townhall.virginia.gov

Proposed 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	9/26/17

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

This proposed 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 Services

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person'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 new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is 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 proposed 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 proposed regulatory action, 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, please indicate.

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 identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

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

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities particularly affected.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the Board of Pharmacy is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail to Elaine Yeatts at Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233 or elaine.yeatts@dhp.virginia.gov or by fax to (804) 527-4434. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: http://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	a) As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation; b) The agency will incur no additional costs for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Since most mailings to the PPG list are handled electronically, there is very little cost involved. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There are no on-going expenditures.
Projected cost of the new regulations or changes to existing regulations on localities.	There is no cost to localities.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Persons authorized to train individuals on the administration of naloxone and to dispense and those entities at which a patient is being treated by the use of instrumentation and diagnostic equipment for the purpose of prescribing controlled substances.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There is no estimate of the number that may be affected. There are 1,168 CSRs issued in Virginia, but it is likely only a small handful of CSRs are issued under these provisions.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	For those entities that opt to pursue a CSR for purposes of storing naloxone, there will be costs associated with storage and recordkeeping. For any person or entity that wants to obtain a CSR, the application fee is $90 and the renewal fee is $90.
Beneficial impact the regulation is designed to produce.	The primary benefit 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.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

The proposed regulatory action is required in order to implement provisions of Chapters 55 and 58 of the 2017 Acts of the Assembly. There are no alternative methods to achieve the essential purpose of the action.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

There is no alternative regulatory method. The requirements a CSR are set in regulation; enacting an expansion to the settings in which a CSR can be issued requires amendments to regulation.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

There was a comment period on the NOIRA from 5/29/17 to 6/28/17; there was no comment.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

There is no impact on the family and family stability.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

The proposed regulations are identical to the emergency regulations.

Current section number	New section number	Current requirement	Proposed change, intent, and likely impact of proposed requirements
690	N/A	Sets out requirement for persons or entities authorized or required to obtain a controlled substances registration	Subsection B is amended to include persons authorized by DBHDS to train individuals on the administration of naloxone to dispense the drug for opioid overdose reversal. Subsection D is amended to specify that the responsible party named on the CSR application may be the person authorized by DBHDS to do the training. Subsection F is added to authorize the issuance of a CSR to an entity for the purpose of establishing a bona fide practitioner-patient relationship that will allow prescribing of a controlled substance for a patient who is being treated by use of telemedicine in compliance with federal requirements. *Amendments to subsections B and F are necessary in order to implement provisions of Chapters 55 and 58 of the 2017 Acts of the Assembly. Each application for a CSR must name a responsible party who is accountable for compliance with requirements of law and regulation.* *In the case of a CSR application for a naloxone trainer as specified in subsection D, the responsible party would be that person in whose name the CSR is issued and who will be possessing and dispensing the drug. The enabling legislation (SB848) and this action will allow dispensing to occur at a site other than that of the controlled substance registration provided the entity possessing the controlled substances registration is in compliance with regulations of the Board.*

			Nonprofit organizations that conduct trainings in the community will be able to distribute naloxone at the locations where training has occurred. *In subsection F, a CSR application issued to an entity for the purpose of establishing a practitioner-patient relationship for tele-prescribing, the responsible entity must be a person who is authorized by the Drug Control Act to administer controlled substances. The entity must be under the general supervision of a prescriber, who is not required to be present when services are being provided to a patient but would be responsible for ensuring that treatment is occurring in accordance with requirements for subsection F. The requirement for supervision of this type of CSR is consistent with subsection A of section 700.* *Most CSBs, the entities where most patients are receiving psychiatric services via telemedicine, already have a CSR for the purpose of serving as an alternative delivery site for patients to receive medications. Therefore, they already have a prescriber or pharmacist who provides general supervision and a responsible party for the entity.* *The enabling legislation authorizing a CSR for such an entity (SB1009) came from a workgroup convened by Senator Dunnavant prior to the Session to address a problem with tele- prescribing of psychiatric drugs by a clinic at UVA hospital. Representatives of various state agencies, UVA hospital, the Medical Society, and the U.S. Drug Enforcement Administration discussed the obstacles in federal and state law. The primary issue was the establishment of a bona-fide prescriber-patient relationship through telemedicine. The DEA requires there to be a licensed provider at each end of the tele-prescribing patient encounter. While the telemedicine encounter by use of instrumentation and diagnostic equipment does meet federal rules for the establishment of a bona fide practitioner-patient relationship, there typically isn't a DEA registrant at the site where the patient is being treated and is receiving the prescription. The intent of the legislation and this action is to overcome that obstacle by authorizing the Board to issue a CSR to a CSB or other entity for the purpose of prescribing by telemedicine; the DEA has*

			indicated that possession of a CSR would satisfy that requirement.
700	N/A	Sets out requirements for supervision of controlled substances registration	Subsection C is amended to include in the access to controlled substances which are in the possession of a CSR registrant to persons authorized by DBHDS to train on administration of naloxone. *Entities issued a CSR for the purpose of tele-prescribing are not specified in section 700 because there will be no controlled substances maintained at that location. The CSR is issued for the purpose of meeting DEA requirements for tele-prescribing.*
710	N/A	Sets out requirements for storage and security for controlled substances registrants	Entities that have a CSR for the purpose of meeting DEA requirements for tele-prescribing are not included in section 710 because they will not be storing drugs. The trainers who are issued a CSR are exempted from requirements for an alarm system as specified in subsection E. They are required to meet the requirements of subsections A-D relating to storage and disposal of drugs that are unwanted or expired.
N/A	735	N/A	A new section is adopted to set out the requirements for dispensing naloxone through a CSR. While the trainers who have a CSR are not required to follow all requirements for alarms and security, it is necessary for them to meet certain requirements for recordkeeping and labeling. Subsection A specifies the records, including a copy of the prescriber's standing order, records of receipts and requirements for storage of records, and a log noting information about dispensing of naloxone. *As noted in subsection D, it is important to have records about the drugs that was dispensed and to whom it was provided. While complete information about the recipient of the naloxone may not be available, it is necessary to have enough information to respond appropriately should there be a recall of a particular lot of the drug.* Subsection B addresses the labeling requirements for the drug, so the recipient and the dispensed have sufficient information to identify the name, strength, date, and information about the entity associated with the CSR, in case there is a problem or the recipient has a question about proper administration. Subsection C requires the drug to be stored and transported appropriately to prevent adulteration. *Since this is potentially a life-saving drug administered in a moment of*

			crisis, it is important that its potency and efficacy be assured to the extent possible. Subsection D sets out requirements for compliance with recall procedures if such an event occurs. Subsection E specifies the period of two years for maintenance of record. *The requirement for maintenance of records, either on-site or off-site, is consistent with other recordkeeping requirements for entities permitted or registered by the Board.*