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	18VAC110-20-10 et seq.
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Drug donation program
Date this document prepared	6/10/09

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Chapter 429 (HB85) of the 2008 Acts of the Assembly required the Board of Pharmacy to promulgate regulations to establish a Prescription Drug Donation Program for accepting unused previously dispensed prescription drugs that meet certain criteria for re-dispensing to patients of free clinics. The second enactment on Chapter 429 required the Board to promulgate regulations to implement the provisions of the act effective within 280 days of its enactment. Therefore, emergency regulations were adopted and became effective April 10, 2009; the proposed regulations are identical to emergency regulations currently in effect.

Legal basis

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 legal authority to promulgate the proposed regulation is found in Chapter 429 of the 2008 Acts of the Assembly (HB85): § 54.1-3411.1. *of the Code of Virginia, relating donation of prescription medications.* The authority to promulgate regulations to establish a drug donation program is mandatory.

Purpose

The purpose of the regulatory action is to comply with a legislative mandate to promulgate regulation for the establishment of a Prescription Drug Donation Program. Requirements for eligible drugs must comply with Virginia law and the federal Drug Enforcement Administration, so the applicability of the program is inherently limited. Given that limitation, the Board has proposed a program that allows for participation without unnecessary expense or burdensome reporting. At the same time, there must be safeguards for the security and efficacy of the drugs that will be re-dispensed to a patient of a free clinic.

The need for a drug donation program has been recognized in other states where such programs are being introduced. For example, Iowa reports that for the time period from March 2007 through December 2007, the drug donation repository received almost 319,000 dosage units worth an estimated $150,000 to program participants who might otherwise not be able to get needed medication. The challenge is to balance the desire to make unused drugs available with the necessity for safety and the limitations on the types of drugs eligible for donation.

As stated above, state and federal law currently limits donation of Schedule II through V drugs; only Schedule VI drugs where official compendium storage requirements are assured and the drugs are in manufacturers' original sealed containers or in sealed individual dose or unit dose packaging that meets official compendium class A or B container requirements are eligible. Additionally, drugs that are restricted in distribution, have an expiration date of less than 90 days from donation or may be considered hazardous cannot be donated and re-dispensed.

It is the responsibility of the pharmacist or pharmacy technician at the donation site to screen drugs for eligibility and to obtain a donor form with contact information and other assurances of proper storage and voluntary donation. The donated drug is thereby tracked from donation to transfer to re-dispensing in order to have a record that ensures compliance with requirements for the program and provides vital information in case of a drug recall or other subsequent issue. While there is some risk with a system in which consumers donate drugs that have been in their possession for re-dispensing to other patients, the Board has included all safeguards necessary to ensure that the risk is minimal. Procedures for collecting donated drugs, storage of such drugs, maintenance of records, destruction of any unused drugs and re-dispensing to patients with valid prescriptions are intended to protect public health and safety within the parameters of a donation program that can be implemented for the public welfare.

Substance

Regulations promulgated pursuant to the legislative mandate set forth requirements for pharmacies that want to register as a drug donation site; criteria for drugs eligible for donation; procedures for collecting donated drugs, including specification of information on a donor form for each drug donated; procedures for transferring and re-dispensing donated drugs; procedures for disposing of any unused donated drugs; and recordkeeping requirements associated with the program.

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 so indicate.

1) The primary advantage of the establishment of a drug donation program is the possibility of an increase in the amount of donated drugs available to persons who utilize free clinics for health care. Additionally, drugs that are donated do not create disposal issues for the water supply or landfills. There are no disadvantages since the criteria for drugs that may be donated to the program are designed to limit the possibility of contamination or adulteration and limit the category to drugs that have no potential for abuse.
2) There are no advantages or disadvantage to the agency or the Commonwealth.
3) There are no other pertinent matters of interest that are not discussed elsewhere in this document.

Requirements more restrictive than federal

There are no requirements of the proposal that are more restrictive than applicable federal requirements.

Localities particularly affected

There are no localities particularly affected.

Public participation

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 may submit comment to the Virginia Regulatory Townhall at **www.townhall.virginia.gov** or submit written comments by mail to Elaine Yeatts at 9960 Mayland Drive, Suite 300, Richmond, VA 23233 or by email to **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 can be found in the Calendar of Events section of the Virginia Register of Regulations. Both oral and written comments may be submitted at that time.

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	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 approximately $1,000 for promulgation of the amended rule, including meetings of the Regulation Committee at which this regulation has been developed. A public hearing would be heard in conjunction with a regularly scheduled board meeting, and to the extent possible, all notifications would be done electronically to minimize the cost. There may be minimal on-going expenditures for the agency related to registration of pharmacies as drug donation sites.
Projected cost of the regulation on localities	None
Description of the individuals, businesses or other entities likely to be affected by the regulation	The businesses affected could be any of the 1647 pharmacies permitted in Virginia; participation is voluntary and expected to be very limited.
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.	It is unknown how many of the permitted pharmacies that are small businesses would register as drug donation sites. Such registration is voluntary.
All projected costs of the regulation for affected individuals, businesses, or other entities.	There are no fees for registration; a pharmacy that chooses to be a drug donation site would incur

Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	some minimal costs for recordkeeping, drug storage and staff time for collection and review of drugs for eligibility to donate and redispense.

Alternatives

There is no option to the promulgation of regulations for the establishment of a drug donation program; it is mandated by Chapter 429 of the 2008 Acts of the Assembly. In order to develop regulations that could be implemented by pharmacies interested in participation in a drug donation program, the Board convened an advisory group consisting of representatives from long-term care and retail pharmacies and DMAS. There was participation in the discussion by representatives of manufacturers, trial lawyers, the Virginia Pharmacists Association and others.

There were a couple of issues identified with the authorizing statute that have been addressed in the passage of HB2352 by the 2009 General Assembly. First, the Virginia Trial Lawyers Association (VTLA) believed that the provision in subsection D of §54.1-3411.1, giving immunity to pharmaceutical manufacturers, was too broad. The organization was concerned that the immunity could extend beyond problems that occurred within the donation program itself and did not want to have a law that would give manufacturers an argument against all product liability. Compromise language amending subsection D and adding subsection E resolved the issue with the concurrence of the VTLA and the Pharmaceutical Research and Manufacturers Association.

The second issue was that the language in subsection C of §54.1-3411.1, which was not new language, expressly prohibited the donation of any drugs paid for by Medicare Part D or Medicaid. The primary source for donated drugs in any drug donation program may be from long term care facilities, and if the majority of these patients are Medicaid or Medicare Part D patients, then the donation program will be limited. CMS does not want drugs donated if the drugs can be returned to the pharmacy for re-sale, and a credit given. That subsection was amended by HB2352 to say provide that unused prescription drugs dispensed for use by persons eligible for coverage under Title XIX or Title XXI of the Social Security Act may be donated unless such donation is prohibited.

Regulatory flexibility analysis

There are no alternative regulatory methods to accomplish the objectives of applicable law.

Public comment

A notice of intended regulatory action was published on April 27, 2009 with comment May 27, 2009. There was no comment received during that period.

Family impact

There is no impact on the family or family stability.

Detail of changes

Current section number	Current requirement	Proposed change and rationale
10	Establishes definitions for words and terms used in the regulation	Adds a definition of a "drug donation site" which must be a permitted pharmacy that registers with the Board for the purpose of receiving or re-dispensing donated drugs. One site may be registered to do both.
400	Deletes the provisions for donation of drugs by nursing homes	With the establishment of regulations for drug donation sites, subsection B of § 54.1-3411.1 (which provides for donation of drugs from nursing homes to free clinics) will be deleted. Accordingly, regulations implementing that subsection are deleted.
New section number	**Current requirement**	**Proposed change and rationale**
740	n/a	Sets out the requirement for registration, including a current, active pharmacy permit, which allows a site to collect, transfer or re-dispense donated drugs to patients of clinics organized in whole or in part for the delivery of health care services to the indigent. It prohibits the sale or distribution of drugs for any other purpose. *The purpose of registration is for the Board to have a record of donation sites, where drugs are being collected, stored, transferred or re-dispensed. Such a record will enable the Board to effectively communicate information to the public and to provide oversight of the program through routine inspections of pharmacies. There is no fee assessed for registration or renewal of registration as a donation site.*
750	n/a	The criteria for eligible drugs are established in state and federal law; they included: 1. Official compendium storage requirements are assured and the drugs are in manufacturers' original sealed containers or in sealed individual dose or unit dose packaging that meets official compendium class A or B container requirements, or better, *Specified in § 54.1-3411.1, subdivision A2.* 2. The drugs bear an expiration date that is not less than 90 days from the date the drug is donated; *An expiration of not less than 90 days is necessary to provide sufficient time for the drug to be screened, processed, transferred, and re-dispensed. It may take time for a patient to present a prescription for a particular drug at the donation site where drugs are being re-dispensed. This helps to ensure the efficacy of the drug for the patient at the free clinic.* and 3. The drugs have not been adulterated or misbranded. *Such drugs would not be eligible for re-dispensing as they could be harmful or ineffective.* Subsection B further provides that the following drugs shall not be

		accepted by a drug donation site: 1. Schedule II-V controlled substances or any other drug, if such return is inconsistent with federal law; 2. Drugs determined to be hazardous for donation based on the pharmacist's professional judgment, experience, knowledge, or available reference materials; 3. Drugs that may only be dispensed to a patient registered with the drug manufacturer under a restricted distribution system; and 4. Drugs that have been previously compounded. *Additional eligibility criteria are necessary to ensure that the drug may be safely re-dispensed without causing patient harm. Drugs that are dispensed only under a restricted distribution system in which a patient has to register with the manufacturer would be too dangerous to include in a donation program (many of those drugs cannot be transferred from one pharmacy to another). Also, drugs that have been compounded have been prepared to be patient-specific and should not be donated for dispensing to another patient.*
760	n/a	Establishes procedures for collecting eligible donated drugs to include: A requirement for a pharmacist or a pharmacy technician under the personal supervision of a pharmacist to receive and conduct the initial screening for eligibility of donated drugs. *An initial screening of donated drugs by a pharmacist or a technician will be necessary because the average consumer may not be aware of the criteria for eligibility.* Once it is determined that a drug is eligible for donation, the donation site must ensure that a donor form is completed and a copy given to the person donating the drug. The donation site must maintain the original donor form. A donor form is not required for drugs donated by a patient residing in a long term care facility or other facility where drugs are administered to that patient, if the drugs are donated directly to the provider pharmacy for that facility and such provider pharmacy is registered as a drug donation site. Subsection C sets out the information that must be on a donor form, including: 1. A statement that the donor is the patient or patient's agent for whom the prescription drug was dispensed; 2. A statement that the donor intends to voluntarily donate the prescription drug for re-dispensing; 3. A statement attesting that the drugs have been properly stored at all times while in the possession of the patient according to official compendium storage requirements; 4. Contact information of the patient or patient's agent; 5. The date of donation; 6. A listing of the donated drugs to include name, strength, and quantity; 7. A statement that private health information will be protected; 8. The signature of the patient or patient's agent; and 9. The initials of the receiving pharmacist, or the initials of the receiving pharmacy technician and supervising pharmacist. *The donor form acts as the invoice for receipt of drugs and is the record that a donation site maintains to verify the quantity and identification of drugs received, transferred, re-dispensed or destroyed. Information on the form is necessary to ensure that the drug is being appropriately donated and to have essential information about the drugs.*

		Subsection C provides that donated prescription drugs must be stored within the prescription department, separate from other drug inventory. *Separate storage is necessary to ensure that donated drugs are not used by the pharmacy for dispensing to persons other than those eligible to receive the drugs through "free clinics."* Subsection D requires that prior to transferring any donated drugs or re-dispensing donated drugs, a pharmacist shall perform a final review of any donated drug for eligibility and shall ensure that all the donor's patient specific information has been removed from previous labeling or rendered unreadable. *The pharmacist at the donation site is responsible for the eligibility of a donated drug and must ensure that patient information from the donor has been effectively removed or is unreadable to protect patient confidentiality.* Subsection E specifies that a drug donation site may not charge a fee for collecting donated drugs.
770	n/a	Section 770 establishes the procedure for transferring donated drugs Subsection A specifies that a drug donation site may only transfer eligible donated prescription drugs to another drug donation site for the purpose of re-dispensing. Subsection B requires that the transferring drug donation site provide a transfer record to the receiving drug donation site that includes the following: 1. The names and addresses of the transferring site and the receiving site; 2. The name, strength, and quantity of each donated drug being transferred; and 3. The date of transfer. *As with other drugs dispensed pursuant to a prescription, this requirement ensures that there is a paper trail of the drug from donation through re-dispensing. Without such requirements, the site receiving the drugs would have no record of what it was receiving and what was available for re-dispensing to a patient with a prescription for a particular drug. If a patient came to a free clinic with a 90-day prescription for 50m. of atenolol to be taken once a day, the dispensing pharmacy at the free clinic would be able to use the transfer record to determine availability of a donated drug.* Subsection C requires the transferring drug donation site to maintain the original transfer record. Subsection D requires that a copy of the transfer record be provided to the receiving drug donation site, the date of receipt shall be recorded on the copy, and the copy be maintained by the receiving drug donation site.
780	n/a	Section 780 sets out the procedure for dispensing of donated drugs Subsection A affirms that a drug donation site re-dispensing donated prescription drugs must comply with applicable federal and state laws and regulations for dispensing prescription drugs. Subsection B states that the pharmacy re-dispensing donated drugs

		may not charge for cost of donated drugs, but may charge a dispensing or administrative fee for each such drug re-dispensed, consistent with provisions of subdivision 10 of §54.1-3301. *Currently, subdivision 10 provides that a free clinic may charge a dispensing or administrative fee not to exceed the current Medicaid dispensing fee. If that section of the Code is amended, the fee for re-dispensing of donated drugs would be consistent with the statute.* C. Recipients of a re-dispensed donated drug shall sign a form prior to receiving the drug that includes a statement that the recipient understands that the drug received has been donated for the purpose of re-dispensing pursuant to §54.1-3411.1. The drug donation site shall maintain this form. D. A drug donation site is under no obligation to obtain a prescription drug that is not in inventory at the time of a request for such drug.
790	n/a	Section 790 sets out the procedures for disposing of donated drugs that cannot be re-dispensed. Subsection A provides that a drug donation site in possession of donated prescription drugs ineligible for re-dispensing shall dispose of such drugs in compliance with 18 VAC110-20-210. Subsection B requires the drug donation site to maintain records of disposal or transfer for disposal of donated prescription drugs separately from other pharmacy disposal records.
800	n/a	Section 800 sets the requirements for maintenance of records. A. All records required for drug donation programs shall be maintained chronologically for two years. B. Records and prescriptions related to donated drugs shall be maintained separately from other pharmacy records. C. Storage of records. 1. Transfer, dispensing, and disposal records may be stored in an electronic database or record; 2. Prescriptions and signed forms, as well as any other records, may be stored as an electronic image which provides an exact, clearly legible, image of the document; or 3. Records may be stored in secured storage, either on or offsite. D. All records in offsite storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent. *All record-keeping requirements for drug donation sites are consistent with those proposed for pharmacies in general in the regulatory review package recently adopted by the Board. In that proposal, there are less restrictive requirements for maintaining records – such as electronic recordkeeping and off-site storage of records – which are reflected in these regulations.*