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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) Chapter citation(s)	18VAC110-20
VAC Chapter title(s)	Regulations Governing the Practice of Pharmacy
Action title	Crisis stabilization services and use of automated drug dispensing systems and remote dispensing systems
Date this document prepared	May 2, 2024

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of the subject matter, intent, and goals of this 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 or changes. If applicable, generally describe the existing regulation.

Chapters 63 and 513 of the 2024 Acts of Assembly direct the Board of Pharmacy to adopt emergency regulations to implement the provisions of those acts. The identical acts change Board of Pharmacy sections of the Code to allow on-site storage and dispensing of necessary medications in crisis stabilization units. The legislation permits the use of remote dispensing systems in certain healthcare facilities using the same requirements that are currently in place for automated drug dispensing systems. Remote dispensing systems are currently used in some programs approved by the Board of Pharmacy as innovative pilot programs under Virginia Code § 54.1-3307.2. The legislation also permits state facilities and services licensed by the Department of Behavioral Health and Developmental Services which serve as site-based crisis stabilization units to use automated drug dispensing devices and remote dispensing systems.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

CSU = crisis stabilization unit
ADD = automated drug dispensing device
CRC = crisis receiving center
CSR = controlled substances registration
RDS = remote dispensing system

Mandate and Impetus (Necessity for Emergency)

Explain why this rulemaking is an emergency situation in accordance with § 2.2-4011 A and B of the Code of Virginia. In doing so, either:

a) *Indicate whether the Governor's Office has already approved the use of emergency regulatory authority for this regulatory change.*
b) *Provide specific citations to Virginia statutory law, the appropriation act, federal law, or federal regulation that require that a regulation be effective in 280 days or less from its enactment.*

As required by § 2.2-4011, also describe the nature of the emergency and of the necessity for this regulatory change. In addition, delineate any potential issues that may need to be addressed as part of this regulatory change.

Chapters 63 and 513 of the 2024 Acts of Assembly direct the Board of Pharmacy to adopt emergency regulations to implement the provisions of those acts. The Board did not determine the nature of the emergency or necessity for the emergency, as this was decided by the General Assembly.

Legal Basis

Identify (1) the promulgating agency, 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 and Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Regulations of the Board of Pharmacy are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Virginia Code § 54.1-2400(6) specifically states that the general powers and duties of health regulatory boards shall be "[t]o promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system."

Purpose

Describe the specific reasons why the agency has determined that this regulation is essential to protect the health, safety, or welfare of citizens. In addition, explain any potential issues that may need to be addressed as the regulation is developed.

The agency has not made this determination. The General Assembly made this determination when it passed and the Governor approved Chapters 63 and 513 of the 2024 Acts of Assembly. The implementation of this legislation alleviates a problem under prior Code language which did not allow all CSUs to store drugs or utilize remote dispensing systems. This hinders the ability to care for individuals in crisis.

Substance

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.

The regulatory changes allow on-site storage and dispensing of necessary medications in CSUs. The regulations also permit the use of remote dispensing systems in certain healthcare facilities using the same requirements that are currently in place for automated drug dispensing systems. The amendments are based on the approved innovative pilot programs currently approved by the Board pursuant to Virginia Code § 54.1-3307.2. Finally, the regulations permit state facilities and services licensed by the Department of Behavioral Health and Developmental Services which serve as site-based CSUs to use ADDs and remote dispensing systems.

Issues

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 advantages to the public are increased access to full crisis stabilization services under the regulatory purview of the Board of Pharmacy. There are no disadvantages to the public.
2) There are no primary advantages or disadvantages to the agency or the Commonwealth.
3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. Any restraint on competition as a result of promulgating these regulations is a foreseeable, inherent, and ordinary result of the statutory obligation of the Board to protect the safety and health of citizens of the Commonwealth. The Board is authorized under § 54.1-2400 "[t]o promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 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 promulgated regulations do not conflict with the purpose or intent of Chapters 1 or 25 of Title 54.1.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. 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 regulatory change.

There are no alternatives to regulation. Chapters 63 and 513 of the 2024 Acts of Assembly require the Board to promulgate regulations to implement the provisions of the legislation.

Periodic Review and Small Business Impact Review Announcement

This NOIRA is not being used to announce a periodic review or small business impact review.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below. In addition, as required by § 2.2-4007.02 of the Code of Virginia describe any other means that will be used to identify and notify interested parties and seek their input, such as regulatory advisory panels or general notices.

The Board of Pharmacy is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, (iii) the potential impacts of the regulation, and (iv) the agency's regulatory flexibility analysis stated in that section of the background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at https://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. Comments may also be submitted by mail, email or fax to Erin Barrett, Agency Regulatory Coordinator, 9960 Mayland Drive, Henrico, VA 23233 or erin.barrett@dhp.virginia.gov or by fax to (804) 915-0382. 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 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.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the emergency regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
20-200	Provides regulations related to storage of drugs, devices, and controlled paraphernalia, and expired drugs	Language is added to subsection A to permit prescriptions prepared for delivery to a patient to be secured in a remote dispensing system as defined in § 54.1-3401 pursuant to 18VAC110-20-490 A. 490 A, as described below, is amended to permit the additional entities and facilities described throughout this document to use ADDs and remote dispensing systems.
20-275	Provides regulations for delivery of dispensed prescriptions	Subsection B 3 is amended to include a reference to compliance with 490 A, where applicable, for drugs waiting to be picked up at or delivered from one pharmacy to a second pharmacy. Subsection C 3 is amended to include the ability to store prescriptions waiting to be picked up in a remote dispensing system as defined in § 54.1-3401 of the Code and pursuant to 490 A. This is a new allowance for remote dispensing systems pursuant to the legislation. Subsection F 3 is amended to include the ability to store prescriptions delivered at an alternate delivery site in a remote dispensing system as defined in § 54.1-3401 of the Code and pursuant to 490 A. This is a new allowance for remote dispensing systems pursuant to the legislation.
20-490	Provides regulations for ADDs	Subsection A previously only permitted hospitals to use ADDs. Consistent with legislation, the amendments add state facilities as defined in § 37.2-100 established pursuant to Title 37.2, facilities defined in § 37.2-100 that are licensed by DBHDS and provide site-based crisis stabilization services, or other facilities authorized by the Board. The amendments also add remote dispensing systems to the regulated devices under the subsection. The inclusion of these additional facilities and remote dispensing systems will allow CSUs to use ADDs and remote dispensing systems to better serve patients and puts into regulation pilot programs previously approved by the Board. An example of state facilities as defined in § 37.2-100 established pursuant to Title 37.2 is Southeastern Virginia Training Center, an intermediate care facility which provides highly structured habilitation services, including life in a residential neighborhood, care support and training, and learning opportunities in areas such as employment, communication, language, self-care, independent living, socialization, and other aspects of life for individuals with intellectual and developmental disabilities.

		Another amendment to subsection A allows a remote dispensing system which solely stores drug labeled and verified by the provider pharmacist for patients to obtain medication to be placed within close proximity of a permitted pharmacy or at a location issued a controlled substance registration pursuant to 20-275 in a secure area under constant surveillance. This is not allowed if it is prohibited under federal law. This amendment is pursuant to the legislation, specifically changes made to § 54.1-3434.02. Subsection B 1 is amended to change “automated dispensing devices” to “automated drug dispensing system and remote dispensing system.” This change is intended to incorporate the changes dictated in the legislation. Subsection B 2 is amended to change “automated dispensing devices” to “automated drug dispensing system and remote dispensing system.” This change is intended to incorporate the changes dictated in the legislation. The subsection is further amended to change the requirement that a device record the identity of the person accessing it by access code to allow other means to record individual access to the device to incorporate the changes dictated in the legislation. New subsection B 3 is added to make an allowance for maintenance of a key used to access the ADD or remote dispensing system in the possession of the director of nursing or an individual designated by the DON who is licensed to administer medications. This change places part of an existing pilot program in regulation. New subsection C 1 is added to require that a pharmacy located outside of the hospital, nursing home, or facility at which the pharmacy services an ADD or remote dispensing system must obtain a controlled substances registration issued in the name of the pharmacy at the address of the facility and a DEA registration (if required by DEA) prior to stocking the ADD or remote dispensing system with drugs in Schedules II through VI. ADDs or remote dispensing systems used exclusively for administration of drugs for emergencies are exempted from this requirement. The legislation requires the described pharmacies to obtain a CSR and DEA registration. The requirement to obtain a CSR and DEA registration prior to stocking an ADD or RDS with controlled substances protects the public by providing the Board and the DEA with a responsible entity for the stocking of the ADD or RDS. New subsection C 2 is added. This subsection clarifies that drugs authorized pursuant to § 54.1-3434.02 may be placed into and removed from ADDs or RDSs.

		Pharmacies that service RDSs which package and label drugs for a specific patient are permitted under the subsection to repackage drugs into bulk bins that are verified for accuracy by a pharmacist pursuant to 18VAC110-20-355. The subsection allows pharmacies using an RDS which only stores patient-specific drugs for patients to obtain their medication to place the pharmacist-verified dispensed drug into the RDS. This incorporates current pilot programs for CSUs that use a technology known as AP Passport to prepare patient-specific drugs for administration. The advantages of this model are that drugs are on-site and staff do not have to wait for a pharmacy to deliver dispensed drugs to the facility. The drugs are labelled specific to patients to aid in the safe administration of drugs to the correct patient. Subsection C 3 (previously C 1) is amended to change "automated dispensing devices" to "automated drug dispensing system or remote dispensing system." This change is intended to incorporate the changes dictated in the legislation. The subsection is further amended to change the word "hospital" to "facility" to incorporate the facilities other than hospitals permitted under the legislation to utilize ADDs and RDSs. Subsection C 4 (previously C 2) is amended to change "automated dispensing devices" to "automated drug dispensing system or remote dispensing system." This change is intended to incorporate the changes dictated in the legislation. Subsection D is amended to clarify that the following provisions now apply to distribution and dispensing of drugs from an ADD or RDS. Subsections D 1 and D 2 are amended to change "automated dispensing devices" to "automated drug dispensing system or remote dispensing system." This change is intended to incorporate the changes dictated in the legislation. New subsection D 3 requires that RDSs that dispense patient-specific drugs into an envelope comply with 18VAC110-20-340 if the medication is assigned an expiration date of no more than 48 hours from the date of the packaging in an envelope. Section 340 provides requirements for packaging standards for dispensed prescriptions. This requirement ensures consistency in packaging standard requirements for dispensed prescriptions, regardless of whether those prescriptions are dispensed from a pharmacist directly to a patient or through an ADD or RDS. New subsection D 4 requires RDSs that dispense multiple medications into a single container for a specific patient provide a medication description as set forth in 340 B on

		the label, medication envelope, or the medication run report. This change, similar to D 3, ensures consistency in packaging standard requirements for dispensed prescriptions. New subsection D 5 waives the pharmacist-verification of a patient-specific dispensed drug from an RDS, which is a requirement under 270, if a pharmacist verified the bulk bins placed in the device and the device incorporates sufficient technology to ensure accuracy of the dispensed drug. This change is one that has been approved by the Board as part of pilot programs and has already been implemented by some CSUs under those pilot programs. Subsections F 1, F 2, and F 3 are amended to change "automated dispensing devices" to "automated drug dispensing system or remote dispensing system." This change is intended to incorporate the changes dictated in the legislation. Subsection F 3 a and b are amended to include dispensing records in audits to incorporate ADDs and RDSs. Subsection G is amended to change "automated dispensing devices" to "automated drug dispensing system or remote dispensing system." This change is intended to incorporate the changes dictated in the legislation. Subsection H 1 is amended to change the word "hospital" to "facility" to incorporate the facilities other than hospitals permitted under the legislation to utilize ADDs and RDSs. Subsection H 4 is amended to include dispensing records to incorporate ADDs and RDSs and to change "automated dispensing devices" to "automated drug dispensing system or remote dispensing system."
20-555	Provides requirements for use of ADDs	The catchline of the section is amended to include "and remote dispensing devices in nursing homes" to clarify what the section applies to. The following subsections are amended to include remote dispensing systems in the requirements or to change "automated dispensing devices" to "automated drug dispensing system or remote dispensing system" or otherwise standardize the language used (such as changing "automated dispensing systems" to "automated drug dispensing systems"): the preamble language; subsection 1; subsection 2; subsection 3; subsection 4; subsection 4 a; subsection 4 d; subsection 5; subsection 7 (renumbered); subsection 10 (renumbered); subsection 14 (renumbered); subsection 15 (renumbered); subsection 16 (renumbered); subsection 17 (renumbered); and 18 d (renumbered). Any changes made in other portions of the subsections listed above will be addressed in specific

		entries. These changes, however, merely conform the allowances and requirements contained in the subsection to existing allowances and requirements for ADDs. The following subsections are amended to add "dispensed" or "dispensing": subsection 14 (renumbered); subsection 14 c (renumbered); subsection 14 d (renumbered); subsection 14 f (renumbered); and subsection 18 d (renumbered). Any changes made in other portions of the subsections listed above will be addressed in specific entries. These changes, however, merely incorporate RDSs by including "dispensing" to other terms such as "administration" or "distribution," which are related to use of ADDs only. Changes to subsection 2 not previously addressed include the requirement that a pharmacy located outside of the nursing home at which the pharmacy services an ADD or remote dispensing system must obtain a controlled substances registration issued in the name of the pharmacy at the address of the facility and a DEA registration (if required by DEA) prior to stocking the ADD or remote dispensing system with drugs in Schedules II through VI. ADDs or remote dispensing systems stocked exclusively with drugs that would be kept in a stat-drug box pursuant to 550 or an emergency drug kit pursuant to 540 are already exempted from this requirement under existing language (although remote dispensing systems are newly included pursuant to the legislation). The legislation requires the described pharmacies to obtain a CSR and DEA registration. The requirement to obtain a CSR and DEA registration prior to stocking an ADD or RDS with controlled substances protects the public by providing the Board and the DEA with a responsible entity for the stocking of the ADD or RDS. The change to subsection 3 not previously addressed is the deletion of the language "For facilities not required to obtain a controlled substance registration," which preceded the language in the subsection limiting access to the ADD or RDS to licensed nurses, pharmacists, prescribers, or registered pharmacy technicians for the purpose of stocking or reloading. This language is deleted because the requirement already applies to all ADDs (now ADDs and RDSs). Subsection 4 d, in addition to changes described above, includes an addition of "or quantity" to the information on the hard-copy record that the ADD or RDS must be capable of producing. Additionally, "if applicable" is added to follow the existing "dose to be administered." These changes are intended to incorporate the information that would be recorded in an RDS but would not have been recorded or produced from an ADD, which was the only system addressed under the existing regulatory language.

		New subsection 6 is added to clarify that drugs authorized pursuant to § 54.1-3434.02 may be placed into and removed from ADDs or RDSs. Pharmacies that service RDSs that package and label drugs for a specific patient are permitted under the subsection to repackage drugs into bulk bins that are verified for accuracy by a pharmacist pursuant to 18VAC110-20-355. Drugs provided in this manner which are intended to be administered by the patient or a person not licensed to administer drugs must comply with labeling requirements contained in Virginia Code §§ 54.1-3410 and 54.1-3463 and board regulations. Directions for use are permitted to be abbreviated when drugs are exclusively administered by persons licensed to administer drugs. These changes are intended to permit use of ADDs and RDSs in nursing homes consistent with previous approved pilot programs of the Board while maintaining patient safety. New subsection 11 requires that RDSs that dispense patient-specific drugs into an envelope comply with 18VAC110-20-340 if the medication is assigned an expiration date of no more than 48 hours from the date of the packaging in an envelope. Section 340 provides requirements for packaging standards for dispensed prescriptions. This requirement ensures consistency in packaging standard requirements for dispensed prescriptions, regardless of whether those prescriptions are dispensed from a pharmacist directly to a patient or through an ADD or RDS. This subsection is identical to new 490 D 3. New subsection 12 is identical to new 490 D 4 and requires RDSs that dispense multiple medications into a single container for a specific patient provide a medication description as set forth in 340 B on the label, medication envelope, or the medication run report. This change, similar to D 3, ensures consistency in packaging standard requirements for dispensed prescriptions. New subsection 13 is identical to new 490 D 5 and waives the pharmacist-verification of a patient-specific dispensed drug from an RDS, which is a requirement under 270, if a pharmacist verified the bulk bins placed in the device and the device incorporates sufficient technology to ensure accuracy of the dispensed drug. This change is one that has been approved by the Board as part of pilot programs and has already been implemented by some facilities under those pilot programs.
20-728	Provides requirements for use of drugs for immediate treatment in CSUs	Subsection A is amended to incorporate the use of Schedule II through V controlled substances in CSUs. The amendments remove the prohibition on CSUs stocking Schedule II through V controlled substances. The intent of this change is to allow CSUs to utilize controlled substances in providing services to patients, as required under the 2024 legislation.

		Subsection B is amended to remove the limitation to only Schedule VI controlled substances for the same reason stated above.