• Drawing the program link between outreach and education, promoting consumer understanding of health care coverage choices, and facilitating consumer selection/enrollment, which in turn support the overarching goal of improved access to quality care, including prevention services, envisioned under the Affordable Care Act.

The current members of the Panel as of February 28, 2020 are: E. Lorraine Bell, Chief Officer, Population Health, Catholic Charities USA; Nazleen Bharmal, Medical Director of Community Partnerships, Cleveland Clinic; Angie Boddie, Director of Health Programs, National Caucus and Center on Black Aging, Inc.; Julie Carter, Senior Federal Policy Associate, Medicare Rights Center; Scott Ferguson, Director of Care Transitions and Population Health, Mount Sinai St. Luke's Hospital; Leslie Fried, Senior Director, Center for Benefits Access, National Council on Aging; David Goldberg, President and CEO of Mon Health System; Jean-Venable Robertson Goode, Professor, Department of Pharmacotherapy and Outcomes Science, School of Pharmacy, Virginia Commonwealth University; Ted Henson, Director of Health Center Performance and Innovation, National Association of Community Health Centers; Joan Ilardo, Director of Research Initiatives, Michigan State University, College of Human Medicine; Cheri Lattimer, Executive Director, National Transitions of Care Coalition; Cori McMahon, Vice President, Tridiuum; Alan Meade, Director of Rehab Services, Holston Medical group; Michael Minor, National Director, H.O.P.E. HHS Partnership, National Baptist Convention USA, Incorporated; Jina Ragland, Associate State Director of Advocacy and Outreach, AARP Nebraska; Morgan Reed, Executive Director, Association for Competitive Technology; Margot Savoy, Chair, Department of Family and Community Medicine, Temple University Physicians; Congresswoman Allyson Schwartz, President and CEO, Better Medicare Alliance; and; Tia Whitaker, Statewide Director, Outreach and Enrollment, Pennsylvania Association of Community Health Centers.

II. Provisions of This Notice

In accordance with section 10(a) of the FACA, this notice announces a meeting of the APOE. The agenda for the September 23, 2020 meeting will include the following:

- Welcome and listening session with CMS leadership
- Recap of the previous (June 25, 2020) meeting
- CMS programs, initiatives, and priorities
- An opportunity for public comment
- Meeting summary, review of recommendations, and next steps

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should submit a written copy of the oral presentation to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. The number of oral presentations may be limited by the time available. Individuals not wishing to make an oral presentation may submit written comments to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

III. Meeting Participation

The meeting is open to the public, but attendance is limited to registered participants. Persons wishing to attend this meeting must register at the website *https://www.eventbrite.com/e/apoe-september-23-2020-virtual-meeting-tickets-114295017474* or contact the DFO at the address or number listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice. This meeting will be held virtually. Individuals who are not registered in advance will be unable to attend the meeting.

IV. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Authority: Sec. 1114(f) of the Social Security Act (42 U.S.C. 1314(f)), sec. 222 of the Public Health Service Act (42 U.S.C. 217a), and sec. 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, sec. 10(a) and 41 CFR part 102–3).

Dated: August 17, 2020.

Lynette Wilson,

Federal Register Liaison, Department of Health and Human Services.

[FR Doc. 2020–18535 Filed 8–21–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

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

ACTION: Notice of amendment.

SUMMARY: The Secretary issues this amendment pursuant to section 319F–3 of the Public Health Service Act to add additional categories of Qualified Persons and amend the category of disease, health condition, or threat for which he recommends the administration or use of the Covered Countermeasures.

DATES: This amendment to the Declaration published on March 17, 2020 (85 FR 15198) is effective as of August 24, 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. Under the PREP Act, a Declaration may be amended as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, § 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 of the nation's health care community to the COVID–19 outbreak. Pursuant to section 319 of the PHS Act, the Secretary renewed that declaration on April 26, 2020, and July 25, 2020. On March 10, 2020, the Secretary issued a Declaration under the PREP Act for medical countermeasures against COVID–19 (85 FR 15198, Mar. 17, 2020) (the Declaration). On April 10, the Secretary amended the Declaration under the PREP Act to extend liability immunity to covered countermeasures authorized under the CARES Act (85 FR 21012, Apr. 15, 2020). On June 4, the Secretary amended the Declaration to clarify that covered countermeasures under the Declaration include qualified countermeasures that limit the harm COVID–19 might otherwise cause.

The Secretary now amends section V of the Declaration to identify as qualified persons covered under the PREP Act, and thus authorizes, certain State-licensed pharmacists to order and administer, and pharmacy interns (who are licensed or registered by their State board of pharmacy and acting under the supervision of a State-licensed pharmacist) to administer, any vaccine that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule (ACIP-recommended vaccines).[1]

The Secretary also amends section VIII of the Declaration to clarify that the category of disease, health condition, or threat for which he recommends the administration or use of the Covered Countermeasures includes 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.

[1] The only vaccines that ACIP has recommended are authorized or approved by the Food and Drug Administration (FDA). PREP Act coverage here is limited to covered persons ordering and administering FDA-authorized or FDA-approved vaccines.

Description of This Amendment by Section

Section V. Covered Persons

Under the PREP Act and the Declaration, a ''qualified person'' is a ''covered person.'' Subject to certain limitations, a covered person is immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration or use of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure. ''Qualified person'' includes

(A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or

(B) ''a person within a category of persons so identified in a declaration by the Secretary'' under subsection (b) of the PREP Act.

42 U.S.C. 247d–6d(i)(8).[2]

By this amendment to the Declaration, the Secretary identifies an additional category of persons who are qualified persons under section 247d–6d(i)(8)(B).[3]

On May 8, 2020, CDC reported, ''The identified declines in routine pediatric vaccine ordering and doses administered might indicate that U.S. children and their communities face increased risks for outbreaks of vaccine-preventable diseases,'' and suggested that a decrease in rates of routine childhood vaccinations were due to changes in healthcare access, social distancing, and other COVID–19 mitigation strategies.[4] The report also stated that ''[p]arental concerns about potentially exposing their children to COVID–19 during well child visits might contribute to the declines observed.'' [5]

On July 10, 2020, CDC reported its findings of a May survey it conducted to assess the capacity of pediatric health care practices to provide immunization services to children during the COVID–19 pandemic. The survey, which was limited to practices participating in the Vaccines for Children program, found that, as of mid-May, 15 percent of Northeast pediatric practices were closed, 12.5 percent of Midwest practices were closed, 6.2 percent of practices in the South were closed, and 10 percent of practices in the West were closed. Most practices had reduced office hours for in-person visits. When asked whether their practices would likely be able to accommodate new patients for immunization services through August, 418 practices (21.3 percent) either responded that this was not likely or the practice was permanently closed or not resuming immunization services for all patients, and 380 (19.6 percent) responded that they were unsure. Urban practices and those in the Northeast were less likely to be able to accommodate new patients compared with rural practices and those in the South, Midwest, or West.[6]

In response to these troubling developments, CDC and the American Academy of Pediatrics have stressed, ''Well-child visits and vaccinations are essential services and help make sure children are protected.'' [7]

The Secretary re-emphasizes that important recommendation to parents and legal guardians here: If your child is due for a well-child visit, contact your pediatrician's or other primary-care provider's office and ask about ways that the office safely offers well-child visits and vaccinations.

Many medical offices are taking extra steps to make sure that well-child visits can occur safely during the COVID–19 pandemic, including:

- Scheduling sick visits and well-child visits during different times of the

[2] *See* Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration under the Act, 5–6 (May 19, 2020), *https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-hhs-ogc.pdf* (last visited Aug. 5, 2020).

[3] *See* Advisory Opinion 20–02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, 3–5 (May 19, 2020), *https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf* (setting forth PREP Act's legal framework for identifying a ''qualified person'' and preemption of state law that is different from, or is in conflict with, that designation).

[4] Jeanne M. Santoli et al., *Effects of the COVID–19 Pandemic on Routine Pediatric Vaccine Ordering and Administration—United States, 2020,* 69 MMWR 591, 592 (2020), *https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6919e2-H.pdf.* (last visited July 15, 2020); *see also* Melissa Jenco, *AAP urges vaccination as rates drop due to COVID–19, AAP News* (May 8, 2020), *https://www.aappublications.org/news/2020/05/08/covid19vaccinations050820* (last visited July 15, 2020).

[5] Jeanne M. Santoli et al., *Effects of the COVID–19 Pandemic on Routine Pediatric Vaccine Ordering and Administration—United States, 2020,* 69 MMWR 591, 592 (2020), *https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6919e2-H.pdf* (last visited July 15, 2020).

[6] Tara M. Vogt, *Provision of Pediatric Immunization Services During the COVID–19 Pandemic: an Assessment of Capacity Among Pediatric Immunization Providers Participating in the Vaccines for Children Program—United States, May 2020,* 69 MMWR 859, 859–61, *https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6927a2-H.pdf* (last visited July 15, 2020).

[7] *Routine Vaccination During the COVID–19 Outbreak,* CDC, *https://www.cdc.gov/vaccines/parents/visit/vaccination-during-COVID-19.html* (last visited July 14, 2020).

day or days of the week, or at different locations.

- Asking patients to remain outside until it is time for their appointments to reduce the number of people in waiting rooms.
- Adhering to recommended social (physical) distancing and other infection-control practices, such as the use of masks.

The decrease in childhood-vaccination rates is a public health threat and a collateral harm caused by COVID–19. Together, the United States must turn to available medical professionals to limit the harm and public health threats that may result from decreased immunization rates. We must quickly do so to avoid preventable infections in children, additional strains on our healthcare system, and any further increase in avoidable adverse health consequences—particularly if such complications coincide with additional resurgence of COVID–19.

Together with pediatricians and other healthcare professionals, pharmacists are positioned to expand access to childhood vaccinations. Many States already allow pharmacists to administer vaccines to children of any age.[8] [9] Other States permit pharmacists to administer vaccines to children depending on the age—for example, 2, 3, 5, 6, 7, 9, 10, 11, or 12 years of age and older.[10] Few States restrict pharmacist-administered vaccinations to only adults.[11] Many States also allow properly trained individuals under the supervision of a trained pharmacist to administer those vaccines.[12]

Pharmacists are well positioned to increase access to vaccinations, particularly in certain areas or for certain populations that have too few pediatricians and other primary-care providers, or that are otherwise medically underserved.[13] As of 2018, nearly 90 percent of Americans lived within five miles of a community pharmacy.[14] Pharmacies often offer extended hours and added convenience. What is more, pharmacists are trusted healthcare professionals with established relationships with their patients. Pharmacists also have strong relationships with local medical providers and hospitals to refer patients as appropriate.

For example, pharmacists already play a significant role in annual influenza vaccination. In the early 2018–19 season, they administered the influenza vaccine to nearly a third of all adults who received the vaccine.[15] Given the potential danger of serious influenza and continuing COVID–19 outbreaks this autumn and the impact that such concurrent outbreaks may have on our population, our healthcare system, and our whole-of-nation response to the COVID–19 pandemic, we must quickly expand access to influenza vaccinations. Allowing more qualified pharmacists to administer the influenza vaccine to children will make vaccinations more accessible.

Therefore, the Secretary amends the Declaration to identify State-licensed pharmacists (and pharmacy interns acting under their supervision if the pharmacy intern is licensed or registered by his or her State board of pharmacy) as qualified persons under section 247d–6d(i)(8)(B) when the pharmacist orders and either the pharmacist or the supervised pharmacy intern administers vaccines to individuals ages three through 18 pursuant to the following requirements:

- The vaccine must be FDA-authorized or FDA-approved.
- The vaccination must be ordered and administered according to ACIP's standard immunization schedule.[16]
- The licensed pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training

[8] For purposes of this amendment, ''State'' shall have the same meaning ascribed to it in 42 U.S.C. 201(f). Under section 201(f), ''State'' includes the several States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

[9] *See, e.g.,* Ala. Code § 34–23–1(5), (21) (2020); Ala. Admin. Code r. 680–X–2–.14(1) (2000); Alaska Stat. Ann. § 08.80.168(a) (West 2020); Cal. Bus. & Prof. Code § 4052(a)(11) (West 2020); Colo. Code Regs. § 719–1:19.00.00 (West 2020); Ga. Code Ann. § 43–34–26.1 (West 2020); Idaho Code Ann. § 54–1704 (West 2020); Idaho Code Ann. § 37–201 (West 2020); Ind. Code Ann. § 25–26–13–31.2(a) (West 2020); Iowa Admin. Code § 657–39.10(6) (2020); La. Admin. Code tit. 46, Pt. LIII, § 521 (2020); Mich. Comp. Laws Ann. § 333.9204 (2020); Miss. Code Ann. § 73–21–73(a), (dd) (West 2000); MO 20 CSR 2220–6.040; MO 20 CSR 2220–6.050; Neb. Rev. Stat. Ann. §§ 38–2806, 38–2837 (West 2000); 175 Neb. Admin. Code. § 8.003.01A(3)(m)(4)(a) (2020); N.H. Rev. Stat. § 318:16–b (2020); Nev. Admin. Code § 639.2971 (2020); N.M. Stat. Ann. § 61–11–2(A), (G), (CC) (West 2020); Okla. Stat. Ann. tit. 59, § 353.30 (West 2020); Or. Rev. Stat. § 689.645 (West 2020); *https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Pages/pharmacy.aspx#:~:text=Immunization%20Resources%20for%20Oregon%20Pharmacists,a%20patient%20of%20any%20age* (last visited Aug. 13, 2020); S.C. Code Ann. § 40–43–190 (2020); S.D. Codified Laws § 36–11–2, S.D. Codified Laws § 36–11–19.1; Tenn. Code Ann. § 63–10–204(1), 39(A) (West 2020); Tex. Occ. Code Ann. § 551.003(33) (2020); 22 Tex. Admin. Code § 295.15(e) (2020); Utah Code Ann. § 58–17b–102(1), (57) (West 2020); Utah Admin. Code R156–17b–621(5) (2020); Va. Code Ann. § 54.1–3408(I) (2020); Wash. Rev. Code Ann. § 18.64.011(1), (28) (West 2020); Wis. Stat. Ann. § 450.035 (West 2020). While these states allow pharmacists to administer vaccines to children of any age, some impose additional requirements. *See, e.g.,* Cal. Bus. & Prof. Code §§ 4052(a)(11), 4052.8 (permitting pharmacists to administer any vaccine listed on the routine immunization schedules recommended by the Advisory Committee on Immunization Practices to persons three years of age and older, but requiring the pharmacist to administer immunizations to persons under three years of age only pursuant to a protocol with a prescriber); Colo. Code Regs. § 719–1:19.00.00 (West 2020) (requiring that pharmacists administer vaccines and immunizations ''per authorization of a physician'').

[10] *See, e.g.,* Ariz. Rev. Stat. Ann. § 32–1974(B) (2020); Ark. Code Ann. § 17–92–101 (2020); D.C. Mun. Reg Tit. 17 sec. 6512.10 (2012); Haw. Rev. Stat. § 461–11.4 (West 2019); 225 Ill. Comp. Stat. Ann. 85/3(d) (West 2020); Kan. Stat. Ann. § 65–1635a (2020); Ky. Rev. Stat. Ann. § 315.010(22) (West 2020); Me. Rev. Stat. Ann. tit. 32, § 13831 (West 2020); Md. Code Ann., Health Occ. § 12–508 (2020); 247 Mass. Code Regs. 16.03 (2020); Minn. Stat. Ann. § 151.01 (West 2020); Mont. Code Ann. § 37–7–105 (West 2019); N.J. Stat. Ann. § 45:14–63 (West 2020); N.Y. Comp. Codes R. & Regs. tit. 8, § 63.9 (2020); N.C. Gen. Stat. Ann. § 90–85.15B (West 2020); N.D. Cent. Code Ann. § 43–15–01 (West 2020); Ohio Rev. Code Ann. § 4729.41 (West 2020); 63 Pa. Cons. Stat. § 390–9.2 (West 2020); P.R. Laws tit. 20, § 410c (2018); 5 R.I. Gen. Laws Ann. § 5–19.1–31 (West 2020); W.Va. Code Ann. § 30–5–7 (West 2020); Wyo Stat. Ann. § 33–24–157 (2020).

[11] *See, e.g.,* Conn. Gen. Stat. § 20–633(a) (West 2012); 24 Del. Code Ann. § 2502(23)(h) (West 2020); Fla. Stat. Ann. § 465.189(1) (West 2020); Vt. Admin. R. of Board of Pharm. § 10.35 (West 2020).

[12] *See, e.g.,* Or. Admin. R. 855–019–0270 (2020) (''[A]n intern who is appropriately trained and qualified in accordance with Section (3) of this rule may perform the same duties as a pharmacist, provided that the intern is supervised by an appropriately trained and qualified pharmacist.'').

[13] *See, e.g., Guidance for Pharmacists and Pharmacy Technicians in Community Pharmacies during the COVID–19 Response,* CDC, *https://www.cdc.gov/coronavirus/2019-ncov/hcp/pharmacies.html* (last updated June 28, 2020) (''As a vital part of the healthcare system, pharmacies play an important role in providing medicines, therapeutics, vaccines, and critical health services to the public.''); Kimberly McKeirnan & Gregory Sarchet, *Implementing Immunizing Pharmacy Technicians in a Federal Healthcare Facility,* 7 Pharmacy 1, 7 (2019), *https://www.mdpi.com/2226-4787/7/4/152/htm* (last visited Aug. 5, 2020) (HHS Indian Health Service study demonstrating ''the effective implementation of immunization-trained pharmacy technicians and the positive impact utilization of pharmacy support personnel can create'' on childhood vaccination rates in medically underserved populations).

[14] *Get to Know Your Pharmacist,* CDC, *https://www.cdc.gov/features/pharmacist-month/index.html* (last visited July 14, 2020).

[15] *Early-Season Flu Vaccination Coverage—United States, November 2018,* CDC, *https://www.cdc.gov/flu/fluvaxview/nifs-estimates-nov2018.htm* (last visited July 14, 2020).

[16] *See Immunization Schedules: For Health Care Providers,* CDC, *https://www.cdc.gov/vaccines/schedules/hcp/index.html* (last visited July 14, 2020). The immunization schedule recommends that certain vaccines be administered only to children of a certain age. For example, the second dose of both the measles, mumps, and rubella vaccine, as well as the varicella vaccine, should not be administered until a child is between four and six years old. *See Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2020,* CDC (Jan. 29, 2020), *https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf* (last visited Aug. 5, 2020).

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.[17]

• 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.[18]

• The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.[19]

• The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period.[20]

• 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.[21]

• The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregivers accompanying the children of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate.[22]

These requirements are consistent with those in many States that permit licensed pharmacists to order and administer vaccines to children and permit licensed or registered pharmacy interns acting under their supervision to administer vaccines to children.[23]

Administering vaccinations to children age three and older is less complicated and requires less training and resources than administering vaccinations to younger children. That is because ACIP generally recommends administering intramuscular injections in the deltoid muscle for individuals age three and older.[24] For individuals less than three years of age, ACIP generally recommends administering intramuscular injections in the anterolateral aspect of the thigh muscle.[25] Administering injections in the thigh muscle often presents additional complexities and requires additional training and resources including additional personnel to safely position the child while another healthcare professional injects the vaccine.[26]

Moreover, as of 2018, 40% of three-year-olds were enrolled in preprimary programs (*i.e.* preschool or kindergarten programs).[27] Preprimary programs are beginning in the coming weeks or months, so the Secretary has concluded that it is particularly important for individuals ages three through 18 to receive ACIP-recommended vaccines according to ACIP's standard immunization schedule. All States require children to be vaccinated against certain communicable diseases as a condition of school attendance. These laws often apply to both public and private schools with identical immunization and exemption provisions.[28] As nurseries, preschools, kindergartens, and schools reopen, increased access to childhood vaccinations is essential to ensuring children can return.

Notwithstanding any State or local scope-of-practice legal requirements, (1) qualified licensed pharmacists are identified as qualified persons to order and administer ACIP-recommended vaccines and (2) qualified State-licensed or registered pharmacy interns are identified as qualified persons to administer the ACIP-recommended vaccines ordered by their supervising qualified licensed pharmacist.[29]

Both the PREP Act and the June 4, 2020 Second Amendment to the Declaration define ''covered countermeasures'' to include qualified pandemic and epidemic products that ''limit the harm such pandemic or epidemic might otherwise cause.'' [30] The troubling decrease in ACIP-recommended childhood vaccinations and the resulting increased risk of associated diseases, adverse health conditions, and other threats are categories of harms otherwise caused by

[17] *Cf., e.g.,* Cal. Bus. & Prof. Code § 4052.8; 3 Colo. Code Regs. § 719–1:19.00.00; 856 Ind. Admin. Code 4–1–1; 46 La. Admin. Code tit. 46Part LIII, § 521; Nev. Admin. Code § 639.2973; 22 Tex. Admin. Code § 295.15(c).

[18] *Cf., e.g.,* Ark. Admin. Code § 070.00.9–09–00–0002; 3 Colo. Code Regs. § 719–1:19.00.00; Nev. Admin. Code § 639.2973; N.H. Rev. Stat. § 318:16–d; Ohio Rev. Code Ann. § 4729.41(B); Or. Admin. R. 855–019–0270 (2020); S.C. Code Ann. §§ 40–43–190(B)(1), (4); Utah Admin. Code r. 156R–17b–621(5); Vt. Admin. Code 20–4–1400:10.35.

[19] *Cf., e.g.,* Ariz. Admin. Code § R4–23–411(D(3); Conn. Gen. Stat. § 20–633(b); D.C. Mun. Regs. tit. 17, § 6512.3; 856 Ind. Admin. Code 4–1–1(c); Iowa Admin. Code r. 657–39.10(2)(A); Kan. Stat. Ann. § 65–1635a(a); La. Admin. Code tit. 46 Part LIII, § 521(D); Me. Rev. Stat. Ann. tit. 32, § 13832; Md. Code Ann., Health Occ. § 12–508(b)(2)(ii); Mont. Code Ann. § 37–7–101(24)(b); N.J. Admin. Code § 13:39–4.21(b)(2); N.D. Cent. Code Ann. § 43–15–31.5; Or. Admin. R. 855–019–0270 (2020); 63 Pa. Stat. Ann. § 390–9.2;(a)(2) 216 R.I. Code R. § 40–15–1.11; S.C. Code Ann. §§ 40–43–190(B)(4); S.D. Admin. R. 20:51:28:02; W. Va. Code St. R. § 15–12–4; Wyo. Admin. Code 059.0001.16 § 7.

[20] *Cf., e.g.,* AR ADC § 070.00.9–09–00–0002; 3 Colo. Code Regs. § 719–1:19.00.00; N.J. Stat. Ann. § 13:39–4.21; S.C. Code Ann. §§ 40–43–190(B)(1), (5); 22 Tex. Admin. Code § 295.15(c); Utah Admin. Code r. 156–17b–621(5); 59–0001–16 Wyo. Code R. § 7.

[21] *Cf., e.g.,* Ala. Admin. Code. r. 680–X–2.14; Ariz. Admin. Code § R4–23–411(E); AR ADC § 070.00.9–09–00–0002; Cal. Code Regs. tit. 16, § 1746.4; Conn. Gen. Stat. § 20–633(b); 225 Ill. Comp. Stat. Ann. 85/3(d)(4); Kan. Stat. Ann. § 65–1635a(a); Mont. Admin. R. 24.174.503; Nev. Rev. Stat. Ann. § 454.213(s); N.H. Rev. Stat. § 318:16–d; N.J. Stat. Ann. § 45:14–63; N.Y. Comp. Codes R. & Regs. tit. 8, § 63.9; N.D. Cent. Code Ann. § 43–15–31.5; Or. Admin. r. 855–019–0280; 216–40; R.I. Code R. § 15–1.11; S.C. Code Ann. §§ 40–43–190(B)(1), (5); S.D. Admin. R. 20:51:28:04; Tenn. Code Ann. § 53–10–211; 22 Tex. Admin. Code § 295.15(c); 04–230 Vt. Code R. § 10.35; Va. Code Ann. § 54.1–3408; Wis. Stat. Ann. § 450.035.

[22] *See, e.g.,* Letter from Kathleen E. Toomey, M.D., M.P.H., Comm'r and State Health Officer, Ga. Dep't of Pub. Health, *available at https://www.gpha.org/immunization/* (last visited July 15, 2020).

[23] *See, e.g.,* AL ST § 34–23–53; 12 AAC 52.992; Cal. Bus. & Prof. Code § 4052; Cal. Bus. & Prof. Code § 4052.8(b); 3 Colo. Code Regs. § 719–1:19.00.00; Ga. Code Ann., § 43–34–26.1; 856 IAC 4–1–1; Iowa Code § 39.10(2)(a); N.M. Admin. Code 16.19.26; Okla. Admin. Code 535:10–11–5; Code 1976 § 40–43–190 (South Carolina).

[24] Vaccine Recommendations and Guidelines of the ACIP, *https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html* (last visited July 29, 2020).

[25] *Id.*

[26] *Id.;* Nicole E. Omecene, *et al., Implementation of pharmacist-administered pediatric vaccines in the United States: major barriers and potential solutions for the outpatient setting, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6594428/* (last visited July 29, 2020).

[27] Preschool and Kindergarten Enrollment, *https://nces.ed.gov/programs/coe/indicator_cfa.asp* (last visited July 29, 2020).

[28] State School Immunization Requirements and Vaccine Exemption Laws, *https://www.cdc.gov/phlp/docs/school-vaccinations.pdf,* (last visited July 29, 2020).

[29] Nothing herein shall affect federal law requirements in 42 CFR part 455, subpart E regarding screening and enrollment of Medicare and Medicaid providers. Moreover, nothing herein shall preempt State laws that permit additional individuals to administer vaccines that ACIP recommends to persons age 18 or younger according to ACIP's standard immunization schedule. For example, Idaho permits pharmacy technicians who meet certain requirements to administer vaccines under the supervision of an immunizing pharmacist. Such technicians can still administer vaccines to the extent they would have been able to absent publication of this amendment. Moreover, pharmacists and pharmacy interns may still order or administer vaccines to individuals ages two or younger to the extent authorized under State law.

[30] 42 U.S.C. 247d–d6(i)(7)(A); 85 FR 35–100, 35–102.

COVID–19 as set forth in Sections VI and VIII of this Declaration.[31] Hence, such vaccinations are ''covered countermeasures'' under the PREP Act and the June 4, 2020 Second Amendment to the Declaration.

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.

Section VIII. Category of Disease, Health Condition, or Threat

As discussed, the troubling decrease in ACIP-recommended childhood vaccinations and the resulting increased risk of associated diseases, adverse health conditions, and other threats are categories of harms otherwise caused by COVID–19. The Secretary therefore amends section VIII, which describes the category of disease, health condition, or threat for which he recommends the administration or use of the Covered Countermeasures, to clarify that the category of disease, health condition, or threat for which he recommends 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.

Amendments to Declaration

Amended Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID–19.

Sections V and VIII of the March 10, 2020 Declaration under the PREP Act for medical countermeasures against COVID–19, as amended April 10, 2020 and June 4, 2020, are further amended pursuant to section 319F–3(b)(4) of the PHS Act as described below. All other sections of the Declaration remain in effect as published at 85 FR 15198 (Mar. 17, 2020) and amended at 85 FR 21012 (Apr. 15, 2020) and 85 FR 35100 (June 8, 2020).

1. Covered Persons, section V, delete in full and replace with:

V. Covered Persons

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

Covered Persons who are afforded liability immunity under this Declaration are ''manufacturers,'' ''distributors,'' ''program planners,'' ''qualified persons,'' and their officials, agents, and employees, as those terms are defined in the PREP Act, 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 an emergency; (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; and (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), vaccines that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule.

Such State-licensed pharmacists and the State-licensed or registered interns under their supervision are qualified persons only if the following requirements are met:

- The vaccine must be FDA-authorized or FDA-approved.
- The vaccination must be ordered and administered according to ACIP's standard immunization schedule.
- The licensed pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (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.
- 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.
- The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.
- The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period.
- 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.
- 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.

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

[31] Jeanne M. Santoli et al., *Effects of the COVID–19 Pandemic on Routine Pediatric Vaccine Ordering and Administration—United States, 2020,* 69 MMWR No. 19, at 591–93 (May 15, 2020), *https://www.cdc.gov/mmwr/volumes/69/wr/mm6919e2.htm;* Cristi A. Bramer et al., *Decline in Child Vaccination Coverage During the COVID–19 Pandemic—Michigan Care Improvement Registry, May 2016–May 2020,* 69 MMWR No. 20, at 630–31 (May 22, 2020), *https://www.cdc.gov/mmwr/volumes/69/wr/mm6920e1.htm.*

terms and conditions of the Declaration apply to such covered countermeasures.

2. Category of Disease, Health Condition, or Threat, section VIII, delete in full and replace with:

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.

Authority: 42 U.S.C. 247d–6d.

Dated: August 19, 2020.

Alex M. Azar II,

Secretary of Health and Human Services.

[FR Doc. 2020–18542 Filed 8–20–20; 4:15 pm]

BILLING CODE 4150–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Tick-Borne Disease Working Group

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As required by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the Tick-Borne Disease Working Group (TBDWG) will hold a virtual meeting. The meeting will be open to the public. For this meeting, the TBDWG will review the draft 2020 report to the HHS Secretary and Congress and review and approve graphics and images for the report. The 2020 report will address ongoing tick-borne disease research, including research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, and interventions for individuals with tick-borne diseases; advances made pursuant to such research; federal activities related to tick-borne diseases; and gaps in tick-borne disease research.

DATES: The meeting will be held online via webcast on September 15, 2020 and September 22, 2020 from 9:00 a.m. to 2:30 p.m. ET both days (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the TBDWG web page at *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2020-9-15/index.html* when this information becomes available.

FOR FURTHER INFORMATION CONTACT: James Berger, Designated Federal Officer for the TBDWG; Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Mary E. Switzer Building, 330 C Street SW, Suite L600, Washington, DC, 20024. *Email: tickbornedisease@hhs.gov; Phone:* 202–795–7608.

SUPPLEMENTARY INFORMATION: The registration link will be posted on the website at *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2020-9-15/index.html* when it becomes available. After registering, you will receive an email confirmation with a personalized link to access the webcast on September 15, 2020 and September 22, 2020

The public will have an opportunity to present their views to the TBDWG orally during the meeting's public comment session or by submitting a written public comment. Comments should be pertinent to the meeting discussion. Persons who wish to provide verbal or written public comment should review instructions at *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2020-9-15/index.html* and respond by midnight September 4, 2020 ET. Verbal comments will be limited to three minutes each to accommodate as many speakers as possible during the 30 minute session. Written public comments will be accessible to the public on the TBDWG web page prior to the meeting.

Background and Authority: The Tick-Borne Disease Working Group was established on August 10, 2017, in accordance with Section 2062 of the 21st Century Cures Act, and the Federal Advisory Committee Act, 5 U.S.C. App., as amended, to provide expertise and review federal efforts related to all tick-borne diseases, to help ensure interagency coordination and minimize overlap, and to examine research priorities. The TBDWG is required to submit a report to the HHS Secretary and Congress on their findings and any recommendations for the federal response to tick-borne disease every two years.

Dated: August 12, 2020.

James J. Berger,

Designated Federal Officer, Tick-Borne Disease Working Group, Office of Infectious Disease and HIV/AIDS Policy.

[FR Doc. 2020–18519 Filed 8–21–20; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel RFA–DK–20–503 Limited Competition: TEDDY Data Coordinating Center.

Date: October 7, 2020.

Time: 3:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Dianne Camp, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7013, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 5947682, *campd@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: August 18, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–18438 Filed 8–21–20; 8:45 am]

BILLING CODE 4140–01–P