and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Lubna Merchant, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4418, Silver Spring, MD 20993–0002, 301–796–5162, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Best Practices in Developing Proprietary Names for Human Prescription Drug Products.'' This guidance describes best practices to help minimize proprietary name-related medication errors and otherwise avoid adoption of proprietary names that contribute to violations of the FD&C Act and its implementing regulations. This guidance also describes the framework FDA uses in evaluating proprietary names that sponsors could use before submitting names for FDA review if they wish.

FDA has long recognized the importance of proprietary name confusion as a potential cause of medication errors and has addressed this issue repeatedly in recent decades. Our focus has been to develop and communicate to sponsors a systematic, standardized, and transparent approach to proprietary name evaluation within the product development, review, and approval process.

In the **Federal Register** of May 29, 2014 (79 FR 30852), FDA announced the availability of a draft guidance entitled ''Best Practices in Developing Proprietary Names for Drugs.'' The guidance announced in this notice finalizes the draft guidance issued in May 2014. The Agency has carefully reviewed and considered the comments it received in developing this final version of the guidance.

FDA received several comments on the guidance and revised the guidance in response to these comments. The revisions include (a) adding a note in the section discussing the United States Adopted Name (USAN) stating that FDA will no longer object to the use of two-letter USAN stems in names for products that do not share any association with the stem in question; (b) streamlining the name simulation study section based on the feedback received; (c) providing clarifications to the section that discusses medical abbreviations, modifiers, and computational methods; (d) separating the content pertaining to nonprescription proprietary names and issuing separate guidance to address the name development process for nonprescription drugs; (e) revising the misbranding discussion for greater clarity and included information on one possible study methodology that sponsors may consider to test proposed names for misbranding concerns; and (f) adding certain definitions and specific criteria for prescreening proprietary name candidates and updating definitions in the glossary and clarified terminology where needed. FDA also revised the document throughout to ensure consistency in terminology, clarified section headings, and reordered information for clarity where applicable.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance entitled ''Best Practices in Developing Proprietary Names for Human Nonprescription Drug Products.'' That draft guidance is issued in response to industry stakeholders' requests to specifically address the approaches for naming of human nonprescription drug products. The draft guidance is being issued to provide greater clarity on the considerations applicable to nonprescription drug products.

The guidance announced in this notice is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Best Practices in Developing Proprietary Names for Human Prescription Drug Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001, and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the document at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: December 4, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–27058 Filed 12–8–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19 and Republication of the Declaration

ACTION: Notice of Amendment and Republished Declaration.

SUMMARY: The Secretary issues this amendment pursuant to section 319F–3 of the Public Health Service Act to amend his March 10, 2020 Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19.

DATES: The amendments to the Declaration are applicable as of February 4, 2020, except as otherwise specified in Section XII.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue

SW, Washington, DC 20201; Telephone: 202–205–2882.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. 247d–6d et. seq., authorizes the Secretary of Health and Human Services (the Secretary) 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.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding Section 319F–3, which addresses liability immunity, and Section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively. Section 319F–3 of the PHS Act has been amended by the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, enacted on March 13, 2013, and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116–136, enacted on March 27, 2020, to expand Covered Countermeasures under the PREP Act.

On January 31, 2020, the Secretary declared a public health emergency pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, effective January 27, 2020, for the entire United States to aid in the response to the Coronavirus Disease 2019 (COVID–19) outbreak, which subsequently became a global pandemic. Pursuant to section 319 of the PHS Act, 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 now further amends the Declaration pursuant to section 319F–3 of the Public Health Service Act. This Fourth Amendment to the Declaration:

(a) Clarifies that the Declaration must be construed in accordance with the Department of Health and Human Services (HHS) Office of the General Counsel (OGC) Advisory Opinions on the Public Readiness and Emergency 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 under Section V of the Declaration and 42 U.S.C. 247d–6d(i)(8)(B), *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 under Section VII of the Declaration and 42 U.S.C. 247d–6d(a)(5) 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 in Section XI 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.

[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).

[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]

The Secretary republishes the Declaration, as amended, in full. Unless otherwise noted, all statutory citations are to the U.S. Code.

Description of This Amendment

Declaration

The Declaration has fifteen sections describing PREP Act coverage for medical countermeasures against COVID–19. 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 amends 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.

Telehealth is widely recognized as a valuable tool to promote public health during this pandemic. According to the Centers for Disease Control and Prevention (CDC),

Telehealth services can facilitate public health mitigation strategies during this pandemic by increasing social distancing. These services can be a safer option for [healthcare personnel (HCP)] and patients by reducing potential infectious exposures. They can reduce the strain on healthcare systems by minimizing the surge of patient demand on facilities and reduce the use of [personal protective equipment (PPE)] by healthcare providers.

Maintaining continuity of care to the extent possible can avoid additional negative consequences from delayed preventive, chronic, or routine care. Remote access to healthcare services may increase participation for those who are medically or socially vulnerable or who do not have ready access to providers. Remote access can also help preserve the patient-provider relationship at times when an in-person visit is not practical or feasible. Telehealth services can be used to:

- Screen patients who may have symptoms of COVID–19 and refer as appropriate
- Provide low-risk urgent care for non-COVID–19 conditions, identify those persons who may need additional medical consultation or assessment, and refer as appropriate
- Access primary care providers and specialists, including mental and behavioral health, for chronic health conditions and medication management
- Provide coaching and support for patients managing chronic health conditions, including weight management and nutrition counseling
- Participate in physical therapy, occupational therapy, and other modalities as a hybrid approach to in-person care for optimal health
- Monitor clinical signs of certain chronic medical conditions (*e.g.,* blood pressure, blood glucose, other remote assessments)
- Engage in case management for patients who have difficulty accessing care (*e.g.,* those who live in very rural settings, older adults, those with limited mobility)
- Follow up with patients after hospitalization
- Deliver advance care planning and counseling to patients and caregivers to document preferences if a life-threatening event or medical crisis occurs
- Provide non-emergent care to residents in long-term care facilities
- Provide education and training for HCP through peer-to-peer professional medical consultations (inpatient or outpatient) that are not locally available, particularly in rural areas.[10]

Similarly, CMS has stressed the importance of telehealth during this pandemic:

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. Innovative uses of this kind of technology in the provision of healthcare is increasing. And with the emergence of the virus causing the disease COVID–19, there is an urgency to expand the use of technology to help people who need routine care, and keep vulnerable beneficiaries and beneficiaries with mild symptoms in their homes while maintaining access to the care they need. Limiting community spread of the virus, as well as limiting the exposure to other patients and staff members will slow viral spread.[11]

Accordingly, CMS and other HHS components has 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.[12]

Moreover, to expand the use of telehealth during this pandemic, the Office for Civil Rights (OCR) at HHS is exercising 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 emergency.[13] This exercise of discretion

[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] Using Telehealth to Expand Access to Essential Health Services during the COVID–19 Pandemic, CDC, updated June 10, 2020, available at *https://www.cdc.gov/coronavirus/2019-ncov/hcp/telehealth.html* (last visited Dec. 1, 2020).

[11] 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 Dec. 1, 2020).

[12] *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-medicaid-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).

[13] 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

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.[14]

Many states have authorized out-of-state healthcare personnel to deliver telehealth services to in-state patients, either generally or in the context of COVID–19.[15]

To help maximize the utility of telehealth, the Secretary declares that the term ''qualified person'' under 42 U.S.C. 247d–6d(i)(8)(B) 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.[16] Nothing in this Declaration shall preempt state laws that permit additional persons to deliver telehealth services.

The Secretary also amends 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 COVID–19 tests and certain vaccines.[17] 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 amends Section V to make explicit that the requirement in that section for certain qualified persons to have a current certificate in basic cardiopulmonary resuscitation is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation 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 amends 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 cardiopulmonary resuscitation 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 42 U.S.C. 247d–6d(i)(8)(B) 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.

enforcement discretion as another example of the Department's desire to support the expanded use of telehealth during this pandemic.

[14] *Id.*

[15] *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/emergencyorder-20-002.pdf?inf_contact_key=c1be7c474d297aa416752a23d269 4901680f8914173f9191b1c0223e68310bb1* (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'').

[16] 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).

[17] *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).

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, 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.

COVID–19 is an unprecedented global challenge that requires a whole-of-nation response that utilizes federal-, state-, and local- distribution channels as well as private-distribution channels. Given the broad scale of this pandemic, the Secretary amends 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 amends 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 makes explicit in Section XI 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. & Mf'g.,* 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. The world is facing an unprecedented global 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. 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. & Mf'g.,* 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. Through the PREP Act, Congress delegated to me the authority to strike the appropriate Federal-state balance with respect to particular Covered Countermeasures through PREP Act declarations.

Section XII. Effective Time Period

The Secretary amends 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. This change is to conform the text of the Declaration to the Third Amendment.[18]

The Secretary also amends 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 is adding Section VII(c) to the Declaration in this Amendment, Section XII provides that Section VII(c) is effective as of the date this amended Declaration is published.

Additional Amendments

The Secretary also makes other, non-substantive amendments.

Declaration, as Amended, for Public Readiness and Emergency Preparedness Act Coverage for Medical Countermeasures Against COVID–19

To the extent any term previously in the Declaration, including its amendments, is inconsistent with any provision of this Republished Declaration, the terms of this Republished Declaration are controlling. This Declaration must be construed in accordance with the Advisory Opinions

[18] *See* 85 FR 52136 (Aug. 24, 2020).

of the Office of the General Counsel (Advisory Opinions). I incorporate those Advisory Opinions as part of this Declaration.[19] This Declaration is a ''requirement'' under the PREP Act.

I. Determination of Public Health Emergency

42 U.S.C. 247d–6d(b)(1)

I have determined that the spread of SARS–CoV–2 or a virus mutating therefrom and the resulting disease COVID–19 constitutes a public health emergency. I further determine that use of any respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, is a priority for use during the public health emergency that I declared on January 31, 2020 under section 319 of the PHS Act for the entire United States to aid in the response of the nation's healthcare community to the COVID–19 outbreak.

II. Factors Considered

42 U.S.C. 247d–6d(b)(6)

I have considered the desirability of encouraging the design, development, clinical testing, or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the Covered Countermeasures.

III. Recommended Activities

42 U.S.C. 247d–6d(b)(1)

I recommend, under the conditions stated in this Declaration, the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures.

IV. Liability Protections

42 U.S.C. 247d–6d(a), 247d–6d(b)(1)

Liability protections as prescribed in the PREP Act and conditions stated in this Declaration are in effect for the Recommended Activities described in Section III.

V. Covered Persons

42 U.S.C. 247d–6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability protections under this Declaration are ''manufacturers,'' ''distributors,'' ''program planners,'' and ''qualified persons,'' as those terms are defined in the PREP Act; their officials, agents, and employees; and the United States.

In addition, I have determined that the following additional persons are qualified persons:

(a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of Emergency, as that term is defined in Section VII of this Declaration; [20]

(b) any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act;

(c) any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act;

(d) a State-licensed pharmacist who orders and administers, and pharmacy interns who administer (if the pharmacy intern acts under the supervision of such pharmacist and the pharmacy intern is licensed or registered by his or her State board of pharmacy), [21] (1) vaccines that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule or (2) FDA-authorized or FDA-licensed COVID–19 vaccines to persons ages three or older. Such State-licensed pharmacists and the State-licensed or registered interns under their supervision are qualified persons only if the following requirements are met:

i. The vaccine must be authorized, approved, or licensed by the FDA;

ii. In the case of a COVID–19 vaccine, the vaccination must be ordered and administered according to ACIP's COVID–19 vaccine recommendation(s).

iii. In the case of a childhood vaccine, the vaccination must be ordered and administered according to ACIP's standard immunization schedule;

iv. The licensed pharmacist must have completed the immunization training that the licensing State requires in order for pharmacists to order and 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

[19] *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). 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.

[20] *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). Nothing herein shall suggest that, for purposes of the Declaration, the foregoing are the only persons authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction.

[21] Some states do not require pharmacy interns to be licensed or registered by the state board of pharmacy. As used herein, ''State-licensed or registered intern'' (or equivalent phrases) refers to pharmacy interns authorized by the state or board of pharmacy in the state in which the practical pharmacy internship occurs. The authorization can, but need not, take the form of a license from, or registration with, the State board of pharmacy. *See* 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 at 2, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Dec. 1, 2020).

Council for Pharmacy Education (ACPE) to order and administer vaccines. Such a 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;

v. The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE. 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;

vi. The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation; [22]

vii. The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period;

viii. The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine; and

ix. The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregiver accompanying the child of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate.

x. The licensed pharmacist and the licensed or registered pharmacy intern must comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention (CDC) COVID–19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID–19 vaccine(s).

(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 licensed or otherwise permitted to practice. When ordering and administering Covered Countermeasures by means of telehealth to patients in a state where the healthcare personnel are not already permitted to practice, the healthcare personnel must comply with all requirements for ordering and administering Covered Countermeasures to patients by means of telehealth in the state where the healthcare personnel are permitted to practice. Any state law that prohibits or effectively prohibits such a qualified person from ordering and administering Covered Countermeasures by means of telehealth is preempted.[23] Nothing in this Declaration shall preempt state laws that permit additional persons to deliver telehealth services.

Nothing in this Declaration shall be construed to affect the National Vaccine Injury Compensation Program, including an injured party's ability to obtain compensation under that program. Covered Countermeasures that are subject to the National Vaccine Injury Compensation Program authorized under 42 U.S.C. 300aa–10 *et seq.* are covered under this Declaration for the purposes of liability immunity and injury compensation only to the extent that injury compensation is not provided under that Program. All other terms and conditions of the Declaration apply to such Covered Countermeasures.

VI. Covered Countermeasures

42 U.S.C. 247d–6b(c)(1)(B), 42 U.S.C. 247d–6d(i)(1) and (7)

Covered Countermeasures are:

(a) Any antiviral, any drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine manufactured, used, designed, developed, modified, licensed, or procured:

i. To diagnose, mitigate, prevent, treat, or cure COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom; or

ii. to limit the harm that COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom, might otherwise cause;

(b) a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in paragraph (a) above;

(c) a product or technology intended to enhance the use or effect of a product described in paragraph (a) or (b) above; or

(d) any device used in the administration of any such product, and all components and constituent materials of any such product.

To be a Covered Countermeasure under the Declaration, a product must also meet 42 U.S.C. 247d–6d(i)(1)'s definition of ''Covered Countermeasure.''

VII. Limitations on Distribution

42 U.S.C. 247d–6d(a)(5) and (b)(2)(E)

I have determined that liability protections are afforded to Covered Persons only for Recommended Activities involving:

(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 (or that are permitted to be used under an Investigational New Drug Application or an Investigational Device Exemption) under the FD&C Act or 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

[22] This requirement is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase ''current certificate in basic cardiopulmonary resuscitation,'' when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. *See* 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).

[23] *See, e.g.,* 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).

ii. a respiratory protective device approved by 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, 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.

As used in this Declaration, the terms ''Authority Having Jurisdiction'' and ''Declaration of Emergency'' have the following meanings:

(a) The Authority Having Jurisdiction means 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.

(b) A Declaration of Emergency means 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 FD&C Act unless such declaration specifies otherwise.

I have also determined that, for governmental program planners only, liability protections are afforded only to the extent such program planners obtain Covered Countermeasures through voluntary means, such as (a) donation; (b) commercial sale; (c) deployment of Covered Countermeasures from federal stockpiles; or (d) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles.

VIII. Category of Disease, Health Condition, or Threat

42 U.S.C. 247d–6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is 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.

IX. Administration of Covered Countermeasures

42 U.S.C. 247d–6d(a)(2)(B)

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 dose [24] 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 this Declaration's liability protections.

X. Population

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(C)

The populations of individuals to whom the liability protections of this 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.

XI. Geographic Area

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(D)

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 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.

COVID–19 is a global challenge that requires a whole-of-nation response. 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. & Mf'g.,* 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. 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. 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. & Mf'g.,* 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 under the PREP Act 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

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

remedy under section 319F–4 of the PHS Act. Through the PREP Act, Congress delegated to me the authority to strike the appropriate Federal-state balance with respect to particular Covered Countermeasures through PREP Act declarations.[25]

XII. Effective Time Period

42 U.S.C. 247d–6d(b)(2)(B)

Liability protections for any respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, through the means of distribution identified in Section VII(a) of this Declaration, begin on March 27, 2020 and extend through October 1, 2024.

Liability protections for all other Covered Countermeasures identified in Section VI of this Declaration, through means of distribution identified in Section VII(a) of this Declaration, begin on February 4, 2020 and extend through October 1, 2024.

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, begin with a Declaration of Emergency as that term is 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, liability protections began on August 24, 2020), and last through (a) the final day the Declaration of Emergency is in effect, or (b) October 1, 2024, whichever occurs first.

Liability protections for all Covered Countermeasures identified in Section VII(c) of this Declaration begin on the date of this amended Declaration and last through (a) the final day the Declaration of Emergency is in effect, or (b) October 1, 2024, whichever occurs first.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d–6d(b)(3)(B) and (C)

I have determined that an additional 12 months of liability protection is reasonable to allow for the manufacturer(s) to arrange for disposition of the Covered Countermeasure, including return of the Covered Countermeasures to the manufacturer, and for Covered Persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasures.

Covered Countermeasures obtained for the SNS during the effective period of this Declaration are covered through the date of administration or use pursuant to a distribution or release from the SNS.

XIV. Countermeasures Injury Compensation Program

42 U.S.C 247d–6e

The PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of the Covered Countermeasures, and benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical and scientific evidence in order for the individual to be considered for compensation. The CICP is administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP is available at the toll-free number 1–855–266–2427 or *http://www.hrsa.gov/cicp/.*

XV. Amendments

42 U.S.C. 247d–6d(b)(4)

Amendments to this Declaration will be published in the **Federal Register**, as warranted.

Authority: 42 U.S.C. 247d–6d.

Dated: December 3, 2020.

Alex M. Azar II,

Secretary of Health and Human Services.

[FR Doc. 2020–26977 Filed 12–8–20; 8:45 am]

BILLING CODE 4150–37–P

[25] 42 U.S.C. 247d–6d(b)(7) provides that ''[n]o court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection.''

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Declaration Under the Public Readiness and Emergency Preparedness Act for Countermeasures Against Marburgvirus and/or Marburg Disease

SUMMARY: The Secretary is issuing this Declaration pursuant to section 319F–3 of the Public Health Service Act to provide limited immunity for activities related to countermeasures against marburgvirus and/or Marburg disease.

DATES: The Declaration is effective as of November 25, 2020.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; Telephone: 202–205–2882.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity 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 medical countermeasures (Covered Countermeasures), except for claims involving ''willful misconduct'' as defined in the PREP Act. This Declaration is subject to amendment as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding Section 319F–3, which addresses liability immunity, and Section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively.

The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, was enacted on March 13, 2013. Among other things, PAHPRA added sections 564A and 564B to the Federal Food, Drug, and Cosmetic (FD&C) Act to provide new authorities for the emergency use of approved products in emergencies and products held for emergency use. PAHPRA accordingly amended the definitions of ''Covered Countermeasures'' and ''qualified pandemic and epidemic products'' in Section 319F–3 of the Public Health Service Act (PREP Act provisions), so that products made available under these new FD&C Act authorities could be covered under PREP Act Declarations. PAHPRA also extended the definition of qualified pandemic and epidemic products that may be covered under a PREP Act Declaration to include products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic or epidemic or against adverse events from these