



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.

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 therefore [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 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 EUA) to “prescribe, administer, deliver, distribute or dispense” covered countermeasures. [Covered countermeasures](#) include

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“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 subsequently 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.”

A third amendment to the HHS Declaration (the Third Amendment), issued August 19, 2020, 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 preemptive purposes, the Amendment nonetheless states that National Vaccine Injury Compensation Program (VICP) will continue to apply to them “for the purposes of liability immunity and injury compensation,” unless compensation is not available under that program.

During the Trump Administration, the General Counsel of HHS 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 April 17, 2020 (as revised 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. Third, 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 nursing home or 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 certain 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 and other countermeasures beyond health care providers already licensed in a given state. The amendments are designed to [accomplish](#) this end 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 members) 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. First, the Amendment [clarifies](#) that qualified pharmacy technicians and supervised pharmacy interns are included as qualified persons authorized to administer these vaccines. Second, the Amendment [expands](#) the vaccines these persons can administer to include seasonal influenza vaccines for adults. Finally, the Eighth Amendment [restates](#) the effective time period for PREP Act liability protections, which will generally extend through October 1, 2024 (unless the relevant Declaration is rescinded earlier).

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 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](#).

Most recently, 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.

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 Tenth Amendment to the PREP Act Declaration. 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 the applicable Declaration of Emergency is in effect, or October 1, 2024, whichever occurs first. Liability protections for other countermeasures [last](#) through October 1, 2024, regardless of whether declarations of emergency are no longer in effect.

Which of these time periods applies to a particular countermeasure depends largely on the means of distribution set forth in [Section VII](#) of the Fourth Amendment to the PREP Act Declaration. The statute [allows](#) the Secretary to make PREP Act immunity “effective only to a particular means of distribution.” In Section VII, the Secretary [limited](#) liability protections for COVID-19 countermeasures to three broad means of distribution:

- (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; or
- (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

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 specific to events that indicate an immediate need to administer and use the Covered Countermeasures, 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 distribution channel—[Section VII\(c\)](#)—the particular use must be made in accordance with the relevant FDA or NIOSH approval.

For countermeasures falling under Section VII(a)—those relating to federal contracts or other federal agreements—PREP Act immunity generally [extends](#) through October 1, 2024. For example, all COVID-19 vaccines distributed in the United States have been [purchased](#) by the federal government (and to varying degrees were [developed](#) using federal funds). These countermeasures therefore generally relate to federal contracts and would be immunized under the PREP Act through October 1, 2024, regardless of whether declarations of emergency for COVID-19 are terminated. The [CICP](#) program would therefore continue to apply to COVID-19 vaccine injuries during this period.

For the Section VII(b) channel of distribution (countermeasures authorized and administered as part of the public health response of a government authority following a Declaration of Emergency) and the Section VII(c) channel (countermeasures authorized by FDA or NIOSH), liability protections [extend](#) through (a) the final day the applicable Declaration of Emergency is in effect, or (b) October 1, 2024, whichever occurs first. Generally speaking, the PREP Act Declaration is legally distinct and [independent](#) from other declarations of emergency, such as the federal [public health emergency](#) under Section 319 of the Public Health Service Act. Under the terms of the PREP Act Declaration, however, the effective time period of liability immunity may be affected by decisions of state, local, and federal governments to terminate public health emergency declarations.

Section XII of the Tenth Amendment also creates exceptions to these general effective time periods. For example, liability protections for uniformed service members and federal government employees [extend](#) through October 1, 2024, regardless of the distribution channel. In addition, the Secretary has exercised his 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 and other such actions appropriate to limit the administration or use of the countermeasures.

Author Information

Kevin J. Hickey
Legislative Attorney

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