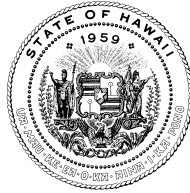


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PREP Act Guidance Document: Pharmacist Administering Vaccines to Minors Between the Age of 3 - 18

Background:

Public Readiness and Emergency Preparedness Act (PREP ACT)

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of the Department of Health and Human Services (Secretary) to issue a declaration (PREP Act declaration) that provides immunity from liability (except for willful misconduct) for claims of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined by the Secretary to constitute a present, or credible risk of a future public health emergency to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures. A PREP Act declaration is specifically for the purpose of providing immunity from liability, and is different from, and not dependent on, other emergency declarations.

Health and Human Services' Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 to Authorize Licensed Pharmacists and Pharmacy Interns to Administer Any Vaccine Recommended by the Advisory Committee on Immunization Practices (ACIP) to Persons Ages 3 -18

Effective August 24, 2020 pursuant to the third amendment to the PREP Act, the Secretary, by this amendment to the Declaration, identified an additional category of persons who are qualified persons under section 247d-6d(i)(8)(B).

According to the Federal Registry...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.

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.

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. 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.”

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 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. 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. Few States restrict pharmacist-administered vaccinations to only adults. Many States also allow properly trained individuals under the supervision of a trained pharmacist to administer those vaccines.

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. As of 2018, nearly 90 percent of Americans lived within five miles of a community pharmacy. 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. 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.
- 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 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.

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.

October 20, 2020, the HHS issued another "Guidance" for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns to administer childhood and COVID-19 vaccines in order to increase access to vaccinations.

States vary on licensure and registration requirements for pharmacy technicians. Some states require certain education, training, and/or certification for licensure or registration; others either have no prerequisites for licensure or registration or do not require licensure or registration at all. For purposes of this guidance, to be a "qualified pharmacy technician," pharmacy technicians working in states with licensure and/or registration requirements must be licensed and/or registered in accordance with state requirements; pharmacy technicians working in states without licensure and/or registration requirements must have a Certified Pharmacy Technician (CPhT) certification from either the Pharmacy Technician Certification Board or National Healthcareer Association.

Therefore, as an Authority Having Jurisdiction under the Secretary's March 10, 2020 declaration under the PREP Act, OASH issues this guidance. Subject to satisfaction of the requirements listed below, this guidance authorizes both qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist to administer FDA-authorized or FDA-licensed COVID-19 vaccines to persons ages three or older and to administer FDA-authorized or FDA-licensed ACIP-recommended vaccines to persons ages three through 18 according to ACIP's standard immunization schedule.

Such qualified pharmacy technicians and State-authorized pharmacy interns will qualify as "covered persons" under the PREP Act, subject to other applicable requirements of

the Act and the requirements discussed below. They may also receive immunity under the PREP Act with respect to all claims for loss caused by, arising out of, relating to, or resulting from, the administration or use of such vaccines. 42 U.S.C. § 247d-6d(a)(1).¹² To qualify as “qualified persons” under 42 U.S.C. § 247d-6d(i)(8)(B) when administering FDA- authorized or FDA-licensed COVID-19 vaccines to persons ages three or older or ACIP- recommended childhood vaccinations to persons ages three through 18, qualified pharmacy technicians and State-authorized pharmacy interns must satisfy the following requirements:

- The vaccination must be ordered by the supervising qualified pharmacist.

- The supervising qualified pharmacist must be readily and immediately available to the immunizing qualified pharmacy technicians.

- The vaccine must be FDA-authorized or FDA-licensed.

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

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

- The qualified pharmacy technician or State-authorized pharmacy intern must complete a practical training program that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines.

- The qualified pharmacy technician or State-authorized pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.

- The qualified pharmacy technician must complete a minimum of two hours of ACPE- approved, immunization-related continuing pharmacy education during the relevant State licensing period(s).

- The supervising qualified 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 and submitting the required immunization information to the state or local immunization information system (vaccine registry).

- The supervising qualified pharmacist is responsible for complying with requirements related to reporting adverse events.

- The supervising qualified pharmacist must review the vaccine registry or other vaccination records prior to ordering the vaccination to be administered by the qualified pharmacy technician or State-authorized pharmacy intern.

- The qualified pharmacy technician and State-authorized pharmacy intern must, if the patient is 18 years of age or younger, inform the patient and the adult caregiver accompanying the patient of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate.
- The supervising qualified pharmacist must comply with any applicable requirements (or conditions of use) as set forth in the CDC's COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s).

This authorization preempts any state and local law that prohibits or effectively prohibits those who satisfy these requirements from administering COVID-19 or routine childhood vaccines as set forth above. It does not preempt state and local laws that permit additional individuals to administer COVID-19 or routine childhood vaccines to additional persons.

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. For individuals less than three years of age, ACIP generally recommends administering intramuscular injections in the anterolateral aspect of the thigh muscle. 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.

Moreover, as of 2018, 40% of three year-olds were enrolled in preprimary programs (*i.e.* preschool or kindergarten programs). 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. 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.

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.” 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 as set forth in Sections VI and VIII of this Declaration. 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.

Such State-licensed pharmacists and the State-licensed or registered interns under their supervision are qualified persons only if they following the requirements previously stated.

Conclusion/FAQs:

1. Can a pharmacist administer a vaccine to minors between 3 – 18 years old?

Response: Yes

2. Under what authority may a pharmacist administer a vaccine to minors between 3 – 18 years old?

Response: Pursuant to the Department of Health and Human Services’ PREP Act

3. What does the State require in order for a pharmacist to administer a vaccine to a minor between the age of 3-18?

Response: The State requires that you comply with ALL HHS requirements specified in the **Federal Register** / Vol. 85, No. 164 / Monday, August 24, 2020 / Notices.

4. Is a prescription required from a health care provider for a pharmacist to administer a vaccine?

Response: No, the HHS PREP Act allows a pharmacist to “order and administer” the vaccines. However, the Board of Pharmacy also highly recommends and encourages pharmacists to work collabora-

tively with the patient's medical home and other health care providers.

5. Can a pharmacy intern administer vaccines to minors?

Response: Yes, the HHS PREP Act does include pharmacy interns who are supervised by a pharmacist.

6. Will the Board of Pharmacy be maintaining a list of pharmacists/pharmacy/pharmacy interns who can perform this activity?

Response: Yes, although strictly voluntary, the Board of Pharmacy will be maintaining a list on their web page of pharmacists/pharmacy/pharmacy interns who submit proof of the required training as specified in the HHS' PREP Act and indicate the name, address and phone number of the pharmacy.

7. What kind of immunity is afforded a pharmacist or pharmacy intern who chooses to perform this activity?

Response: Please see the link below:

<https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx>

8. Can a pharmacy technician administer vaccines to minors?

Response: Yes, as long as all requirements of the HHS' PREP Act are met.