

NewsBREAK | May 11

HHS Updates Declaration Under the PREP Act for Medical Countermeasures Against COVID-19

Regulatory NewsBREAK

- On January 31, 2020, HHS declared a public health emergency (Declaration) pursuant to the Public Readiness and Emergency Preparedness Act (PREP Act), in response to the COVID– 19 outbreak.
- HHS is issuing an amendment updating its Declaration and stating that COVID-19 presents a credible risk of a future public health emergency.
- The amendment extends PREP Act coverage through December 31, 2024, for manufacturing, distribution, administration, and use of Covered Countermeasures while they are authorized for emergency use (EUA) by the Food and Drug Administration (FDA) to allay any concerns about liability arising during an EUA authorization period.
- The amendment extends PREP Act coverage through December 31, 2024, for manufacturing, distribution, administration, and use of Covered Countermeasures that are FDA-licensed COVID-19 vaccines, and any FDA-approved or -cleared in vitro diagnostic product or other device used to treat, diagnose, cure, prevent, or mitigate COVID-19.
- The amendment extends PREP Act coverage through December 31, 2024, to Qualified Persons who are licensed pharmacists to order and administer, and pharmacy interns and qualified pharmacy technicians to administer, COVID-19 vaccines, seasonal influenza vaccines, and COVID-19 tests.
- This amendment is effective as of May 11, 2023, through December 31, 2024.

See the Notice of Amendment for additional details.

More on This Topic

Notice of Amendment

For questions, please reach out to <u>Tyler Thorne</u>.

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