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July 26, 2019

Re: WVBOP – 15 CSR 15

The Board has made no revisions to 15 CSR 15 as proposed by the agency.

CVS Health: The Board believes 14 days is ample time to notify the Board of a new pharmacist-in-charge. Additionally, the Board does not want to remove the requirement for the pharmacy to report violations of board rules or laws by licensed pharmacists.

Sincerely,

Ryan L. Hatfield
General Counsel



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Via Electronic Mail

June 25, 2018

Mr. Ryan Hatfield
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Ryan.L.Hatfield@wv.gov

RE: CVS Health comments in regards to amendments to Board of Pharmacy Rules:

Title 15 Series 7 BOARD OF PHARMACY RULES FOR REGISTRATION OF PHARMACY TECHNICIANS;

Title 15 Series 1 LICENSURE AND PRACTICE OF PHARMACY

Title 15 Series 12 BOARD OF PHARMACY RULES FOR IMMUNIZATIONS ADMINISTERED BY PHARMACISTS AND PHARMACY INTERNS;

Title 15 Series 15 REGULATIONS GOVERNING PHARMACY PERMITS;

Dear Mr. Hatfield,

I am writing to you in my capacity as Pharmacy Regulatory Affairs Director for CVS Health and its family of pharmacies located across the country. CVS Health appreciates the opportunity to submit comments on the West Virginia Board of Pharmacy ("Board") proposed administrative regulation and would like to thank the Board for their constant vigilance to continuously improve regulations that enhance patient care and guide the practice of pharmacy in West Virginia. Through our integrated offerings across the spectrum of pharmacy care, we are uniquely positioned to provide greater access to care, engage plan members in behaviors that improve their health, and lower overall costs for health plans and their members. CVS Health provides multiple points of care to patients via our retail, mail, infusion, long-term-care, specialty pharmacies and MinuteClinics.

Pharmacists provide high quality, accessible patient care services, including medication management, immunizations, preventive screenings, and chronic care management. Despite a growing need for increased access to patient care services, community pharmacists spend only 21% of their professional time performing patient care services that are not associated with dispensing prescriptions.¹ To further enhance and optimize patient care services delivered at community pharmacies, leveraging and expanding current roles of the pharmacy technician should be considered in community pharmacies. This means working towards a unified vision for pharmacy technician practice, which aligns pharmacy technician roles related to dispensing medications and supporting

patient care services with their current education and training.² Increasing the scope of pharmacy technician practice to include administrative and supportive tasks for pharmacist-provided patient care services will allow pharmacists to more effectively and efficiently provide for patients' medication-related needs.³ Most importantly, some states have a patient safety track record of success with expanded pharmacy technicians roles that spans over four decades.⁴

The national pharmacy landscape reveals an overwhelming safety track record of success and shift towards pharmacy technicians:

- Accepting verbal prescriptions
- Performing and receiving prescription transfers
- Performing technician product verification
- Contacting prescriber offices for clarifications
- Administering immunizations

We request that the Board consider amending additional sections of rules to allow for pharmacy technicians to receive oral prescription orders, perform and receive prescription transfers, perform technician product verification, perform non-clinical clarifications of orders and administer immunizations. Supplemental studies to support the requested amendments for the expansion of pharmacy technician functions, allowing pharmacists to focus on higher order of clinical care such as collaborative pharmacy practice or participation in statewide protocols. ⁶⁷⁸⁹

Please find comments and suggested revisions in blue below added to your draft amendments.

PHARMACY TECHNICIANS

BOARD OF PHARMACY RULES FOR REGISTRATION OF PHARMACY TECHNICIANS

§15-7-5. Duties and Restrictions of a Pharmacy Technician and Pharmacy Technician Trainee.

5.1. A pharmacy technician or pharmacy technician trainee may not:

~~5.1.a. receive verbal prescription drug orders and reduce these orders to writing either manually or electronically;~~

5.1.b. interpret and evaluate prescription drug orders;

5.1.c. select drug products;

5.1.d. interpret patient medication records and perform drug regimen reviews;

5.1.e. deliver the prescription to the patient before a pharmacist performs the final check of the dispensed prescription to ensure that the prescription has been dispensed accurately as prescribed;

5.1.f. communicate to the patient or the patient's agent, information about the prescription drug or device which in the exercise of the pharmacist's professional judgment, the pharmacist considers significant;

5.1.g. communicate to the patient or the patient's agent, information concerning any prescription drugs dispensed to the patient by the pharmacy; ~~or~~

~~5.1.h. receive or place a call for a transferred prescription;~~

~~5.1.i. any act within the practice of pharmacist care that involves discretion or independent professional judgment; or~~

~~5.1.j. any function which the registrant has not been trained and the function has not been specified in a written protocol with competency established.~~

5.2. The duties of a registered pharmacy technician or pharmacy technician trainee may include, but are not limited, to the following:

5.2.a. the placement, receipt, unpacking and storage of drug orders;

5.2.b. maintenance of the work area and equipment in a clean and orderly condition;

5.2.c. the ordering and stocking of all pharmacy supplies;

5.2.d. the checking of all prescription and non-prescription stock for outdates and the processing of outdated returns;

5.2.e. the operation of the cash register. However the pharmacy technician shall

5.2.e.1. only handle the complete transaction on refill prescriptions when specifically requested to do so by the pharmacist and when the patient has no questions for the pharmacist;

5.2.e.2. only handle the transactions on new prescriptions after counseling by the pharmacist has been offered; and

5.2.e.3. refer all questions regarding over the counter and prescription drug product selection or advice to the pharmacist;

~~5.2.f. the filing of completed hard copies of new prescriptions, (except schedule-II drugs) in numerical order; a pharmacist shall file schedule-III drug prescription hard copies;~~

5.2.g. the placement of completed prescription orders on the will-call shelf;

5.2.h. the wrapping of completed orders for mailing and the logging of mailed and delivered orders into a record;

5.2.i. the printing of third-party billings, the processing of the billings for mailing and the transmission of electronically handled third-party billings;

5.2.j. the reconciliation of third-party payments;

5.2.k. the contacting of third-party billers and payers if problems arise while handling a patient's insurance transmissions;

5.2.l. the posting of patient purchases to private charge accounts and assisting with the printing and distribution of the monthly statements;

5.2.m. the handling of non-professional phone calls to or from:

5.2.m.1. patients requesting refills of prescriptions by number and patient name;

5.2.m.2. physicians' offices authorizing refills, ~~if no changes in the prescription are involved, and where the patient's name, medication and strength, number of doses, and date of prior fill is stated. The pharmacy technician shall refer any other inquiries by the prescribing physician's office to the pharmacist;~~

5.2.m.3. patients concerning price information that has been calculated by computer;

5.2.m.4. patients concerning business hours, mailing and delivery services, and the availability of goods and services;

5.2.m.5. patients asking if their prescriptions are refillable and the number of refills remaining. Any interpretation of the proper length of time between refills must be handled by the pharmacist;

5.2.m.6. wholesalers and distributors dealing with the ordering of goods and supplies; and

5.2.m.7. physicians' offices regarding patient profile information, where no interpretation or judgment is necessary and only after the pharmacy technician verifies to whom the information is being given.

5.2.n. the acceptance of refill requests and the acceptance of new written prescriptions from patients or their agents after determining the following: the patient's correct name, address, phone number, birth date, drug allergies, disease state(s), and the method of payment;

5.2.o. the entering of prescription data and patient profile data into the computer. The pharmacy technician shall refer any information needing clarification or interpretation to the pharmacist. The pharmacy technician or pharmacy technician trainee shall:

5.2.o.1. Monitor the label printing; and

5.2.o.2. Alert the pharmacist to any duplication of medication, drug therapy overlap, drug interactions, drug-disease state interactions, and any questions that arise from entering the information.

5.2.p. the performance of tasks under the pharmacist's supervision, such as obtaining stock bottles for prescription filling;

5.2.q. the counting and pouring from stock bottles for individual prescriptions only under the direct supervision of a pharmacist. The pharmacist shall initial the hard copy of the prescription and the label to account for the accuracy of the prescription contents and the accuracy of the labeling;

5.2.r. the reconstitution and restoration of the original form of medication previously altered for preservation and storage by the addition of a specific quantity of an appropriate diluent requiring no calculations. The pharmacy technician or pharmacy technician trainee may assist in the preparation of sterile-parenteral/enteral-products compounded sterile preparations under the direct supervision of a pharmacist. In all cases, the pharmacist shall check and verify the accuracy of the pharmacy technician or pharmacy technician trainee; ~~and~~

5.2.s. the weighing or measuring of specific ingredients for the pharmacist to use in extemporaneous compounding. In all cases the accuracy of the weighing and measuring must be verified by the pharmacist; ;

~~5.2.t. under the direct supervision of a licensed pharmacist a pharmacy technician may perform the following with the appropriate training:~~

~~5.2.t.1. Perform pharmacy technician product verification where no clinical judgment is necessary and the pharmacist provides the final verification;~~

~~5.2.t.2. Complete a list of a patient's current prescription and nonprescription medications to provide for medication reconciliation;~~

~~5.2.t.3. Supervise registered pharmacy technicians and pharmacy technician trainees;~~

~~5.2.t.4. Medical records screening; and~~

~~5.2.t.5. Additional duties approved by the board;~~

~~5.2.t.6. Accepting new verbal prescription orders, including refill authorizations, for non-controlled drugs from a prescriber or a prescriber's agent;~~

~~5.2.t.7. Contacting a prescriber or prescriber's agent to obtain clarification for a prescription order if the clarification does not require the exercise of professional judgment;~~

~~5.2.t.8. Administer immunizations as allowed by state law/rule by pharmacist;~~

~~5.2.t.9. Receive or place calls for a transferred prescription;~~

~~5.2.t.10. Additional duties approved by the board.~~

5.3. The pharmacist-in-charge shall not allow anyone within the pharmacy area to perform pharmaceutical care other than, pharmacists, registered pharmacy technicians, pharmacy technician trainees and pharmacy interns. A ratio of no more than four pharmacy technicians and/or pharmacy technician trainees per on-duty pharmacist operating in any pharmacy shall be maintained. This ratio shall not include pharmacy interns.

5.4. A ~~registered-pharmacy-technician-or~~ pharmacy technician trainee shall not handle any telephone calls for new prescriptions from a physician's office and shall immediately transfer the calls to a pharmacist, except in the case of refill requests as set forth in subsection 5.2.m.

5.5. A person who handles a prescription drug only during the point of sale to provide the prescription drug to a patient and accept payment is not subject to the licensure requirements of West Virginia Code of State Rules §15-7. This handling process includes the cashier having access to the pharmacy's operating system to verify unique information for each patient. A pharmacy may require an individual to complete a criminal background check before he or she is hired.

LICENSURE AND PRACTICE OF PHARMACY

§ 15-1-8. Transferring Prescription Orders Between Pharmacies.

8.2.1. The transferring pharmacist ~~or pharmacy intern or pharmacy technician;~~

BOARD OF PHARMACY RULES FOR IMMUNIZATIONS ADMINISTERED BY PHARMACISTS AND PHARMACY INTERNS OR PHARMACY TECHNICIANS

In the Spring of 2017, the Idaho State Board of Pharmacy expanded the role of technicians where 30 technicians were trained and began administering immunizations after the pharmacists determined the appropriateness of the vaccine for the patient. The pilot was a success and since that time, Idaho pharmacy technicians have administered thousands of immunizations with zero complaints relating to technician administering vaccines received by the Board to date. ⁹

CVS Health encourages the Board to review the literature provided and allow technicians to administer immunizations as provided below.

§15-12-1. General.

1.1. Scope. — To provide the rules for pharmacists and pharmacy interns to administer immunizations to patients in this State through joint rulemaking by the West Virginia Board of Pharmacy, Board of Medicine, and Board of Osteopathy.

1.2. Authority. — W. Va. Code § 30-5-7.

1.3. Filing Date. — ~~March 23, 2018.~~

1.4. Effective Date. — ~~March 23, 2018.~~

1.5. Sunset Date — This rule shall terminate and have no further force or effect on ~~March 23, 2020.~~

§15-12-2. Definitions.

2.1. "Board" means the West Virginia Board of Pharmacy.

2.2. "Immunizations" means the action of making a person immune to infection, typically by inoculation.

2.3. "Personal supervision" means the supervising immunizing pharmacist is physically present in the room during the administration of an immunization.

§15-12-3. Immunizations.

3.1 The immunizations listed below may be administered by a pharmacist or pharmacy intern or pharmacy technician as follows:

3.1.a. to any person eighteen years of age or older, including:

3.1.a.1. Influenza;

3.1.a.2. Pneumococcal;

3.1.a.3. Hepatitis A;

3.1.a.4. Hepatitis B;

3.1.a.5. Herpes Zoster;

3.1.a.6. Tetanus, tetanus-diphtheria, commonly referred to as "Td", or tetanus-diphtheria-and-pertussis, commonly referred to as "Tdap";

3.1.a.7. Meningococcal; and

3.1.a.8. Human Papilloma Virus (HPV).

3.2.b. to any person age eleven through ~~eighteen~~ ~~seventeen~~ years of age, with written informed parental consent, when presented with a prescription from a physician and there are no contraindications to that patient receiving that immunization, including:

3.2.b.1. Influenza; and

3.2.b.2. Human Papilloma Virus (HPV).

§15-12-4. Qualifications.

§.1 A licensed pharmacist as provided in section three provided the pharmacist has met all of the following requirements:

4.1.a. registered with the board to administer immunizations;

4.1.b. successfully completed the American Pharmacists Association's (APhA) immunization training program, or other immunization training course as may be approved by the Board, which courses shall be based on the standards established for immunization training by the Centers for Disease Control and Prevention in the public health service of the United States Department of Health and Human Services;

4.1.c. maintains current certification in basic life-support training, including basic cardiopulmonary resuscitation (CPR), from the American Heart Association, or the American Red Cross; and

4.1.d. completed 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. The continuing education shall be by a provider approved by the Accreditation Council for Pharmacy Education (A.C.P.E.).

4.2. A pharmacy intern or pharmacy technician licensed by the Board may administer immunizations as permitted by this rule provided that:

4.2.a. the pharmacy intern or pharmacy technician is under the personal supervision by a pharmacist who is registered with the board to administer immunizations; and

4.2.b. has completed all of the training and current certification ~~required by subsections 4.2.b. and 4.2.c. of this section~~, which includes at a minimum:

(a) current Basic Life Support (BLS) certification; and

(b) successful completion of a training program which includes at a minimum:

(i) didactic and practical training for administering injectable drugs;

(ii) the current Advisory Committee on Immunization Practices (ACIP) of the United States Center for Disease Control and Prevention guidelines for the administration of immunizations; and

(iii) the management of an anaphylactic reaction.

(2) Sources for the appropriate training include:

(a) ACPE approved programs; and

(b) curriculum-based programs from an ACPE accredited college of pharmacy, state or local health department programs and other Board recognized providers.

4.3. It is unprofessional conduct for a pharmacist or pharmacy intern or pharmacy technician to administer an immunization, who is not in compliance with this rule.

§15-12-5. Registration.

5.1. Prior to administering immunizations, a pharmacist shall submit an application supplied by the Board for review and approval of the Board, providing that all of the requirements of Section 4.1. have been met. The application shall be submitted along with a required fee of \$10.00. Provided all requirements of Section 4.1. have been met and the required fee is received, the Board shall issue a registration to administer immunizations. Registrations shall expire biennially on June 30 of year in which the pharmacist's license to practice pharmacy expires.

5.2. The registration shall be posted conspicuously at any location at which the pharmacist is administering an immunization.

5.3. Prior to administering immunizations, a pharmacy intern or pharmacy technician shall provide to his or her supervising pharmacist documentation that the pharmacy intern or pharmacy technician has completed all of the training and current certification required by subsections ~~4.1.b. and 4.1.c.~~ 4.2.b. of this rule. The supervising pharmacist shall maintain this documentation in the pharmacy where the pharmacist and pharmacy intern or pharmacy technician who administers an immunization is employed or otherwise practicing at the time any immunization is administered by a pharmacy intern or pharmacy technician.

§15-12-6. Immunizations.

6.1. Immunizations authorized by this rule shall be administered:

6.1.a. In accordance with definitive treatment guidelines for immunizations promulgated by the latest notice from the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), including, but not limited to, CDC's recommended immunization schedule for adults and children and adolescents, including the footnotes provided for each schedule, available at <https://www.cdc.gov/vaccines/schedules/index.html>; or

6.1.b. In accordance with an order from a properly authorized practitioner for minors age eleven through eighteen, the order shall be a prescription from an authorized physician.

6.2. Administration shall be done in accordance with the training required by Section 4.1.b. of this Series, including, but not limited to indications, contraindications, route of administration, sanitary environment for administration, specifics regarding administration, and storage requirements for each specific immunization authorized by this rule, and, when done pursuant to a prescription, in accordance therewith;

6.3. Administration shall include implementation of the CDC's recommended appropriate observation for an adverse reaction of an individual following an immunization.

6.4. Under no circumstances may a pharmacist delegate his or her authority to administer immunizations to any other person, ~~including but not limited to any pharmacy technician~~, except as otherwise provided herein for a properly pharmacy intern or pharmacy technician who is administering under the direct supervision of the pharmacist.

6.5. A current Vaccine Information Statement, as provided by CDC, shall be provided to each person receiving an immunization for each immunization administered.

§15-12-8. Emergencies.

8.1. A pharmacist or pharmacy intern or pharmacy technician authorized to administer immunizations under this rule may administer epinephrine and diphenhydramine in the management of an acute allergic reaction to an immunization following guidelines issued by CDC.

8.2. A pharmacist or pharmacy intern or pharmacy technician shall have a readily retrievable emergency response plan as outlined by the CDC, and maintain a readily retrievable emergency kit to manage an acute allergic reaction to an immunization administered.

STERILE COMPOUNDING

Compounding is a critical part of the practice of pharmacy. CVS Health recommends the Board specifically reference USP Chapter 797 to provide consistent guidance for all persons who prepare compounding sterile products.

LICENSURE AND PRACTICE OF PHARMACY

§ 15-1-12. Sterile Pharmaceutical Compounding.

~~12.1. Permitting and Control. The Board shall enforce all applicable standards set forth by the United States Pharmacopeial Convention Chapter 797.~~

PHARMACY PERMITS

The pharmacist-in-charge is a critical leadership position for the pharmacies in West Virginia. To ensure that we have the time to hire the correct personnel, pharmacist-in-charge, for this position we are asking for additional time to fill this position, always ensuring that the pharmacy is compliant.

Additionally, §15-15-8.3 is concerning. The provision as written puts the onus on the employer to determine that a violation of Board laws and rules has occurred, and then make a report to the Board. CVS Health requests the Board further examine the need for this provision and provide further detail as to the application of this section. Without further explanation of the impact of this provision on pharmacy practice, the Board office and the disciplinary process, CVS Health recommends striking §15-15-8.3.

REGULATIONS GOVERNING PHARMACY PERMITS

§15-15-5. Surrender of registration.

~~8.1. When a pharmacist-in-charge changes at a pharmacy, both the pharmacist-in-charge and pharmacy must notify the Board in writing within fourteen (14) (30) days. The original permit should be copied and the change in pharmacist-in-charge written on the original and copy of the permit. The copy of the modified permit shall be posted in the pharmacy. The original modified permit should be surrendered to the Board along with a ten-dollar (\$10.00) fee for the new registration reflecting the new pharmacist-in-charge. Upon receipt of the notification, the Board shall provide for the new registration to the pharmacy. An interim pharmacist-in-charge may be designated for a period not to exceed sixty (60) days. If an interim pharmacist-in-charge is designated who is not the permanent pharmacist-in-charge, the fee shall not be charged, and a new permit shall not be issued until a permanent pharmacist-in-charge is designated.~~

~~8.1.15-8. Notification.~~

~~8.1. The violation of any of these rules shall be considered cause for disciplinary action.~~

~~8.2. An employer who employs a licensed pharmacist shall notify the Board within fourteen (14) thirty (30) days, in writing, of any discharge or termination of the licensed pharmacist or change of the status of the pharmacist-in-charge.~~

~~8.3. A person who employs a licensed pharmacist shall immediately notify the Board in writing of any violation of Board rules or laws by the licensed pharmacist.~~

CVS Health is grateful for the opportunity to comment and is available to partner with the Board throughout the rulemaking process. In addition to the comments provided, I have submitted supporting documentation, including peer-reviewed research manuscripts that speak to the patient safety and benefits of the full scope of pharmacy technician roles. If you have any questions or need additional information, please contact me directly at 614-572-9008.

Best regards,



John Long RPh, MBA

Enclosure: (9)

1. Gaither CA, et al. Final report of the 2014 National Sample Survey of the Pharmacist Workforce to determine contemporary demographic, practice characteristics and quality of work-life. 2014. Available from:
<https://www.sacp.org/sites/default/files/finalreportofthenationalpharmacistworkforcestudy2014.pdf>
(Accessed February 20, 2019).
2. Zellmer WA, et al. Toward uniform standards for pharmacy technicians: Summary of the 2017 Pharmacy Technician Stakeholder Consensus Conference. *Am J Health Syst Pharm.* 2017;74(17):1321-1332.
3. Adams AJ. Advancing technician practice: Deliberations of a regulatory board. *Research in Social and Administrative Pharmacy.* 2018;14(1):1-5.
4. Frost TP, Adams AJ. Expanded pharmacy technician roles: Accepting verbal prescriptions and communicating prescription transfers. *Res Social Adm Pharm.* 2017;13(6):1191-1195.
5. Chopski, N. (2019, July 5). [Letter to Mark Johnston]. Idaho State Board of Pharmacy, Boise, ID.
6. Atkinson, D., Adams, A. & Bright, D. (2017) Should Pharmacy technicians administer immunizations? *Innovations in Pharmacy*, 8, 1 – 5.
7. McKeirnan, K., Frazier, K., Nguyen, M., & MacLean, L.(2018). Training Pharmacy Technicians To Administer Immunizations *Journal of the American Pharmacists Association*, 58,174-178.
<https://doi.org/10.1016/j.japh.2018.01.003>
8. Bertsch, T., McKeirnan, K., Frazier, K., Vanvoorhis, L., Shin, S., & Le, K. (2019) Supervising Pharmacists' Opinions about pharmacy technicians as immunizers. *Journal of the American Pharmacist Association*, 1-6. <https://doi.org/10.1016/j.japh.2019.03.008>
9. Adams, A., Desselle, S., & McKeirnan, K. (2018). Pharmacy Technician-Administered Vaccines: on Perceptions and Practice Reality. *Pharmacy*, 6, 124-128.