Virginia Regulatory Town Hall

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Proposed Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-20
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Possession and repackaging of drugs in certain mental health facilities
Date this document prepared	3/9/11

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

Chapter 28 (HB150) of the 2010 Acts of the Assembly requires the Board of Pharmacy to promulgate regulations to authorize community services boards and behavioral health authorities to possess, repackage and deliver or administer medications and crisis stabilization units to store and administer a stock of drugs needed for emergency treatment. Regulations promulgated pursuant to the legislative mandate set forth requirements for registration of a community service board (CSB) or behavioral health authority (BHA) to possess, repackage and deliver or administer drugs and for a program to train non-pharmacists in repackaging for CSB's or BHA's. Regulations include labeling, storage, recordkeeping, destruction and other requirements for repackaging in these facilities (which do not have a pharmacy), persons authorized to repackage, and information to clients about repackaged drugs. There are also curricula and instructional criteria for approval of repackaging training programs and for expiration and renewal of program approval. Finally, there are provisions for stocking, recordkeeping and administration of Schedule VI at a crisis stabilization unit for immediate treatment of patients as necessary.

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.

CSB = community service board
BHA = behavioral health authority

Legal basis

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) promulgating entity, i.e., the agency, board or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

The legal authority to promulgate the proposed regulation is found in Chapter 28 of the 2010 Acts of the Assembly (HB150): http://leg1.state.va.us/cgi-bin/legp504.exe?101+ful+CHAP0028. The authority to promulgate regulations to establish criteria for possession and repackaging by CSB's and BHA's is mandatory.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

The purpose of the planned regulatory action is to comply with a legislative mandate to promulgate regulation for community services boards, behavioral health authorities, and clinics established by the Virginia Department of Behavioral Health and Developmental Services to receive, store, retain, and repackage prescription drug orders dispensed to a patient for the purpose of assisting a client with self-administration of the drug. The regulations also provide for registration of crisis stabilization units to maintain stocks of Schedule VI drugs necessary for immediate treatment of patients admitted to the unit.

House Bill 150 (2010) was introduced to address a problem for community services boards (CSB's) and behavioral health authorities (BHA's) in handling the unique prescription needs of its patient population following closure by the state of the Community Resource Pharmacy, which had provided most pharmacy services to the CSBs. The legislation does three things:

1) It authorizes the CSBs and BHA's to retain prescription medications for certain patients including but not limited to those who may be homeless or live in a residence where prescriptions are likely to be stolen, who may need assistance or monitoring of self

administration, who may not be capable of self administering, or who may not be a good candidate for keeping the entire dispensed prescription due to suicide risks.
2) It authorizes CSB and BHA personnel, who hold appropriate licensure or who have passed a training course approved by the Board of Pharmacy, to repackage a portion of a patient's medication to assist that patient with self-administration and compliance with dosage instructions.
3) It authorizes residential crisis stabilization units to maintain a floor-stock of Schedule VI controlled substances that may be needed for immediate administration for patients admitted to the units in order to treat a crisis situation and prevent inpatient hospitalization.

Because of the urgent need for the change in law and for regulations to implement those changes, the bill had an emergency enactment clause as well as a provision for emergency regulations by the Board of Pharmacy. Regulations addressing storage, repackaging, recordkeeping and training of persons who handle drugs will ensure that client or patient needs are being met while protecting the security and integrity of the drugs and the health and safety of the client and general population.

Substance

Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the "Detail of changes" section.)

Regulations promulgated pursuant to the legislative mandate set forth requirements for registration of a community service board (CSB) or behavioral health authority (BHA) to possess, repackage and deliver or administer drugs and for a program to train non-pharmacists in repackaging for CSB's or BHA's. Regulations include labeling, storage, recordkeeping, destruction and other requirements for repackaging in these facilities (which do not have a pharmacy), persons authorized to repackage, and information to clients about repackaged drugs. There are also curricula and instructional criteria for approval of repackaging training programs and for expiration and renewal of program approval. Finally, there are provisions for stocking, recordkeeping and administration of Schedule VI at a crisis stabilization unit for immediate treatment of patients as necessary.

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 the regulatory action poses no disadvantages to the public or the Commonwealth, please indicate.

1) The advantage to the public is assurance that a board-registered community service board or behavioral health authority facility has followed appropriate procedures in the storing, retaining, and repackaging of dispensed prescription drug orders for the purpose of assisting clients with self-administration. Without proper training, there are concerns about drug safety and security and about improper dispensed of prescriptions that enable a person to remain in a community-based program. There are no disadvantages.
2) The advantage to the Commonwealth is facilitation of community treatment for persons who might otherwise require in-patient care.
3) This is the replacement of an emergency regulation in effect from 12/10/10 to 12/9/11.

Requirements more restrictive than federal

Please identify and describe any requirements of the proposal, which are more restrictive than applicable federal requirements. Include a rationale 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.

There are no applicable 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/agency 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**.** Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

A public hearing will be held and notice of the public hearing may appear on the Virginia Regulatory Town Hall website (www.townhall.virginia.gov) and the 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 requirements create the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.	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 or entities for necessary functions of regulation. There would be a one-time expense of less than $1,000 for promulgation of the amended rule. All notifications will be done electronically to minimize the cost. The on-going expenditures for the agency related to approval of training program for CSB's and BHA's will be offset by a modest fee.
Projected cost of the *new regulations or changes to existing regulations* on localities.	None
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	The entities that would be affected by the ability to use non-licensed persons trained to repackage would be CSB's and BHA's.
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 (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There are 40 locally-run CSB's. The Board does not have a number for BHA's.
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. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. 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	The only cost would be $50 for Board-approval of a training program curriculum, which would allow a CSB or BHA to train a non-pharmacist to repackage drugs for clients in compliance packaging. The alternative (currently used by CSB's) is the use of a licensed pharmacist to perform that task. The Virginia Association of Community Service Boards is working on a format for a training program that could be approved and utilized by

regulations.	local boards, so each individual board would not have to apply for board approval.
Beneficial impact the regulation is designed to produce.	Compliance with statute to develop regulations for repackaging of drugs at CSB's and BHA's. The ability of community-based programs to repackage prescription drugs for clients without employing or contracting with a pharmacist should reduce costs for their operations.

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.

A working committee of the Board of Pharmacy met on February 23, 2010 to draft language for emergency regulations pursuant to the passage of HB 150. Specifically, the language addressed authorization for a board-registered community service board or behavioral health authority facility in the storing, retaining, and repackaging of dispensed prescription drug orders for the purpose of assisting clients with self-administration. The committee drafted the emergency regulations related to the training, packaging, labeling, and record keeping for such repackaging. Additionally, the Committee drafted language for the emergency regulations to allow a board-registered crisis stabilization unit to stock Schedule VI controlled substances necessary for the immediate treatment of patients admitted to the crisis stabilization unit. Assisting board members and staff in drafting regulations were Mary Ann Bergeron, Executive Director of Virginia Association of Community Services Boards, Michael O'Connor, Executive Director of Henrico County Community Service Board, Ken Pritchard, pharmacist with Tidewater CSB, and Susan Hoover and Beth Rafferty with Richmond Behavioral Health Authority. House Bill 150 was approved by the Governor on March 4, 2010, and the Board adopted emergency regulations at its meeting on March 9, 2010. The emergency regulations were approved by the Governor on December 9, 2010 and became effective on December 20, 2010. Thus far, there are no training programs approved, so the Board has not identified any alternatives to the regulations adopted.

Regulatory flexibility analysis

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.

Since there is a specific statutory mandate for the promulgation of regulations, there are no alternative methods consistent with health, safety and welfare that will accomplish the objectives of applicable law.

Public comment

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

The Notice of Intended Regulatory Action was published and provided to the public participation mailing list on January 3, 2011 with comment requested until February 2, 2011. No comment was received.

Family impact

Please assess the impact of the proposed 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.

Failure to adopt and approve regulations to implement provisions of HB150 would have a serious impact on the family and family stability as clients of CSB's and BHA's may not have adequate access to medications necessary to keep them safe and stable in the community.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact if implemented in each section. Please describe the difference between the requirements of the new provisions and the current practice or if applicable, the requirements of other existing regulations in place.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all provisions of the new regulation or changes to existing regulations between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

Current section number	Current requirement	Proposed change, rationale, and consequences
20	Sets out fees for licensees and permit holders	Adds a fee of $50 for approval of a repackaging training program, a fee of $30 for renewal of approval every two years and a $10 late fee for renewal after the deadline. *Nominal fees are set for handling the paperwork involved in review of the curriculum, qualifications of instructors and*

		retention of documentation for training programs. The fees may not be sufficient to cover all costs but are deliberately so there is no financial disincentive to community service boards in getting people appropriately trained.
275	Establishes rules for delivery of dispensed prescriptions to alternative delivery sites.	Subsection A is amended to clarify that dispensed orders for Schedule VI drugs may be delivered to alternative sites, but Schedule II through V drugs may not be delivered unless authorized. *Such deliveries are currently not authorized by federal law, so the regulation needed to be consistent and not confusing.*
690	Sets out the requirements for entities or persons that must obtain a controlled substance registration in order to maintain a stock of drugs	In subsection B, crisis stabilization units are added to the list of entities without in-house pharmacies that may be registered by the board for a controlled substance registration. With the passage of HB150, such units are now authorized by law to maintain a stock of drugs to be used for emergency treatment of patients in such units. Subsection D is amended to clarify that the person responsible for the controlled substances at a controlled substance registrant must be someone who is authorized by law to administer such controlled substances.
700	Sets out the requirements for supervision in facilities that hold a controlled substance registration	Subsection C is amended to expand access to controlled substances to persons who have completed repackaging training for a CSB or a BHA (see definitions below). A second amendment adds repackaging of prescription drug orders at a CSB or BHA is within the scope of practice of a pharmacy technician, if approved by the supervising pharmacist. A third amendment specifies that access to stock drugs in a crisis stabilization unit is limited to prescribers, nurses or pharmacists; access does not include any unlicensed persons or technicians.
New section number	**Current requirement**	**Proposed change and rationale**
685	n/a	For the purpose of use in Part SVI on Controlled Substances Registration, "CSB" is defined as a community services board facility licensed by the Department of Behavioral Health and Developmental Services that holds a controlled substances registration issued by the board. "BHA" is defined as a behavioral health authority facility licensed by the Department of Behavioral Health and Developmental Services that holds a controlled substances registration issued by the board.
725	n/a	Section 725 sets out all requirements for repackaging in a CSB or BHA. Subsection A define “repackaging" for the purposes of this section as removing a drug from a container already dispensed and labeled by a pharmacy or medical practitioner authorized to dispense, for a particular client of a CSB or BHA, and placing it in a container designed for a person to be able to repackage his own dispensed prescription medications to assist with self-administration and compliance with dosage instructions.

		The purpose of defining repackaging as it applies to the activity by an unlicensed person in a CSB or BHA is to ensure that it is not confused with repackaging performed in a pharmacy and to clarify that training in "repackaging" as defined in this section does not qualify an individual to repackage drugs in other settings and for other purposes. The regulations also stipulate that such repackaging does not include the preparation of a patient-specific label which includes drug name, strength, or directions for use or any other process restricted to a pharmacist or pharmacy technician under the direct supervision of a pharmacist. *Preparation of such a label is an act restricted in law to a pharmacist, pharmacy technician under the direct supervision of a pharmacist, or physician licensed to dispense.* Subsection B specifies those persons who are authorized to repackage, including a pharmacist, pharmacy technician, nurse, or another person who has successfully completed a board-approved training program for repackaging of prescription drug orders as authorized by statute. If a CSB or BHA uses non-licensed persons who have received specific repackaging training, it must maintain documentation of completion of an approved training program for at least one year from date of termination of employment or cessation of repackaging activities. *Inspectors for the board will check on whether the CSB or BHA has followed regulations on storage, recordkeeping, etc. and whether persons who are authorized to do so are repackaging the drugs dispensed to clients of the facility.* Subsection C sets out the requirements for repackaging to include: 1. The repackaging of a dispensed prescription drug order pursuant to § 54.1-3420.2 shall only be done at a CSB or BHA. 2. The repackaging of dispensed prescription drugs shall be restricted to solid oral dosage forms and a maximum of a 14-day supply of drugs. 3. The drug container used for repackaging pursuant to this section shall bear a label containing the client's first and last name, and name and 24-hour contact information for the CSB or BHA. 4. A clean, well-closed container that assists the client with self-administration shall be used when multiple doses of a repackaged drug are provided to the client at one time. 5. A prescription drug order shall not be repackaged beyond the assigned expiration date noted on the prescription label of the dispensed drug, if applicable, or beyond one year from the date the drug was originally dispensed by a pharmacy, whichever date is earlier. *All requirements are intended to improve compliance with dosage directions, minimize risks, and improve the safety of the drugs being dispensed. Drugs will typically be repackaged into*

		re-usable medication planning packaging (plastic containers with separate compartments for days of the week and times of day that consumers often purchase to repackage their own medications). Subsection D requires that at the time a repackaged drug is initially given to a client, and upon any subsequent change in the medication order, the client must be provided written information about the name and strength of the drug and the directions for use. Such written information shall have been prepared by a pharmacy or by a nurse at the CSB or BHA. *This written information is intended to provide the client, client's family, or any other health care provider in an emergency with information about drug names, strengths, dosage directions, and dispensing pharmacy name since this information resides on the dispensed pharmacy container with labeling which will in many cases have been retained at the CSB or BHA.* Subsection E sets out the requirements for retention, storage and destruction of repackaged drugs. It provides that: 1. Any portion of a client's prescription drug order not placed into a container intended to assist with self-administration may be either given to the client or retained by the CSB or BHA for subsequent repackaging. If retained by the CSB or BHA, the remaining portion shall be stored within the board-approved drug storage location in the original labeled container, and shall only be used for the client for whom the drug was originally dispensed. *Drugs maintained at a CSB or BHA have been prescribed and dispensed by a pharmacy for a specific patient or client. The drugs must be kept in a secure location and not given out to other clients.* 2. Any portion of a prescription drug order remaining at the CSB or BHA that has exceeded any labeled expiration date or one year from the original pharmacy dispensing date on the label shall be separated from unexpired drugs, stored within a designated area of the board-approved drug storage location, and destroyed within 30 days of expiration with the written agreement of the client. Remaining portions of discontinued prescription drug orders retained by the CSB or BHA shall also be separated from active stock and either returned to the client or destroyed within 30 days of discontinuance with the written agreement of the client. *To ensure the drug's safety and integrity, rules are written for handling of expired drugs or discontinued medications.* Subsection F sets out the rules for keeping records, as follows: 1. A record of repackaging shall be made and maintained for one year from the date of repackaging and shall include the following: a. Date of repackaging; b. Name of client; c. Prescription number of the originally dispensed prescription drug order;

		d. Pharmacy name; e. Drug name and strength; f. Quantity of drug repackaged; and g. Initials of the person performing the repackaging and verifying the accuracy of the repackaged drug container. *Recordkeeping is important to be able to track what drugs have been dispensed and given to clients in case of errors, recalls or other need for information.* 2. A record of destruction shall be made and maintained for one year for any prescription drug orders destroyed by the CSB or BHA and shall include the following: a. Date of destruction: b. Name of client; c. Prescription number of the originally dispensed prescription drug order; d. Drug name and strength; e. Quantity of drug destroyed; and f. Initials of the person performing the destruction.
726	n/a	Section 726 establishes the criteria for a training program in repackaging. Subsection A provides that any person wishing to apply for approval of a repackaging training program must submit the $50 application fee and an application on a form approved by the board and must meet the criteria established in this section. The application must name a program director who is responsible for compliance with this section. *An application is necessary in order for the board to have basic information on which to base its approval and to have a contact person accountable for the program and its content.* Subsection B sets out the requirements for the curriculum of a training program to include instruction in current laws and regulations applicable to a CSB or BHA for the purpose of assisting a client with self-administration and in the following repackaging tasks: 1. Selection of an appropriate container; 2. Proper preparation of a container in accordance with instructions for administration; 3. Selection of the drug; 4. Counting of the drug; 5. Repackaging of the drug within the selected container; 6. Maintenance of records; 7. Proper storage of drugs; 8. Translation of medical abbreviations; 9. Review of administration records and prescriber's orders for the purpose of identifying any changes in dosage

		administration; 10. Reporting and recording the client's failure to take medication; 11. Identification, separation and removal of expired or discontinued drugs; and 12. Prevention and reporting of repackaging errors. *The curriculum for the program is intending to minimally prepare a person to accomplish this limited repackaging with safety and accuracy. The person must be able to read a prescription label, correctly remove the drugs and appropriately package the dosages in compliance packaging or boxes. The person responsible for repackaging must also know what to do if the client has not been compliant with medications, if there are changes in orders, and if an error has occurred.* Subsection C establishes requirements for instructors and a program director. Instructors for the program shall be either (i) a pharmacist with a current license in any jurisdiction and who is not currently suspended or revoked in any jurisdiction in the United States; or (ii) a pharmacy technician with at least one year of experience performing technician tasks who holds a current registration in Virginia or current PTCB certification and who is not currently suspended or revoked in any jurisdiction in the United States. The program director shall maintain a list of instructors for the program. *The only persons qualified to teach someone to accurately and safely repackage drugs are persons who have had training and experience in repackaging and are deemed to be competent in those tasks.* Subsection D sets general requirements for the program to include: 1. The length of the program shall be sufficient to prepare a program participant to competently perform repackaging consistent with §54.1-3420.2 and 18 VAC 110-20-725. *The board did not stipulate the number of hours for a program since it may vary depending on the experience of the trainee, the number of persons being trained and other factors.* 2. The program shall include a post-training assessment to demonstrate the knowledge and skills necessary for repackaging with safety and accuracy. *While there is no standardized test of competency, the program must assure that there is a post-test assessment.* 3. A program shall provide a certificate of completion to participants who successfully complete the program and provide verification of completion of the program for a participant upon request by a CSB or BHA or by the board. 4. The program shall maintain records of training completion by persons authorized to repackage in accordance with §54.1-3420.2. Records shall be retained for two years from date of completion of training or termination of the program.

		A certificate of completion is necessary for the person to be able to demonstrate training to employers (CSB's and BHA's) and to representatives of the board. 5. The program shall report within 14 days any substantive change in the program to include a change in program name, program director, name of institution or business if applicable, address, program content, length of program, or location of records. *A report of substantive changes is necessary in order for the board to maintain an accurate record of training programs.* Subsection E provides that a repackaging training program approval expires after two years, after which the program may apply for renewal. For continued approval, the program must submit the renewal application, renewal fee, and a self-evaluation report on a form provided by the board at the time of renewal notification. Renewal of a program's approval is at the discretion of the board, and the decision to renew will be based on documentation of continued compliance with the criteria set forth in this section. *Requirements for renewal of a training program are similar to those for a pharmacy technician training program, which must also be approved by the board.*
727	n/a	Section 727 provides criteria for pharmacists repackaging for clients of a CSB or BHA as an alternative to repackaging by a person trained for that purpose. A pharmacist repackaging for a CSB or BHA must ensure compliance packaging that complies with the requirements of 18 VAC 110-20-340 B and 18 VAC 110-20-725, subsections G, H, and J. A primary provider pharmacy may also provide this service in compliance with the provisions of 18 VAC 110-20-535.
728	n/a	Section 728 establishes rules stocked at crisis stabilization units for immediate treatment. Subsection A provides that a crisis stabilization unit must obtain a controlled substances registration in order to maintain a stock of Schedule VI controlled substances for immediate treatment of patients in crisis. Schedule II-V controlled substances cannot be stocked. The responsible party listed on the application must be a nurse who regularly administers controlled substances at the crisis stabilization unit and the supervising practitioner must be either the medical director for the unit or a pharmacist from a provider pharmacy. *Different from the CSB or BHA where drugs have been individually prescribed for a client and dispensed by a pharmacist, drugs administered at a crisis stabilization unit for immediate treatment to stabilize a patient would come from a stock of drugs maintained at the facility. Therefore, it is necessary for the responsible party to be the person who regularly administers at the unit and for the supervising practitioner to be medical director (doctor) or a pharmacist from the pharmacy that provides the drugs.* Subsection B provides that, in consultation with a provider

		pharmacist, the medical director for the unit must determine the list of controlled substances to be stocked at the crisis stabilization unit. The list shall be limited to Schedule VI controlled substances and only those drugs routinely used for treatment of patients admitted for crisis stabilization. Only drugs on this drug list may be stocked. *By limiting the drugs available for administration to those routinely used for treatment, there is control on the amount and number of drugs available in the unit.* Subsection C requires that a nurse administering a drug from this stock pursuant to an oral order of a prescriber in accordance with § 54.1-3423, to record such order in the patient's medical record. Subsection D sets out basic requirements for records maintained by the crisis stabilization unit to include: 1. A record shall be maintained of all drugs received as stock by the crisis stabilization unit. 2. A record shall be made documenting administration or other authorized disposition of stocked drugs that includes the following: a. Name of patient; b. Date and time of administration; c. Drug name, strength, and quantity administered; d. Name or initials of person administering; and e. Prescriber name. 3. Records shall be maintained at the same location listed on the controlled substances registration or, if maintained in an off-site database, retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent. Any computerized system used to maintain records shall also provide retrieval via computer monitor display or printout of the history for drugs administered during the past two years. It shall also have the capacity of producing a printout of any data which the registrant is responsible for maintaining. *As with records of Schedule VI drugs maintained by other types of facilities, regulations allow the unit to maintain records electronically off-site provided they are retrievable within 48 hours. The database must have the capacity to printout a history of drug administration for review.* 4. Manual records may be maintained as an electronic image that provides an exact image of the document and is clearly legible.