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## STATEMENT REGARDING U.S. Dept. HHS DECLARATION UNDER "PREP" ACT AUTHORIZING PHARMACISTS AND INTERNS TO ORDER AND ADMINISTER VACCINES

On August 19, 2020 the Department of Health and Human Services Office of the Secretary issued its Third Amendment to the Public Readiness and Emergency Preparedness Act for Medical Countermeasure Against COVID-19. The Third Amendment, available <a href="here">here</a>, temporarily expands the authority of appropriately trained and registered pharmacists to order and administer and supervise a pharmacy intern to administer certain vaccines. The Third Amendment is only active during the federally-declared COVID-19 public health emergency. HHS has issued this declaration due to the "troubling decrease in [Advisory Committee on Immunization Practices] ACIP-recommended childhood vaccinations and the resulting increase risk of associated diseases, adverse health conditions, and other threats are categories of harm otherwise caused by COVID-19."

The WV Board of Pharmacy recognizes the need for the provision of this care to patients throughout WV. There are numerous considerations should pharmacists in WV decide to exercise the authority from the Third Amendment and provide vaccinations to children age 3 years and up. Every pharmacist has the responsibility to be educated on best practices in vaccinating children and ensuring the safety and well-being of his/her patients.

The Board notes that the Third Amendment to the Declaration does conflict with certain provisions of the WV Pharmacy Practice Act and §15-12 Rules for Immunizations Administered by Pharmacists and Pharmacy Interns. The Board concludes the Third Amendment as authorized by the Public Readiness and Emergency Preparedness Act preempts state law in so far as state law would prohibit the ordering and administration of vaccinations as allowed by the Third Amendment. The following update is prepared to provide an overview comparison of the WV pharmacy immunization requirements and the HHS Third Amendment. A WV immunizing pharmacist who orders and administers pediatric vaccines in compliance with DHHS' declaration during the federally-declared COVID-19 public health emergency shall not be deemed by the WV Board of Pharmacy to be in violation of the WV Pharmacy Practice Act or §15-12. The overview is not intended to be a comprehensive guide for all pharmacist immunization requirements under state and federal law.

Comparison of WV Pharmacist/Intern Immunization vs. HHS Third Amendment

1. ORDER: As qualified persons under section 247d-6d(i)(8)(B), the state licensed pharmacist (and pharmacy interns acting under their supervision if the pharmacy intern in licensed or registered by his or her State Board of Pharmacy), may <u>order</u> and administer vaccines to individuals ages 3-18 years pursuant to specific requirements (see <u>Here</u>.) In WV, pharmacists (and interns) may administer immunizations in accordance with the CDC's recommended immunization schedule for adults, children, and adolescents to a person age 11 through 17, with

written informed parental consent when presented with a prescription from a physician and there are no contraindications to that patient receiving that vaccine. During a declared State of Emergency, a licensed pharmacist or pharmacy intern may administer any immunization approved or authorized by the Food and Drug Administration. This is a difference from WV law.

- 2. AGE: As qualified persons under section 247d-6d(i)(8)(B), the state licensed pharmacist (and pharmacy interns acting under their supervision if the pharmacy intern in licensed or registered by his or her State Board of Pharmacy), may order and administer vaccines to individuals ages 3-18 years pursuant to specific requirements (see Here.) In WV, pharmacists (and interns) may administer immunizations in accordance with the CDC's recommended immunization schedule for adults, children, and adolescents to a person age 11 through 17, with written informed parental consent when presented with a prescription from a physician and there are no contraindications to that patient receiving that vaccine. During a declared State of Emergency, a licensed pharmacist or pharmacy intern may administer any immunization approved or authorized by the Food and Drug Administration. This is a difference from WV law.
- 3. FDA-authorized or FDA-licensed: <u>WV</u> and the HHS Third Amendment require the vaccine to be FDA-authorized or FDA-licensed. <u>This is the same as WV law.</u>
- 4. ACIP's standard immunization schedule: The HHS Third Amendment requires the vaccine to be ordered and administered to ages 3-18 years according to ACIP's standard immunization schedule. Licensed pharmacists (and interns) may administer immunizations in accordance with the CDC's recommended immunization schedule for adults, children, and adolescents to a person age 11 through 17, with written informed parental consent when presented with a prescription from a physician and there are no contraindications to that patient receiving that vaccine. Both require administration according to the CDC/ACIP standard recommended immunization schedule.
- 5. TRAINING: Per the HHS Third Amendment, pharmacists must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE), including hands-on injection technique, clinical evaluation of indications and contraindications of vaccines and the recognition and treatment of emergency reactions to vaccines. Also, the pharmacist and intern must complete a practical personal training program that is approved by the ACPE. These training requirements are the same required in Chapter 30-5 and §15-12-9. Additionally, WV requires that to be an immunizing pharmacist, §15-12-5 requires registration with the BOP. This is the same as WV law.

Pharmacist training focuses on subcutaneous and deltoid intramuscular injections. The DHHS Third Amendment notes, "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 ages three and older."

- 6. CPR: Per the HHS Third Amendment, the licensed pharmacist and pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation. §15-12-4.1.c requires the pharmacist or pharmacy intern to maintain a current certification in basic life-support training, including basic cardiopulmonary resuscitation (CPR), from the American Heart Association, or the American Red Cross. This is not a new requirement and is the same as WV law.
- 7. CONTINUING EDUCATION: Per the HHS Third Amendment, the licensed pharmacist must complete a minimum of two hours of ACPE-approved immunization-related continuing pharmacy education during each State licensing period. Per WV §15-12-4.1.d requires the pharmacist complete a minimum of two hours of continuing pharmacy education related to immunizations each licensing year for a total of 4 (four) hours each renewal period. This is not a new requirement.
- 8. REPORTING: Per the HHS Third Amendment, the licensed pharmacist must comply with the recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines. Per WV §15-12-7:

- An immunization questionnaire and consent form shall be completed for each person receiving an immunization:
- A record of the immunization administration shall be forwarded to the primary care physician or other licensed health care provider as identified by the person receiving the immunization, within not more than 30 days of the date of the administration;
- In the event that the patient affirmatively indicates in writing that he or she does not have a primary care physician or other health care provider to whom to forward the report, the pharmacist or pharmacy intern shall document such in the immunization record, and provide a record of the immunization administration to the patient;
- In the event that the patient affirmatively indicates in writing that he or she does not have a primary care physician or other health care provider to whom to forward the report, the pharmacist or pharmacy intern shall document such in the immunization record, and provide a record of the immunization administration to the patient;
- The pharmacist shall report the administration of the patient immunization to the West Virginia Statewide Immunization Information (WVSII) database in the format and containing such information as may be required by the WVSII within not more than 30 days of the date of the administration;
- The immunization questionnaire and consent form and record of the immunization administration shall be filed in the pharmacy in a manner that will allow timely retrieval, and shall be kept on file for a time period not less than five years from the date of the immunization;
- A pharmacist shall report all adverse events to the Vaccine Adverse Events Reporting System (VAERS), and promptly provide a copy of all reports to the Board; the West Virginia Department of Health and Human Resources Bureau for Public Health, Office of Epidemiology and Prevention Services, Division of Immunization Services; and the patient's primary care physician or other licensed health care provider as identified by the person receiving the immunization.

  This is not a new requirement. WV reporting requirements are above.
- 9. WELL-CHILD VISIT: Per the HHS Third Amendment, 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. WV licensed pharmacists are currently required to have a prescription and parental consent when vaccinating ages 11-17 years and notify the primary care provider for all vaccinations within 30 days. The notification of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate is a new requirement.

A WV immunizing pharmacist who orders and administers pediatric vaccines in compliance with DHHS' declaration during the federally-declared COVID-19 public health emergency shall not be deemed by the WV Board of Pharmacy to be in violation of the WV Pharmacy Practice Act or §15-12.

Should you have any questions, please feel free to contact the Director of Professional and Regulatory Affairs, Krista Capehart, at 304-206-5767.