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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	Periodic review
Date this document prepared	3/15/22

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 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.

The Board has identified several provisions that it will consider for amendments, including: 1) a change to the definition of "personal supervision" to allow audio-visual technology by pharmacist on premises for supervision of compounding in pharmacies; 2) amendments to the unprofessional conduct section relating to a safe working environment; 3) requirements for additional information on a pharmacy permit or nonresident pharmacy registration application; 4) requirement for an applicant for a pharmacy permit to report to the Board any prior disciplinary action by a regulatory authority, prior criminal convictions, or ongoing investigations related to the practice of pharmacy; 5) an allowance for a pharmacist to use his professional judgment to alter or adapt a prescription, to change dosage, dosage form or directions, to complete missing information, or to extend a maintenance drug; 6) change in the provision that allows dispensing of a Schedule II drug for up to six months after the date on which the prescription was issued; 7) removal of the restriction that a stat-drug box contain no

more than 20 solid dosage units per schedule of Schedules II through V drugs; and 8) clarification regarding administration records, particularly if drug administered by someone other than the pharmacist whose initials are captured on the dispensing record.

Acronyms and Definitions

Define all acronyms or technical definitions used in this form.

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."

The impetus for this regulatory action is implementation of recommendations from the Board's periodic review of regulations. A General Notice was published with comment on the report of results requested from January 17, 2022 to February 25, 2022. There was one comment on this chapter.

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 statutory authority for the Board to promulgate regulations to regulate the practice of pharmacy is found in:

§ 54.1-3307. Specific powers and duties of Board.

A. The Board shall regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices. The Board shall also control the character and standard of all drugs, cosmetics and devices within the Commonwealth, investigate all complaints as to the quality and strength of all drugs, cosmetics, and devices and take such action as may be necessary to prevent the manufacturing, dispensing, selling, distributing, processing, compounding and disposal of such drugs, cosmetics and devices that do not conform to the requirements of law.

The Board's regulations shall include criteria for:

1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered.

2. Compliance with the prescriber's instructions regarding the drug, its quantity, quality and directions for use.

3. Controls and safeguards against diversion of drugs or devices.

4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.

5. Maintenance of complete records of the nature, quantity or quality of drugs or substances distributed or dispensed, and of all transactions involving controlled substances or drugs or devices so as to provide adequate information to the patient, the practitioner or the Board.

6. Control of factors contributing to abuse of legitimately obtained drugs, devices, or controlled substances.

7. Promotion of scientific or technical advances in the practice of pharmacy and the manufacture and distribution of controlled drugs, devices or substances.

8. Impact on costs to the public and within the health care industry through the modification of mandatory practices and procedures not essential to meeting the criteria set out in subdivisions 1 through 7 of this section.

9. Such other factors as may be relevant to, and consistent with, the public health and safety and the cost of rendering pharmacy services.

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 amendments being considered are necessary to protect public health and safety by ensuring that pharmacists are working under conditions that allow for safe practice and by removing any barriers to practice that are not essential to the security and efficacy of drugs being dispensed.

Substance

Briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

The Board has identified several sections that it will consider for amendments:

- Section 10, amend definition of "personal supervision" to allow audio-visual technology by pharmacist on premises for supervision of compounding in pharmacies
- Section 25, amend the unprofessional conduct section to add language such as:
    - acting in a manner that causes an individual to feel threatened or intimidated so that such individual is discouraged from reporting a public safety concern in good faith or is discouraged from cooperating with an employee of the Department of Health Professions in the conduct of an investigation or inspection.
    - failure to provide a working environment for all pharmacy personnel that protects the health, safety, and welfare of a patient including:
        - sufficient personnel to prevent fatigue, distraction, or other conditions that interfere with a pharmacist's ability to practice with competency and safety or creates an environment that jeopardizes patient care;
        - appropriate opportunities for uninterrupted rest periods and meal breaks;
        - adequate time for a pharmacist to complete professional duties and responsibilities including:
            - drug utilization review;
            - immunization;
            - counseling;
            - verification of the accuracy of a prescription
    - introducing external factors such as productivity or production quotas or other programs to the extent that they interfere with the ability to provide appropriate professional services to the public;
    - incentivizing or inducing the transfer of a prescription absent professional rationale.
- Section 110, amend to address appropriate opportunities for uninterrupted rest periods and meal breaks which may or may not require the pharmacy to close.
- Section 110, amend to include additional information to be required on a pharmacy permit or nonresident pharmacy registration application and include a requirement to notify board of any changes within timeframe consistent with current laws.

- Section 110, subsection J, amend to require an applicant for a pharmacy permit to report to the Board any prior disciplinary action by a regulatory authority, prior criminal convictions, or ongoing investigations related to the practice of pharmacy
- Section 110, extending timeframe beyond 14 days for notification of a change in the PIC
- Section 270, allow a pharmacist to use his professional judgment to alter or adapt a prescription, to change dosage, dosage form or directions, to complete missing information, or to extend a maintenance drug.
- Including a requirement for an e-profile identification number for facilities
- Extending timeframe beyond 14 days for notification of a change in the PIC
- Section 275, subsections B, C, and F, consider including exemption to requirement for returning to initiating pharmacy any prescriptions not delivered to the patient if prohibited under federal law.
- Section 275, amend to include record requirement for an alternate delivery site further delivering the drug to a patient's home.
- Section 290, consider amendment to provision that allows dispensing of a Schedule II drug for up to six months after the date on which the prescription was issued
- Section 550, amend to remove the restriction that a stat-drug box contain no more than 20 solid dosage units per schedule of Schedules II through V drugs
- Section 690 to prohibit controlled substance registration from being issued to private dwelling or residence just as there is a current prohibition on such issuance of a pharmacy permit.
- Clarifying expectation regarding administration records, particularly if drug administered by someone other than the pharmacist whose initials are captured on the dispensing record.
- Including a requirement for an e-profile identification number for facilities.
- Clarifying that pharmacists and pharmacy technicians may administer CLIA-waived tests.
- Clarifying that pharmacy technicians may independently take medication histories including drug name, dose, and frequency.
- Allowing a nationally certified pharmacy technician to electronically transfer a Schedule VI refill prescription that is not an on-hold prescription when authorized by the pharmacist-in-charge.

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.

Licenses and permits issued by the Board of Pharmacy are mandated by Chapter 33 of Title 54.1 of the Code of Virginia. There are no alternatives for implementation of the mandates other than the promulgation of reasonable regulations that are enforceable and protect the public health and safety.

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, and (iii) the potential impacts of the regulation.

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 Erin Barrett, 9960 Mayland Drive, Suite 300, Henrico, VA 23233; (804) 367-4688; FAX (804) 527-4434; erin.barrett@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.