



HHS Amends PREP Act Declaration to Expand Liability Protections and Access to COVID-19 Countermeasures via Telehealth

On December 3, 2020, the Secretary of the U.S. Department of Health and Human Services (HHS) issued an amendment to his March 10, 2020 Declaration under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 (“Prep Act Declaration”).

The PREP Act authorizes the Secretary of HHS to issue a declaration to provide liability protections to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from, the manufacture, distribution, administration, or use of certain medical countermeasures (Covered Countermeasures), except for claims involving “willful misconduct,” as defined in the PREP Act. Such declarations are subject to amendment as circumstances warrant.

On January 31, 2020, the Secretary declared a public health emergency, effective January 27, 2020, for the entire United States to aid in the response to the Coronavirus Disease 2019 (COVID–19) outbreak. The Secretary renewed that declaration on April 21, 2020, July 23, 2020, and October 2, 2020. On March 10, 2020, the Secretary issued a declaration under the PREP Act for medical countermeasures against COVID–19.¹ On April 10, the Secretary amended the Declaration to extend liability protections to Covered Countermeasures authorized under the CARES Act.² On June 4, the Secretary amended the Declaration to clarify that Covered Countermeasures under the Declaration include qualified pandemic and epidemic products that limit the harm that COVID-19 might otherwise cause.³ On August 19, the Secretary amended the Declaration to add additional categories of Qualified Persons and to amend the category of disease, health condition, or threat for which he recommends the administration or use of Covered Countermeasures.⁴

The Secretary recently further amended the Declaration. This Fourth Amendment to the Declaration:

- a. Clarifies that the Declaration must be construed in accordance with HHS Office of the General Counsel (OGC) Advisory Opinions on the Public Readiness and Emergency

¹ 85 FR 15198 (Mar. 17, 2020).

² 85 FR 21012 (Apr. 15, 2020).

³ 85 FR 35100 (June 8, 2020).

⁴ 85 FR 52136 (Aug. 24, 2020).

Preparedness Act and the Declaration (Advisory Opinions).⁵ The Declaration incorporates the Advisory Opinions for that purpose.

- b. Incorporates authorizations that the HHS Office of the Assistant Secretary for Health (OASH) has issued as an Authority Having Jurisdiction.⁶
- c. Adds an additional category of Qualified Persons, i.e., 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.⁷
- d. Modifies and clarifies the training requirements for certain licensed pharmacists and pharmacy interns to administer certain routine childhood or COVID-19 vaccinations.
- e. Makes explicit that Section VI covers all qualified pandemic and epidemic products under the PREP Act.
- f. Adds a third method of distribution that would provide liability protections for, among other things, additional private-distribution channels.
- g. Makes explicit in Section IX that there can be situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act and this Declaration's liability protections.
- h. Makes explicit that there are substantial federal legal and policy issues, and substantial federal legal and policy interests, in having a unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities. The world is facing an unprecedented pandemic. To effectively respond, there must be a more consistent pathway for Covered Persons to manufacture, distribute, administer or use Covered Countermeasures across the nation and the world.

⁵ See, e.g., Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration under the Act, Apr. 17, 2020, as Modified on May 19, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-advisory-opinion-hhs-ogc.pdf> (last visited Dec. 1, 2020); Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf> (last visited Dec. 1, 2020); Advisory Opinion 20-03 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, Oct. 22, 2020, as Modified on Oct. 23, 2020, available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO3.1.2_Updated_FINAL_SIGNED_10.23.20.pdf (last visited Dec. 1, 2020); Advisory Opinion 20-04 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, Oct. 22, 2020, as Modified on Oct. 23, 2020, available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO%204.2_Updated_FINAL_SIGNED_10.23.20.pdf (last visited Dec. 1, 2020).

⁶ See, e.g., Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity Under the PREP Act, OASH, Apr. 8, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf> (last visited Dec. 1, 2020); Guidance for PREP Act Coverage for COVID-19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities, OASH, Aug. 31, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-coverage-for-screening-in-congregate-settings.pdf> (last visited Dec. 1, 2020); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf> (last visited Dec. 1, 2020); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing, OASH, Oct. 20, 2020, available at <https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf> (last visited Dec. 1, 2020); PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures, Oct. 29, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-authorization-pharmacies-administering-covered-countermeasures.pdf> (last visited Dec. 1, 2020) (collectively, OASH PREP Act Authorizations).

⁷ "Telehealth, telemedicine, and related terms generally refer to the exchange of medical information from one site to another through electronic communication to improve a patient's health." Medicare Telemedicine Health Care Provider Fact Sheet, Mar. 17, 2020, available at <https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet> (last visited on Dec. 2, 2020). For the Declaration and the Fourth Amendment, the term "telehealth" includes telehealth, telemedicine, and related terms as described by the Centers for Medicare & Medicaid (CMS).

- i. Revises the effective time period of the Declaration in light of the amendments to the Declaration.⁸

Details Summary of this Amendment

Declaration

The Declaration has fifteen sections describing PREP Act coverage for medical countermeasures against COVID-19. The OGC has issued Advisory Opinions interpreting the PREP Act and reflecting the Secretary's interpretation of the Declaration.⁹ The Secretary now amends the Declaration to clarify that the Declaration must be construed in accordance with the Advisory Opinions. The Secretary expressly incorporates the Advisory Opinions for that purpose.

Section V. Covered Persons

Section V of the Declaration describes Covered Persons, including additional qualified persons identified by the Secretary, as required under the PREP Act. The Secretary amended Section V to specify an additional category of qualified persons. Specifically, healthcare personnel who are permitted to order and administer a Covered Countermeasure through telehealth in a state may do so for patients in another state so long as the healthcare personnel comply with the legal requirements of the state in which the healthcare personnel are permitted to order and administer the Covered Countermeasure by means of telehealth.

CMS and other HHS divisions have substantially expanded the scope of services paid under Medicare when furnished using telehealth technologies during this pandemic. Other HHS components have also taken steps to expand the use of telehealth during the pandemic.¹⁰ Additionally, to expand the use of telehealth during this pandemic, the Office for Civil Rights (OCR) at HHS exercised enforcement discretion and will not impose penalties for noncompliance with the regulatory requirements under the Health Insurance Portability and Accountability Act (HIPAA) Rules against covered healthcare providers that serve patients through everyday communications technologies during the COVID-19 nationwide public health

⁸ In addition, the Fourth Amendment makes certain non-substantive changes. Those should not be interpreted to change any substantive provisions.

⁹ See, e.g., Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration under the Act, Apr. 17, 2020, as Modified on May 19, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-advisory-opinion-hhs-ogc.pdf> (last visited Dec. 1, 2020); Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf> (last visited Dec. 1, 2020); Advisory Opinion 20-03 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, Oct. 22, 2020, as Modified on Oct. 23, 2020, available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO3.1.2_Updated_FINAL_SIGNED_10.23.20.pdf (last visited Dec. 1, 2020); Advisory Opinion 20-04 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, Oct. 22, 2020, as Modified on Oct. 23, 2020, available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO%204.2_Updated_FINAL_SIGNED_10.23.20.pdf (last visited Dec. 1, 2020).

¹⁰ See, e.g., Trump Administration Drives Telehealth Services in Medicaid and Medicare, CMS, Oct. 14, 2020, available at <https://www.cms.gov/newsroom/press-releases/trump-administration-drives-telehealth-services-medicare-and-medicare> (last visited Dec. 1, 2020); Secretary Azar Announces Historic Expansion of Telehealth Access to Combat COVID-19, Mar. 17, 2020, available at <https://www.hhs.gov/about/news/2020/03/17/secretary-azar-announces-historic-expansion-of-telehealth-access-to-combat-covid-19.html> (last visited Nov. 30, 2020); OIG Policy Statement Regarding Physicians and Other Practitioners That Reduce or Waive Amounts Owed by Federal Health Care Program Beneficiaries for Telehealth Services During the 2019 Novel Coronavirus (COVID-19) Outbreak, Mar. 17, 2020, available at <https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/policy-telehealth-2020.pdf> (last visited Nov. 30, 2020).

emergency.¹¹ This exercise of discretion applies to widely available communications apps, such as FaceTime or Skype, when used in good faith for any telehealth treatment or diagnostic purpose, regardless of whether the telehealth service is directly related to COVID-19.¹² Many states have also authorized out-of-state healthcare personnel to deliver telehealth services to in-state patients, either generally or in the context of COVID-19.¹³

To help maximize the utility of telehealth, the Secretary declared that the term “qualified person” includes 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. When ordering and administering Covered Countermeasures through telehealth to patients in a state where the healthcare personnel are not already permitted to do so, the healthcare personnel must comply with all requirements for ordering and administering Covered Countermeasures to patients through telehealth in the state where the healthcare personnel are licensed or otherwise permitted to practice. Any state law that prohibits or effectively prohibits such a qualified person from ordering and administering Covered Countermeasures through telehealth is preempted.¹⁴ Nothing in the Declaration preempts state laws that permit additional persons to deliver telehealth services.

The Secretary also amended Section V to include several examples of Covered Persons who are Qualified Persons, because they are authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures. Those examples include certain pharmacists, pharmacy interns, and pharmacy technicians who order or administer certain

¹¹ OCR Announces Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency, Mar. 17, 2020, available at <https://www.hhs.gov/about/news/2020/03/17/ocr-announces-notification-of-enforcement-discretion-for-telehealth-remote-communications-during-the-covid-19.html> (last visited Dec. 1, 2020). The PREP Act does not provide immunity against federal enforcement actions brought by the federal government. We refer to this exercise of enforcement discretion as another example of the Department’s desire to support the expanded use of telehealth during this pandemic.

¹² *Id.*

¹³ See, e.g., 2020 Alaska Laws Ch. 10 (S.B. 241) Sec. 7 (healthcare provider can perform telehealth if, among other things, “the health care provider is licensed, permitted, or certified to provide healthcare services in another jurisdiction and is in good standing in the jurisdiction that issued the license, permit, or certification”); CT Exec. Order No. 7G, Sec. 5(b), Mar. 19, 2020, available at <https://portal.ct.gov/-/media/Office-of-the-Governor/Executive-Orders/Lamont-Executive-Orders/Executive-Order-No-7G.pdf> (last visited Dec. 1, 2020) (“Subsection (a)(12)’s requirements for the licensure, certification or registration of telehealth providers shall be suspended for such telehealth providers that are Medicaid enrolled providers or in-network providers for commercial fully insured health insurance providing telehealth services to patients”); Fl. Emerg. Order, DOH No. 20-002, *In Re: Suspension of Statutes, Rules, and Orders, Made Necessary by COVID-19*, Mar. 16, 2020, available at http://www.flhealthsource.gov/pdf/emergencyyorder-20-002.pdf?inf_contact_key=c1be7c474d297aa416752a23d2694901680f8914173f9191b1c0223e68310bb1 (last visited Dec. 1, 2020) (“For purposes of preparing for, responding to, and mitigating any effect of COVID-19, health care professionals not licensed in this state may provide health care services to a patient licensed in this state using telehealth, notwithstanding the requirements of section 456.47(4)(a) through (c), (h), and (i), Florida Statutes ...This exemption shall apply only to the following out of state health care professionals holding a valid, clear, and unrestricted license in another state or territory in the United States who are not currently under investigation or prosecution in any disciplinary proceeding in any of the states in which they hold a license: physicians, osteopathic physicians, physician assistants, and advanced practice registered nurses.”); IA Emer. Dec., Sec. 39 (Nov. 10, 2020), available at <https://governor.iowa.gov/sites/default/files/documents/Public%20Health%20Proclamation%20-%202020.11.10.pdf> (last visited Dec. 1, 2020) (temporarily suspending any statute or rule defining a doctor or medical staff as “requiring all doctors and medical staff be licensed to practice in this state, to the extent that individual is licensed to practice in another state”); NH Emer. Order # 15 Pursuant to Exec. Order 2020-4, Sec. 1, Mar. 23, 2020, available at <https://www.governor.nh.gov/sites/g/files/ehbemt336/files/documents/emergency-order-15.pdf> (last visited Dec. 1, 2020) (“any out-of-state medical provider whose profession is licensed within this State shall be allowed to perform any medically necessary service as if the medical provider were licensed to perform such service within the state of New Hampshire subject to,” among other things, the medical provider being “licensed and in good standing in another United States jurisdiction”).

¹⁴ Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary’s Declaration under the Act, May 19, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf> (last visited Dec. 1, 2020).

COVID-19 tests and certain vaccines.¹⁵ These examples are not an exclusive or exhaustive list of persons who are qualified persons identified by the Secretary in Section V.

The Secretary also amended Section V to make explicit that the requirement in that section for certain qualified persons to have a current certificate in basic CPR is satisfied by, among other things, a certification in basic CPR by an online program that has received accreditation from the American Nurses Credentialing Center, the Accreditation Council for Pharmacy Education (ACPE), or the Accreditation Council for Continuing Medical Education.

The Secretary also amended Section V's training requirements for licensed pharmacists to order and administer certain childhood or COVID-19 vaccines. To order and administer vaccines, the licensed pharmacist must have completed the immunization training that the licensing State requires in order for pharmacists to administer vaccines. If the State does not specify training requirements for the licensed pharmacist to order and administer vaccines, the licensed pharmacist must complete a vaccination training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE) to order and administer vaccines. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.

Other than the basic CPR requirement and the practical training program requirement, this Amendment does not change the requirements for a pharmacist, pharmacy intern, or pharmacy technician to be a "qualified person" under the PREP Act who can order or administer childhood or COVID-19 vaccines pursuant to the Declaration.

Section VI. Covered Countermeasures

The Secretary amends Section VI to make explicit that Section VI covers all qualified pandemic and epidemic products under the PREP Act.

Section VII. Limitations on Distribution

The Secretary may specify that liability protections are in effect only for Covered Countermeasures obtained through a particular means of distribution. The Declaration previously stated that liability immunity is afforded to Covered Persons only for Recommended Activities related to: (a) present or future federal contracts, cooperative agreements, grants,

¹⁵ See, e.g., [Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity Under the PREP Act, OASH](https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf), Apr. 8, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf> (last visited Dec. 1, 2020); [Guidance for PREP Act Coverage for COVID-19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities, OASH](https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-coverage-for-covid-19-screening-tests-at-nursing-homes-assisted-living-facilities-long-term-care-facilities-and-other-congregate-facilities.pdf), Aug. 31, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-coverage-for-covid-19-screening-tests-at-nursing-homes-assisted-living-facilities-long-term-care-facilities-and-other-congregate-facilities.pdf> (last visited Dec. 1, 2020); [Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act, OASH](https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf), Sept. 3, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf> (last visited Dec. 1, 2020); [Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing, OASH](https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf), Oct. 20, 2020, available at <https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf> (last visited Dec. 1, 2020); [PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures, OASH](https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-authorization-pharmacies-administering-covered-countermeasures.pdf), Oct. 29, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-authorization-pharmacies-administering-covered-countermeasures.pdf> (last visited Dec. 1, 2020).

other transactions, interagency agreements, or memoranda of understanding or other federal agreements; or (b) 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.

Given the broad scale of this pandemic, the Secretary amended the Declaration to extend PREP Act coverage to additional private-distribution channels, as set forth below.

The amended Section VII adds that PREP Act liability protections also extend to Covered Persons for Recommended Activities that are related to any Covered Countermeasure that is:

- a. Licensed, approved, cleared, or authorized by the Food and Drug Administration (FDA) (or that is permitted to be used under an Investigational New Drug Application or an Investigational Device Exemption) under the Federal Food, Drug, and Cosmetic (FD&C) Act or Public Health Service (PHS) Act to treat, diagnose, cure, prevent, mitigate or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom; or
- b. A respiratory protective device approved by the National Institute for Occupational Safety and Health (NIOSH) under 42 CFR part 84, or any successor regulations, 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, or the transmission of SARS-CoV-2 or a virus mutating therefrom.

To qualify for this third distribution channel (but not necessarily to qualify for the other distribution channels), a Covered Person must manufacture, test, develop, distribute, administer, or use the Covered Countermeasure pursuant to the FDA licensure, approval, clearance, or authorization (or pursuant to an Investigational New Drug Application or Investigational Device Exemption), or the NIOSH approval.

This third distribution channel may extend PREP Act coverage when there is no federal agreement or authorization 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. For example, a manufacturer, distributor, program planner, or qualified person engages in manufacturing, testing, development, distribution, administration, or use of a COVID-19 test pursuant to an FDA Emergency Use Authorization for that COVID-19 test. If the Covered Person satisfies all other requirements of the PREP Act and Declaration, there will be PREP Act coverage even if there is no federal agreement to cover those activities and those activities are not part of the authorized activity of an Authority Having Jurisdiction.

Section IX. Administration of Covered Countermeasures

The Secretary amended Section IX to make explicit that there can be situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act and this Declaration's liability protections.

Section XI. Geographic Area

The Secretary made explicit that there are substantial federal legal and policy issues, and 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), in having a unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities. To effectively respond, there must be a more consistent pathway for Covered Persons to manufacture, distribute, administer or use Covered Countermeasures across the nation and the world. Thus, there are substantial federal legal and policy issues, and 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), in having a uniform interpretation of the PREP Act. Under the PREP Act, the sole exception to the immunity from suit and liability of covered persons is an exclusive Federal cause of action against a Covered Person for death or serious physical injury proximately caused by willful misconduct by such Covered Person. In all other cases, an injured party's exclusive remedy is an administrative remedy under section 319F-4 of the PHS Act.

Section XII. Effective Time Period

The Secretary amended Section XII to provide that liability protections for all Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction, as identified in Section VII(b) of this Declaration, begins with a "Declaration of Emergency," as defined in Section VII (except that, with respect to qualified persons who order or administer a routine childhood vaccination that ACIP recommends to persons ages three through 18 according to ACIP's standard immunization schedule, PREP Act coverage began on August 24, 2020), and lasts through (a) the final day the Declaration of Emergency is in effect, or (b) October 1, 2024, whichever occurs first.

The Secretary also amended Section XII to provide that liability protections for all Covered Countermeasures identified in Section VII(c) of this Declaration begins on the date of this amended Declaration and lasts through (a) the final day the Declaration of Emergency is in effect, or (b) October 1, 2024, whichever occurs first. Because the Secretary added Section VII(c) to the Declaration in the Amendment, Section XII provides that Section VII(c) is effective as of the date the amended Declaration was published.

Additional Amendments

The Secretary also made other, non-substantive amendments and clarifications, including that the Declaration must be construed in accordance with the Advisory Opinions of the Office of the General Counsel (Advisory Opinions) and incorporating those Advisory Opinions as part of the Declaration.¹⁶

¹⁶ See, e.g., [Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration under the Act](https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-advisory-opinion-hhs-ogc.pdf), Apr. 17, 2020, as Modified on May 19, 2020, at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-advisory-opinion-hhs-ogc.pdf> (last visited Dec. 1, 2020); [Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act](https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf), May 19, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf> (last visited Dec. 1, 2020); [Advisory Opinion 20-03 on the Public Readiness and](https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-03-hhs-ogc-prep-act.pdf)

Additionally, the Secretary clarified the definition of “administration of Covered Countermeasures. Specifically, the Administration of the Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for the purpose of distributing and dispensing countermeasures.

Where there are limited Covered Countermeasures, not administering a Covered Countermeasure to one individual in order to administer it to another individual can constitute “relating to . . . the administration to . . . an individual” under 42 U.S.C. 247d-6d. For example, consider a situation where there is only one dose¹⁷ of a COVID-19 vaccine, and a person in a vulnerable population and a person in a less vulnerable population both request it from a healthcare professional. In that situation, the healthcare professional administers the one dose to the person who is more vulnerable to COVID-19. In that circumstance, the failure to administer the COVID-19 vaccine to the person in a less-vulnerable population “relat[es] to the administration to” the person in a vulnerable population. The person in the vulnerable population was able to receive the vaccine only because it was not administered to the person in the less-vulnerable population. Prioritization or purposeful allocation of a Covered Countermeasure, particularly if done in accordance with a public health authority’s directive, can fall within the PREP Act and the Declaration’s liability protections.

The populations of individuals to whom the liability protections of the Declaration extend include any individual who uses or is administered the Covered Countermeasures in accordance with this Declaration.

Liability protections are afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability protections are afforded to program planners and qualified persons when the countermeasure is used by or administered to this population, or the program planner or qualified person reasonably could have believed the recipient was in this population.

Liability protections are afforded for the administration or use of a Covered Countermeasure without geographic limitation.

Liability protections are afforded to manufacturers and distributors without regard to whether the Covered Countermeasure is used by or administered in any designated geographic area; liability protections are afforded to program planners and qualified persons when the

Emergency Preparedness Act and the Secretary’s Declaration under the Act, Oct. 22, 2020, as Modified on Oct. 23, 2020, available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO3.1.2_Updated_FINAL_SIGNED_10.23.20.pdf (last visited Dec. 1, 2020); *Advisory Opinion 20-04 on the Public Readiness and Emergency Preparedness Act and the Secretary’s Declaration under the Act*, Oct. 22, 2020, as Modified on Oct. 23, 2020, available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO%204.2_Updated_FINAL_SIGNED_10.23.20.pdf (last visited Dec. 1, 2020). This is not to suggest that other PREP Act declarations should be construed in a manner contrary to the interpretation provided in the Advisory Opinions.

¹⁷ For simplicity, this example assumes a patient only requires one dose of the vaccine.

countermeasure is used by or administered in any designated geographic area, or the program planner or qualified person reasonably could have believed the recipient was in that geographic area.