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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) 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
Date this document prepared	3/21/17

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to eighteen months), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation. 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 of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

Emergency regulations are 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 substances registration
CSB = community services board
DEA = Drug Enforcement Administration
DBHDS = Department of Behavioral Health and Developmental Services

Emergency Authority

The APA (Code of Virginia § 2.2-4011) states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006. Please explain why this is an emergency situation as described above, and provide specific citations to the Code of Virginia or the Appropriation Act, if applicable.

Chapter 55 of the 2017 Acts of the Assembly became effective on February 20, 2017. It had a third enactment requiring the Board of Pharmacy to promulgate regulations within 280 days of enactment. The Act authorizes the Board to issue a CSR for the purpose of allowing DBHDS trainers in the administration of naloxone to possess and dispense the drug to persons receiving training.

Chapter 58 of the 2017 Acts of the Assembly became effective on February 20, 2017. It had a third enactment requiring the Board of Pharmacy to promulgate regulations within 280 days of enactment. The Act authorizes the Board to issue a CSR to an entity for the purpose of establishing a bona fide practitioner-patient relationship for a person being prescribed controlled substances through telemedicine.

Therefore, the emergency action is authorizes under Code of Virginia § 2.2-4011.

Legal basis

Other than the emergency authority described above, please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and 2) the promulgating entity, i.e., agency, board, or person.

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 describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

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.

Need

Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

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 describe any changes that are proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Set forth the specific reasons the agency has determined that the proposed regulatory action is essential to protect the healthy, safety, or welfare of Virginians.

Current section number	New section number	Current requirement	Proposed change, intent, and likely impact of proposed requirements
690	N/A	Sets out requirement for	Subsection B is amended to include persons

		persons or entities authorized or required to obtain a controlled substances registration	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.*

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

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

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments. Please also indicate whether a Regulatory Advisory Panel or a Negotiated Rulemaking Panel has been used in the development of the emergency regulation and whether it will also be used in the development of the permanent regulation.

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**) or by mail to Elaine Yeatts, 9960 Mayland Drive, Suite 300, Henrico, VA 23233; by email to elaine.yeatts@dhp.virginia.gov; by fax to (804) 527-4434. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action 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.

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.