

HEALTH OCCUPATIONS**PHARMACISTS – PHYSICIANS – ANTITRUST – COLLABORATIVE
AGREEMENTS BETWEEN PHARMACISTS AND PHYSICIANS
RELATING TO DRUG THERAPY**

November 28, 2001

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You have requested our opinion on several questions for the benefit of a work group organized during the legislative interim to consider possible legislation on “collaborative agreements” between pharmacists and physicians related to drug therapy. On behalf of one of the participants in the work group you have asked:

(1) What legal authority currently permits a pharmacist to enter into a collaborative agreement or protocol with a physician concerning drug therapy in an institutional setting such as a hospital? Are such collaborative agreements limited to institutional settings where the physician and pharmacist work in the same location?

(2) To what extent may such an agreement or protocol permit a pharmacist to modify a prescription issued by a physician?

(3) Assume that the General Assembly enacts a law to allow collaborative agreements between physicians and pharmacists, subject to the approval of licensing boards, under which a pharmacist could modify a physician’s prescription according to an agreed-upon protocol without prior authorization from the physician. What are the antitrust implications of a licensing board’s refusal to approve such an agreement?

For the reasons set forth below, we conclude:

(1) Under current law, a pharmacist who works in an inpatient institution may dispense prescription drugs pursuant to a “medication protocol” established by the institution in accordance with regulations of the Board of Pharmacy. However, a pharmacist may not dispense a prescription drug without a written or oral prescription from an authorized prescriber. Because the pharmacist

does not have independent prescribing authority, the pharmacist may only begin, modify, or discontinue drug therapy in accordance with the directions given by the prescriber. Thus, a pharmacist acting pursuant to a physician’s reference to a medication protocol may dispense only the drug, dosage, dosage form, and route of administration specified in the protocol. While the regulations limit the use of medication protocols to institutional settings, they do not require that the physician and pharmacist work in the same location.¹

(2) Under current law, a pharmacist may not modify a prescription provided by a physician absent a direction from the physician, whether or not the pharmacist is acting pursuant to a medication protocol.

(3) If the General Assembly were to pass a law allowing “collaborative agreements” between physicians and pharmacists subject to the approval of regulatory boards, that law should clearly indicate the grounds on which a proposed agreement could be rejected in order to immunize such decisions from challenge under the antitrust laws.

I

Background

A. Issuing and Filling Prescriptions

A prescription is a direction to dispense a drug or device that, under State or federal law, may be dispensed only by prescription. *See* Annotated Code of Maryland, Health-General Article (“HG”), §21-220(a), (f); *see also* Annotated Code of Maryland, Article 27, §300(b). A prescription may be written or oral. HG §21-220(b). If the prescription is oral, the pharmacist may not dispense the drug unless the pharmacist promptly writes out and files the prescription. *Id.*

¹ This conclusion is consistent with the advice previously provided by Assistant Attorney General Paul J. Ballard. *See* Memorandum of Paul J. Ballard to LaVerne G. Naesea dated September 18, 2001.

No single State law specifies the contents of a valid prescription.² However, the necessary elements of a prescription may be inferred from statutes that govern the dispensing and labeling of prescription drugs. Generally, a prescription will include the identity of the patient, the specification, strength, and dosage form of the drug, directions for use, the date of the prescription, an indication whether or not chemically similar drugs may be substituted, and a statement as to whether and how often the prescription may be refilled. *See* Annotated Code of Maryland, Health Occupations Article (“HO”), §12-504 (circumstances under which pharmacist may substitute generically equivalent drug of “same dosage form and strength” for specified brand name drug); HO §12-505(b)-(c) (pharmacist must include on label the date the prescription is dispensed, the drug’s expiration date, the name and strength of the drug, and any appropriate handling instructions); HO §12-506 (circumstances under which pharmacist may refill a prescription without authorization); HG §21-221(a) (“[i]f stated in the prescription,” a dispensed drug must be labeled with the name of the patient, any directions for use, and any cautionary statements); Article 27, §300(c) (prescription label requirements).

State law authorizes certain health care providers to issue prescriptions. Such “authorized prescribers” include physicians, dentists, podiatrists, veterinarians, certain nurse midwives and nurse practitioners, and other individuals “authorized by law to prescribe prescription or nonprescription drugs or devices.” HO §12-101(b); *see also* 71 *Opinions of the Attorney General* 142 (1986). The General Assembly has not, however, conferred prescribing authority on pharmacists.

The traditional function of the pharmacist is to prepare and dispense³ prescription drugs and to provide information to patients and providers concerning those drugs and any problems concerning

² A prescription for a controlled dangerous substance must include the name of the drug, strength, dosage form, quantity prescribed, directions for use, and the name, address, and registration number of the prescriber. COMAR 10.19.03.07E; 21 C.F.R. §1306.05.

³ “Dispensing” is the “procedure which results in the receipt” of the drug or device by the patient and that entails the interpretation of the prescription, the selection and labeling of the drug or device, and the measuring and packaging of the drug or device in accordance with law. HO §12-101(f).

the use or monitoring of drugs. HO §12-101(p)(ii)-(iii), (v)-(vi) (definition of “practice pharmacy”). The law restricts a pharmacist’s discretion in filling a prescription. Absent special instructions from the prescriber, a pharmacist may not fill a prescription more than 120 days after it is issued. HO §12-503. A pharmacist may only dispense a prescription medication in accordance with the directions of the prescriber subject to other legal restrictions. For example, a pharmacist may substitute a generically equivalent drug or device for a brand name product only under certain circumstances. HO §12-504. No substitution is permitted if the prescriber specifies that the prescription is to be dispensed “only as directed.” HO §12-504(b)(1). A pharmacist may not ordinarily refill a prescription unless the prescriber authorizes the refill. HO §12-506.

Like many states, Maryland has expanded the role of the pharmacist beyond the dispensing function to encompass patient education and therapeutic monitoring. Recently, the General Assembly recognized an expanded scope of practice for pharmacists that includes “pharmaceutical care”⁴ and the monitoring of prescriptions. *See* Chapter 614, Laws of Maryland 1997, *codified in pertinent part at* HO §12-101(l), (p)(i),(iv). Some states have expanded the pharmacist’s role even more broadly by authorizing pharmacists to enter into agreements with physicians under which the pharmacist may order laboratory tests, initiate drug therapy, modify drug doses, or discontinue drug therapy under a plan agreed upon with the patient’s physician.⁵ Brushwood, *From Confrontation*

⁴ “Pharmaceutical care” is defined as:

the provision of a patient’s drug regimen for the purpose of achieving definite outcomes related to the cure or prevention of a disease, elimination or reduction of a patient’s symptoms, or arresting or slowing of a disease process by identifying, resolving, or preventing actual or potential drug therapy problems and which may include patient counseling and providing information to licensed and certified health care providers.

HO §12-101(l).

⁵ The Virginia Attorney General recently addressed the question whether a pharmacist acting under such an agreement would violate a
(continued...)

to Collaboration: Collegial Accountability and the Expanding Role of Pharmacists in the Management of Chronic Pain, 29 J. Law, Medicine, & Ethics 69, 75 (2001). Such therapy management agreements are now authorized in at least 27 states. *Id.* at 69 & n.2.

B. Failed Legislation Concerning Therapy Management Agreements

During its 2001 legislative session, the General Assembly considered legislation that would have amended the Maryland Pharmacy Act, HO §12-101 *et seq.*, to permit certain pharmacists to enter into “therapy management agreements” with other health care providers. Senate Bill 772 (2001). That bill would have authorized a pharmacist with a doctoral degree or equivalent training to enter into a written agreement with a physician, dentist, or podiatrist under which the pharmacist could have performed specified “cooperative procedures.” Proposed HO §12-6A-01(b). These procedures would have included:

- (1) modification, continuation, and discontinuation of drug therapy under written patient-specific protocols;
- (2) the ordering of laboratory tests; and

⁵ (...continued)

Virginia statute that prohibits the therapeutic substitution of a chemically dissimilar drug without the explicit consent of the prescribing physician. The Virginia Attorney General related the use of a protocol under such a collaborative agreement to the pharmacist’s filling of a prescription as follows:

To the extent that a protocol provides for *a specific drug therapy*, it constitutes the prescriptive order of the physician. Whenever a pharmacist alters or changes the drug therapy in accordance with the protocol, the pharmacist does so at the direction of the physician’s order. In such a situation, the pharmacist is not prescribing but is merely following the physician’s instructions to dispense the drug.

1999 Va. Op. Atty. Gen. 159 (1999), 1999 WL 1568337 at *4 (emphasis added).

(3) other patient care management measures related to monitoring or improving the outcomes of drug or device therapy.

Proposed HO §12-6A-03(b). The “cooperative procedures” would have been limited by the scope of practice of the providers who entered into the agreement. Proposed HO §12-6A-03(a). In addition, an agreement could only pertain to a medical condition for which there were existing protocols “clinically accepted as the standard of care” or protocols approved under regulations issued by the Board of Pharmacy and the relevant licensing board for the other party to the agreement. Proposed HO §§12-6A-03(c), 12-6A-07.

The proposed legislation would have authorized the Board of Pharmacy and licensing boards for other providers to adopt regulations to implement the legislation. Proposed HO §12-6A-07. Among other things, the regulations would have delineated relevant criteria for determining those pharmacists eligible to enter into therapy management agreements, established guidelines for the use of protocols, and created procedures for the approval or disapproval of specific protocols by the Board of Pharmacy and other relevant licensing boards. Proposed HO §12-6A-07(b).

Under the proposed legislation, no cooperative procedure could have been performed by a pharmacist without the voluntary consent of the patient. Proposed HO §§12-6A-04, 12-6A-05(a).

The proposed legislation passed the Senate, but failed in the House. At the suggestion of the House Environmental Matters Committee, an informal working group known as the Drug Therapy Management Work Group was formed to study the issue over the 2001 interim and determine whether a bill could be devised acceptable to all interested parties.

II

Analysis

A. Arrangements Between Prescribers and Pharmacists under Current Law

1. Regulations Governing Institutional Medication Protocols

The General Assembly has authorized the State Board of Pharmacy to adopt regulations “that ... establish standards for practicing pharmacy ..., including ... standards for filling and refilling prescriptions...” HO §12-205(a)(3)(ii). Under that authority the Board has adopted regulations that permit pharmacists in institutional settings to fill prescriptions according to medication protocols adopted by the institution and referenced by an authorized prescriber. COMAR 10.34.03.

a. Nature of a Medication Protocol

The regulations contemplate that an institution will establish “institutional policies and procedures governing each individual situation for which medication orders are implied due to a therapeutic or diagnostic intervention.” COMAR 10.34.03.12B(1)(b). Such procedures or “medication protocols” are defined as “a course of treatment predetermined by the institution and the generally accepted medical practice for the proper completion of a particular therapeutic or diagnostic intervention ordered by an authorized prescriber and which, if necessary, allows the pharmacist to infer the existence of certain medication orders.” COMAR 10.34.03.02B(6).

The regulations define “medication order” as “a patient-specific order” that contains detailed information, including the date of the order, the drug name, the amount and form of dosage, the route of administration, and the signature of the authorized prescriber. COMAR 10.34.03.02B(5).

The regulations refer to “implied” medication orders and to circumstances under which a pharmacist may “infer the existence” of a medication order. The use of those terms does not permit a pharmacist to create a prescription that has not already been issued

by an authorized prescriber.⁶ As noted above, a pharmacist may dispense a prescription drug only on the written or oral prescription of an authorized prescriber. HG §21-220(a). Pharmacists are not authorized prescribers, and the Pharmacy Board has no power to confer prescribing authority. A medication protocol, however, may provide a shorthand reference that a physician or other authorized prescriber may invoke to prescribe a particular course or combination of medications.

Thus, the regulations do not permit a pharmacist to hypothesize a prescription – *i.e.*, to determine what medication or dosage a physician *would* prescribe if the physician had the same information as the pharmacist, with the hope or expectation that the physician will later ratify that determination. Rather, the pharmacist is limited to determining, based on the protocol referenced by the physician, whether the physician has actually prescribed a particular medication and dosage for a particular patient.

For example, a physician could reference a particular protocol that calls for administration of a certain combination of drugs at a certain frequency during a specified period of time, followed by a different combination or dosage during a later stage of treatment. Similarly, by reference to a protocol, the physician could direct the pharmacist to change the dosage or medication in circumstances specifically identified in the protocol – *e.g.*, if a particular test result falls within specified parameters. However, any changes in medication, dosage, or administration and the timing of those changes must be evident from the protocol, and not simply left to the pharmacist’s discretion. The protocol itself must contain the information necessary for a valid prescription.

b. Restriction to Institutional Settings

Because the term “medication protocol” in the regulations refers to “a course of drug treatment predetermined by the *institution...*,” the use of such protocols is limited by definition to institutional settings. *See also* COMAR 10.34.03.01 (limiting scope of regulations to inpatient settings and pharmacies in institutions other than long-term care facilities). The regulations define

⁶ Thus, for example, the verb “infer,” as used in the regulation, must be interpreted to mean “to derive as a conclusion from facts or premises” rather than to “guess or surmise”. *See* Merriam-Webster’s On-line Collegiate Dictionary, <www.m-w.com/cgi-bin/dictionary>.

“institution” as an entity “other than a nursing home whose primary purpose is to provide a physical environment for patients to obtain inpatient or emergency care, except for urgent care facilities that are not part of an institution.” COMAR 10.34.03.01B(3). Thus, the practice authorized by the regulations may occur only in those types of institutions. However, there is no requirement in the regulations that the prescriber and pharmacist who follow a protocol in prescribing and dispensing medication necessarily work in the same location.

2. Whether Prescription May Be Modified by Pharmacist

You have asked to what extent a pharmacist may be authorized by a “collaborative agreement” to “modify” a prescription issued by a physician. Nothing in the Maryland Pharmacy Act currently permits a pharmacist to modify a prescription of a physician without authorization from the prescriber. As noted above, the legislation proposed during the past session of the General Assembly would have permitted a pharmacist to enter into a written agreement with a physician that would authorize the pharmacist to perform “cooperative procedures,” including modification of drug therapy under written protocols. However, that bill failed.

The Maryland Medical Practice Act provides a mechanism under which pharmacists could have authority to modify prescriptions issued by physicians. Under that statute, a physician may delegate duties to other health care providers to the extent permitted by regulations or orders of the Board of Physician Quality Assurance. *See* HO §14-306. Among the duties that may be delegated is the act of prescribing medication. *See 80 Opinions of the Attorney General* 173, 175 (1995) (delegation of prescribing authority to physician assistants).⁷ However, to date, the Board of Physician Quality Assurance has not adopted regulations that would

⁷ In a somewhat analogous situation, the Iowa Attorney General concluded that Iowa law authorized state licensing boards for physicians and pharmacists to adopt regulations under which a physician could delegate to a pharmacist the authority to administer a medication. *Opinion of the Attorney General of Iowa* No. 00-11-7 (November 29, 2000), 2000 WL 33258474. *See also* 1999 Va. Op. Atty. Gen. 159 (1999), 1999 WL 1568337 at *4 (analogizing collaborative agreements under Virginia legislation to delegation of medical acts by physician to physician assistants and nurse practitioners).

authorize the delegation of prescribing authority – or the authority to modify a prescription – to pharmacists. Because such a regulation would likely also involve the dispensing of prescription drugs or devices, it would have to be adopted by both the Board of Physician Quality Assurance and the Board of Pharmacy. HO §14-306(d).

B. Antitrust Implications

Finally, you have asked about the antitrust implications if a licensing board were authorized to approve a collaborative agreement under which a pharmacist could modify a prescription, and the board refused to approve a particular agreement.

Both the federal and State antitrust laws prohibit practices that unreasonably restrain competition. *See* 15 U.S.C. §1 *et seq.*; Annotated Code of Maryland, Commercial Law Article, §11-201 *et seq.* These prohibitions can apply to the actions of State licensing boards, which are often composed of members who are themselves licensees, or owners, directors, or employees of a licensee.⁸ As Attorney General Sachs noted in a previous opinion of this Office, “there is some danger that members of a [licensing and regulatory board] may be in violation of the antitrust laws when they impose regulations or take other actions that, in effect, impede competition within the industry that the Board regulates.... [S]tate regulatory officials are not, by virtue of their status alone, exempt from federal antitrust laws.” 65 *Opinions of the Attorney General* 13, 14 (1980) (citations omitted).

A licensing board’s refusal to approve a collaborative agreement could be challenged under the antitrust laws as anti-competitive. However, even if a board’s rejection of an agreement restricted competition, that decision may be immune from attack under the antitrust laws in accordance with the state action immunity doctrine. *See Parker v. Brown*, 317 U.S. 341, 350-51 (1943) (federal

⁸ For example, the licensing boards mentioned in the 2001 proposed legislation concerning cooperative procedures between pharmacists and other health care providers are all comprised primarily of licensees. *See* HO §4-202(a) (9 of 15 members of State Board of Dental Examiners to be licensed dentists); HO §12-202(a) (10 of 12 members of State Board of Pharmacy to be licensed pharmacists); HO §14-202(a) (11 of 15 members of Board of Physician Quality Assurance to be practicing licensed physicians); HO §16-202(a) (5 of 7 members of Board of Podiatric Medical Examiners to be licensed podiatrists).

antitrust laws are not “intended to restrain state action or official action directed by a state”). To enjoy such immunity, the challenged action must be based on a clearly articulated and affirmatively expressed state policy.⁹ See *California Retail Liquor Dealers Ass’n v. Midcal Aluminum, Inc.*, 445 U.S. 97 (1980).

Thus, if the General Assembly were to enact a law that authorized collaborative agreements for the modification of prescriptions and required approval of such an agreement by regulatory boards, the Legislature should clearly state in the statute the criteria for approval or rejection of proposed agreements.¹⁰

III

Conclusion

For the reasons stated above, it is our opinion that:

(1) Under current law, a pharmacist who works in an inpatient institution may dispense prescription drugs pursuant to a “medication protocol” established by the institution in accordance with regulations of the Board of Pharmacy. However, a pharmacist may not dispense a prescription drug without a written or oral prescription from an authorized prescriber. Because the pharmacist does not have independent prescribing authority, the pharmacist may

⁹ Private parties who invoke the state action immunity doctrine must also show that the challenged practice is actively supervised by the state. See *California Retail Liquor Dealers Ass’n v. Midcal Aluminum, Inc.*, 445 U.S. 97 (1980); *FTC v. Ticor Title Ins. Co.*, 504 U.S. 621 (1992). This element of the state action doctrine is generally not applied to state agencies themselves. See *Town of Hallie v. City of Eau Claire*, 471 U.S. 34, 46 n.10 (1985); *Earles v. State Board of Certified Public Accountants*, 139 F.3d 1033 (5th Cir.), cert. denied, 525 U.S. 982 (1998) (active supervision not required for state board action to come within doctrine); see generally 1 Areeda & Hovenkamp, *Antitrust Law* ¶226b at p.466 (2d ed. 2000).

¹⁰ We note that the unsuccessful legislation proposed in 2001 would not have made collaborative agreements themselves subject to the approval of the licensing boards, but would have authorized a mechanism for the board approval or disapproval of specific protocols at the request of prescribing providers. If similar legislation were introduced in the future, we would recommend that it clearly indicate the criteria for approval or rejection of a protocol.

only begin, modify, or discontinue drug therapy in accordance with the directions given by the prescriber. Thus, a pharmacist acting pursuant to a physician’s reference to a medication protocol may dispense only the drug, dosage, dosage form, and route of administration specified in the protocol. While the regulations limit the use of medication protocols to institutional settings, they do not require that the physician and pharmacist work in the same location.

(2) Under current law, a pharmacist may not modify a prescription provided by a physician absent a direction from the physician, whether or not the pharmacist is acting pursuant to a medication protocol.

(3) If the General Assembly were to pass a law allowing “collaborative agreements” between physicians and pharmacists subject to the approval of regulatory boards, that law should clearly indicate the grounds on which a proposed agreement could be rejected in order to immunize such decisions from challenge under the antitrust laws.

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Editor’s Note:

After this opinion was issued, the General Assembly enacted legislation authorizing therapy management contracts between physicians and pharmacists. Chapter 249, Laws of Maryland 2002.