

Opinion

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OPINION
OF
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Opinion No. 88-50

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TO: James Daily
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QUESTIONS:

1. Is the Board of Pharmacy authorized to require physicians to keep records of samples of dangerous drugs that they dispense to their patients?
2. Is the Board of Pharmacy authorized to require physicians to label samples they dispense?

CONCLUSIONS:

1. Yes.
2. Yes.

ANALYSIS:

Section 26-1-16 of the New Mexico Drug, Device and Cosmetic Act ("Act"), Sections 26-1-1 to 26-1-26 NMSA 1978 (Repl. 1987), provides in part:

B. Practitioners licensed in this state may prescribe, provide samples of and dispense any dangerous drug to a patient where there is a valid physician-patient relationship. A record of all such dispensing shall be kept showing the date the drug was dispensed and bearing the

name and address of the patient to whom dispensed. It is the duty of every licensed physician ... when dispensing any dangerous drug, to mark on the dispensing container the name of the patient, the date dispensed, the name and address of the person dispensing the drug, the name and strength of the drug, expiration date where applicable, adequate directions for use and the prescription number when applicable. All official compendium requirements for the preservation, packaging, labeling and storage of dangerous drugs are applicable where drugs are held for dispensing to the public, whether by a pharmacy, clinic, hospital or practitioner.

....

E. It is unlawful ... for any person to possess any dangerous drug unless such substance has been dispensed to him either directly by a practitioner or on a prescription.

F. All records required to be kept under the provisions of the New Mexico Drug, Device and Cosmetic Act shall be preserved for a period of three years, provided that records requirements do not apply to the administration of a drug to a patient upon whom the practitioner personally attends....

Before the legislature amended Subsection B by 1987 N.M. Laws, ch. 270, §6, it read: "Practitioners licensed in this state may dispense or prescribe any dangerous drugs.... A record of all such dispensations, except administration to a patient upon whom the practitioner personally attends, shall be kept...." The 1987 amendments did not alter the prohibition against possessing a dangerous drug unless it has been "dispensed" by a practitioner or on a prescription, the exemption from record-keeping requirements for physicians that "administer" drugs to patients, and the requirement that physicians keep records of and label drugs that they dispense. Rather, the 1987 amendment simply authorized physicians to "provide samples" of drugs. The question therefore is whether Section 26-1-16, as amended, allows a physician to provide a drug "sample" without complying with the record-keeping and labeling requirements that apply to "dispensing."

The Act does not define "dispense." However, Section 61-11-2(F) of the Pharmacy Act, Sections 61-11-1, 61-11-2 and 61-11-4 to 61-11-28 NMSA 1978 (Repl. 1986), defines it as: "[I]ssuing to a patient or a person acting on his behalf, one or more unit doses of medication and may result from compounding or from repackaging from a bulk or original container." A "dose" is "the measured quantity of a medicine or other therapeutic agent to

be taken at one time or in a period of time." Webster's Third New International Dictionary at 676 (1961). A physician who provides to a patient a sample of medication "issues" to that patient one or more "doses of medication."

The Legislature, however, has distinguished between "samples" and other "dispensing" in Subsection 26-1-16(B). Webster's Third New International Dictionary at 2,008 (1961) defines "sample" as "a trial package of a product distributed without cost to potential consumers." This statutory distinction arguably manifests the Legislature's intent that a "trial package" of a drug provided by a manufacturer's representative to a physician for his distribution to a patient did not warrant the record-keeping and labeling that Section 26-1-16(B) requires when practitioners "dispense" drugs.

We reject this conclusion for two reasons. First, we must construe Subsection 26-1-16(B) in the context of the other provisions of the Act. See N.M. State Bd. of Educ. v. Board of Educ., 95 N.M. 588, 592, 624 P.2d 530, 534 (1981). The Legislature did not distinguish between dispensing and providing samples in other parts of Section 26-1-16. Subsection 26-1-16(E) prohibits possession of a dangerous drug unless a physician has dispensed or prescribed it. The only exception to Subsection 26-1-16(F)'s record-keeping requirements is a doctor's administration of a drug to a patient. Therefore, under these two provisions, giving a patient a drug sample is a form of dispensing.

Second, exempting doctors' provision of drug samples to patients from labeling and record-keeping requirements conflicts with the Act's general purpose of protecting the public from dangerous drugs. In Pharmaceutical Mfrs. Ass'n v. New Mexico Bd. of Pharmacy, 86 N.M. 571, 575, 525 P.2d 931, 935 (Ct.App.), cert. quashed, 86 N.M. 657, 526 P.2d 799 (1974), the court upheld Board of Pharmacy regulations that required licensing of drug manufacturers, distributors and agents. It stated:

[T]heir primary purpose is the protection of the public from dangerous drugs.... That purpose is well within the traditional definition of police power....

The state interest in drug control is substantial and ever growing.... [T]hat interest is magnified by a corresponding federal interest. The regulations questioned here, and their authorizing statutes are part of a coordinated state-federal drug abuse prevention system.

In State v. Collins, 61 N.M. 184, 187, 297 P.2d 325, 327 (1956), in upholding a statute that restricted use of the word "drug store," the court stated:

We regard the business of selling drugs and medicines as so intimately connected with and having such a vital relationship to the health, safety and welfare of the public that there ought not to be any doubt that its regulation falls within the authority of the Legislature in the exercise of its police power.

The Legislature, in exercise of its police power to protect the health, safety and welfare of the public, imposes on dispensing practitioners the duty to keep records and properly label the drugs they dispense to patients. We understand that most of the drugs that physicians provide to patients are in the form of samples. To imply an exemption from these duties for samples might well negate them and thwart the Legislature's intent to regulate practitioner dispensing.

The New Mexico Court of Appeals has broadly interpreted the word "dispense" as used in a related statute. In New Mexico Bd. of Pharmacy v. New Mexico Bd. of Osteopathic Med. Examiners, 95 N.M. 780, 626 P.2d 854 (Ct.App. 1981), the court held that the Board of Osteopathic Medical Examiners could not authorize osteopathic physicians' assistants to "prescribe" controlled substances, because the underlying act prohibited any rule that would allow assistants to "dispense" dangerous drugs. The court disagreed with the Osteopathic Board's argument that its rule authorized only "prescribing," and did not authorize "dispensing." The court stated:

The Controlled Substances Act is a comprehensive statute designed to enable the State to try to control the drug abuse problem. It specifies, with considerable particularity, who can dispense controlled substances which have a potential for abuse. To adopt appellee's position would constitute an impermissible enlargement of the class of persons authorized by the Act to dispense these substances, whether "dangerous" or not.

Id. at 782, 626 P.2d at 856. This decision counsels us to interpret the phrase "all such dispensing" broadly, in accordance with the statute's purpose, to include the giving of samples. To interpret otherwise, without clear legislative direction, restricts the State's exercise of its police powers in this area.

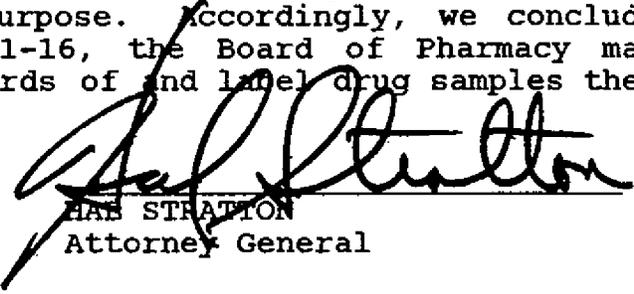
Applying record-keeping and labeling requirements to drug samples that physicians give to patients clearly protects the public. The federal Prescription Drug Marketing Act of 1987, Pub.L. No. 100-293, 102 Stat. 95, requires manufacturers to keep records of physicians' requests for samples. Id. §5, 102 Stat. at 97-98. In its report on the Act, the Senate Finance Committee wrote: "The purpose of the legislation is to curb operation of the diversion market for prescription drugs that operates outside of normal channels of distribution and makes it difficult to protect American consumers from misbranded, subpotent, adulterated, expired or counterfeit pharmaceuticals. S.Rep. No. 303, 100th Cong., 2d Sess. 2 (1988). Subsection 26-1-16(B)'s record-keeping requirements furthers the same goal.

The labeling requirements are equally important. Physicians' failure to label drugs they provide to patients create problems for poison center personnel:

"We have encountered some extremely serious poisonings, especially in pediatric and elderly patients. The lack of labeling (on physician-dispensed Rx's) often impedes treatment, since we have no idea what was ingested or how much." ... Physician-dispensed samples swallowed by children are another vexation: "There is inadequate labeling on these drug samples.... The physician fails to fill in the space provided for instructions to the particular patient." "[O]ur main problem with physician dispensing is with samples. The patients frequently forget the directions or what the medicine is used for."

S. Siegelman, "When MD-Dispensing Creates Problems at Poison Centers," American Druggist at 13 (March, 1987).

The Act is designed to protect the public. The Legislature's intent in amending Section 26-1-16 is not entirely clear. But to interpret the provision to relieve practitioners of responsibility for keeping records of those to whom they give sample drugs and of labeling those drugs would conflict with other provisions of the Act as well as its general purpose. Accordingly, we conclude that, pursuant to Section 26-1-16, the Board of Pharmacy may require physicians to keep records of and label drug samples they give to patients.


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