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# The PREP Act and COVID-19: Two Years Later

Advisory  
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The Public Readiness and Emergency Preparedness Act (PREP Act) provides immunity from liability to certain entities and individuals for claims of loss that have a causal relationship to the administration or use of a Covered Countermeasure in the event the Secretary of Health and Human Services (HHS) makes a determination that a threat to health constitutes, or in the future may constitute, a public health emergency. On March 10, 2020, the Secretary of HHS issued a PREP Act Declaration, effective as of February 4, 2020, to provide liability immunity to “Covered Persons” who engage in “Recommended Activities” related to “Covered Countermeasures” against COVID-19 (COVID-19 Declaration). Since the COVID-19 Declaration, there have been ten amendments issued by the Secretary of the HHS, six advisory opinions from the HHS General Counsel, and seven additional guidances published by the HHS Secretary. This Advisory provides an overview of these amendments and guidances.

## Background on the PREP Act and The COVID-19 Declaration

The COVID-19 Declaration defines Covered Countermeasures as:

... any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.

In general, these are products that are approved, cleared or licensed by FDA; authorized for investigational use, i.e., an Investigational New Drug (IND) or Investigational Device Exemption (IDE), by FDA, authorized under an Emergency Use Authorization EUA by FDA, or otherwise permitted to be held or used for emergency use in accordance with federal law.

Under the COVID-19 Declaration, liability immunity is afforded to Covered Persons for “Recommended Activities” involving Covered Countermeasures that are related to:

- Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements; or
- Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of an emergency.

The COVID-19 Declaration defines “Authority Having Jurisdiction” to mean the public agency or its delegate that has legal responsibility and authority for responding to an incident based on political or geographical (e.g., city, county, tribal, state, or federal boundary lines) or functional (e.g., law enforcement, public health) range or sphere of authority. “Covered Persons” include manufacturers, distributors, program planners, qualified persons, along with their officials, agents, and employees, as well as the United States. Further information on the PREP Act can be found in our earlier guidance, located [here](#).

The amendments, guidances and advisory opinions that have been published since the enactment of the COVID-19 Declaration are described briefly below. These updates have generally had the objective of broadening the scope of immunity provided under the PREP Act. For example, the Fourth Amendment establishes that, in certain situations, not administering a Covered Countermeasure to a particular individual can fall within the PREP Act, and several Amendments expand the definition of Covered Person to include individuals such as pharmacists. Furthermore, the advisory opinions provide that a reasonable belief standard should apply when determining the limits of PREP Act immunity.

The updates have also allowed the PREP Act and COVID-19 declaration to evolve as the public response to the pandemic has progressed. Indeed, recent Amendments expand the scope of individuals who are considered Covered Persons for the purposes of administering vaccines and COVID-19 therapeutics, and address tangential medical issues such as the decrease in the rate of childhood immunizations seen during the pandemic. Taken together, the use of amendments, guidances and advisory opinions have been an effective tool for the government to quickly address a changing landscape and help direct the public’s response to the pandemic.

## Amendments to the COVID-19 Declaration

- **First Amendment (April 15, 2020):** This amendment extends the definition of Covered Countermeasures to include covered countermeasures authorized by the CARES Act, namely respiratory protective devices approved by the National Institute for Occupational Health and Safety (NIOSH). The full text of the first amendment can be found [here](#).
- **Second Amendment (June 8, 2020):** This amendment clarifies that Covered Countermeasures under the Declaration include qualified pandemic and epidemic products that limit the harm COVID-19 might otherwise cause. The language, “limit the harm such a pandemic or epidemic might otherwise cause,” was included in the preamble to the Declaration, but not in the definition of a Covered Countermeasure. This amendment notes that products that limit the harm that COVID-19 might otherwise cause are those that would not have been manufactured, administered, used, but for the COVID-19 pandemic, even when the products are used for health threats or conditions other than COVID-19. The full text of the second amendment can be found [here](#).
- **Third Amendment (August 24, 2020):** This amendment adds to the definition of Covered Persons, certain state-licensed pharmacists to order and administer, and certain pharmacy interns, to administer, approved vaccines to persons ages three to 18. This amendment also revises the definition of the category of disease, health condition or threat which the use of Covered Countermeasures is aimed to address to include not only COVID-19 caused by SARS-CoV-2 or a virus mutating therefrom, but also other diseases, health conditions, or threats that may have been caused by COVID-19, SARS-CoV-2, or a virus mutating therefrom, including the decrease in the rate of childhood immunizations, which will lead to an increase in the rate of infectious diseases. This amendment addresses a report from the CDC that there was a decrease in pediatric vaccine ordering and administration as a result of the COVID-19 pandemic, and permits certain qualified pharmacists to administer vaccines to children. The full text of this amendment can be found [here](#).
- **Fourth Amendment (December 3, 2020):** The fourth amendment provides several updates. This amendment adds an additional category to Covered Persons, healthcare personnel using telehealth to order or administer Covered Countermeasures for patients in a state other than the state where the healthcare personnel are permitted to practice, and extends PREP Act coverage to situations where a Covered Person satisfies all other requirements of the PREP Act, even if there is no federal agreement to cover those activities and those activities are part of private distribution channels. This amendment also provides that there can be situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act’s liability protections.

<sup>1</sup> The amendment also notes that there is a “substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng’g. & Mfg.*, 545 U.S. 308 (2005),

<sup>2</sup> in having a unified, whole-of-nation response to the COVID-19 pandemic.” The other updates from the fourth amendment, along with the full amendment text are available [here](#).

- **Fifth Amendment (January 28, 2021):** The fifth amendment expands the list of Qualified Persons (which is included in the definition of Covered Persons) authorized to administer FDA-approved COVID-19 vaccines to two additional categories of persons: (1) healthcare providers who are licensed in a state to prescribe, dispense, and/or administer COVID-19 vaccines in any state or jurisdiction where the PREP Act applies, and (2) physicians, registered nurses, and practical nurses whose licenses expired within the past five years who prescribe, dispense, and/or administer COVID-19 vaccines in any state. This amendment also adds that [t]he plain language of the PREP Act makes clear that there is complete preemption of state law.”

<sup>3</sup> The full text of the fifth amendment can be found [here](#).

- **Sixth Amendment (February 16, 2021):** The sixth amendment expands the categories of Qualified Persons to include Federal employees, contractors and volunteers authorized by their Department or agency to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure as any part of their duties or responsibilities. The full text of the sixth amendment can be found [here](#).

- **Seventh Amendment (March 11, 2021):** The seventh amendment expands the categories of Qualified Persons to include licensed healthcare professionals who may not ordinarily prescribe, dispense or administer vaccines, additional healthcare providers with recently expired licenses, and students in a healthcare profession training program, subject to appropriate training, supervision, and other specified requirements. These health care professionals include midwives, paramedics, EMTs, physician assistants, respiratory therapists, dentists, podiatrists, optometrists or veterinarians. The full text of the seventh amendment can be found [here](#).

- **Eighth Amendment (August 4, 2021):** The eighth amendment clarifies that qualified pharmacy technicians are authorized to administer childhood vaccinations and COVID-19 vaccinations that are Covered Countermeasures, and expands the authorization for qualified pharmacy technicians and interns to administer seasonal influenza vaccines under the supervision of a pharmacist to persons aged 19 and older. The full text of the eighth amendment can be found [here](#).

- **Ninth Amendment (September 14, 2021):** The ninth amendment clarifies that licensed pharmacists are authorized to order and administer, and certain pharmacy interns and pharmacy technicians, are authorized to administer, COVID-19 therapeutics that are Covered Countermeasures. The full text of the ninth amendment can be found [here](#).

- **Tenth Amendment (January 7, 2022):** The tenth amendment expands the scope of authority for licensed pharmacists to order and administer, and qualified pharmacy interns to administer, seasonal influenza vaccines. The full text of the tenth amendment can be found [here](#).

## HHS General Counsel Advisory Opinions

HHS receives requests from various industry stakeholders regarding the scope and limitations of the PREP Act. In response, the HHS General Counsel’s office publishes Advisory Opinions addressing many of these inquiries that set out the views of the HHS Office of the General Counsel. Moreover, the Fourth Amendment to the COVID-19 Declaration, provides that the Declaration must be interpreted in accordance with the HHS General Counsel Advisories, and incorporated those Advisory Opinions into the Declaration for that purpose.

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- **First Advisory Opinion (May 19, 2020):** The first advisory opinion provides a list of Covered Countermeasures that were subject to Emergency Use Authorization (EUA), which can be found [here](#). Products used for COVID-19 can be considered Covered Countermeasures if they are subject to an EUA. The advisory opinion also provides that a reasonable belief standard will apply to the determination as to what is a Covered Countermeasure. Therefore, a person or entity that otherwise meets the requirements for PREP Act immunity will not lose that immunity, even if the product is not a Covered Countermeasure or they are not a Covered Person, as long as that person or entity reasonably could have believed that the product was a Covered Countermeasure and they were a Covered Person. The opinion also encourages all Covered Persons using or administering Covered Countermeasures to document the reasonable precautions they have taken to safely use the Covered Countermeasures. The full text of the first advisory opinion can be found [here](#).
- **Second Advisory Opinion (May 19, 2020):** This second advisory opinion responds to questions regarding whether the PREP Act preempts state licensing laws that restrict the ability for pharmacists to order and administer COVID-19 diagnostics. The advisory opinion provides that state and local authorities cannot prohibit Qualified Persons from ordering and administering Covered Countermeasures. The PREP Act declaration designates licensed pharmacists as Qualified Persons for the purpose of administering FDA-authorized COVID-19 tests, independent of state licensing laws. Further, the PREP act expressly preempts state of local requirements that prohibit this activity and states cannot challenge the declaration because the PREP Act provides that “No court of the United States, or any state, shall have subject matter jurisdiction to review . . . any action by the Secretary” pursuant to his declaration under the PREP Act. The full text of the second advisory opinion can be found [here](#).
- **Third Advisory Opinion (October 23, 2020):** The third advisory addresses vaccination-related issues. First, the advisory explains that because states or local authorities cannot impose any requirement that would prohibit activities authorized by the Secretary in a PREP Act declaration, states or local authorities are not prohibited from enacting less stringent licensing laws because they won’t be prohibiting the authorized activity. Second, under the third amendment to the declaration, certain pharmacists and pharmacy interns were added to the definition of Qualified Persons for the ordering/administering of COVID-19 vaccinations. Therefore any state or local law that requires a pharmacist to enter into a collaborative-practice agreement as a condition of administering the vaccines would be preempted if it prohibits a pharmacist from ordering and administering the vaccines. Lastly, the advisory opinion provides that when drugs are used to counteract COVID-19 vaccine reactions, they are subject to PREP Act immunity. The full text of the third advisory opinion can be found [here](#).
- **Fourth Advisory Opinion (October 23, 2020):** The fourth advisory opinion provides guidance on the definitions of “Program Planner” and “Authority Having Jurisdiction” under the PREP Act and the COVID-19 Declaration. For Program Planners, the advisory opinion provides that any individual or organization can become a Program Planner when they act in accordance with the PREP Act and the COVID-19 Declaration. The advisory opinion also notes that an applicable Authority Having Jurisdiction that recommends or requires using Covered Countermeasures in certain circumstances may qualify as authorizations under the PREP Act and the COVID-19 Declaration. Therefore, a Covered Person that complies with the public-health guidance issued by an Authority Having Jurisdiction over the person’s activity or location can qualify for PREP Act immunity. If there are conflicts among such guidances, PREP Act coverage will apply to a Covered Person using a Covered Countermeasure in accordance with any guidance. The full text of the fourth advisory opinion can be found [here](#).
- **Fifth Advisory Opinion (January 8, 2021):** The fifth advisory opinion provides that the PREP Act is a complete preemption statute. The advisory states that “[t]he *sine qua non* of a statute that completely preempts is that it establishes either a federal cause of action, administrative or judicial, as the only viable claim or vests exclusive jurisdiction in a federal court. The PREP Act does both.” The advisory further notes that “ordaining the metes and bounds of PREP Act protection in the context of a national health emergency necessarily means that the case belongs in federal court.” Furthermore, the advisory opinion expands on the Fourth Amendment and provides that decision-making that leads to the non-use of a Covered Countermeasure can be covered by the PREP Act. The advisory opinion notes that this decision-making is “the gist of program planning,” however, “the failure to purchase any PPE, if not the outcome of some form of decision-making process may not be sufficient to trigger the PREP Act.” The full text of the fifth advisory opinion can be found [here](#).

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- **Sixth Advisory Opinion (January 12, 2021):** The sixth advisory opinion clarifies that the language in the PREP Act Authorizations: “must be ordered and administered according to ACIP’s COVID vaccine recommendation(s),” means that the vaccine must be one that ACIP recommends for the prevention of COVID-19, and it does not mean that the vaccine must be administered pursuant to any particular guidance or recommendation (e.g., given to a specific priority group). The full text of the sixth advisory opinion can be found [here](#).

## HHS Assistant Secretary of Health Guidance

The PREP Act provides immunity to Covered Persons for Recommended Activities involving Covered Countermeasures that are related to activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction. The Office of the Assistant Secretary for Health has issued the following guidance documents as an Authority Having Jurisdiction under the COVID-19 Declaration.

- **Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act (April 8, 2020):** This guidance authorizes licensed pharmacists to order and administer COVID-19 tests, including serology tests, that are authorized by the FDA, and states that by doing so, such pharmacists will qualify as Covered Persons. The full text of this guidance can be found [here](#).
- **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):** This guidance extends coverage under the PREP Act to licensed healthcare practitioners prescribing or administering point-of-care COVID-19 tests, using anterior nares specimen collection or self-collection, for screening in congregate facilities across the U.S, as long as the tests are authorized, approved, or cleared by the FDA. The full text of this guidance can be found [here](#).
- **Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act (September 3, 2020):** This guidance authorizes state-licensed pharmacists to order and administer, and certain pharmacy interns to administer, to persons ages three or older, COVID-19 vaccinations that have been authorized or licensed by the FDA. Such pharmacists and pharmacy interns will qualify as “covered persons” under the PREP Act subject to certain requirements. The full text of this guidance can be found [here](#).
- **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):** This guidance followed up on the September 3, 2020 guidance and clarifies that the pharmacy intern must be authorized by the state or board of pharmacy in the state in which the practical pharmacy internship occurs, but this authorization need not take the form of a license from, or registration with, the state board of pharmacy. Furthermore, this guidance authorizes qualified pharmacy technicians and state-authorized pharmacy interns to administer COVID-19 tests, including serology tests, that the FDA has approved, cleared or authorized. The full text of this guidance can be found [here](#).
- **PREP Act Authorization for Pharmacists Distributing and Administering Certain Covered Countermeasures (October 29, 2020):** In furtherance of the Amendments to the COVID-19 Declaration declaring pharmacists Covered Persons when administering certain Covered Countermeasures, this guidance clarifies that pharmacies are also Qualified Persons when their staff pharmacists order and administer, or their pharmacy interns and pharmacy technicians administer, Covered Countermeasures consistent with the terms and conditions of the COVID-19 Declaration and guidances. The full text of this guidance can be found [here](#).
- **Guidance for National Guard Personnel Regarding COVID-19 Vaccines and Immunity under the PREP Act (December 18, 2020):** This guidance authorizes qualified Guardsmen as Covered Persons to administer to persons ages three or older, COVID-19 vaccinations that have been authorized or licensed by the FDA. Such Guardsmen will qualify as “Covered Persons.” The full text of this guidance can be found [here](#).
- **Guidance for Departments of Defense Personnel, Contractors, and Volunteers Regarding COVID-19 Vaccines and Immunity under the PREP Act (February 2, 2021):** This guidance authorizes qualified DOD personnel, contractors, and volunteers as Covered Persons to administer COVID-19 vaccinations that have been authorized or licensed by (FDA). The full text of this guidance can be found [here](#).

The PREP Act is a critical statute that was intended to provide extremely broad protection for covered countermeasures and has been central in supporting the development and implementation of countermeasures to further the public’s response to the COVID-19 pandemic. However, it remains to be seen how the scope of the PREP Act and the impact of these documents will be adjudicated in courts as more cases relating to the PREP Act are filed.

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