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Final Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC110-20-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Pharmacy
Action title	Controlled substances registration for certain entities
Date this document prepared	9/25/18

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations*.

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

This final action replaces emergency regulations which were adopted to authorize issuance of a controlled substances registration to: 1) persons who have been trained in the administration of naloxone in order to possess and dispense the drug to persons receiving training; and 2) an entity for the purpose of establishing a bona fide practitioner-patient for prescribing when treatment is provided by telemedicine in accordance with federal rules. As applicable, regulations for controlled substances registrants are amended to include record-keeping, security, and storage requirements.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

CSR = controlled substance registration
CSB = community services board
DEA = Drug Enforcement Administration
DBHDS = Department of Behavioral Health and Developmental Service

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On September 25, 2018, the Board of Pharmacy adopted amendments to 18VAC110-20, Regulations Governing the Practice of Pharmacy.

Mandate and Impetus

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously-reported information, include a specific statement to that effect.

There are no changes to the previously-reported information.

Legal Basis

Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Pharmacy the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards
The general powers and duties of health regulatory boards shall be:
...
6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. ...

The specific authority of the Board to issue CSRs to the entities specified in the amended regulations is found in Chapters 55 and 58 of the 2017 Acts of the Assembly:

§ 54.1-3408. Professional use by practitioners.

…Y. Notwithstanding any other law or regulation to the contrary, a person who is authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone for use in opioid overdose reversal and who is acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal and that has obtained a controlled substances registration from the Board of Pharmacy pursuant to § 54.1-3423 may dispense naloxone to a person who has completed a training program on the administration of naloxone for opioid overdose reversal approved by the Department of Behavioral Health and Developmental Services, provided that such dispensing is (i) pursuant to a standing order issued by a prescriber, (ii) in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, and (iii) without charge or compensation. The dispensing may occur at a site other than that of the controlled substance registration provided the entity possessing the controlled substances registration maintains records in accordance with regulations of the Board of Pharmacy. A person to whom naloxone has been dispensed pursuant to this subsection may possess naloxone and may administer naloxone to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

§ 54.1-3423. Board to issue registration unless inconsistent with public interest; authorization to conduct research; application and fees.

…G. *The Board may register an entity at which a patient is treated by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically for the purpose of establishing a bona fide practitioner-patient relationship and is prescribed Schedule II through VI controlled substances when such prescribing is in compliance with federal requirements for the practice of telemedicine and the patient is not in the physical presence of a practitioner registered with the U.S. Drug Enforcement Administration. In determining whether the registration shall be issued, the Board shall consider (i) the factors listed in subsection A, (ii) whether there is a documented need for such registration, and (iii) whether the issuance of the registration is consistent with the public interest.*

Purpose

Please explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.

The primary purpose of the proposed amendments to regulations for a controlled substances registration is to address the mental health needs and opioid crisis in the Commonwealth. The goal of amendments allowing entities, such as CSBs, to serve as the point of contact for telemedicine will increase access to psychiatric services in more rural parts of the state where

those specialty practices are few and far between. The goal of amendments allowing community trainers to obtain a CSR is to increase access to naloxone by allowing people other than pharmacists to dispense the drug. Some nonprofit organizations that are authorized by DBHDS to provide training to persons in the community have been successful in obtaining resources to purchase naloxone at a reduced rate. However, under current law, they cannot store it or dispense it. Allowing these community organizations to dispense the medication will promote access to this lifesaving drug.

In spite of recent efforts to facilitate access to naloxone, which has proven to save lives, the number of deaths related to opioid overdose continues to rise. The primary purpose of the proposed amendments is to increase access to naloxone by allowing people other than pharmacists to dispense the drug. Likewise, to address a problem with tele-prescribing of psychiatric drugs by a clinic at UVA hospital, the solution for continuation of those services appears to be issuance of a CSR to a community services board where the examination and treatment can occur in accordance with state and federal law and regulation and the practitioner-patient relationship can be established for the purpose of prescribing. Both uses of a CSR are intended to address the critical needs for mental health treatment and dispensing of a medication that saves lives in an overdose crisis. Regulations are crafted to increase access to psychiatric medications and naloxone without unnecessarily and unduly compromising the board's requirements for drug safety and integrity.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

This action replaces emergency regulations which were adopted to authorize issuance of a controlled substances registration to: 1) persons who have been trained in the administration of naloxone in order to possess and dispense the drug to persons receiving training; and 2) an entity for the purpose of establishing a bona fide practitioner-patient for prescribing when treatment is provided by telemedicine in accordance with federal rules. As applicable, regulations for controlled substances registrants are amended to include record-keeping, security, and storage requirements.

Issues

Please identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.

1) The primary advantage to the public is the potential for more availability of naloxone for persons who have been trained in its use or for the possibility of telemedicine and tele-

prescribing for patients in underserved areas who may be receiving care via instrumentation and diagnostic equipment. There are no disadvantages to the public;
2) There are no advantages or disadvantages to the agency; and
3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The Board is authorized under § 54.1-2400 to "*promulgate regulations in accordance with the Administrative Process Act which are reasonable and necessary to administer effectively the regulatory system.*" Additionally, the Code of Virginia requires:
The Board's regulations shall include criteria for:
1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered…
4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.
The proposed regulations are permissive and do not represent any restraint on competition.

Requirements More Restrictive than Federal

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than applicable federal requirements. If there are no changes to previously-reported information, include a specific statement to that effect.

This regulatory action will allow tele-prescribing consistent with federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any other state agencies, localities, or other entities that are particularly affected by the regulatory change. If there are no changes to previously-reported information, include a specific statement to that effect.

Other State Agencies Particularly Affected – Community service boards

Localities Particularly Affected – None

Other Entities Particularly Affected – Community groups/person authorized by DBHDS to train persons in the administration of naloxone and dispense for opioid overdose reversal.

Public Comment

Please summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Ensure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency or board. If no comment was received, enter a specific statement to that effect.

A comment period was announced from 7/9/18 to 9/7/18. There was a public hearing on 8/23/18. No public comment was received.

Detail of Changes Made Since the Previous Stage

*Please list all changes that made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Please put an asterisk next to any substantive changes.*

There have been no changes since the previous stage was published.