

Bob Ferguson ATTORNEY GENERAL OF WASHINGTON

1125 Washington Street SE • PO Box 40100 • Olympia WA 98504-0100

January 22, 2013

The Honorable Linda Evans Parlette Washington State Senator, District 12 PO Box 40412 Olympia, WA 98504-0412

The Honorable Randi Becker Washington State Senator, District 2 PO Box 40402 Olympia, WA 98504-0402

The Honorable Steve Conway Washington State Senator, District 29 PO Box 40429 Olympia, WA 98504-0429

The Honorable Paul Harris Washington State Representative, District 17 PO Box 40600 Olympia, WA 98504-0600

The Honorable Karen Keiser Washington State Senator, District 33 PO Box 40433 Olympia, WA 98504-0433 The Honorable Eileen Cody Washington State Representative, District 34 PO Box 40600 Olympia, WA 98504-0600

The Honorable David Frockt Washington State Senator, District 46 PO Box 40446 Olympia, WA 98504-0600

The Honorable Laurie Jinkins Washington State Representative, District 27 PO Box 40600 Olympia, WA 98504-0600

The Honorable Steve Tharinger Washington State Representative, District 24 PO Box 40600 Olympia, WA 98504-0600

Dear Senators and Representatives:

By letter previously acknowledged, you have requested an opinion on the following question:

Must pharmacists be recognized as health care providers and compensated for their clinical services under Washington's "every category of provider" law, RCW 48.43.045?

January 22, 2013 Page 2

BRIEF ANSWER

Pharmacists are health care providers and must be compensated for services included in the basic health plan that are within the scope of the pharmacist's practice if the pharmacist agrees to abide by stated standards related to cost containment, management, and clinically efficacious health services.

ANALYSIS

The "every category of provider" law, RCW 48.43.045, requires health plans to permit every category of health care provider to provide health services or care for conditions included in the basic health plan services, if the health services or care is within the health care provider's permitted scope of practice and the provider agrees to abide by certain enumerated standards. Thus, to answer your question, we must answer the following questions: Is a pharmacist a health care provider? Do pharmacists provide health services or care for conditions included in the basic health plan services? Are the services within the scope of the pharmacist's practice? Can pharmacists agree to the enumerated standards? I will address each question in turn.

Is a pharmacist a health care provider?

A "health care provider" is "[a] person regulated under Title 18 or chapter 70.127 RCW, to practice health or health-related services or otherwise practicing health care services in this state consistent with state law[.]" RCW 48.43.005(23)(a). "'Health care service' means that service offered or provided by health care facilities and health care providers relating to the prevention, cure, or treatment of illness, injury, or disease." RCW 48.43.005(24).

Pharmacists are regulated under RCW 18.64. And pharmacists practice health care services. See RCW 18.64.011(23) (defining the "practice of pharmacy"); RCW 7.70.020 (defining "health care provider" as including pharmacists); WAC 182-530-1050 (defining "practitioner" as an "individual who has met the professional and legal requirements necessary to provide a health care service, such as a . . . pharmacist"). Therefore, a pharmacist is a health care provider.

Do pharmacists provide health services or care for conditions included in the basic health plan services?

"'Basic health plan services' means that schedule of covered health services, including the description of how those benefits are to be administered, that are required to be delivered to an enrollee under the basic health plan, as revised from time to time." RCW 48.43.005(6). The administrator of the basic health plan, the administrator of the Washington State Health Care Authority, revises a schedule of covered basic health care services "including physician services,"

^{1 &}quot; 'Basic health plan' means the plan described under chapter 70.47 RCW[.]" RCW 48.43.005(4).

ATTORNEY GENERAL OF WASHINGTON

January 22, 2013 Page 3

inpatient and outpatient hospital services, prescription drugs and medications, and other services that may be necessary for basic health care." RCW 70.47.060(1). The Schedule of Benefits listed in the Basic Health 2012 Member Handbook includes a pharmacy benefit as a covered service. http://www.basichealth.hca.wa.gov/documents/22-405.pdf 2012 (see page 30, App. A at "L."). However, the pharmacy benefit does not list any specific, non-dispensing services that a pharmacist may provide, but rather only describes the drug benefit.

The failure to list various services a pharmacist may provide does not end the inquiry. As the "every category of provider" law is written, if a service is covered, a provider may provide the service if it is within the provider's scope of practice.

Are the services within the scope of the pharmacist's practice?

A pharmacist may only provide services that are within the scope of the pharmacist's practice.² Pharmacists are required to be licensed under RCW 18.64. RCW 18.64.020. RCW 18.64 also defines the scope of the practice of pharmacy:

"Practice of pharmacy" includes the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy and use; the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; the participating in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; the providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices.

RCW 18.64.011(23). The terms "pharmacist" and the "practice of pharmacy" are defined in several regulations, all referring back to RCW 18.64 or mimicking the language of this statute. See WAC 246-860-020³ (Department of Health); WAC 284-43-130⁴ (Office of the Insurance

² A pharmacist commits unprofessional conduct when he practices beyond the scope of practice as defined by law or rule. RCW 18.130.180(12).

[&]quot;(6) 'Pharmacist' means a person licensed by the Washington state board of pharmacy to engage in the practice of pharmacy."

⁴ "(24) 'Pharmacy services' means the practice of pharmacy as defined in chapter 18.64 RCW and includes any drugs or devices as defined in chapter 18.64 RCW."

[&]quot;(30) 'Supplementary pharmacy services' or 'other pharmacy services' means pharmacy services involving the provision of drug therapy management and other services not required under state and federal law but that may be rendered in connection with dispensing, or that may be used in disease prevention or disease management."

January 22, 2013 Page 4

Commissioner); WAC 182-530-1050⁵ (Health Care Authority). Additionally, most of the terms within the definition of the practice of pharmacy are likewise defined in that statute. See RCW 18.64.020. RCW 18.64.020 does not, however, define "monitoring of drug therapy and use" or "initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs." Thus, the plain language of RCW 18.64.011(23) describes the scope of the practice of pharmacy as largely revolving around dispensing, administering, and storing of drugs and devices. However, the two undefined clauses purport to allow pharmacists to monitor and initiate drug therapy under written agreements, establishing guidelines and protocols, with physicians.

WAC 246-863-110 defines the term "monitoring drug therapy" to mean "a review of the drug therapy regimen of patients . . . for the purpose of evaluating and rendering advice to the prescribing practitioner regarding adjustment of the regimen." Monitoring of drug therapy includes collecting and reviewing patient drug use histories, measuring and reviewing patient vital signs, and ordering and evaluating the results of laboratory tests relating to drug therapy when in accordance with the policies and procedures or protocols which have been developed by the pharmacist and prescribing practitioners. WAC 246-863-110. In 1989, the Washington Supreme Court, in dicta, analyzed the term "monitoring drug therapy" and noted that "without benefit of a patient's medical history, the pharmacist is not qualified to determine the propriety of a particular drug regimen." *McKee v. American Home Prods. Corp.*, 113 Wn.2d 701, 716, 782 P.2d 1045 (1989). The Court further opined that a pharmacist does not have a duty to

⁵ "Pharmacist" - A person licensed in the practice of pharmacy by the state in which the prescription is filled.

[&]quot;Practice of pharmacy" - The practice of and responsibility for:

⁽¹⁾ Accurately interpreting prescription orders;

⁽²⁾ Compounding drugs;

⁽³⁾ Dispensing, labeling, administering, and distributing of drugs and devices;

⁽⁴⁾ Providing drug information to the client that includes, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices;

⁽⁵⁾ Monitoring of drug therapy and use;

⁽⁶⁾ Proper and safe storage of drugs and devices;

⁽⁷⁾ Documenting and maintaining records;

⁽⁸⁾ Initiating or modifying drug therapy in accordance with written guidelines or protocols previously established and approved for a pharmacist's practice by a practitioner authorized to prescribe drugs; and

⁽⁹⁾ Participating in drug use reviews and drug product selection.

⁶ McKee was decided in 1989 in a 5-4 decision. The issue before the Court was whether pharmacists had a duty to warn consumers of potential hazards of a drug prescribed by a physician. The Court quickly resolved that issue on procedural evidentiary grounds. McKee, 113 Wn.2d at 707. However, due to the "importance of the issue

ATTORNEY GENERAL OF WASHINGTON

January 22, 2013 Page 5

question the judgment of the prescribing physician and it would be inappropriate to interject the pharmacist into the physician-patient relationship and interfere with ongoing treatment. *Id.* at 712. The legislature did not amend the definition of practice of pharmacy in response to the *McKee* decision; nor did the Department of Health amend the definition of "monitoring drug therapy." *But see* 42 U.S.C. 1396r-8(g)(2)(A) (establishing standards of care for pharmacists including governing patient counseling).

The McKee Court did not discuss the other clause in RCW 18.64.011(23) permitting pharmacists to perform some non-dispensing services: "the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs[.]" And the plain language of the clause addresses the McKee Court's concerns regarding a pharmacist interfering in the physician-patient relationship because it requires written guidelines or protocols to be established between the physician and the pharmacist. Consistent with this authorization, collaborative drug therapy agreements were developed allowing a pharmacist to "initiat[e] or modify[] . . . drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs[.]" Under collaborative drug therapy agreements a physician agrees to train, provide oversight, and authorize a pharmacist to be an extender for the services described in the agreement. The Board of Pharmacy approves collaborative drug therapy agreements for various types of care, for example immunizations, anti-coagulation, emergency contraceptive protocol, nicotine replacement, hypertension, and pain management, to name a few. There are approximately 3,000 collaborative drug therapy agreements approved by the Board.

In your letter you provide a list of clinical services, not related to dispensing, that you state pharmacists currently provide, including anti-coagulation services, contraception initiation and continuation, chronic disease management services, and immunization services. Those services may be within the scope of the practice of pharmacy so long as a collaborative drug therapy agreement exists between the pharmacist and a physician.

Can pharmacists agree to the enumerated standards?

The every category of provider law requires providers to agree to abide by standards related to:

- (A) Provision, utilization review, and cost containment of health services;
- (B) Management and administrative procedures; and
- (C) Provision of cost-effective and clinically efficacious health services.

and public interest" (id. at 707) involved, the Court discussed the practice of pharmacy at length, in dicta, citing the definition of the practice of pharmacy in RCW 18.64 (then located in subsection 11). Id. at 713, 717.

ATTORNEY GENERAL OF WASHINGTON

January 22, 2013 Page 6

RCW 48.43.045(1)(a)(ii). WAC 284-43-205(2) elaborates on these requirements noting that "health carriers may determine that particular services for particular conditions by particular categories of providers are not cost-effective or clinically efficacious, and may exclude such services from coverage or reimbursement under a health plan. Any such determinations must be supported by relevant information or evidence of the type usually considered and relied upon in making determinations of cost-effectiveness or clinical efficacy." There is the potential for duplication of billing for services if both a physician and pharmacist are providing similar services. These statutory requirements work to prevent this type of situation and allow a health carrier to make determinations consistent with the statute and regulation. Therefore, if pharmacists can agree to abide by the enumerated standards, they must still be able to show that they are cost-effective and clinically efficacious.

I hope the foregoing information will prove useful. This is an informal opinion and will not be published as an official Attorney General Opinion.

Sincerely

JENNIFER S. STEELE

Assistant Attorney General

(206) 389-2106

wros