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July 26, 2019

Re: WVBOP -- 15 CSR 1

The Board has declined to accept any revisions to 15 CSR 1 as proposed by the agency.

TSG Consulting Comment: A grace period for compliance for USP standards is unwarranted. USP already receives comments on proposed standards. Additionally, USP generally gives six months for facilities to become compliant from the time the revised standards become official.

American Academy of Dermatology Association/West Virginia Medical Association/American Society for Dermatological Surgery Association Comment: USP standards apply to all compounding facilities. Thus, the Board does not feel that carve outs at the state level are appropriate.

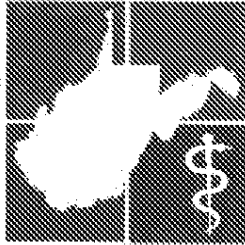
CVS Health Comment: Pharmacy technicians may not transfer prescription orders per WV code.

Sincerely,

Ryan L. Hatfield
General Counsel



AMERICAN ACADEMY of
DERMATOLOGY | ASSOCIATION



West Virginia
State Medical
Association

July 26, 2019

Ryan Hatfield, General Counsel
West Virginia Board of Pharmacy
2310 Kanawha Blvd E.
Charleston, WV 25311

Dear Mr. Hatfield:

On behalf of the undersigned organizations representing nearly 50 dermatologists in West Virginia and approximately 14,000 dermatologists nationwide, we appreciate the opportunity to provide comments on a proposal that would require the West Virginia Board of Pharmacy to enforce all standards adopted by the U.S. Pharmacopeial Convention (USP) concerning sterile compounding. This proposal may potentially impact dermatology's decades-long record of safely preparing and administering low-risk medications in the office setting.

One in four Americans suffers from a skin disease. Dermatologists diagnose and treat more than 3,000 diseases, including skin cancer, psoriasis, immunologic diseases, and many genetic disorders. As dermatologists on the front lines fighting skin cancer and treating numerous skin diseases, we advocate for our patients to have access to compounded medications, especially in-office preparations.

The undersigned dermatology organizations are actively engaging with USP regarding the in-office preparation of buffering lidocaine with epinephrine in order to establish at least a 12-hour exemption. Therefore, we urge the Board to refrain from adopting Section 1.3 Immediate Use of Chapter 797 – Sterile Compounding until the issue is finalized.

Requiring USP Compliance for Physician Practices is Unreasonable and Burdensome

On June 1, the USP finalized its revisions to Chapter 797, which provides compounded sterile preparation standards. This chapter explicitly applies to physicians when a regulatory body, such as a pharmacy board, adopts such standards. It is relevant to dermatology and other specialties that require in-office preparations, such as buffered lidocaine composed of lidocaine with epinephrine and sodium bicarbonate, to perform office-based procedures. Compliance with the full chapter is unreasonable and burdensome for clinical settings. Requirements include performing manipulations inside a certified ISO 5 area, conducting routine environmental monitoring, and conducting personnel sampling (including glove fingertip sampling). Chapter 797 includes a time-based exemption, which may be workable for some specialties, but it imposes significant restrictions on dermatology's ability to provide safe and effective care to our patients, as outlined below.

Patient Need for Buffered Lidocaine and Preparation in the Clinical Setting

An in-office preparation especially important to the practice of dermatology is buffered lidocaine. The two medications that comprise buffered lidocaine, lidocaine with or without epinephrine and sodium bicarbonate, are both approved by the FDA. Sodium bicarbonate is added to lidocaine with or without epinephrine using aseptic technique to neutralize the pH of the preparation. This process is "buffering." The buffering of lidocaine significantly decreases the subjective pain of the injection and increases the onset of the local anesthesia for the patient.¹ According to the American Academy of Dermatology's "Guidelines for the use of local anesthesia in office-based dermatologic surgery": "The addition of sodium bicarbonate to local anesthetic, particularly lidocaine with epinephrine, is recommended to decrease the pain of delivery by subcutaneous or intradermal infiltration."² The strength of this recommendation was given an "A" in this guideline meaning that the "[r]ecommendation [is] based on consistent and good quality patient-oriented evidence." After this local anesthetic takes effect, dermatologists are then able to perform procedures such as biopsies, excisions, or Mohs micrographic surgery.

Dermatologists buffer lidocaine ahead of their patient visits for the day because multiple buffered lidocaine syringes are frequently administered throughout the day to perform procedures such as skin biopsies and skin cancer surgery. A four-hour exemption is included, but four hours will not facilitate access to buffered lidocaine especially during skin cancer curative Mohs surgery, which usually last much longer than an hour. The

¹ Afolabi O, Murphy A, Chung B, Lalonde DH. The effect of buffering on pain and duration of local anesthetic in the face: A double-blind, randomized controlled trial. *Can J Plast Surg.* 2013 Winter;21(4): 209-212.

² Kouba DJ, LoPiccolo MC, Alam M, Bordeaux JS, Cohen B, Hanke CW, et al. Guidelines for the use of local anesthesia in office-based dermatologic surgery. *J Am Acad Dermatol.* 2016 Feb 27. pii:S0190-9622(16)00074.

Mohs surgeon or his or her clinical staff would have to exit the sterile field, buffer the lidocaine, and then re-enter the sterile field. Having physicians, who are compounding a small volume of low-risk sterile preparations for their own patients as a part of patients' treatment plans that same day, comply with the chapter's full requirements as if they were pharmacies or outsourcing facilities is unreasonable and burdensome. Without including an accommodation for dermatologists, we will likely be forced to forgo buffering lidocaine resulting in significantly increased patient-reported pain when administering lidocaine with or without epinephrine. Patients may also be forced to refer their patients to surgeons who can have an anesthesiologist administer general anesthesia in a hospital setting.

Requiring dermatologists to obtain buffered lidocaine from pharmacies or outsourcing facilities is both cost-prohibitive and not logistically feasible especially for dermatologists who are in private practice. While remaining safe, we recognize that buffered and diluted lidocaine with epinephrine begins to lose its vasoconstrictive efficacy after seven days.³ While it is the best practice to use buffered lidocaine prior to this amount of time, requiring transit time between the pharmacy or outsourcing facility is unreasonable and can result in medical waste if the buffered lidocaine is not used prior to the beyond-use date (BUD) determined by the pharmacy or outsourcing facility. In addition, our organizations cannot in good faith encourage our member dermatologists to use outsourcing facilities that have deficiencies that FDA inspectors cited in a Form FDA-483 issued including those who have advertised dermatology products to our general memberships.⁴ Consequently, as they have done safely for years, dermatologists need to be able to continue to safely prepare buffered lidocaine and administer it to their own patients in the clinical setting without unreasonable burdens.

Physician Offices Should Not Be Treated the Same as Larger Compounding Facilities

Released in January 2018, FDA's 2018 Compounding Policy Priorities Plan provided, in part:

These guidance documents will be followed by revised draft guidance describing examples of conditions that the FDA considers to be insanitary and in violation of the FD&C Act. This guidance will address concerns raised by some providers who compound small quantities of drugs in their offices for patient use, and as part of their routine clinical practice. This came up in the setting of certain dermatological procedures, for example. The FDA plans to better define the circumstances under which we believe drugs are being mixed and applied in a

³ Pascuet E, Donnelly RF, Garceau D, Vaillancourt R. Buffered Lidocaine Hydrochloride Solution With and Without Epinephrine: Stability in Polypropylene Syringes. *The Canadian Journal of Hospital Pharmacy*. 2009;62(5):375-80

⁴ E.g., U.S. Food and Drug Administration Form FDA-483. Edge Pharmacy Services, LLC. Issued March 8, 2018. Available at: <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM503285.pdf>.

manner that creates negligible patient risk, and therefore wouldn't be subject to the same compliance policy under the agency's risk-based approach to implementing these requirements.⁵

The FDA specifically mentioned in-office preparations used in dermatological procedures, highlighting that the medications prepared are in small quantities, in the office setting, and for the physicians' patient use. The FDA acknowledged that the mixing and application of these in-office preparations are of negligible patient risk and physicians should not be subject to the same standards as larger compounding facilities. We ask that the USP consider the same factors as FDA highlighted – namely: small quantities, office setting, own patient use, routine clinical practice, negligible patient risk – when deciding how to facilitate patient access to CSPs prepared in the clinical setting, especially buffered lidocaine.

Peer-Reviewed Journal Articles Support the Safety of Buffered Lidocaine

Dermatologists share the Board's concern about the safety of compounded sterile preparations and have performed and rely upon studies published in peer-reviewed journal articles supporting the safety of buffered lidocaine specifically. Pate et al. found that syringes filled with lidocaine; lidocaine and epinephrine; lidocaine with sodium bicarbonate; and lidocaine, epinephrine, and sodium bicarbonate and stored for up to four weeks, when prepared using aseptic technique and when stored in controlled room and controlled cold temperatures, are not prone to bacterial or fungal contamination.⁶ Zero of the 160 samples showed growth where streaked. This study had a larger sample size than a 1999 study, where 36 syringes of buffered lidocaine with epinephrine and sodium bicarbonate stored in room temperature were also not prone to bacterial or fungal contamination.⁷

Lidocaine and other local anesthetics used in dermatology have antimicrobial properties.⁸ The sodium bicarbonate that the lidocaine with epinephrine is mixed with has been found to enhance the bactericidal effect of lidocaine.⁹ Dermatologists,

⁵ U.S. Food and Drug Administration. 2018 Compounding Policy Priorities Plan. Available at: <https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacypecompounding/ucm592795.htm>.

⁶ Pate DA, Shimizu I, Akin R, Snodgrass K, Emrick A. Safety of Prefilled Buffered Lidocaine Syringes With and Without Epinephrine. *Dermatol Surg*. 2016 Mar;42(3):361-65.

⁷ Melman D, Siegel DM. Prefilled Syringes: Safe and Effective. *1999 Dermatol Surg* 25(6):492-93.

⁸ Johnson SM, Saint John BE, Dine AP. Local Anesthetics as Antimicrobial Agents: A Review. *Surg Infect*. 2008;9:205–213.

⁹ Thompson KD, Welykyj S, Massa MC. Antibacterial activity of lidocaine in combination with a bicarbonate buffer. *J Dermatol Surg Oncol*. 1993 Mar;19(3):216-20.

pharmacists, and other researchers have also performed other studies that support stability¹⁰ as well as effectiveness of buffered lidocaine.^{11, 12, 13, 14, 15, 16}

Our organizations appreciate the opportunity to comment on this proposal, and we share the Board's concerns about the safety of the medications prepared and administered to patients. Should the Board adopt USP standards, we urge the Board to set forth an exemption of at least twelve-hours for buffered lidocaine. This does not present a risk to patient safety when prepared in the clinical setting but would adversely impact patients if not accessible. As explained above, this allows buffered lidocaine to be prepared ahead of patient visits for that day to help ensure valuable time is not taken away from patient interaction.

The undersigned dermatology organizations continue to work closely with USP on the in-office preparation of buffering lidocaine with epinephrine, and the need for physicians to prepare buffered lidocaine ahead of patient visits to facilitate access and avoid interruption of longer procedures such as Mohs surgery. Our organizations are working on establishing at least a 12-hour exemption. The revisions adopted by USP include an exemption for compounded medications administered within four hours after preparation, effective December 1, 2019. Because our work with USP is ongoing and has not yet been finalized, we urge you to refrain from requiring dermatologists to comply with Section 1.3 Immediate Use [Compounded Sterile Preparations] of USP Chapter 797 – Sterile Compounding.

If you have any questions or would like additional information or to discuss, please contact the staff representative to the undersigned organizations, Lisa Albany, JD, director, state policy at lalbany@aad.org or (202) 712-2615.

Sincerely,

American Academy of Dermatology Association
American Society for Dermatologic Surgery Association
West Virginia State Medical Association

¹⁰ Larson PD, Ragi G, Swandby M, Darcey B, Poizin G, Carey P. Stability of buffered lidocaine and epinephrine used for local anesthesia, *J Dermatol Surg Oncol*. 1991 May;17(5):411-14.

¹¹ Colacic KB, Overton DT, Moore K. Pain reduction in lidocaine administration through buffering and warming. *Am J Emerg Med*. 1998 Jul;16(4):353-56.

¹² Bartfield JM, Homer PJ, Ford DT, Sternklar P. Buffered lidocaine as a local anesthetic: an investigation of shelf life. *Ann Emerg Med*. 1992 Jan;21(1):16-19.

¹³ McKay W, Morris R, Mushlin P. Sodium Bicarbonate Attenuates Pain on Skin Infiltration, *Anesth Analg*. 1987 Jun;66(6):572-74.

¹⁴ Martin AJ. pH-Adjustment and Discomfort Caused by the Intradermal Injection of Lignocaine. *Anaesthesia*. 1990 Nov;45(11):975-78.

¹⁵ Morsen OH, Roman CM, Mohammed BA, Andersen G. [Neutralization of lidocaine-adrenaline. A simple method for less painful application of local anesthesia]. *Ugeskr Laeger*. 2000;162(33): 4391.

¹⁶ Lugo-Janer G, Padial M, Sanchez JL. Less Painful Alternatives for Local Anesthesia. *J Dermatol Surg Oncol*. 1993 Mar;19(3):237-40.



John Long
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Via Electronic Mail

June 25, 2018

Mr. Ryan Hatfield
General Counsel
West Virginia Board of Pharmacy
2310 Kanawha Blvd. East
Charleston, West Virginia 25311
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 receive these orders by 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 pick-up 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 II 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. ⁸

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~~ ~~sixteen~~ 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 4.1.b. and 4.1.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.a. and 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.

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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., Vanvoorbis, 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.

TSGCONSULTING

1210 Kanawha Blvd. East
Charleston, WV 25301

July 22, 2019

Ryan Hatfield
West Virginia Board of Pharmacy
3210 Kanawha Boulevard East
Charleston, WV 25301

Dear Mr. Hatfield:

I am writing on behalf of Appalachian Regional Healthcare, which operates hospitals in Beckley and Hinton, in regard to amendments to **Legislative Rule 39CSR1**. We support the rule but have a minor modification we ask the board to consider. The section of concern is:

§ 15-1-12. Sterile Pharmaceutical Compounding.

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

Our concern is that, when the United States Pharmacopoeial Convention (USPC) updates standards with the language that is proposed, as well as the current rule, those standards become effective immediately with no state action. There is no time for phase-in to comply with the new standard provided for in the new rule or the current rule, as I read it.

Sometimes, the changes do not require significant capital investment, and in some cases, they do. Currently, there are proposed changes that may become effective in December, and Beckley ARH is spending in excess of \$1 million to comply. We appreciate the board's willingness to work with regulated entities to provide time to comply with this set of updates to the standards.

Our concern is we do not see any language in the current rule or the proposed rule that officially grants the board that ability when there is a USPC update. We ask that a phase-in period be established in the rule in the case of an USPC update or, as an alternative, wording be inserted to the proposed rule directing the board to provide a reasonable phase-in period when the USPC standards are updated.

Other boards that have similar federal guidelines are required to come back to the legislature every time the new standards are updated. We believe our suggestion is a mid-ground approach that protects the public's safety and assists a regulated entity in making changes to comply new with USPC standards.

As background, ARH expects to be compliant with the new USPC standards on or near the first of December, and we appreciate the support of the board's staff in that endeavor. We are only looking to the next update and to provide a process for transition.

Sincerely yours,

Tom Susman

Tom Susman

§.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.

§15-12-8. Notification.

§.1. The violation of any of these rules shall be considered cause for disciplinary action.

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

§.3. A person who employs a licensed pharmacist shall immediately notify the Board in writing of any violation of these rules or rules 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)