PRELIMINARY DETERMINATION
NOTICE OF INTENDED REGULATORY ACTION

DEPARTMENT OF HEALTH PROFESSIONS
BOARD OF PHARMACY
18 VAC 110-30-10 et seq.

Regulations Governing Physician Selling Drugs

A. Legal authority to promulgate the contemplated regulation.

The Board of Pharmacy is seeking to publish a Notice of Intended Regulatory Action in order to begin a biennial review of its regulations in concurrence with Public Participation Guidelines of the Board (18 VAC 110-10-10 et seq.).

18 VAC 110-10-100. Biennial review of regulations.

A. At least once each biennium, the board shall conduct an informational proceeding to receive comment on all existing regulations as to their effectiveness, efficiency, necessity, clarity, and cost of compliance.

B. Such proceeding may be conducted separately or in conjunction with other informational proceedings or hearings.

C. Notice of the proceeding shall be transmitted to the Registrar for inclusion in The Virginia Register and shall be sent to the mailing list identified in 18 VAC 85-10-30.

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

§ 54.1-2400 establishes the general powers and duties of health regulatory boards including the responsibility to ensure practitioner competency and to promulgate regulations in accordance with the Administrative Process Act which are reasonable and necessary to effectively 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:

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

9. 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 (§ 9-6.14:1 et seq.). 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.

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.

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

B. Statement of potential issues to be addressed.

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.

In addressing the issue of inconsistency with the law and regulations for the practice of pharmacy, the Board will consider revisions which 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 needs to be clearly spelled out in this regulation. The statutory requirements for what information is to be included on a prescription label have changed and need to be reflected in amendments to this regulation.

In addressing the issue of providing more flexibility in the utilization of technology, the Board will consider 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.

C. Statement setting forth the reasoning for the contemplated regulation.

While 18 VAC 110-10-100 requires a biennial review of the Board's regulations, the Board is not required to publish a Notice of Intended Regulatory Action in order to have an “informational proceeding” which provides an opportunity for public comment.

However, in this case, the Board is seeking permission to publish a NOIRA because it has identified several issues of concern for possible regulatory action. Those issues are as follows:

A) Regulations have not been amended since November 3, 1993. 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.

B) Regulations 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.

D. Alternatives to be considered.

In seeking alternatives to regulation, the Board will consider any comment it receives as a result of its informational proceeding and written public comment. The Regulatory/Legislative Committee will review the Pharmacy Practice Act (Chapter 33 of Title 54.1), the Drug Control Act (Chapter 34 of Title 54.1), and the current regulations for the practice of pharmacy (18 VAC 110-20-10 et seq.) It will recommend to the Board any revisions to regulation which will clarify, make the requirements less burdensome, or provide for necessary consistency with current law and regulation for the practice of pharmacy. The Board will consider any changes which are recommended as necessary to provide greater assurance of public health and safety in the delivery of pharmaceutical care in physicians' offices.