Form: TH- 02

Virginia
Regulatory
Town Hall

Proposed Regulation
Agency Background Document

Agency Name:	Board of Pharmacy, Department of Health Professions
VAC Chapter Number:	18 VAC 110-30
Regulation Title:	Regulations Governing the Physicians Selling Drugs
Action Title:	Review of regulations
Date:	1-24-00

This information is required pursuant to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99), and the *Virginia Register Form,Style and Procedure Manual*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

Amendments to regulations are proposed pursuant to a review of the regulations governing physicians selling who sell prescription drugs in their practice. The regulations are amended to provide consistency with current practices in pharmacy and with the Board's regulations for licensed pharmacies. Requirements for inspections, storage of drugs, access to selling areas, disposal of unwanted drugs, and electronic maintenance of records have been modified to conform them to pharmacy regulations and reduce the regulatory burden. Other requirements, such as those for labeling and special packaging have been amended for consistency with current law. The rules are intended to ensure the health, safety and welfare of the consumer who purchases prescriptions from a physician and for the security and integrity of prescription drugs consistent with the Board's statutory mandate in Chapters 33 and 34 of Title 54.1 of the Code of Virginia.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

18 VAC 110-30-10 et seq. Regulations Governing the Physicians Selling Drugs was promulgated under the general authority of Title 54.1 of the Code of Virginia.

Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations, levy fees, administer a licensure and renewal program, and discipline regulated professionals.

§ 54.1-2400. General powers and duties of health regulatory boards.--The general powers and duties of health regulatory boards shall be:

1. To establish the qualifications for registration, certification or licensure in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.

2. To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.

3. To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.

4. To establish schedules for renewals of registration, certification and licensure.

5. To levy and collect fees for application processing, examination, registration, certification or licensure and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory boards.

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 and Chapter 25 of this title.

7. To revoke, suspend, restrict, or refuse to issue or renew a registration, certificate or license which such board has authority to issue for causes enumerated in applicable law and regulations.

8. To appoint designees from their membership or immediate staff to coordinate with the Intervention Program Committee and to implement, as is necessary, the provisions of Chapter 25.1 (§ 54.1-2515 et seq.) of this title. Each health regulatory board shall appoint one such designee.

9. To take appropriate disciplinary action for violations of applicable law and regulations.

10. To appoint a special conference committee, composed of not less than two members of a health regulatory board, to act in accordance with § 9-6.14:11 upon receipt of information that a practitioner of the appropriate board may be subject to disciplinary action. The special conference committee may (i) exonerate the practitioner; (ii) reinstate the practitioner; (iii) place the practitioner on probation with such terms as it may deem appropriate; (iv) reprimand the practitioner; (v) modify a previous order; and (vi) impose a monetary penalty pursuant to § 54.1-2401. The order of the special conference committee shall become final thirty days after service of the order unless a written request to the board for a hearing is received within such time. If service of the decision to a party is accomplished by mail, three days shall be added to the thirty-day period. Upon receiving a timely written request for a hearing, the board or a panel of the board shall then proceed with a hearing as provided in § 9-6.14:12, and the action of the committee shall be vacated. This subdivision shall not be construed to affect the authority or procedures of the Boards of Medicine and Nursing pursuant to §§ 54.1-2919 and 54.1-3010.

11. To convene, at their discretion, a panel consisting of at least five board members or, if a quorum of the board is less than five members, consisting of a quorum of the members to conduct formal proceedings pursuant to § 9-6.14:12, decide the case, and issue a final agency case decision. Any decision rendered by majority vote of such panel shall have the same effect as if made by the full board and shall be subject to court review in accordance with the Administrative Process Act. No member who participates in an informal proceeding conducted in accordance with § 9-6.14:11 shall serve on a panel conducting formal proceedings pursuant to § 9-6.14:12 to consider the same matter.

12. To issue inactive licenses and certificates and promulgate regulations to carry out such purpose. Such regulations shall include, but not be limited to, the qualifications, renewal fees, and conditions for reactivation of such licenses or certificates.

The authority for the Board to issue licenses to physicians to dispense drugs is found in § 54.1-3304:

§ 54.1-3304. Licensing of physicians to dispense drugs; renewals.
For good cause shown, the Board may grant a license to any physician licensed under the laws of Virginia authorizing such physician to dispense drugs to persons to whom a pharmaceutical service is not reasonably available. This license may be renewed annually. Any physician or

osteopath so licensed shall be governed by the regulations of the Board of Pharmacy when applicable.

The office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the proposed is to amend regulations pursuant to changes in a review of the regulations governing physicians selling who sell prescription drugs in their practice. The regulations are proposed to ensure the protection for the health, safety and welfare of the consumer who purchases prescriptions from a physician and for the protection and integrity of prescription drugs consistent with the Board's statutory mandate in Chapters 33 and 34 of Title 54.1 of the Code of Virginia.

The proposed regulations promulgated by the Board are essential to protect patients in the Commonwealth whose health is dependent on the accuracy and availability of prescription drugs. The regulations for physicians selling drugs out of their practice are intended to provide the same public protection and assurance of drug safety and efficacy as do the regulations for pharmacists selling drugs out of the pharmacy. Rules for record-keeping, inventories, labeling, packaging, disposal, etc. were intended to be consistent for both types of practitioners, since the physician who is filling and dispensing prescriptions from his practice is engaged in the practice of pharmacy. Over the years, there have been numerous changes in the law and in regulations for the practice of pharmacy which have not been correspondingly made in 18 VAC 110-30-10 et seq.

Some amendments to regulations for physicians selling drugs are necessary for greater clarity and consistency, and others are intended to ensure that requirements are reflective of the current practice of pharmacy and are sufficient to provide the patient with safe, efficient service while protecting as much as possible against drug diversion.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement providing detail of the regulatory action's changes.

18 VAC 110-30-10. Definitions.

The proposed amendments define the terms "board", "controlled substance" and "sale" in order to provide clarity in the interpretation and enforcement of the regulations. The definition of "practitioner" is modified because the Board of Medicine now issues an inactive license, the holder of which would not be qualified to sell prescription drugs.

18 VAC 110-30-15. Fees.

The Board has proposed a new section to consolidate all fee requirements which are currently listed in sections 20 and 30. The $300 fee for reinstatement of a license that has been revoked or suspended indefinitely is consistent with a similar fee for pharmacists.

18 VAC 110-30-20. Application for licensure.

Amendments are added to clarify the eligibility of a licensed practitioner to apply for licensure to sell drugs. Since the Board of Medicine is now authorized to issue inactive licenses, it is necessary to specify that an applicant must hold a current, active license to practice and that any disciplinary action taken by the Board of Medicine will constitute grounds for denial, restriction or other disciplinary action by the Board of Pharmacy.

18 VAC 110-30-30. Renewal of license.

Changes are proposed for editing and removal of references to specific fees now included in section 15.

18 VAC 110-30-31. Inactive status.

Amendments (previously in section 60) set forth the conditions for election of an inactive license and the requirements by which it may be reactivated.

18 VAC 110-30-50. Licensees ceasing to sell controlled substances; inventory required prior to disposal.

An amendment allows the licensee who no longer desires to sell controlled substances to take an inactive status or surrender his license. Also, an amendment is added to clarify that the term "practitioner" means, in this case, a person "authorized by law to possess such drugs."

18 VAC 110-30-60. Inactive status.

The section is repealed and requirements now set forth in section 31.

18 VAC 110-30-70. Maintenance of a common stock of controlled substances.

An amendment is proposed to specify that an inspection is only required prior to issuance of the first license to any one location. Subsequent licenses may be issued without an inspection at the discretion of the Board.

18 VAC 110-30-90. Physical standards.

An amendment to this section is proposed to conform these regulations to the physical standards established by regulation for a pharmacy. For example, drugs maintained for administration or samples (not for sale) may be stored in the pharmacy provided they are clearly separate from the rest of the stock.

18 VAC 110-30-100. Access to selling area.

The amended language addresses a question which often arises about whether the selling and storage area could be within a physician's office; it would be allowed provided certain criteria set forth in the regulation are met.

18 VAC 110-30-110. Minimum equipment.

The amendments are consistent with amendments to pharmacy regulations and eliminate or modify requirements according to more current standards.

18 VAC 110-30-160. Disposal of Schedule II through VI controlled substances.

Amendments are proposed to make regulations consistent with current DEA requirements and with those currently in effect for licensed pharmacies.

18 VAC 110-30-170. Sign and written prescription requirements.

An amendment modifying the disclosure sign is proposed to make the requirement clearer.

18 VAC 110-30-190. Manner of maintaining records for Schedule II through VI controlled substances sold.

An amendment is proposed to allow the maintenance of records in an automated data processing system; it is consistent with such requirements for a licensed pharmacy.

18 VAC 110-30-200. Automated data processing records of sale.

An amendment clarifies that the signature of a licensee on the printout or logbook only verifies the accuracy of data entered under his initials. If there are multiple licensees creating dispensing records in the database, each must sign daily.

18 VAC 110-30-210. Repackaging of controlled substances; records required; labeling requirements.

An editorial amendment in the title of the section has been proposed.

18 VAC 110-30-220. Labeling of prescription as to content and quantity.

Amendments to this section conform the labeling requirements to those specified in the general pharmacy regulations and currently required by state and federal law.

18 VAC 110-30-240. Special packaging.

Amendments to this section conform the special packaging requirements to those specified in the general pharmacy regulations and currently required by state and federal law.

18 VAC 110-30-255. Purchase of drugs.

An amendment is proposed to specify that a licensee may only purchase drugs from a wholesale distributor licensed or registered by the board. An identical provision was recently added to regulations for pharmacies.

18 VAC 110-30-260. Returning of controlled substances.

An amendment clarifies that any return of controlled substances must be consistent with federal law and regulations.

18 VAC 110-30-270. Grounds for disciplinary action.

Grounds for disciplinary action currently set forth in section 270 are also found in

§ 54.1-3316 of the Code of Virginia and are therefore unnecessary in regulation. An amendment specifies that a licensee who has had disciplinary action by a board of medicine or who no longer holds an active, current license may have an application for renewal or initial issuance denied.

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 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, please include a sentence to that effect.

ISSUE: Need to update regulations for greater consistency with laws and regulations governing the practice of pharmacy.

18 VAC 110-30-10 et seq. has not been amended since November 3, 1993. When the Board conducted its last regulatory review pursuant to Executive Order 15 (94), there were several "housekeeping" amendments recommended, but regulatory action was not initiated. Since that time, the general regulations for the practice of pharmacy have been amended a number of times to conform requirements in current practice and procedures that have changed with the advent of newer technology. For example, the rules for Physician Selling Drugs do not provide for the maintenance of records in a data system with the ability to produce a hard copy of the

record. Likewise, rules of the DEA on the return and disposal of unwanted drugs have changed and need to be amended in these regulations accordingly.

The amended rules also allow for more flexibility in the utilization of space within the doctor's office and in the storage of controlled substances maintained for other purposes, such as administration and sample-distribution. Amendments would also remove unnecessary requirements such as maintaining a copy of the USPDI reference book and allow the use of an electronic scale rather than prescription balances and weights. The specific grounds for disciplinary action listed in section 270 are unnecessary because they are already provided in § 54.1-3316 of the Code of Virginia, which has now been cited in regulation.

During its current review of regulations, the Board determined that it was necessary to address the issue of providing greater utilization of technology. The Board considered and recommended several revisions in the manner of maintaining records, in the provisions for disposal of Schedule II through V controlled substances and in other areas where physicians may employ better technology while continuing to protect the public and the safety of the drug supply.

In addition, regulations for physicians selling drugs are not consistent with the law and rules for pharmacists in such areas as the labeling of prescriptions and the requirements for counseling of patients prior to dispensing and delivering a prescription to a patient. In addressing the issue of inconsistency with the law and regulations for the practice of pharmacy, the Board considered revisions that are necessary to protect the public. For example, the current rule for making an exception to providing child-proof packaging is for the pharmacist to have a signed release by the patient. That protection for both the consumer and the person filling the prescription has been more clearly spelled out in this regulation. The statutory requirements for information that is to be included on a prescription label have changed and need to be reflected in amendments to this regulation. The statute requires that any entity that engages in the wholesale distribution of drugs in the Commonwealth be licensed as a wholesale distributor. Regulations for pharmacies require that they purchase only from a licensed distributor; regulations for physicians who sell drugs need to be consistent.

Effective in 2000, physicians may elect to take an inactive status at the time of their biennial renewal. Therefore, the Board of Pharmacy had to consider an amendment to specify that a license to sell and dispense prescription drugs could only be issued to a physician who holds an active license. It was also necessary to clarify that any disciplinary action taken by the Board of Medicine or any other medical board could constitute grounds for denial or restrictions on the license to sell.

Advantages and disadvantages

There are no disadvantages of amended regulations to the public or the regulated entities. Patients are better served and protected by consistency with law and regulation governing the practice of pharmacy. Greater utilization of technology and more flexibility in the selling area and storage of prescription drugs may enhance the ability of practitioners to serve their patients. Amended regulations should provide more clarity which is beneficial to practitioners

seeking to comply with rules of the Board.

Likewise, there are no disadvantages to the agency. Amendments to regulations will make the rules governing physicians selling drugs more clear and in conformity with current law and therefore more enforceable.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

Projected cost to the state to implement and enforce:

(i) Fund source: As a special fund agency, the Board of Pharmacy must generate sufficient revenue to cover its expenditures from non-general funds, specifically the fees it charges to physicians selling drugs for necessary functions of regulation.

(ii) Budget activity by program or subprogram: There is no change required in the budget of the Commonwealth as a result of this program.

(iii) One-time versus ongoing expenditures: The agency will incur some costs (less than $3000) for mailings to the Public Participation Guidelines Mailing List, conducting a public hearing, and sending copies of final regulations to regulated entities. However, every effort will be made to incorporate those into anticipated mailings and board meetings already scheduled.

Projected cost on localities:

There is no projected costs to localities.

Description of entities that are likely to be affected by regulation:

The entities that are likely to be affected by these regulations would be physicians who sell prescription drugs in their practice because those services are not readily available from pharmacies in the marketplace due to geographic isolation or other factors. There would be no additional costs for compliance with these regulations for physicians selling drugs. Fees for applications and renewals are not being changed, and no new requirements for which would additional costs would be incurred are being imposed. For some licensees, there may be modest savings since the utilization of automated data processing has been made less burdensome and a required reference volume has been eliminated. For a few licensees, the new

provision permitting the selling and dispensing area to be located within the doctor's personal office may alleviate the need for the creation of a separate space for that purpose.

Estimate of number of entities to be affected:

There are currently 243 physicians licensed to dispense drugs in the Commonwealth.

Projected costs to the affected entities:

There would be no additional costs for compliance with these regulations for physicians selling drugs. Fees for applications and renewals are not being changed, and no new requirements for which would additional costs would be incurred are being imposed. For some licensees, there may be modest savings since the utilization of automated data processing has been made less burdensome and a required reference volume has been eliminated. For a few licensees, the new provision permitting the selling and dispensing area to be located within the doctor's personal office may alleviate the need for the creation of a separate space for that purpose.

Citizen input in development of regulation:

In the development of regulations through the Regulation Committee and the board, opportunities for citizen input were made available. The Board drafted regulations with a consideration for any fiscal impact on licensees and for consistency with the current practice and regulation of pharmacies. The Board does not anticipate a negative impact on the entities affected by regulation or on the public.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

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Alternatives

Please describe the specific 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.

These regulations have not been amended since November 3, 1993. When the Board conducted its last regulatory review pursuant to Executive Order 15 (94), there were several "housekeeping" amendments recommended, but regulatory action was not initiated. Since that time, the general regulations for the practice of pharmacy have been amended a number of times to conform requirements to current practice and procedures which have changed with the advent of newer technology. For example, the rules for Physician Selling Drugs do not provide for the maintenance of records in a data system with the ability to produce a hard copy of the record. Rules of the DEA on the return and disposal of unwanted drugs have changed and need to be amended in these regulations accordingly.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

The Notice of Intended Regulatory Action was published on September 27, 1999 and subsequently sent to the Public Participation Guidelines Mailing List of the Board; there was no comment received.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

Prior to that adoption of proposed amendments, the Regulatory Committee of the Board met in an open meeting to review the current regulations in light of regulations governing the practice of pharmacy. The clarity and reasonableness of the language that was adopted had the approval of the Assistant Attorney General who worked with the Regulatory Committee in drafting regulatory language and of the board members who represent various types of pharmacy practice and the citizens of the Commonwealth.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

Public Participation Guidelines of the Board of Pharmacy (18 VAC 110-10-10 et seq.) require a thorough review of regulations each biennium. Therefore, the Regulation Committee of the Board will review this set of regulations in 2002 and will bring any recommended amended regulations to the full board for consideration.

Finally, the Board receives public comment at each of its meetings and will consider any request for amendments. Petitions for rule-making also receive a response from the Board during the mandatory 180 days in accordance with its Public Participation Guidelines.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which 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.

The agency has reviewed the proposed regulation in relation to its impact on the institution of the family and family stability. There would be no effect of the proposal on the authority and rights of parents, economic self-sufficiency or the martial commitment. While the proposed regulation will update the practice of physicians selling drugs in the utilization of newer technology, it is unlikely that such efficiencies would have any direct benefit to disposable family income.