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	Unprofessional conduct
Date this document prepared	2/26/09

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

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.

In its proposed regulatory action, the Board has added a section on unprofessional conduct to address certain issues and licensee conduct that have been problematic and to supplement the statutory provision in § 54.1-3316 that establishes grounds for disciplinary action based on "unprofessional conduct specified in regulations promulgated by the Board." The Board has added rules to include, but not be limited to, patient confidentiality, unethical behavior, sexual misconduct, failure to report a know dispensing error in a manner that protected the public, and inappropriate delegation of pharmacy acts to subordinates.

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.

PIC = pharmacist-in-charge

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.

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 will 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.

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 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 utilizing regulations from other boards and a compilation of unprofessional conduct regulations from other states to determine those provisions that should be set out in Virginia regulation, the Board developed regulatory language to ensure that it has the necessary authority to protect the public health and safety from unprofessional conduct or substandard care.

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.)

The Board has added section 25, which provides that certain practices shall constitute unprofessional conduct within the meaning of the Code of Virginia in § 54.1-3316.

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 this proposal is greater protection for the public by having clearer, more definitive language about behaviors and actions that may constitute unprofessional conduct in a pharmacy. There are no disadvantages.
2) There are no disadvantages of these provisions to the agency or the Commonwealth; more specific provisions in regulation to supplement those stated in the Code will allow more explicit charges in a disciplinary notice, which will be beneficial to both the agency and the respondent. The Board does not anticipate more than a 4 or 5 additional disciplinary proceedings or notices of disciplinary action, because it currently manages to state the charges for such conduct under general provisions of the Code.
3) There are no other pertinent matters.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal, which are more restrictive than applicable federal requirements. Include 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 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 by the proposed regulation.

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 by mail, email or fax 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. Comments may also be submitted on the Regulatory Townhall at: **www.townhall.virginia.gov** 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 requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including	a) As a special fund agency, the Board must generate

(a) fund source, and (b) a delineation of one-time versus on-going expenditures.	sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation; b) The agency will incur some one-time costs (less than $1,000) for mailings to the Public Participation Guidelines mailing lists and conducting a public hearing. Every effort will be made to incorporate those into anticipated mailings and meetings already scheduled; there are no on-going expenditures.
Projected cost of the *new regulations or changes to existing regulations* on localities.	There are no costs to localities.
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	Pharmacists, pharmacy interns, pharmacy technicians and pharmacies are all subject to these regulations.
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.	Pharmacists – 9964 Pharmacy interns – 1396 Pharmacy technicians – 9502 Pharmacies – 1688 (resident) & 544 (non-resident) The persons regulated by these regulated would be employed by pharmacies, and it is unknown how many of those are small businesses. Most pharmacies are part of a large chain operation or contained within a hospital system.
All projected costs of the *new regulations or changes to existing regulations* for affected individuals, businesses, or other entities. Please be specific and do 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 regulations.	There are no costs for compliance.
Beneficial impact the regulation is designed to produce.	Will enable to the Board to more effectively discipline unprofessional conduct by increased specificity and will serve as an educational tool for licensees.

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.

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 identified general provisions that are necessary for public protection in Virginia. In the development of regulatory language, the Board also identified certain misconduct unique to the practice of pharmacy that should be addressed in regulation.

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.

The Board could continue to rely on the broad authority it has through the statute to charge respondents with misconduct, but there are gaps and generalities in the statutory provisions that the promulgation of regulations will address. § 54.1-3316 provides that the Board specify *in regulation* those actions or behaviors that would be considered unprofessional conduct.

Public comment

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

There were no comments received during the public comment period following publication of the NOIRA on June 9, 2008. Thereafter, the Board developed draft language for section 25 on unprofessional conduct and discussed the draft at a meeting held on September 3, 2008. Since there were questions from board members and others, the draft was referred to the Regulation Committee, which met on November 13, 2008. In the interim, the draft was distributed to interested parties for comment, concerns, additions, etc. With the exception of a couple of requests for clarification, responses from all pharmacy-related associations and groups were supportive of the draft, which was subsequently adopted by the Board at its meeting on December 10, 2008.

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.

There is no potential impact on the institution of the family.

Detail of changes

Please detail 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 detail the difference between the requirements of the new provisions and the current practice or if applicable, the requirements of other existing regulations in place.

The proposal adds a new section of regulation, numbered 25.

18VAC110-20-25. Unprofessional conduct.

The following practices shall constitute unprofessional conduct within the meaning of § 54.1-3316 of the Code of Virginia:

1. Failing to comply with provisions of § 32.1-127.1:03 of the Code of Virginia related to the confidentiality and disclosure of patient records or related to provision of patient records to another practitioner or to the patient or his personal representative;

While the Code specifies that a violation of laws and regulations governing the practice of pharmacy, there is no provision for a violation of patient privacy or other provisions in the Health Records Act. With this addition, the Board could charge a licensee with unlawful disclosure of patient records or failing to provide a patient record upon request. If a pharmacist refuses to give another pharmacy or a prescriber a patient record, at the patient's request, it could be detrimental to the patient health and safety.

2. Willfully or negligently breaching the confidentiality of a patient, unless otherwise required or permitted by applicable law;

A breach of confidentiality may occur beyond the disclosure of a patient record; it could involve a pharmacist (or intern or technician) who discusses the prescriptions that have been filled for a specific patient with friends or others – thus negligently breaching confidentiality.

3. Failing to maintain confidentiality of information received from the Prescription Monitoring Program, obtaining such information for reasons other than to assist in determining the validity of a prescription to be filled, or misusing information received from the program;

Confidentiality of information in the Prescription Monitoring Program is absolutely essential to its effectiveness, so a breach of that confidentiality or use of the information contained therein could be a serious act of unprofessional conduct.

4. Engaging in disruptive or abusive behavior in a pharmacy or other health care setting that

interferes with patient care or could reasonably be expected to adversely impact the quality of care rendered to a patient;

The Board has had a report of a pharmacist striking a patient in the pharmacy; the behavior that would constitute a violation would have to be disruptive or abusive that interferes or adversely affects patient care. A billing dispute, an argument with a co-worker, and other similar actions would not likely be considered disruptive or abusive unless they escalated into a situation in which patients are adversely affected.

5. Engaging or attempting to engage in a relationship with a patient that constitutes a professional boundary violation in which the practitioner uses his professional position to take advantage of the vulnerability of a patient or his family, including but not limited to sexual misconduct with a patient, or other conduct that results or could result in personal gain at the expense of the patient;

This provision is identical to regulatory language found in other board regulations; the intent is to include sexual misconduct with a patient but broaden the scope of the provision to include a boundary violation in which the pharmacist uses his position to take advantage of a patient or his family.

6. Failing to maintain adequate safeguards against diversion of controlled substances;

Since the pharmacy is responsible of the safety and security of the drugs, this provision would make it clear that if there is ongoing diversion of drugs, the pharmacy and/or the pharmacist may also be held responsible by not having effective systems in place to detect diversion.

7. Failing to appropriately respond to a known dispensing error in a manner that protects the health and safety of the patient;

A couple of comments from interested parties requested clarification of this provision and were satisfied that it was clear that the pharmacist could not be responsible for dispensing errors that were not known to him (patient discovers that he has the wrong medication) and does not report it to the pharmacist). The pharmacist is required to respond to a known dispensing error appropriately (calling the patient to notify them, calling the prescriber to describe the error and any possible problem from an incorrect dosage, etc.)

8. Delegating a task within the practice of pharmacy to a person who is not adequately trained to perform such a task;

There is a scope of practice for a pharmacy technician and pharmacy intern, but the supervising pharmacist is responsible for their action, and therefore is responsible for delegating only those tasks for which someone has been adequately trained.

9. Failing by the PIC to ensure that pharmacy interns and pharmacy technicians working in the pharmacy are registered, and that such registration is current;

Initially, this provision placed the responsibility on any pharmacist in the pharmacy to ensure that interns and technicians were appropriately registered, but the Board determined that it was an unrealistic expectation for many pharmacies in which there may be a number of part-time pharmacists working. Therefore, the regulation was amended to specify the PIC, the pharmacist-in-charge, who is responsible for ensuring that technicians and interns are currently registered with the Board.

10. Failing to exercise professional judgment in determining whether a prescription meets requirements of law before dispensing.

§ 54.1-3303 requires a dispensed to ensure that there has been a practitioner-patient relationship established for a valid prescription. It is incumbent on the pharmacist to check on a prescription for which he has uncertainty about its validity. Pharmacists must use professional judgment in determining the extent to which they must go to make that

	determination, so a violation of this provision would be determined on a case-by-case basis.