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BUREAU OF COMPETITION

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

COMMISSION APPROVED

November 26, 1986

Mr. William G. Miller, Jr.
Joint Secretary of the State Examining Boards
160 Pryor Street, SW
Atlanta, Georgia 30303

Dear Mr. Miller:

The Federal Trade Commission's Bureaus of Competition, Consumer Protection, and Economics[1] are pleased to submit comments regarding the rules proposed by the Georgia State Board of Pharmacy ("Board") with respect to the dispensing of prescription drugs by physicians and certain other health care practitioners. We offer these comments because we believe that dispensing by practitioners provides service and price competition among practitioners and between practitioners and pharmacists, to the benefit of consumers. We are concerned that the proposed regulations unjustifiably restrict dispensing by practitioners, and may deprive consumers of these benefits.

Practitioner Dispensing

The dispensing of medication by practitioners of the healing arts is a traditional part of medical, dental, and veterinary practice. While many consumers purchase prescription drugs from a pharmacist pursuant to a prescription order issued by a practitioner, others, most prevalently but not exclusively in rural areas not conveniently served by a pharmacy, purchase medication from their practitioner. Indeed, until recently the family physician who made house calls and dispensed medication was a familiar figure. As competition among practitioners for patients has increased in recent years, more practitioners have begun to offer the additional service of dispensing prescription drugs to patients. Practitioner dispensing has long been permitted by federal[2] and state law. In Georgia, licensed

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1 These comments represent the views of the Bureaus, and not necessarily those of the Commission. The Commission, however, has authorized submission of these comments.

2 Federal regulations permit practitioners to dispense controlled substances listed in Schedules II through V (21 C.F.R §§1306.02(b), 1306.11(b), 1306.21(b), and 1306.31(b)(1986), subject to specific record-keeping requirements (21 C.F.R §1304.03(b) and (d)(1986)).

practitioners including physicians, dentists, podiatrists, and veterinarians have statutory authority to dispense drugs.[3]

Dispensing by practitioners benefits consumers by maximizing the number of qualified sources from which they may purchase prescription drugs, and by offering increased convenience to consumers who may desire, when they are ill, to avoid making a separate trip to a pharmacy to purchase prescription drugs. The competition resulting from dispensing by practitioners may enhance the incentive for pharmacists to offer lower prices and additional services to consumers.

Opponents of practitioner dispensing allege that it may injure consumers by creating incentives for practitioners to over-prescribe, or to limit product selection to those drugs available in the practitioner's office, in order to increase revenues. But the desire to maintain the reputation of being a reliable practitioner should reduce such incentives. Even assuming that such incentives exist, this would not justify a restraint on an entire category of transactions by practitioners, just as the fact that some pharmacists may recommend the purchase of vitamins or over-the-counter medications in part because of their retail margins does not justify a restraint on the selling of such items by all pharmacists. The incentive to abuse dispensing authority for economic gain appears to be no greater than the incentive to overuse any other services offered to patients, including, for example, follow-up visits, in-house laboratory testing or diagnostic imaging. If inappropriate dispensing occurs, it may be dealt with by less restrictive means, such as peer review and law enforcement.

The Proposed Regulations

Recent amendments to the Georgia drug statutes (Act No. 1537, Acts 1986, eff. Apr. 17, 1986) subject practitioners who dispense drugs to much the same regulatory requirements as pharmacists. For example, the amendments require practitioners who dispense drugs to adhere to the same record-keeping, labeling, packaging, and storage requirements imposed upon pharmacists and pharmacies. The amendments also make it clear that practitioners are subject to the same restrictions imposed upon pharmacists with respect to the use of nonlicensed assistants, both as to their number and their duties.

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3 Under Georgia's pharmacy statutes, a practitioner has the authority "to use, mix, prepare, dispense, prescribe, and administer drugs in connection with medical treatment to the extent provided by the laws of this state" (Ga. Code Ann. §79A-102(19)).

The Board's proposed regulation, however, imposes discriminatory restraints on practitioner dispensing without any apparent justification. As we discuss below, the proposed regulation would impose costs on practitioners that are not imposed upon pharmacies, and would prevent ambulatory care centers and other group practices from achieving efficiencies in dispensing. Such restraints may unnecessarily deter practitioners from offering prescription drug dispensing services. This would deny to consumers the benefits of competition and consumer choice now provided by practitioner dispensing.

Proposed regulation 480-28-.06 provides:

> (a) The practitioner must personally perform the complete act of dispensing drugs, including drug selection, drug labeling, and counseling of the patient for whom the drug is prescribed. The practitioner's assistant may be permitted to type a label or count or pour ingredients for medication only under the direct supervision of the dispensing practitioner.
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> (b) The practitioner may dispense only his privately owned medication to his own patients.

The requirement in subsection (a) that the practitioner must personally perform the complete act of dispensing (except for those limited specified acts that may be delegated to a directly supervised assistant) may frustrate efficient use of practitioner time and expertise in group practices. We are aware of no reason why it would be harmful for one practitioner to perform part of the process, such as drug selection and labeling, and for another practitioner to perform the counseling function. There is no corresponding requirement in the Board's regulations that a pharmacist personally perform the complete act of dispensing.

Proposed subsection (a) also appears to require patient counseling by dispensing practitioners. While the value of patient counseling is not in dispute, there is no apparent justification for imposing a counseling requirement upon dispensing practitioners while not imposing a similar counseling requirement on pharmacists.

Subsection (b) of the proposed regulation could be interpreted to require that each dispensing practitioner individually own an inventory of prescription drugs. This would impose the costs of duplicative inventories on group practices, including not only the cost of the drugs but also space, storage,

and record-keeping costs. This requirement is not imposed upon pharmacies that employ more than one pharmacist. The only conceivable rationale for this requirement would be to facilitate regulatory accountability. But it appears to be no more difficult to audit individual practitioners using a central inventory than it is to audit the activities of individual pharmacists who use a single inventory at a pharmacy. Moreover, we are not aware of any reason to require greater accountability for dispensing practitioners than for pharmacists.

The requirement in subsection (b) that a practitioner dispense only to his own patients also may prevent more efficient methods of group practice. A group practice might use the time and expertise of its members more efficiently by allowing one practitioner to dispense medication prescribed by another practitioner, for example when a patient seeks a refill. There is no apparent justification for regulations that permit a practitioner's prescription to be dispensed by a pharmacist, but not by another practitioner within the same group practice.

Actions that restrain competition, undertaken by a board composed largely of competing professionals, raise serious antitrust concerns. The proposed regulations impose restraints on competition that do not appear to reflect a clearly articulated and affirmatively expressed policy of the Georgia legislature to deter practitioner dispensing or otherwise restrain competition among practitioners or between practitioners and pharmacists. An agreement by a group of competitors that has the purpose or effect of excluding another group of competitors from the market could constitute a violation of the federal antitrust laws.

Conclusion

The likely effect of the proposed regulation would be to inhibit dispensing by practitioners, and thus to deny to consumers the benefits of choice, convenience and price competition that are now provided by such dispensing. The Federal Trade Commission has been actively seeking to encourage increased competition in the health care sector as a mechanism for lowering prices and increasing the range and quality of services available. Adoption of the proposed regulation would impede competition for patients among practitioners, and between practitioners and pharmacists in the sale of prescription drugs. Such a result would be harmful to consumers. Indeed,

adoption of the proposed regulation by agreement among the practicing pharmacists who are members of the Board may place the Board at risk under the federal antitrust laws.

Sincerely,

Jeffrey I. Zuckerman
Director
Bureau of Competition