

Opinion No. 2009-094

September 9, 2009

The Honorable Steve Faris
State Senator
29476 Highway 67
Malvern, Arkansas 72104-6833

Dear Senator Faris:

I am writing in response to your request for my opinion on the following four (4) questions:

- 1) Does A.C.A. § 17-92-102(a) permit duly licensed physicians with prescriptive authority to distribute pre-packaged pharmaceuticals, which they have prescribed to their own patients, for a profit?
- 2) Does A.C.A. § 17-92-102(a) permit duly licensed nurse practitioners with prescriptive authority to distribute pre-packaged pharmaceuticals, which have been prescribed to patients, for a profit?
- 3) Does A.C.A. § 17-92-102(a) permit duly licensed physician assistants with prescriptive authority to distribute pre-packaged pharmaceuticals, which have been prescribed to patients, for a profit?
- 4) Does A.C.A. § 17-92-102(a) permit duly licensed dentists with prescriptive authority to distribute pre-packaged pharmaceuticals, which they have prescribed to their own patients, for a profit?

RESPONSE

First, some initial clarification of the terminology used in your questions is necessary. When you say “distribute pre-packaged pharmaceuticals, which they have prescribed to their own patients, for a profit,” I assume that you are referring to a practice commonly known as point-of-care dispensing. With point-of-care dispensing, the prescriber essentially fills the prescription and sells it to the patient in-office.¹

I further assume that you are *not* referring to the sale of drug samples obtained from representatives of pharmaceutical companies. Under the Prescription Drug Marketing Act, no person may sell, purchase, or trade, or offer to sell, purchase or trade a drug sample. 21 U.S.C. § 353(c)(1).

Second, I am unsure of the exact focus of your questions, each of which has several aspects. I cannot definitively determine whether it is the professional status of the person dispensing, the pre-packaging of the drugs or the profit making aspect of point-of-care dispensing that most concerns you. However, because you have asked essentially the same question regarding four different types of health care professionals, I will assume that the professional status of the dispenser is your main focus. Accordingly, this opinion will primarily focus on which of the professionals that you mentioned are authorized to engage in point-of-care dispensing. I will also briefly address the profit making aspect of this practice in an effort to address all potential concerns.

Regarding the “pre-packaged” aspect of the drugs in question, there are a number of complex federal laws and regulations governing the packaging of prescription drugs. These provisions are beyond the scope of an opinion from this office. Moreover, you have not specified exactly how the drugs in question are packaged, except to say they are “pre-packaged.” This lack of specific information would make it impossible for me to determine whether the applicable provisions have been complied with in any event. Therefore, for purposes of this opinion, I will assume that when the Board of Pharmacy licenses a distributor to do business in this state, the drugs that are being distributed are properly packaged.

¹ A number of companies offer dispensing systems designed to assist physicians and dentists in offering these services. See, e.g., www.dispensequick.com and www.nationspharm.com. I will note that such companies must be properly licensed as wholesale distributors by the Board of Pharmacy to do business in Arkansas.

With those caveats in mind, in my opinion, the answer to your first question is that A.C.A. § 17-92-102(a), standing alone, does not permit any particular activity. As explained further below, licensed physicians may, however, engage in point of care dispensing pursuant to A.C.A. § 17-95-102. It is my further opinion that the authority to engage in such activity for a profit may be inferred from the language of that section. In response to your second question, it is my opinion that neither A.C.A. § 17-92-102(a) nor any other provision permits nurse practitioners with prescriptive authority (advanced nurse practitioners granted prescriptive authority by the Arkansas State Board of Nursing pursuant to A.C.A. § 17-87-310) to distribute pre-packaged pharmaceuticals for a profit, i.e., engage in point-of-care medication dispensing. In response to your third question, it is my opinion that neither A.C.A. § 17-92-102(a) nor any other provision permits physician assistants with prescriptive authority (physician assistants who have been properly delegated prescriptive authority by their supervising physician(s) pursuant to A.C.A. § 17-105-108) to distribute pre-packaged pharmaceuticals for a profit, i.e., engage in point-of-care medication dispensing. In response to your fourth question, it is my opinion that dentists may engage in point-of-care dispensing pursuant to Article III. F. of the Rules and Regulations of the Arkansas State Board of Dental Examiners. It is my further opinion that the authority to engage in such activity for a profit may be inferred from the language of the regulation.

Question 1: Does A.C.A. § 17-92-102(a) permit duly licensed physicians with prescriptive authority to distribute pre-packaged pharmaceuticals, which they have prescribed to their own patients, for a profit?

Arkansas Code Annotated § 17-92-102 is found in the chapter of the Arkansas Code that governs pharmacists and pharmacies. The subsection that you cited states in relevant part:

Nothing in this section and [other named sections of the same chapter] shall . . . apply to physicians, dentists, or veterinarians compounding or dispensing their own prescriptions.

Arkansas Code Annotated § 17-92-102(a) (2001 Repl.)

This language does not *directly* permit physicians to do anything. It does, however, prevent certain key provisions that govern pharmacists and pharmacies

from applying to physicians.² For example, A.C.A. § 17-92-403 prevents any person except a pharmacy student serving as an intern from filling a prescription when a licensed pharmacist is not present. The subsection that you cited, however, subsection 17-92-102(a), prevents subsection 17-92-403 from applying to physicians. Thus, while A.C.A. § 17-92-102 does not, on its face, permit physicians to dispense pharmaceuticals directly to their own patients, it appears to recognize that such activity is otherwise permitted.

The provision more directly on point is found at A.C.A. § 17-95-102. That section states, in relevant part:

(a) A dispensing physician is a physician licensed under the Arkansas Medical Practices Act, §§ 17-95-201-17-95-207, 17-95-301-17-95-305, and 17-95-401-17-95-411, who purchases legend drugs to be dispensed to his or her patients for the patients' personal use and administration outside the physician's office.

(b) This section shall not apply to physicians who only dispense drugs in injectable form unless they are controlled substances, in which case the section shall fully apply.

(c) The dispensing physician shall:

(1) Personally dispense legend drugs and the dispensing of such drugs may not be delegated;

(2) Keep records of all receipts and distributions of legend drugs. The records shall be subject to inspection by the proper enforcement authority and shall be readily accessible for inspection and maintained in a central registry; and

(3) Label legend drugs with the following information:

(A) Patient's name and address;

² Technically, A.C.A. § 17-92-102(a), as it currently stands, does not prevent several relevant provisions applicable to pharmacies and pharmacists, e.g., A.C.A. § 17-92-302 (prohibiting the unlicensed practice of pharmacy), from applying to the named professionals. In my opinion, however, A.C.A. § 17-92-102(a), although ripe for legislative clarification, does prevent enough key provisions, e.g., A.C.A. § 17-92-403, from applying to said professionals to make it clear that they are otherwise permitted to dispense their own prescriptions.

(B) Prescribing physician's address and narcotic registry number issued by the Drug Enforcement Administration of the United States Department of Justice;

(C) Date of dispensing; and

(D) Directions and cautionary statements, if any, as required by law.

(d) No physician licensed under the Arkansas Medical Practices Act, §§ 17-95-201-17-95-207, 17-95-301-17-95-305, and 17-95-401-17-95-411, shall dispense legend drugs without prior approval by the Arkansas State Medical Board after application to the board and on the showing of need. Licensed physicians who were dispensing in the ordinary course of their practice for the twelve (12) months immediately prior to July 4, 1983, shall be exempt from the requirements of this subsection.

(e) The board shall enforce the provisions of this section and is authorized and directed to adopt regulations to carry out its purpose.

Arkansas Code Annotated § 17-92-105 (2001 Repl.).³

Turning to the profit-making aspect of your question, while Arkansas Code Annotated § 17-95-102 makes clear that a licensed physician may dispense legend drugs provided that certain requirements are met, it does not separately address the profit-making aspect of such a practice. In fact, my research has not uncovered any provision that specifically addresses the authority of physicians to make a profit by dispensing their own prescriptions.

Section 17-95-102 states that a dispensing physician “purchases legend drugs to be dispensed to his or her patients[.]” It is my opinion that this language tends to suggest a commercial transaction. Although the word “dispense” rather than the word “sell” is used with respect to the patient, I believe one could reasonably conclude that “dispense” is used here in a broad sense that includes giving the drug to the patient as part of a commercial transaction, i.e., for a profit.

³ Regulation 12 of the Rules and Regulations of the Arkansas State Medical Board is the regulation adopted to carry out the purpose of the law.

I also note that Attorney General Opinion 91-327, issued by one of my predecessors, concludes that licensed physicians may “sell” prescription drugs so long as they meet the relevant statutory requirements. I can find no reason to disagree with this opinion. To the best of my knowledge, legend drugs are not typically dispensed to patients wholesale. Rather, it is my understanding that those dispensing such drugs generally make some profit from the transaction. Because dispensing legend drugs nearly always involves a profit to the dispenser and the power to dispense legend drugs has been expressly given to physicians by the legislature, it is my opinion that a licensed physician’s authority to dispense for a profit may be inferred.

In sum, it is my opinion that A.C.A. § 17-92-102(a) does not *directly* permit the described activity; however, it does appear to recognize that such activity is otherwise permitted. Rather, A.C.A. § 17-95-102(a) is the provision that directly permits such activity, in my opinion.

Question 2: Does A.C.A. § 17-92-102(a) permit duly licensed nurse practitioners with prescriptive authority to distribute pre-packaged pharmaceuticals, which have been prescribed to patients, for a profit?

Again, it is my opinion that Section 17-92-102(a), standing alone, does not permit any particular activity.

It is true that some nurse practitioners (those who are advanced practice nurses and have met all other relevant requirements) have prescriptive authority. *See* A.C.A. §§ 17-87-310 & 17-92-110. However, prescriptive authority does not necessarily equal dispensing authority.

First and foremost, there is simply no provision or regulation that grants advanced practice nurses dispensing authority.

Moreover, advanced practice nurses do not benefit from the exemption from the pharmacy laws granted by A.C.A. § 17-92-102(a). According to the plain language of A.C.A. § 17-92-102(a), the only exempt professionals are physicians, dentists, and veterinarians.⁴ Because advanced practice nurses are not exempt,

⁴ I will note that Op. Att’y Gen. 2001-186, issued by one of my predecessors, opines that the omission of advanced practice nurses from the exemption “does not . . . indicate a legislative intent to exclude advanced practice nurses from the stated exemption.” The quoted statement was based on the fact that the profession

they are subject to provisions such as the aforementioned A.C.A. § 17-92-403, which prevents any person except a pharmacy student serving as an intern from filling a prescription when a licensed pharmacist is not present.

Finally, in order to be granted prescriptive authority, an advanced practice nurse must have a collaborative practice agreement with a licensed physician who has a comparable scope of practice. A.C.A. § 17-87-310(a)(2). Even assuming that the physician in question has been approved as a dispensing physician by the Arkansas State Medical Board, a physician's *dispensing* authority is personal to that physician and may not be delegated to anyone else. A.C.A. § 17-95-103(c)(1).⁵ This means that there is no provision that would allow an advanced practice nurse to obtain dispensing authority derivatively.

In sum, it is my opinion that neither A.C.A. § 17-92-102(a) nor any other provision permits advanced practice nurses with prescriptive authority to distribute pre-packaged pharmaceuticals for a profit, i.e. engage in point-of-care medication dispensing.

Question 3: Does A.C.A. § 17-92-102(a) permit duly licensed physician assistants with prescriptive authority to distribute pre-packaged pharmaceuticals, which have been prescribed to patients, for a profit?

The reasoning behind this response is similar to the reasoning behind my response to your second question. First, although physician assistants have prescriptive authority pursuant to the terms of A.C.A. § 17-105-108, there is no provision or regulation that grants physician assistants dispensing authority. Moreover, as previously discussed in relation to advanced practice nurses, A.C.A. § 17-92-102(a) does not exempt physician assistants from the provisions governing pharmacies and pharmacists. Finally, all prescriptive authority enjoyed by

of advanced practice nursing did not exist at the time the exemption was enacted and might tend to suggest the view that advanced practice nurses with prescriptive authority are authorized to dispense. In my opinion, the exemption must be interpreted consistent with its plain language. The legislature is capable of amending the statute to exempt advanced practice nurses if it wishes to do so. Moreover, my research indicates that the Arkansas State Board of Nursing does not issue dispensing permits for advanced practice nurses. Therefore, to the extent that 2001-186 suggests that the exemption in question applies to advanced practice nurses, I must respectfully disagree. Disagreement on this limited point *should not*, however, be construed as disagreement with the remainder of 2001-186, which involves distribution of drug samples and is consequently unrelated to the present inquiry.

⁵ Please note the distinction between dispensing authority and prescribing authority. A physician's *prescribing* authority may be delegated under certain specific circumstances. *See, e.g.* A.C.A. 17-105-108.

physician assistants is clearly derivative in nature. *See* A.C.A. § 17-105-108. As previously stated, a dispensing physician cannot delegate his or her dispensing authority. A.C.A. § 17-95-103(c)(1).

In sum, it is my opinion that neither A.C.A. § 17-92-102(a) nor any other provision permits physician assistants with prescriptive authority (physician assistants who have been properly delegated prescriptive authority by their supervising physician(s) pursuant to A.C.A. § 17-105-108) to distribute pre-packaged pharmaceuticals for a profit, i.e., engage in point-of-care medication dispensing.

Question 4: Does A.C.A. § 17-92-102(a) permit duly licensed dentists with prescriptive authority to distribute pre-packaged pharmaceuticals, which they have prescribed to their own patients, for a profit?

The analysis set forth in response to your first question is largely relevant to properly licensed dentists.

Again, A.C.A. § 17-92-102 is found in the chapter of the Arkansas Code that governs pharmacists and pharmacies and states in relevant part:

Nothing in this section and [other named sections of the same chapter] shall . . . apply to physicians, dentists, or veterinarians compounding or dispensing their own prescriptions.

Arkansas Code Annotated § 17-92-102(a) (2001 Repl.)

While this provision, standing alone, does not directly give dentists the authority to engage in point-of-care dispensing, it appears to recognize that such activity is otherwise permitted because it exempts dentists, like physicians, from certain key provisions applicable to pharmacists and pharmacies.

Unlike physicians, there is no statute that directly gives dentists dispensing authority. However, Article III. F. of the Rules and Regulations of the Arkansas State Board of Dental Examiners affirmatively permits dentists to dispense “legend drugs to treat diseases, disorders, and conditions of the oral cavity, maxillofacial area, and the adjacent and associated structures and their impact on the human body” if prior approval of the Board of Dental Examiners is properly

obtained.⁶ Administrative regulations will not be set aside unless they are arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law. *McLane Co., Inc. v. Davis*, 353 Ark. 539, 110 S.W. 3d 251 (2003). Because A.C.A. § 17-92-102 appears to recognize that dentists have the authority to dispense, it is my opinion that Article III.F. accords with other relevant law and is, therefore, proper.

Finally, despite the fact that Article III. F. (like A.C.A. §17-92-102 for physicians) does not directly address the profit-making aspect of your question, I believe that the authority to dispense for a profit may properly be inferred because the power to dispense legend drugs (an activity generally undertaken for a profit) has been expressly given. Article III. F. is worded very similarly to A.C.A. § 17-95-102 dealing with dispensing physicians and states that a dispensing dentist “purchases legend drugs . . . to be dispensed to his or her patients[.]” Again, it is my opinion that this language tends to suggest a commercial transaction and that one could reasonably conclude that “dispense” is used here in a broad sense that includes giving the drug to the patient as part of a commercial transaction, i.e., for a profit.

In sum, it is my opinion that A.C.A. § 17-92-102(a) does not *directly* permit the described activity; however, it recognizes that such activity is otherwise permitted. Article III. F. of the Rules and Regulations of the Arkansas State Board of Dental Examiners is the direct source of authority for such activity.

Assistant Attorney General Jennie Clingan prepared the foregoing opinion, which I hereby approve.

Sincerely,

DUSTIN McDANIEL
Attorney General

DM:JLC/cyh

⁶ A comprehensive list of rules and requirements for dispensing dentists can be found in the Rules and Regulations of the Arkansas State Board of Dental Examiners at III. F. 1-6.