

The PREP Act and COVID-19, Part 2: The PREP Act Declaration for COVID-19 Countermeasures

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To encourage the expeditious development and deployment of medical countermeasures during a public health emergency, the Public Readiness and Emergency Preparedness Act ([PREP Act](#)) authorizes the Secretary of Health and Human Services (HHS) to limit legal liability for losses relating to the administration of medical countermeasures such as diagnostics, treatments, and vaccines. In a declaration effective beginning February 4, 2020 ([the HHS Declaration](#)), the Secretary of HHS (the Secretary) invoked the PREP Act and declared Coronavirus Disease 2019 (COVID-19) to be a public health emergency warranting liability protections for covered countermeasures. Under the HHS Declaration and its amendments, covered persons are generally [immune](#) from legal liability (i.e., they cannot be sued for money damages in court) for losses relating to the administration or use of covered countermeasures against COVID-19. The sole exception to PREP Act immunity is for death or serious physical injury caused by “[willful misconduct](#).” However, individuals who die or suffer serious injuries directly caused by the administration of covered countermeasures may be [eligible](#) to receive compensation through the [Countermeasures Injury Compensation Program \(CICP\)](#).

[Part 1](#) of this two-part Sidebar reviews the structure of the PREP Act and provides an overview of the CICP. This second part examines the HHS Declaration related to the COVID-19 pandemic in detail and discusses the scope of the PREP Act’s liability immunity as it applies to COVID-19 countermeasures. It also discusses the effective time periods for PREP Act immunity and how they apply after the May 11, 2023, [termination](#) of the federal public health emergency (PHE) declared for COVID-19 under Section 319 of the Public Health Service Act (the [Section 319 PHE](#)).

HHS’s COVID-19 Declaration and Amendments

On March 10, 2020, the Secretary invoked the PREP Act and [determined](#) that COVID-19 constitutes a public health emergency. The HHS Declaration [authorizes](#) PREP Act immunity for the “manufacture, testing, development, distribution, administration, and use” of covered countermeasures. These activities, however, [must either](#) relate to present or future federal contracts, or be part of the public health response to COVID-19 authorized by an “authority having jurisdiction,” such as federal, state, Tribal, or local

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governments. The immunity applies to all covered persons as defined in the PREP Act, [including](#) any person authorized by state and local public health agencies (or an emergency use authorization) to “prescribe, administer, deliver, distribute or dispense” covered countermeasures. [Covered countermeasures](#) include “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.” The “administration” of a covered countermeasure [includes](#) “physical provision of the countermeasures” to patients, as well as “activities and decisions directly relating to . . . delivery, distribution and dispensing of” the countermeasures. The [HHS Declaration provides](#) PREP Act immunity “without geographic limitation.”

The HHS Declaration has since been amended many times to broaden the scope of PREP Act immunity. First, in April 2020, [the Secretary amended](#) the Declaration to include respiratory protective devices approved by the National Institute for Occupational Safety and Health (NIOSH) as covered countermeasures, pursuant to amendments to the PREP Act made by [Section 3103](#) of the Coronavirus Aid, Relief, and Economic Security Act ([CARES Act](#)). Second, in June 2020, the [Secretary amended](#) the Declaration to clarify that drugs, biological products, and devices that “limit the harm COVID-19 might otherwise cause” are covered countermeasures, and that the HHS Declaration reaches “all qualified pandemic and epidemic products defined under the PREP Act.”

The [Third Amendment](#) to the HHS Declaration was issued in August 2020 and expanded the definitions of covered diseases and covered persons. First, HHS expanded the categories of disease representing a public health emergency [to reach not just](#) COVID-19, but also “other diseases, health conditions, or threats that may have been caused by COVID-19, SARS-CoV-2, or a virus mutating therefrom.” Such “other diseases” [include](#) diseases resulting from “the decrease in the rate of childhood immunizations, which will lead to an increase in the rate of infectious diseases.” The Third Amendment thus [declares](#) that pediatric vaccines (if licensed by FDA and recommended by the Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP)) are covered countermeasures. [Relying](#) on the PREP Act’s preemption provision, the Third Amendment adds a new category of “qualified persons” in order to [authorize](#) state-licensed pharmacists to administer ACIP-recommended vaccines to children aged 3 to 18, [notwithstanding](#) state laws to the contrary, if the pharmacists comply with certain federal requirements.

In December 2020, the Secretary issued a [Fourth Amendment](#) to the HHS Declaration. Among other things, the Fourth Amendment [states](#) that the HHS Declaration “must be construed in accordance with” the HHS advisory opinions (discussed below), which are expressly “incorporate[d]” into the Declaration. The Fourth Amendment makes “explicit” that the HHS Declaration (1) [covers](#) “all qualified pandemic and epidemic products” within the meaning of the statute; and (2) [may apply](#) to claims based on *not* administering a covered countermeasure, such as when the countermeasure is in short supply. The Fourth Amendment further [creates](#) a new category of “qualified persons” to cover health care providers using telehealth to order or administer covered countermeasures across state lines; [adds](#) a third covered means of distribution to extend liability protections to “additional private distribution channels”; and [clarifies](#) the licensing requirements for pharmacists to administer routine pediatric vaccinations under the Third Amendment, while expanding this category to include FDA-authorized COVID-19 vaccines as well.

In 2021, at the beginning of the Biden Administration, the Acting Secretary of HHS issued a series of four amendments to the HHS Declaration, all [intended](#) to “expand the pool” of people who may administer COVID-19 vaccines beyond health care providers already licensed in a given state. The amendments seek to [accomplish](#) this by broadening the definition of “covered persons” who may administer COVID-19 vaccines (or other vaccines and countermeasures), and preempting state laws to the contrary.

Under the [Seventh Amendment](#), issued in March 2021, the covered persons who may administer COVID-19 vaccines as part of state, federal, and Tribal vaccination efforts [included](#) (1) health care professionals licensed by a state to administer vaccines, including outside their state of licensure; (2) members of uniformed services (such as the National Guard) and certain authorized federal contractors, volunteers,

and employees; (3) state-licensed midwives, paramedics, emergency medical technicians (EMTs), physician assistants, respiratory therapists, dentists, podiatrists, optometrists, and veterinarians; (4) physicians, registered and practical nurses, pharmacists, pharmacy interns, midwives, paramedics, EMTs, respiratory therapists, dentists, physician assistants, podiatrists, optometrists, and veterinarians whose licenses became inactive, expired, or lapsed within the previous five years; and (5) certain medical, nursing, pharmacy, dental, podiatry, optometry, veterinary, and other students under the supervision of a practicing health care professional. Most of these groups must meet [additional requirements](#) to be covered under the PREP Act, such as completion of CDC training, an observation period by a practicing health care professional, a current certificate in cardiopulmonary resuscitation, and compliance with applicable recordkeeping and reporting requirements.

The [Eighth Amendment](#), issued in August 2021, expands upon the Third and Fourth Amendments' PREP Act coverage for state-licensed pharmacists who administer COVID-19 vaccines or ACIP-recommended pediatric vaccines. The Amendment [clarifies](#) that qualified pharmacy technicians and supervised pharmacy interns are authorized to administer these vaccines, and [expands](#) the vaccines these persons can administer to include seasonal influenza vaccines for adults. Similarly, the [Ninth Amendment](#) issued in September 2021 seeks to expand the pool of providers who may administer COVID-19 therapeutics, such as monoclonal antibodies. The Ninth Amendment [authorizes](#) state-licensed pharmacists, pharmacy interns, and qualified pharmacy technicians to administer these therapeutics, notwithstanding state law requirements and subject to a number of [requirements](#). Lastly, the [Tenth Amendment](#) issued in December 2021 further [expanded](#) the providers who may administer seasonal influenza vaccines to include certain pharmacists and pharmacy interns, including in states other than those in which they are licensed.

On May 9, 2023—two days before the Secretary terminated the Section 319 PHE for COVID-19—HHS issued the [Eleventh Amendment](#) to the Declaration. This amendment [extended](#) PREP Act immunity for some uses of COVID-19 countermeasures (including the administration of COVID-19 vaccines) through December 31, 2024. Without the Eleventh Amendment, liability protections for many uses of COVID-19 countermeasures that were “not related to any [federal] agreement” would have [ended](#) along with the Section 319 PHE, unless some other federal, state, or local emergency declaration applied.

On December 11, 2024—a few weeks before the Eleventh Amendment's time period extensions were due to expire—HHS issued the [Twelfth Amendment](#) to the Declaration. This amendment further extended PREP immunity time periods for some COVID-19 countermeasures for an additional five years (i.e., until December 31, 2029). The new effective time periods under the Twelfth Amendment are discussed in detail below.

HHS PREP Act Advisory Opinions

During the Trump Administration, the HHS General Counsel issued six advisory opinions on the PREP Act. Although these opinions are nonbinding and [lack the force of law](#), they may inform the judicial interpretation of the PREP Act if courts find their reasoning [persuasive](#).

First, in an [omnibus advisory opinion](#) issued in April 2020, the General Counsel summarized the elements for immunity under the PREP Act and set forth his view that [immunity extends to](#) (1) persons who “reasonably could have believed” that they were covered persons (even if they were not); and (2) products that a person “reasonably could have believed” were covered countermeasures (even if they were not). Second, in May 2020, the [General Counsel set forth his opinion](#) that the PREP Act preempts any state or local requirement that effectively prohibits a pharmacist from ordering and administering an FDA-authorized COVID-19 diagnostic test. In October 2020, the General Counsel issued a [third advisory opinion](#) expressing his view that, with respect to the administration of pediatric vaccines by pharmacists authorized under the Third Amendment, the PREP Act preempts only more stringent state licensing laws, and that epinephrine, if used to treat an acute reaction to an ACIP-recommended vaccination, is a covered

countermeasure. Fourth, and also in October 2020, the General Counsel re-emphasized the breadth of PREP Act immunity, explaining that (1) private businesses may qualify as “program planners” (and thus covered persons) when performing certain functions, and (2) activities authorized by an “authority having jurisdiction” include uses of covered countermeasures recommended by applicable public-health guidance, such as CDC guidance. The fifth advisory opinion of January 2021 analyzes whether PREP Act immunity may apply to claims based on the “non-use of a covered countermeasure,” such as allegations that a health care facility negligently failed to provide personal protective equipment to residents and workers. Lastly, in January 2021, the General Counsel opined that compliance with ACIP’s vaccine allocation recommendations was not a precondition for PREP Act immunity.

Effective Time Periods Under the PREP Act

The PREP Act [allows](#) the Secretary to identify in its declaration, for each covered countermeasure, the time “periods during which [PREP Act immunity] is in effect,” which “may be designated by dates, or by milestones or other description of events.” In addition, the Secretary may [extend](#) immunity to “a date after the ending date [specified in the declaration]” to allow for a reasonable period “for the manufacturer to arrange for disposition of the covered countermeasure” and “take such other actions as may be appropriate to limit administration or use of the covered countermeasure.”

For COVID-19 countermeasures, the current effective time periods for PREP Act coverage are set forth in [Section XII](#) of the Twelfth Amendment to the HHS Declaration. The applicable time period for liability immunity may depend on the type of COVID-19 countermeasure, the means of distribution, the covered person who administers the countermeasure, and other factors. Under Section XII, immunity for some uses of COVID-19 countermeasures [expired](#) in May 2023 along with the Section 319 PHE, unless some other federal, state, or local emergency declaration is still in effect. For example, the immunity for licensed pharmacists to administer ACIP-recommend vaccines other than COVID-19 vaccines (i.e., routine childhood vaccinations) generally [ended](#) in May 2023.

The immunity for other COVID-19 countermeasures (or particular uses of them) extends through December 31, 2029, under the current Declaration. Specifically, PREP Act immunity lasts through the end of 2029, regardless of the termination or the Section 319 PHE or other emergency declarations, [for](#)

- covered countermeasures that “related to present or future federal contracts . . . and other federal agreements” (e.g., where the federal government purchased or distributed the countermeasure);
- covered countermeasures authorized by FDA under an Emergency Use Authorization (as opposed to non-emergency FDA approvals or licensures) to diagnose, cure, prevent, mitigate, or limit the harm of COVID-19;
- FDA-licensed COVID-19 vaccines (e.g., those by [Pfizer-BioNTech](#) and [Moderna](#));
- FDA-cleared or approved in vitro diagnostic products for COVID-19 (i.e., tests for the presence of SARS-CoV-2, the virus that causes COVID-19).

PREP Act coverage also [extends](#) through 2029 for licensed pharmacists to administer COVID-19 vaccines or seasonal influenza vaccines (but not for other ACIP-recommended pediatric vaccines). In addition, the Secretary has exercised authority under the PREP Act to [provide](#) an additional 12 months of coverage beyond these end dates to allow manufacturers to arrange for the disposition of the countermeasures.

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