UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

BUREAU OF COMPETITION

November 27, 1989

Mr. Jack B. Carson
Executive Director
Virginia Board of Pharmacy
1601 Rolling Hills Drive
Richmond, VA 23229-5005

Dear Mr. Carson:

The staff of the Bureau of Competition of the Federal Trade Commission is pleased to respond to your notice inviting comments with respect to the regulations proposed by the Virginia Board of Pharmacy ("Board") for the dispensing and sale of prescription drugs by practitioners of the healing arts.[1] We offer these comments because we believe that dispensing by practitioners provides service and price competition among physicians[2] and between physicians and pharmacists, which are likely to benefit consumers. We are concerned that the requirement in Part II, Section 2.3 of the proposed regulations[3] that a dispensing physician personally perform the selection, compounding, preparation, packaging, and labeling of a prescription drug may unnecessarily restrict dispensing by physicians, and thus may reduce competition and consumer choice.

Interest and Experience of the Staff of the Federal Trade Commission

For more than a decade, the Commission and its staff have investigated the competitive effects of restrictions on the business practices of state-licensed professionals, including dentists, lawyers, physicians, pharmacists and other non-

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[1] These comments are the views of the staff of the Bureau of Competition of the Federal Trade Commission. They are not necessarily the views of the Commission or of any individual Commissioner.

[2] We use the term "physician" in this letter to mean a doctor of medicine, osteopathy, or podiatry.

[3] VR530-01-2, "Regulations of the Virginia Board of Pharmacy: Standards for Practitioners of the Healing Arts to Sell Controlled Substances."

physician health care providers. The goal of the Commission has been to identify those restrictions on practice that impede competition or increase costs without providing adequate countervailing benefits to consumers.[4]

Physician Dispensing

We do not endorse physician dispensing as preferable to pharmacist dispensing. Rather, we support consumer choice among qualified providers of prescription drugs. Physician dispensing maximizes consumers' options in the purchasing of prescription drugs, and we believe it may increase competition among physicians and between physicians and pharmacists and lead to lower prices and better services.

The dispensing of prescription drugs by physicians is a traditional part of medical practice that was once quite common and is currently authorized in all but a few states. Some consumers may value the option of obtaining prescription drugs prescribed by their physician without having to make a separate trip to a pharmacy. Indeed, the same patient may have different preferences at different times. For example, a parent with a two-year-old child suffering the pain of an ear infection may desire one-stop shopping, whereas the same parent may prefer to purchase prescription vitamins for the child at a pharmacy. There are increasing numbers of group medical practices and walk-in clinics that, in response to consumer demand, are providing additional options and convenience, and this trend is generating increased competition in the sale of prescription drugs.

The Proposed Regulations

Pursuant to its authority to "license and regulate the dispensing of controlled substances by [physicians],"[5] the Board

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[4] The Commission's staff has submitted comments concerning legislative and regulatory proposals to enact such restrictions in regard to physician dispensing. Letters to William G. Miller, Jr., Joint Secretary, Georgia State Examining Boards (November 26, 1986 and June 26, 1987); letter to C. Earl Hill, M.D., President, Maryland State Board of Medical Examiners (December 31, 1986); letter to the Honorable Tim Leslie, California General Assembly (May 1, 1987); and letter to Senator Nicholas A. Spano, (New York State Senate) (June 2, 1989).

[5] 1989 Va. Acts ch. 510, § 54.1-3304.1.

proposes to subject physicians who sell prescription drugs to a variety of regulations designed to promote the health and safety of the public. Regulations that do not serve that purpose generally, or do not serve that purpose in the specific context of physician dispensing, may needlessly increase the costs borne by physicians and deter them from providing dispensing services that their patients value. For this reason, the Board may wish to ensure that its regulations are carefully tailored to address any health and safety issues associated with the dispensing of prescription drugs by physicians to their patients without imposing any unnecessary restrictions.[6] Thus, the Board might conclude that a particular restriction need not be imposed on physicians in light of their training and the type or volume of dispensing they perform.

Proposed regulation Part II, § 2.3 provides:

> The selection of the controlled substance from the stock, any compounding, preparation or packaging of a controlled substance or the preparation of a label for a controlled substance to be transferred to a patient shall be personally performed by the licensee (emphasis added).

The requirement that a physician personally perform the enumerated activities in the process of dispensing may needlessly frustrate efficient use of physician time and expertise. The Board does not require that a pharmacist personally perform these activities when dispensing a prescription. Indeed, the Board specifically permits pharmacists to be assisted by student externs, interns, and others in preparing and packaging

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[6] See generally the statement of Bernard L. Henderson, Jr., Director of the Virginia Department of Health Regulatory Boards. In an undated attachment distributed with the Board of Pharmacy's current regulations, Mr. Henderson stated that:

> Regulations of any type constitute restraints on the exercise of free choice. Government should only exercise its power to regulate when it is found that regulation is clearly necessary for the preservation of the health, safety, and welfare of the public. Each provision of every regulation must have as its sole legitimate purpose the protection of the public, must constitute the least burdensome method of achieving that purpose, and must be no more restrictive than the minimally acceptable standard of care to be provided to the public.

prescriptions and performing clerical functions. The only specific activity the Board requires that a pharmacist personally perform is that, after a prescription drug is prepared but prior to its delivery, "the pharmacist shall inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of dispensing as a certification of the accuracy of, and the responsibility for, the entire transaction."[7] We are aware of no reason why physicians should not similarly be assisted by members of their staffs in performing the activities involved in dispensing controlled substances.

We have supported the adoption of regulations requiring dispensing physicians to meet health and safety standards, including requirements that (1) physicians give notice to their licensing board of their intent to dispense, (2) physicians meet standards for recordkeeping, labeling, packaging, storage, and the use of support personnel, (3) there be a physician-in-charge, (4) physicians follow specified procedures in the event of loss or theft of controlled substances, and (5) physicians' offices be inspected. Such regulations may protect public health and safety while allowing consumers to choose among qualified providers of prescription drugs.

Conclusion

The likely effect of any regulation that imposes a burden on physician dispensing and is not carefully drawn to promote health and safety would be to inhibit dispensing by physicians, and thus reduce the benefits of choice, convenience, and price competition. We believe that consumers should not be deprived of these potential benefits unless real evidence demonstrates not only that physician dispensing has harmed or is likely to harm public health and safety, but also that less restrictive health and safety standards are insufficient to protect the public.

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[7] VR530-01-1, Regulations of the Virginia Board of Pharmacy, Part VI, § 6.4 (February 1, 1988).

Mr. Jack B. Carson
Virginia Board of Pharmacy

Adoption of Part II, Section 2.3 of the proposed regulations, in particular, might impede competition for patients among physicians, and between physicians and pharmacists, and could be harmful to consumers.

Sincerely,

Kevin J. Arquit
Director
Bureau of Competition