

September 28, 2020

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Dear provider of healthcare-related services,

On September 3, 2020, the United States (U.S) Department of Health and Human Services (HHS) provided a Guidance for Licensed Pharmacists and Pharmacy Interns regarding COVID-19 Vaccines and Immunity under the Public Readiness and Emergency Preparedness Act (PREP Act). The PREP Act provides immunity from liability for claims of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to disease or risk for public health, except when there is willful misconduct.

The Secretary of Health amended Section V of the PREP Act to include: state-licensed pharmacists to order and administer, and state-licensed or registered pharmacy interns to administer (under the supervision of a licensed pharmacist), any childhood vaccination that the Advisory Committee on Immunizations Practices (ACIP) recommends to person ages 3 to 18 years and COVID-19 vaccinations to person ages 3 years or older, when available, during the public health emergency. The public policy changes came from emergent patterns on immunization that showed a decline in routine childhood vaccination rates. Some of the causes for these patterns in decline include parental concerns about potentially exposing their children to COVID-19 during well-child visits, reduced capacity and office hours of pediatric health practice sites, among others.

The Guidance for Pharmacists and Pharmacy Interns includes some requirements that must be complied to provide childhood immunizations (3 to 18 years) and COVID-19 vaccines (3 years and older):

| Requirements | |
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| Licensing | -Pharmacists must have a valid state-license to practice the pharmacy profession. -Pharmacy Interns must have a valid state-license or be registered as a pharmacy intern under the supervision of a qualified pharmacist. |
| Training | -Pharmacists 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 |

| Requirements | |
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| | <p>contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines. The pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each state-licensing period.</p> <p>-Pharmacy Interns must complete an ACPE-approved practical training program that must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.</p> <p>-Both pharmacists and pharmacy interns must have a current certificate in basic cardiopulmonary resuscitation.</p> |
| Vaccines | <p>-Vaccines must be FDA-authorized or FDA-license.</p> <p>-The vaccination must be ordered and administered according to the ACIP COVID-19 vaccine recommendation.</p> |
| Record keeping and reporting | <p>-Pharmacists must comply with record-keeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including reviewing the vaccine registry or other vaccination records before administering a vaccine.</p> <p>-Pharmacists must inform the patient's primary care provider and submit the required information to the local vaccine registry, including adverse events.</p> |
| Education to patients during well-child visits | <p>-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.</p> |
| <p>The licensed pharmacists and the licensed or registered pharmacy interns must comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s).</p> | |

This authorization preempts any State and local law that prohibits or effectively prohibits those who satisfy these requirements from ordering or administering COVID-19 vaccines as set forth above.

Additional information can be found on the American Pharmacist Association (APhA) and the U.S. Department of HHS websites. Since the COVID-19 pandemic is dynamic, we strongly encourage the frequent revision of updated information provided by the FDA, the Centers for

Disease and Control Prevention (CDC), and the World Health Organization (WHO) to assure that your practices are consistent with the most updated information. It is also important to keep up-to-date about the role of pharmacists in the COVID-19 vaccination response.

PharmPix is committed to our member's health and wellness, and to support you as the COVID-19 pandemic continues to evolve. It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, you can access our recent communications at our providers' portal: <https://www.pharmpix.com/providers/>.

Regards,

Clinical Department

References:

- American Pharmacist Association (APhA). (2020). Pharmacy orgs applaud HHS expanding pharmacists' role in childhood vaccine access. Retrieved from <https://www.pharmacist.com/article/pharmacy-orgs-applaud-hhs-expanding-pharmacists-role-childhood-vaccine-access>
- Santoli JM, Lindley MC, DeSilva MB, et al. Effects of the COVID-19 Pandemic on Routine Pediatric Vaccine Ordering and Administration — United States, 2020. MMWR Morb Mortal Wkly Rep 2020;69:591–593. DOI: <http://dx.doi.org/10.15585/mmwr.mm6919e2>
- U.S. Department of Health and Human Resources. (2020). HHS Expands Access to Childhood Vaccines during COVID-19 Pandemic. Retrieved from <https://www.hhs.gov/about/news/2020/08/19/hhs-expands-access-childhood-vaccines-during-covid-19-pandemic.html>