



Notice of Intended Regulatory Action (NOIRA) 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	Unprofessional conduct
Document preparation date	12/27/07

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

In its proposed regulatory action, the Board intends to add a section on unprofessional conduct to address certain issues and licensee conduct that has been problematic. The Board will consider adding rules to include, but not be limited to, patient confidentiality, unethical behavior, sexual misconduct, assault on a patient or another employee, inappropriate delegation of pharmacy acts to subordinates.

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., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

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 Code of Virginia has established grounds for disciplinary actions by the Board of Pharmacy against its licensees. Regulations on standards of conduct would expand and clarify the statutory provisions.

§ 54.1-3316. Refusal; revocation; suspension and denial.

The Board may refuse to admit an applicant to any examination; refuse to issue a license, permit, certificate, or registration to any applicant; or reprimand, impose a monetary penalty, place on probation, impose such terms as it may designate, suspend for a stated period of time or indefinitely, or revoke any license, permit, certificate, or registration if it finds that an applicant or a person holding a license, permit, certificate, or registration:

1. Has been negligent in the practice of pharmacy or in any activity requiring a license, permit, certificate, or registration from the Board;
2. Has engaged in unprofessional conduct specified in regulations promulgated by the Board;
3. Has become incompetent to practice pharmacy or to engage in any activity requiring a license, permit, certificate, or registration from the Board because of a mental or physical condition;
4. Uses drugs or alcohol to the extent that he is rendered unsafe to practice pharmacy or to engage in any activity requiring a license, permit, certificate, or registration from the Board;
5. Has engaged in or attempted any fraud or deceit in connection with the practice of pharmacy or any activity requiring a license, permit, certificate, or registration from the Board, including any application to the Board for such license, permit, certificate, or registration;
6. Has engaged in activities beyond the scope of a license, permit, certificate, or registration or has assisted or allowed unlicensed persons to engage in the practice of pharmacy or perform duties related to the practice of pharmacy for which a license or registration is required;
7. Has violated or cooperated with others in violating any provisions of law or regulation relating to practice of pharmacy or any activity requiring a license, permit, certificate, or registration from the Board;

8. Has had revoked or suspended any registration issued by the United States Drug Enforcement Administration or other federal agency that is necessary to conduct an activity also requiring a license, permit, certificate, or registration from the Board;
9. Has engaged in the theft or diversion of controlled substances or has violated any federal drug law or any drug law of Virginia or of another state;
10. Has had denied, suspended, or revoked in any other state a license to practice pharmacy or any license, permit, certificate, or registration necessary to conduct an activity requiring a license, permit, certificate, or registration from the Board, or has surrendered in another state such license, permit, certificate, or registration;
11. Has been convicted of any felony or of any misdemeanor involving moral turpitude;
12. Has issued or published statements intended to deceive or defraud about his professional service or an activity requiring a license, permit, certificate, or registration from the Board;
13. Has conducted his practice, or activity requiring a license, permit, certificate, or registration from the Board in such a manner as to be a danger to the health and welfare of the public; or
14. Has failed to comply with requirements of this chapter or any regulation of the Board relating to continuing education.

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed. Include the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. Delineate any potential issues that may need to be addressed as the regulation is developed.

The 2007 General Assembly amended the statutes relating to grounds for denial or disciplinary action against a license by the Board of Pharmacy. The previous, very narrowly-defined section relating to “unprofessional conduct” was repealed and those activities specifically listed in Section 54.1-3316 (11) and (12) as grounds for disciplinary action. In addition, Section 54.1-3316 (4) was expanded to include unprofessional conduct “specified in regulations promulgated by the Board.” The intent of this action is to promulgate such regulations.

After publication of the Notice of Intended Regulatory Action, the Board will consider any comment received and will utilize regulations from other boards and a compilation of unprofessional conduct provisions from other states to determine those provisions that should be set out in regulation to ensure that the Board has the necessary authority to protect the public health and safety from unprofessional conduct or substandard care.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action.

The Board has been aware that there has been practitioner misconduct or substandard patient care not currently addressed in law or regulation. In some cases, current provisions are general enough to incorporate that conduct and establish grounds for disciplinary actions. However, there is a need to further specify certain provisions in order to give licensees a more precise regulatory standard by which to practice and to authorize the Board to act more decisively.

To assist board members in consideration of issues relating to unprofessional conduct, board staff compiled an extensive document consisting of regulations of other health profession boards (Medicine, Audiology & Speech-Language Pathology, Counseling, Physical Therapy, Psychology & Nursing) and of pharmacy regulations from some other states. From that document, the Board will identify provisions that are necessary for public protection in Virginia. In the development of regulatory language, the Board will identify conduct that should be addressed in regulation and will utilize applicable regulations from other sources.

Family impact

Assess the potential 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.

There is no impact of the proposed regulatory action on the institution of the family and family stability.