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

APPROVED

December 31, 1986

C. Earl Hill, M.D., President
Maryland State Board of Medical Examiners
201 West Preston Street
Baltimore, Maryland 21201

Dear Dr. Hill:

The Federal Trade Commission's Bureaus of Competition, Consumer Protection, and Economics are pleased to respond to the request of the Maryland State Board of Medical Examiners ("Board") for our views regarding the practice and regulation of the dispensing of prescription drugs by physicians. We understand that the Board is considering regulations to implement recent legislation regarding physician dispensing (Chapter 691 of the Acts of Maryland, 1986, approved May 27, 1986, effective January 1, 1987). We believe that dispensing by physicians and other health care practitioners increases service and price competition among practitioners, and between practitioners and pharmacists, to the benefit of consumers. We urge the Board to preserve and encourage such competition in any rules and regulations it may adopt concerning the dispensing of prescription drugs by physicians.

Physician Dispensing

The dispensing of medication by physicians is a traditional part of medical practice. Indeed, until about thirty years ago, the family physician who made house calls and dispensed medication was a familiar figure. Today, most consumers receive a prescription order from their physician and purchase the prescribed drugs from a pharmacist. Other consumers, often but not exclusively located in rural areas not served by a nearby pharmacy, still purchase medication from their physician. And as competition among physicians has increased in recent years, more physicians have begun to offer their patients the convenience of dispensing prescription drugs.

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

11

Dispensing by physicians benefits consumers by maximizing the number of qualified sources from which they may purchase prescription drugs, and by enabling consumers to avoid making a separate trip to a pharmacy. The competition resulting from dispensing by physicians may enhance the incentive for pharmacists to offer lower prices and additional services to consumers.

Opponents of physician dispensing allege that it may injure consumers by encouraging physicians to over-prescribe, or to limit product selection to those drugs available in the physician's office, in order to increase revenues. In our view, the physician's desire to maintain a reputation for integrity should reduce such incentives. Even assuming that such incentives exist, restraining an entire category of transactions by physicians is not justified. The fact that some pharmacists may recommend the purchase of vitamins or over-the-counter medications because of their high retail margins does not justify. a restraint on the selling of such items by 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.

Opponents also argue that physician dispensing eliminates the system of "checks and balances" in which pharmacists review prescriptions for errors, possible allergic reactions, or potential adverse interactions with other prescription or overthe-counter drugs the consumer may be using. In practice, of course, pharmacists frequently do not conduct such reviews. Moreover, to the extent that physician dispensing eliminates the opportunity for pharmacists to act as a "check" on physician prescribing errors, this loss may be counter-balanced by a significant benefit: the elimination of medication errors that occur because of miscommunications between physicians and pharmacists, such as misinterpretations of written prescriptions. None of the arguments against dispensing of prescription drugs by physicians presents a compelling case for depriving consumers of the benefits of service and price competition that are likely to result.

For example, the Commission on Medical Discipline has the authority to discipline physicians who promote the sale of drugs or goods to a patient "so as to exploit the patient for financial gain." Md. Health Occ. Code Ann. \$14-504(11) (1986).

Regulation of Physician Dispensing in Maryland

Physician dispensing has long been permitted by federal and most state laws. In Maryland, physicians have not been prohibited from personally preparing and dispensing prescription drugs. The amendments recently enacted by the Maryland legislature require physicians to apply to the State Board of Medical Examiners, demonstrate to the Board's satisfaction that such dispensing is in the public interest, and obtain the Board's written approval to dispense. In addition, the amendments limit dispensing by physicians to their own patients, require that dispensing physicians not have a substantial financial interest in a pharmacy, and require that dispensing physicians meet certain labeling and record-keeping requirements. The amendments authorize the Board, after consulting with the State Board of Pharmacy, to adopt rules and regulations regarding the dispensing of prescription drugs by licensed physicians.

The statutory requirement that a physician applying for permission to dispense meet a public interest standard requires the Board to determine what showing will meet this standard. The legislature declined to impose restrictive conditions upon applicants. As originally introduced, Senate Bill 830 was hostile to physician dispensing. It contained a preamble purporting to set forth as state policy that (1) dispensing by physicians and certain other health care practitioners should be discouraged if adequate pharmaceutical service is available; (2) such practitioners should derive their income solely from the sale of their professional services; and (3) dispensing by such practitioners should be limited, absent exceptional circumstances, to starter doses. The bill would have required physicians seeking to dispense to demonstrate for the Board that there was a "need" for such dispensing, that adequate pharmaceutical services were unavailable, or that "exceptional circumstances" warranted such dispensing. The legislature considered and rejected all of those provisions and required only that the Board find that approval of a physician's application to dispense is in the public interest.

For example, federal regulations permit physicians to dispense controlled substances listed in Schedules II through V (21 C.F.R 5\$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)).

⁴ Md. Health Occ. Code Ann. §12-102(b) (1986).

We do not believe that the public interest is served by restrictions on physician dispensing designed to protect the economic interests of specific groups or individuals. We recommend strongly that the Board not require a demonstration of "need" for physician dispensing, of "unavailability" of pharmacies, or of "exceptional circumstances." The public interest will best be served by maximizing the number of qualified sources from which consumers may purchase prescription drugs. As discussed above, this will increase consumer choice and enhance the incentive of sellers of prescription drugs to offer lower prices and a wider range of services.

To minimize regulatory impediments to physician dispensing, we suggest that the Board adopt a presumption that, in general, physician dispensing is in the public interest. Such a presumption should operate to permit the routine and expeditious approval of applications, except where the Board believes that there is evidence to rebut the presumption in the case of a particular physician. Applicants should not be required to meet burdensome standards of proof that might impose unnecessary costs or delays, and thus deter physicians from seeking approval.

Conclusion

The Federal Trade Commission actively encourages competition in the health care sector to promote lower prices, higher quality, and an increased variety of available services. Physician dispensing increases competition among physicians, and between physicians and pharmacists, thereby benefitting consumers. We believe the Board would best serve the public interest by seeking to facilitate and encourage physician dispensing in any regulations it may adopt.

Sincerely,

Jektrey I. Zuckerman

Director

Bureau of Competition