



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 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” beginning on February 4, 2020, and ending as late as October 1, 2025.

The HHS Declaration has since been amended many times to broaden the scope of PREP Act immunity, and interpreted by HHS through its advisory opinions. First, on April 10, 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, on June 4, 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 on August 19, 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.” In particular, 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 also adds a new category of “qualified persons” 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. (Although pediatric vaccines are treated as covered countermeasures for preemption purposes, the Amendment states that the [National Vaccine Injury Compensation Program](#) (VICP) will continue to apply to them “for the purposes of liability immunity and injury compensation.”)

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 on April 17, 2020 (and revised on May 19, 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, on May 19, 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. On October 23, 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 on October 23, 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 8, 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. Finally, on January 12, 2021, the General Counsel [opined](#) that compliance with ACIP’s vaccine allocation recommendations (i.e., administering the COVID-19 vaccine to prioritized groups first) is not a precondition for PREP Act immunity.

On December 3, 2020, the Secretary issued a [fourth amendment](#) to the HHS Declaration (Fourth Amendment). Among other things, the Amendment [states](#) that the HHS Declaration “must be construed in accordance with” the HHS advisory opinions, which are expressly “incorporate[d]” into the Declaration. The Fourth Amendment makes several changes to expand the scope of PREP Act immunity, including “mak[ing] 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 expressly include FDA-authorized COVID-19 vaccines as well.

Following the change in presidential 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 are designed 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 on March 11, 2021, the covered persons who may administer COVID-19 vaccines as part of state, federal, and Tribal vaccination efforts [include](#) (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 on August 4, 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](#), effective as of September 14, 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, on December 30,

2021, the Secretary of HHS issued the [Tenth Amendment](#) to the COVID-19 PREP Act Declaration to further [expand](#) 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—HHS issued the [Eleventh Amendment](#) to the Declaration. This amendment, first [announced](#) on April 14, 2023, extends PREP Act immunity for certain COVID-19 countermeasures through December 31, 2024. Prior to the Eleventh Amendment, liability protections for some COVID-19 countermeasures that are “not related to any [federal] agreement” would have [ended](#) along with the Section 319 PHE (unless some another federal, state, or local emergency declaration applied). The effect of the Eleventh Amendment on the effective time periods for PREP Act immunity is explained below.

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 Eleventh Amendment. The applicable time period for liability immunity may depend on the type of countermeasure, the means of distribution, the covered person who administers the countermeasure, and other factors. Under Section XII, liability protections for some countermeasures [extend](#) through the final day of the applicable Declaration of Emergency, or December 31, 2024, whichever occurs first. Liability protections for other countermeasures [last](#) through December 31, 2024, regardless of whether the Section 319 PHE or other Declarations of Emergency have expired. In other words, liability protections for some COVID-19 countermeasures under the PREP Act terminated in May 2023 along with the Section 319 PHE. For many other COVID-19 countermeasures, PREP Act immunity is to continue to apply to administrations of that countermeasure through December 31, 2024.

The time period that applies to a particular countermeasure depends largely on the means of distribution. [Section VII](#) of the Eleventh Amendment sets forth five means of distribution eligible for PREP Act immunity, which in turn determine when PREP Act immunity ends for a particular countermeasure. Those five categories [are](#):

- (a) 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;
- (b) Covered Countermeasures that are related to 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 Emergency;
- (c) Covered Countermeasures that are:
 - i. Licensed, approved, cleared, or authorized by the FDA . . . to treat, diagnose, cure, prevent, mitigate, or limit the harm from COVID-19 . . . ; or
 - ii. a respiratory protective device approved by NIOSH ... that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS Act to prevent, mitigate, or limit the harm from COVID-19
- (d) Covered Countermeasures that are authorized by the FDA under [an Emergency Use Authorization] to treat, diagnose, cure, prevent, mitigate, or limit the harm from COVID-19 . . . ; or

(e) Covered Countermeasures that are COVID-19 vaccines licensed by the FDA to prevent, mitigate, or limit the harm from COVID-19 . . . and any approved or cleared in vitro diagnostic product or other device used to treat, diagnose, cure, prevent, or mitigate COVID-19

For the second distribution channel—Section VII(b)—an “Authority Having Jurisdiction” **includes** state, local, and federal public agencies with appropriate jurisdiction, and a “Declaration of Emergency” **includes** “any declaration by any authorized local regional, state, or federal official of an emergency . . . with the exception of a federal declaration in support of an Emergency Use Authorization under Section 564 of the [Federal Food, Drug, and Cosmetic Act] unless such declaration specifies otherwise.” To qualify for the third, fourth, and fifth distribution channels—Sections VII(c), VII(d), and VII(e)—the countermeasure **must** be made and used in accordance with the relevant FDA or NIOSH authorization or approval.

For countermeasures falling under Section VII(a)—those relating to federal contracts or other federal agreements—PREP Act immunity generally **extends** through December 31, 2024. The same rule **applies** to Section VII(d) and VII(e) countermeasures—the two new categories added in the Eleventh Amendment. These categories explicitly include any authorized or licensed COVID-19 vaccine, FDA-approved tests for COVID-19 (in vitro diagnostics), and any countermeasure authorized by FDA for use against COVID-19 under an emergency use authorization (EUA). In other words, under the changes made by the Eleventh Amendment, liability protections for COVID-19 vaccines, tests, and EUA-authorized oral antivirals will generally **continue** through December 31, 2024. The **CICP** would therefore continue to apply to COVID-19 vaccine and other covered countermeasure injuries during that period.

For the Section VII(b) and Section VII(c) channels of distribution, liability protections may end earlier than December 31, 2024. Protection for activities authorized as part of a government authority’s public health response following a Declaration of Emergency (and for some FDA and NIOSH approved countermeasures that do not qualify under Sections VII(c) or VII(d)) only **extends** through (a) the final day the applicable Declaration of Emergency is in effect, or (b) December 31, 2024, whichever occurs first. If a countermeasure does not fall into Sections VII(a), VII(d) or VII(e), and no other Declaration of Emergency applies, PREP Act protections for these activities thus ended along with the Section 319 PHE on May 11, 2023.

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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