

Public Readiness and Emergency Preparedness (PREP) Act

Update

Twelfth Amendment to the Declaration under the PREP Act for COVID-19 Medical Countermeasures

On December 11, 2024, Secretary Becerra signed the 12th amendment to the declaration under the PREP Act for COVID-19 Medical Countermeasures. The Secretary issues this amendment pursuant to section 319F-3 of the Public Health Service Act to extend the duration of the Declaration to December 31, 2029, and to republish the Declaration in full.

(<https://public-inspection.federalregister.gov/2024-29108.pdf>)

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of the Department of Health and Human Services (Secretary) to issue a PREP Act declaration. The declaration provides immunity from liability (except for willful misconduct) for claims:

- of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions
- determined by the Secretary to constitute a present, or credible risk of a future public health emergency
- to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures

A PREP Act declaration is specifically for the purpose of providing immunity from liability, and is different from, and not dependent on, other emergency declarations.

COVID-19 PREP Act Declarations

The end of the COVID-19 Public Health Emergency Declaration does not automatically terminate PREP Act coverage. To learn more, view our COVID-19 PREP Act FAQs (</legal/PREPact/Pages/PREP-Act-Question-and-Answers.aspx#COVID>).

Declaration and Amendments +

Advisory Opinions of the General Counsel +

HHS Guidance -

- Guidance for National Guard Personnel Regarding COVID-19 Vaccines and Immunity under the PREP Act (December 18, 2020) (</legal/PREPact/Pages/national-guard-prep-act.aspx>)
- Guidance for Department of Defense Personnel, Contractors, and Volunteers Regarding COVID-19 Vaccines and Immunity under the PREP Act (February 2, 2021) (</legal/PREPact/Pages/prep-act-guidance-DoD-COVID.aspx>)
- PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures (October 29, 2020) (<https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-authorization-pharmacies-administering-covered-countermeasures.pdf>)

- Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing (October 20, 2020)
(<https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf>)
- Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act (September 3, 2020)
(<https://www.hhs.gov/sites/default/files/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf>)
- Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act (April 8, 2020) (<https://www.hhs.gov/sites/default/files/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf>)
- Guidance for PREP Act Coverage for COVID-19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities (August 31, 2020)
(<https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-coverage-for-screening-in-congregate-settings.pdf>)

Other Current PREP Act Declarations

Smallpox, Mpox, and Other Orthopox



- Smallpox Medical Countermeasures (amended effective January 1, 2016)
(<https://www.federalregister.gov/articles/2015/12/09/2015-31092/smallpox-medical-countermeasures-amendment>)
- Notice of Amendment to the January 1, 2016 Republished Declaration Under the Public Readiness and Emergency Preparedness Act
(<https://www.federalregister.gov/documents/2022/10/03/2022-21412/notice-of-amendment-to-the-january-1-2016-republished-declaration-under-the-public-readiness-and>)
- PREP Act Coverage: Frequently Asked Questions for Mpox (/legal/PREPact/Pages/PREP-Act-FAQs-Monkeypox.aspx)

Viral Hemorrhagic Fevers



Nerve Agents and Insecticides



Zika Virus



Pandemic Influenza



Anthrax



Acute Radiation Syndrome



Botulinum Toxin



PREP Act ([/legal/PREPact/Pages/default.aspx](#))

About the PREP Act



PREP Act Frequently Asked Questions



Expanding the COVID-19 Vaccination Workforce

