



February 24, 2000

Ms. Gay Dodson, R.Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
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333 Guadalupe Street, Box 21
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Opinion No. JC-0186

Re: Whether state law permits the use of an automated dispensing machine to dispense prescription drugs at a nursing home (RQ-0121-JC)

Dear Ms. Dodson:

On behalf of the Texas State Board of Pharmacy (the "Board"), you ask whether state law permits the use of an automated dispensing machine to dispense prescription drugs at a nursing home. We conclude that because the machine you describe dispenses prescription drugs, a function that state law generally reserves to licensed pharmacies, the facility where it is located must be licensed as a pharmacy and must be under a pharmacist's continuous onsite supervision as required by the Texas Pharmacy Act, TEX. OCC. CODE ANN., tit. 3, subtit. J, chs. 551-566 (Vernon 2000) (the "Act").¹ The automated dispensing machine you describe would not be under a pharmacist's continuous onsite supervision and is therefore not permitted under the Act.

You provide the following description of the type of automated dispensing machine at issue:

The automated dispensing system is a machine, which is designed to mechanically sort and then individually label and package oral medications for administration to patients in long-term care facilities (i.e., nursing homes). A licensed pharmacist would load the machine with bulk medications. A nurse at a nursing home would input a prescription order into an on-site computer. Then a pharmacist at an off-site pharmacy would review the prescription order with the patient's medication record. When the review is complete, the pharmacist would send the order to the automated dispensing system at the nursing home and instruct the machine to prepare and dispense the prescription for the patient. Access to the bulk medications contained in the automated dispensing system other than those dispensed would be limited to a licensed pharmacist.

¹In the last legislative session, the Seventy-sixth Legislature codified the Act, former article 4542a-1, in title 3, subtitle J of the Occupations Code. We refer to the Act as codified unless otherwise noted.

Letter from Gay Dodson, R.Ph., to Elizabeth Robinson, Chair, Opinion Committee, Office of the Attorney General, at 1 (Oct. 4, 1999) (on file with Opinion Committee) [hereinafter "Request Letter"].

The Board seeks our opinion "regarding the use of an automated dispensing system at a facility which does not have a valid pharmacy license, such as a nursing home, and the dispensing of controlled substances and/or dangerous drugs through the use of such a system by a pharmacist not physically located at the facility." *Id.* In order to resolve this issue, you pose two questions:

1. Under the provisions of the Texas Dangerous Drug Act, Chapter 483, Health and Safety Code, and the Texas Controlled Substances Act, Chapter 481, Health and Safety Code, may a pharmacy store bulk unlabeled dangerous drugs and/or controlled substances in an automated dispensing system at a facility, such as a nursing home, if this facility is not licensed as a pharmacy and is at a location other than the licensed pharmacy?

2. If bulk unlabeled dangerous drugs and/or controlled substances may be stored in such a system, does a pharmacist have to be physically present at the facility where the automated dispensing system is located when a prescription is dispensed using the system?

Id. at 1-2. Because we conclude that the automated dispensing machine you describe is not permitted under the Texas Pharmacy Act, we do not reach your question about the Dangerous Drug Act and Controlled Substances Act and storage of drugs at a nursing home in an automatic dispensing machine.

We answer your query based on the licensing requirements of the Act and the Act's extensive and detailed definitions of technical terms, which the Code Construction Act mandates that we apply. *See* TEX. GOV'T CODE ANN. § 311.011(b) (Vernon 1998) ("Words and phrases that have acquired a technical or particular meaning, whether by legislative definition or otherwise, shall be construed accordingly."); *see also* TEX. OCC. CODE ANN. § 1.002 (Vernon 2000) (Code Construction Act "applies to the construction of each provision in this code except as otherwise expressly provided by this code").

The Act defines a "pharmacy" as "a facility at which a prescription drug or medication order is received, processed, or dispensed under this subtitle, Chapter 481 or 483, Health and Safety Code, or the [federal] Comprehensive Drug Abuse Prevention and Control Act of 1970." TEX. OCC. CODE ANN. § 551.003(31) (Vernon 2000) (emphasis added). "Dispense" means "to prepare, package, compound, or label, in the course of professional practice, a prescription drug or device for delivery to an ultimate user or the user's agent under a practitioner's lawful order." *Id.* § 551.003(16); *see also id.* § 551.003(13) ("Deliver" or "delivery" means "the actual, constructive, or attempted

transfer of a prescription drug or device or controlled substance from one person to another, with or without consideration.”), (22) (“Labeling” means the process of affixing a label . . . to a drug or device container . . .”). Under the Act, a “pharmacist” is a person licensed by the Board to practice pharmacy. *See id.* § 551.003(28). The “practice of pharmacy” includes, among other things, “being responsible for: (i) dispensing a prescription drug order or distributing a medication order; [and] (ii) compounding or labeling a drug or device.” *Id.* § 551.003(33)(E).

The dispensing of prescription drugs is an essential function of both a pharmacy and a pharmacist, which the Act is intended to govern. Only certain persons—namely health care professionals, college of pharmacy professors, drug researchers—and home and community support services agencies are permitted to dispense drugs outside the Act’s scope. *See id.* § 551.004.

As you have described the automatic dispensing machine, an offsite “pharmacist would send [an] order to the automated dispensing system at the nursing home and instruct the machine to prepare and dispense the prescription for the patient.” Request Letter at 1. The machine would “individually label and package oral medications for administration to patients” from the bulk medications stored in the machine. *See id.* Based on this description, it appears that the machine would “package . . . or label, in the course of professional practice, a prescription drug or device for delivery to an ultimate user or the user’s agent under a practitioner’s lawful order,” TEX. OCC. CODE ANN. § 551.003(16) (Vernon 2000), and would thus “dispense” prescription drugs within the meaning of the Act, *see id.* For this reason, we conclude that a nursing home where such a machine is located would be “a facility at which a prescription drug or medication order is . . . dispensed” and therefore would be a “pharmacy” within the meaning of the Act. *See id.* § 551.003(31).

Under the Act, a pharmacy must be licensed by the Board. *See id.* § 560.001(a) (“A person may not operate a pharmacy in this state unless the pharmacy is licensed by the board.”). A separate pharmacy license is required for each principal place of business of a pharmacy and only one pharmacy license may be issued for each specific location. *See id.* § 560.102.

The Act provides for five pharmacy classifications. A Class A pharmacy license or community pharmacy license authorizes a pharmacy to dispense a drug or device to the public. *See id.* § 560.051(b). A Class B pharmacy license authorizes a pharmacy to dispense a radioactive drug or device to the public. *See id.* § 560.051(c). A Class C institutional pharmacy license may be issued to a pharmacy located in: a hospital or other inpatient facility licensed under chapter 241 or 577 of the Health and Safety Code; a hospice inpatient facility licensed under chapter 142 of the Health and Safety Code; an ambulatory surgical center licensed under chapter 243 of the Health and Safety Code; or a state hospital. *See id.* § 560.051(d), *as amended by* Act of May 27, 1999, 76th Leg., R.S., ch. 1518, § 1, 1999 Tex. Gen. Laws 5241. A Class D clinic pharmacy license authorizes a pharmacy to dispense a limited type of drug or device. *See* TEX. OCC. CODE ANN. § 560.051(e) (Vernon 2000). Finally, a Class E nonresident pharmacy license pertains to a pharmacy located in another state. *See id.* § 560.051(f). The board may determine the classification under which a pharmacy may be licensed. *See id.* § 560.051(g). Given these classifications, it appears that the location of an automated drug dispensing machine would generally require a Class A pharmacy

license although a Class C license might be available with regard to a machine located at a nursing home with licensed hospital facilities.

All pharmacies must be supervised by a pharmacist. *See id.* § 562.101(a). The degree of supervision required depends upon the type of pharmacy. Under section 562.101 of the Act, a Class A pharmacy “is required to be under the continuous on-site supervision of a pharmacist during the time the pharmacy is open for pharmacy services.” *Id.* § 562.101(b). Similarly, a Class C pharmacy in an institution with more than 100 beds “is required to be under the continuous on-site supervision of a pharmacist during the time the pharmacy is open for pharmacy services.” *Id.* § 562.101(c). A smaller institution “is required to have the services of a pharmacist on a part-time or consulting basis according to the needs of the institution.” *Id.* § 562.101(d). We assume that most nursing homes associated with licensed hospitals are associated with hospitals with more than 100 beds.

Section 562.101 generally requires that a pharmacist be physically present at a Class A or larger-institution Class C pharmacy when it is open for “pharmacy services.” This supervision requirement clearly contemplates a traditional retail establishment that is open for business during certain hours of the day. However, we cannot conclude that this requirement is inapplicable to a pharmacy operating by way of the type of automated dispensing machine you describe, which would dispense drugs at intermittent times at the instruction of a pharmacist located off-site. The Act makes no exception to the continuous on-site supervision requirement for Class A pharmacies or the Class C pharmacies to which it applies. Nor does the Act authorize the Board to make exceptions to the requirement by rule.

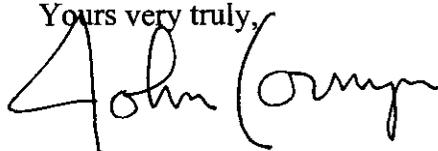
In sum, the Act includes in the definition of “pharmacy” facilities at which prescription drugs are dispensed and generally requires the licensing of all such facilities. The Act also generally requires licensed pharmacies to operate under the continuous onsite supervision of a pharmacist and does not provide an exception for the type of automated dispensing machine described in your query. Thus, the automated dispensing machine you describe, which by definition would dispense drugs without the onsite supervision of a pharmacist, is not permitted under the Act.

Finally, we are aware that one point of automated drug dispensing machines is to eliminate the expense of such onsite supervision and to reduce the cost of providing prescription drugs to nursing home patients. While the Act may not take into account the advanced technology you describe, which appears to allow a pharmacist to closely supervise via computer the dispensing of prescription drugs by a machine at an off-site location, it is clear in prohibiting the off-site supervision you describe. We are not at liberty to depart from the Act’s terms. Although it may be the case that the Act should be amended to specifically address, and perhaps embrace, such technological advances, that is a policy choice that must be made by the legislature rather than this office.

S U M M A R Y

The Texas Pharmacy Act, TEX. OCC. CODE ANN., tit. 3, subtit. J, chs. 551-566 (Vernon 2000), includes in the definition of "pharmacy" all facilities at which prescription drugs are dispensed and generally requires the licensing of all such facilities. The Act also generally requires licensed pharmacies to operate under the continuous onsite supervision of a pharmacist and does not provide an exception for the type of automated dispensing machine described in your query. Thus, an automated prescription drug dispensing machine, which would dispense prescription drugs without the onsite supervision of a pharmacist, is not permitted under the Act.

Yours very truly,



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