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Proposed Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC110-30-10 et seq.
VAC Chapter title(s)	Regulations for Practitioners of the Healing Arts to Sell Controlled Substances
Action title	Licenses for practitioners in nonprofit facilities and limited-use permits for facilities
Date this document prepared	3/31/2021

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), 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 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. If applicable, generally describe the existing regulation.

Amendments to Chapter 30 will: 1) amend the term "practitioner" to include nurse practitioners or physician assistants for the purpose of issuance of a limited-use license; and 2) include the allowance for issuance of a limited-use permit for nonprofit facilities for the sale of Schedule VI drugs, excluding the combination of misoprostol and methotrexate, and hypodermic needles and syringes used in administration of such drugs.

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.

N/A

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

Adoption of amendments to regulations by emergency action is required to comply with the second enactment clauses of Chapters 609 and 610 of the 2020 Acts of the General Assembly. The Board of Pharmacy is mandated to promulgate regulations for issuance of limited-use licenses to nonprofit organizations for dispensing of certain drugs and hypodermic needles and syringes for the administration of these drugs..

2. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment.

The proposed regulations will replace emergency regulations currently in effect.

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 and Acts of 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 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 (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system, which shall include provisions for the satisfaction of board-required continuing education for individuals registered, certified, licensed, or issued a multistate licensure privilege by a health regulatory board through delivery of health care services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those health services. 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.).

The specific statutory provisions for regulations governing issuance of a limited-use license for a practitioner at a nonprofit facility are found in:

§ 54.1-3304.1. Authority to license and regulate practitioners; permits.

A. The Board of Pharmacy shall have the authority to license and regulate the dispensing of controlled substances by practitioners of the healing arts. Except as prescribed in this chapter or by Board regulations, it shall be unlawful for any practitioner of the healing arts to dispense controlled substances within the Commonwealth unless licensed by the Board to sell controlled substances.

B. Facilities from which practitioners of the healing arts dispense controlled substances shall obtain a permit from the Board and comply with the regulations for practitioners of the healing arts to sell controlled substances. Facilities in which only one practitioner of the healing arts is licensed by the Board to sell controlled substances shall be exempt from fees associated with obtaining and renewing such permit.

C. The Board of Pharmacy may issue a limited-use license for the purpose of dispensing Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances to a doctor of medicine, osteopathic medicine, or podiatry, a nurse practitioner, or a physician assistant, provided that such limited-use licensee is practicing at a nonprofit facility. Such facility shall obtain a limited-use permit from the Board and comply with regulations for such a permit.

§ 54.1-3467. Distribution of hypodermic needles or syringes, gelatin capsules, quinine or any of its salts.

A. Distribution by any method, of any hypodermic needles or syringes, gelatin capsules, quinine or any of its salts, in excess of one-fourth ounce shall be restricted to licensed pharmacists or to others who have received a license or a permit from the Board.

B. Nothing in this section shall prohibit the dispensing or distributing of hypodermic needles and syringes by persons authorized by the State Health Commissioner pursuant to a comprehensive harm reduction program established pursuant to § 32.1-45.4 who are acting in accordance with the standards and protocols of such program for the duration of the declared public health emergency.

C. Nothing in this section shall prohibit the dispensing or distributing of hypodermic needles and syringes by persons authorized to dispense naloxone in accordance with the provisions of subsection Y of § 54.1-3408 and who, in conjunction with such dispensing of naloxone, dispenses or distributes hypodermic needles and syringes. Nothing in this section shall prohibit the dispensing of hypodermic needles and syringes for the administration of prescribed drugs by

prescribers licensed to dispense Schedule VI controlled substances at a nonprofit facility pursuant to § 54.1-3304.1.

Purpose

Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.

The purpose of the regulation (and the authorizing legislation) is to expand access to certain Schedule VI drugs and hypodermic needles and syringes for the administration of these drugs to underserved persons who seek services from nonprofit clinics. Limited licenses will only be issued for dispensing of Schedule VI drugs, so no drugs scheduled by the Drug Enforcement Administration can be dispensed. There is accountability to the Board of Pharmacy for the facility permit and to the Boards of Medicine and Nursing for the limited license issued to the practitioner. Therefore, there are sufficient protections for the health and safety of the drugs and the citizens of the Commonwealth.

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.

Amendments to Chapter 30 will: 1) amend the term "practitioner" to include nurse practitioners or physician assistants for the purpose of issuance of a limited-use license; and 2) include the allowance for issuance of a limited-use permit for nonprofit facilities for the sale of Schedule VI drugs, excluding the combination of misoprostol and methotrexate, and hypodermic needles and syringes used in administration of such drugs. The allowance set out in § 54.1-3304.1 excludes the sale of a combination of misoprostol and methotrexate, so that is also excluded in regulation.

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 advantage to the public will be the expansion of access to and availability of certain prescription drugs and hypodermic needles and syringes for administration of these drugs at nonprofit clinics. Some of those clinics are run by nurse practitioners or physician assistants, who are otherwise not eligible for a practitioner of the healing arts to sell controlled substances license. There are no disadvantages.
2) There are no advantages or disadvantages to this agency or the Commonwealth.

3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The Board is authorized under § 54.1-2400 to promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that 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.) This proposal is consistent with the agency's statutory responsibility to protect public health and safety and to protect the integrity and safety of prescription drugs in the Commonwealth.

Requirements More Restrictive than Federal

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

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected - none

Localities Particularly Affected - none

Other Entities Particularly Affected – non-profit clinics that dispense medications, such as a free clinic or Planned Parenthood

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is change versus the status quo.

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail;	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

b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	regulation. All notifications will be done electronically. There are no on-going expenditures.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	No impact
For all agencies: Benefits the regulatory change is designed to produce.	No impact

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	None
Benefits the regulatory change is designed to produce.	None

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	Persons likely to be affected by the amendments would be nurse practitioners and physician assistants who provide care in non-profit health clinics that dispense Schedule VI drugs.
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There is no estimate of the number who would be directly affected. There are currently 139 permitted facilities from which doctors who are licensed by the Board of Pharmacy to dispense are practicing, but it is likely most of those are for-profit practices such as Patient First. There is no estimate of the number of non-profit facilities that will seek a limited-use permit for the dispensing of Schedule VI drugs or the number of nurse practitioners or physician assistants who will apply for licensure to dispense.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	The application cost for a facility to obtain a permit to dispense is $315, which includes the cost of an inspection. The cost for a practitioner of the healing arts license (including nurse practitioners and physician assistants in non-profit facilities) is $235. The authorizing legislation was sought by non-profit facilities, which were well-aware of the costs for facility permits and practitioners of the healing arts licensure.
Benefits the regulatory change is designed to produce.	Amendments will allow nurse practitioners and physician assistants practicing at non-profit facilitiessuch as free clinics or Planned Parenthood without an in-house pharmacy to obtain licensure to offer a broader range of health

	care to patients/clients to include dispensing of Schedule VI drugs, excluding the combination of misoprostol and methotrexate,and hypodermic needles and syringes for administration of the drugs.

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.

The second enactment of Chapters 609 and 610 require the promulgation of regulations to implement amended provision of § 54.1-3304.1 of the Code of Virginia. There are no alternatives to the adoption of regulations by the Board.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, 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) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing 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 regulatory change.

There is no regulatory flexibility; the authority to dispense drugs requires a practitioner to be licensed and to dispense from a permitted facility.

Periodic Review and Small Business Impact Review Report of Findings

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

Public Comment

Summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. If no comment was received, enter a specific statement to that effect.

A Notice of Intended Regulatory Action was published on 02/01/2021 for comment until 03/03/2021.
There are no comments posted on Townhall or received by mail by the Board.

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.

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 this 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://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Elaine Yeatts, 9960 Mayland Drive, Suite 300, Richmond, VA 23233; phone (804) 367-4688; fax (804) 527-4434; Elaine.yeatts@dhp.virginia.gov. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage, and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (https://townhall.virginia.gov) and on the Commonwealth Calendar website (https://commonwealthcalendar.virginia.gov/). 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.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
30-10		Sets out definitions for words and terms used in the Chapter	The term “practitioner” is amended to be inclusive of the term “practitioner of the healing arts” which is the term used in § 54.1-3304.1. For the purpose of issuing a limited-use permit for a nonprofit facility,

			the term is also inclusive of a nurse practitioner or a physician assistant.
30-20		Establishes the requirement for an application for a license for a practitioner of the healing arts to sell controlled substances to his/her own patients.	Subsection B is added to include the allowance for issuance of a license for a practitioner as prescribed in subsection C of § 54.1-3304.1. Subsection C is amended to delete language duplicated in the definition of a "practitioner" in section 10.
30-30		Establishes the requirement for an application for a facility permit in which a practitioner of the healing arts may sell controlled substances	Subsection B is added to include the allowance for issuance of a limited-use permit as prescribed in subsection C of § 54.1-3304.1.
30-40		Sets out the acts to be performed by a person who is licensed to sell, including his supervisory responsibilities	Subsection A 2 is amended to clarify that the person being supervised by a licensee would not be another licensee, since each of them is individually responsible for their actions. A physician doesn't supervise the work of another physician and assume responsibility for that person's actions.
30-270		Establishes grounds for disciplinary action	Section 270 is amended to add the categories of practitioner (nurse practitioner and physician assistant) included in the statute.

The proposed regulations are identical to the emergency regulations currently in effect.