under certain circumstances. These oral antiviral treatments are available at over 40,000 provider locations, including over 35,000 retail pharmacies.

- **No change to the “Test to Treat” program.** Pharmacists and other providers prescribing tests in the “[Test to Treat](#)” program will continue to receive liability protection under the PREP Act.

The protections provided by the PREP Act declaration have helped millions of Americans receive convenient and timely COVID-19 vaccines, treatments, and tests. Recognizing this, the amended declaration that Secretary Becerra will sign will extend important protections to continue to facilitate such access and may address additional issues not covered here. HHS will share additional guidance on any further extensions of PREP Act coverage when the amended declaration is published.



THE SECRETARY OF HEALTH AND HUMAN SERVICES

WASHINGTON, D.C. 20201

April 14, 2023

Dear Governor:

As I shared in my February 9 [letter](#) to you, the U.S. Department of Health and Human Services (HHS) is planning for the federal Public Health Emergency (PHE) declared under the Public Health Service Act for COVID-19 to end on May 11. While COVID-19 is not over, we are in a position to end the emergency phase of our response because of the Administration's whole-of-government approach to combatting the virus. Along with the February 9 letter, I shared a [Fact Sheet](#) explaining some of what will and will not change as a result of the end of the PHE. As we enter the final month of the COVID-19 PHE and continue the process of transitioning the emergency policies enabled by the COVID-19 emergency declarations, I would like to provide clarity regarding the future of coverage of COVID-19 countermeasures under the *Public Readiness and Emergency Preparedness Act* (PREP Act).

The protections provided by the PREP Act have helped millions of Americans receive convenient and timely COVID-19 vaccines, treatments, and tests. Recognizing this, I am announcing today that I intend to amend the PREP Act declaration to extend certain important protections that will continue to facilitate such access. Attached is a Fact Sheet outlining key details. This Fact Sheet is not exhaustive, and the amended declaration may address additional issues not covered here. HHS will share additional guidance on any further extensions of PREP Act coverage when the amended Declaration is published.

Addressing COVID-19 remains a significant public health priority for the Administration. In the month remaining before the end of the PHE, HHS will continue to work closely with its partners, including Governors, state, local, Tribal, and territorial agencies, industry, and advocates to ensure an orderly transition. Thank you for your sustained partnership as we work to safeguard and advance the health and well-being of the American people.

Sincerely,

A handwritten signature in blue ink, appearing to read "Xavier Becerra".

Xavier Becerra