DATE: November 11, 2020, revised September 16, 2021
WHAT: Board Policy Statement Number 20-12-11
WHY: UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES ISSUES DECLARATION UNDER PUBLIC READINESS AND EMERGENCY PREPAREDNESS ("PREP") ACT AUTHORIZING QUALIFIED PHARMACY TECHNICIANS TO ADMINISTER ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP) RECOMMENDED VACCINES TO PEDIATRIC PATIENTS AGES THREE YEARS TO EIGHTEEN YEARS AND FDA-APPROVED COVID-19 VACCINES TO PATIENTS DURING THE PUBLIC HEALTH EMERGENCY

On August 24, 2020, the U.S. Department of Health and Human Services (HHS) issued a declaration under the PREP Act authorizing pharmacists “to order and administer,” and a “supervised pharmacy intern” “to administer” certain vaccines to patients ages three (3) to eighteen (18) during the federally declared COVID-19 public health emergency. The purpose of this declaration was to mitigate a potential “decrease in rates of routine childhood vaccinations . . . due to changes in healthcare access, social distancing, and other COVID-19 mitigation strategies.” This is a new authorization for pharmacists in South Dakota which allows for ordering and administering certain vaccines without a prescription or protocol. The declaration includes the pharmacist obligations to complete this activity including training and reporting requirements.

On September 3, 2020, HHS issued a declaration authorizing pharmacists “to order and administer,” and a “supervised pharmacy intern acting under the supervision of [a] qualified pharmacist” “to administer” FDA-approved COVID-19 vaccines, when available, to patients ages three (3) years or older during the federally-declared public health emergency. This is a new authorization for a pharmacist to be able to order a COVID-19 vaccine without a prescriber order or protocol and includes similar training and reporting requirements.

On October 20, 2020, HHS issued another declaration under the PREP Act authorizing “qualified pharmacy technicians” to administer ACIP-recommended vaccines to patients ages three (3) to eighteen (18) and FDA-approved COVID-19 vaccines to patients ages three (3) years or older under the supervision of a qualified pharmacist (https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf). Note: This declaration also clarified the ability of qualified pharmacy interns to administer such vaccines. This is a new authorization for South Dakota Pharmacy Technicians as they have not previously been allowed to immunize.

HHS defines a “qualified pharmacy technician” as a technician “licensed and/or registered in accordance with state requirements.” Under South Dakota rules, registered pharmacy technicians do not have authority to administer vaccines (or any other drug). The HHS authorization, however, “preempts any state and local law that prohibits or effectively prohibits [qualified pharmacy] technicians from administering COVID-19 or routine childhood vaccines” as outlined in the declaration.

In addition to being registered, the pharmacy technician must comply with the following requirements to be eligible to administer vaccines pursuant to this declaration:
• The pharmacy technician must be registered with the Board of Pharmacy. In SD, technicians are required to become Certified. We strongly encourage Certified and Grandfathered technicians train as immunizers.
• The vaccination must be ordered by the supervising qualified pharmacist (or a prescriber).
• The supervising qualified pharmacist must be readily and immediately available to the qualified pharmacy technicians administering vaccines.
• 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. Note: Because pharmacy technicians in South Dakota had no prior authority to administer vaccines, few, if any, are likely to have completed this type of training program. This training must be completed and documented prior to a technician administering any vaccine. The Pharmacists-in-Charge in each pharmacy are responsible for ensuring that any pharmacy technician administering vaccines has received the required training and it is documented.
• The qualified pharmacy technician or state-authorized pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation. Note: This training must be completed and documented prior to administration of any vaccine. The Pharmacists-in-Charge in each pharmacy are responsible for ensuring that any pharmacy technician or administering vaccines has obtained basic CPR certification.
• 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). Note: South Dakota law does not require pharmacy technicians to obtain continuing education for registration. Certified technicians are required by their certifying entity -- PTCB or NHA -- to obtain continuing education to renew their certification with those entities. The Pharmacists-in-Charge are responsible for ensuring that any pharmacy technician administering vaccines under this declaration obtains the required immunization-related CE during the 2021 registration year.
• The supervising qualified pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction where vaccines are administered, including informing the patient’s primary care provider when appropriate/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 and that vaccination administrations should not be viewed as a substitute for a well-child visit with a pediatrician or other licensed primary care provider.
• The supervising qualified pharmacist must comply with any applicable requirements (or conditions of use) and ensure compliance from any immunizer under his or her supervision 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).

On several occasions, the PREP Act has been amended with additions to the Qualified Individuals who are covered under the PREP Act.
On August 4, 2021, the Eighth Amendment to the PREP Act adds seasonal influenza vaccine to the COVID-19 Countermeasure and allows for technicians to administer influenza vaccine. **This is new authority.**

On September 9, 2021, the Ninth Amendment to the PREP Act added COVID-19 Therapeutics to COVID-19 Countermeasures which may be ordered by a pharmacist and administered by a pharmacist, intern or technician with proper training. **This is new authority.**

*A South Dakota immunizing pharmacist, who orders vaccines and therapeutics, and qualified pharmacists, pharmacy interns, and pharmacy technicians who administer vaccines and therapeutics in compliance with DHHS declarations of the PREP Act during the federally declared COVID-19 public health emergency shall not be deemed by the Board of Pharmacy to be in violation of the South Dakota Pharmacy Practice Act, SDCL 36-11, or rules in ARSD 20:51.*

**Source:**
