



STATE OF KANSAS

Office of the Attorney General

1st Floor, State Capitol Bldg. (913) 296-2215 Topeka, Kansas 66612

Curt T. Schneider,
Attorney General

December 16, 1975

ATTORNEY GENERAL OPINION NO. 75- 455

The Honorable T. D. Saar, Jr.
State Senator
903 Kings Free Highway
Pittsburg, Kansas 66762

Mr. James W. Cleland
President
Kansas State Board of Pharmacy
Rural Route 1
Wakeeney, Kansas

Re: State Board of Pharmacy--Adult Care Homes--"Unit
Dose Systems" and "Freedom of Choice"

Synopsis: Board of Pharmacy has acted within its statutory
authority to hold informal hearings, to issue guidelines
and to approve unit dose drug distribution systems.

Unit dose systems operating in this state as approved
by the Board of Pharmacy do not violate the "freedom
of choice" concept as provided by federal regulation
and absent statutory provisions to the contrary do not
violate any provisions of Kansas law.

* * *

Gentlemen:

This office has been requested to issue an opinion relative to
the position taken by the State Board of Pharmacy with regard
to a system of dispensing drugs to patients in adult care
facilities referred to as "unit dose drug distribution." The
Board has investigated several such systems in recent months
and permitted a number of pharmacies to operate these systems
which precipitates your primary question whether the Board has
acted within its statutory authority in so "approving" this

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method of drug distribution. Collaterally the additional question is asked whether unit dose drug distribution as it presently functions deprives the individual patient what is popularly referred to as "freedom of choice" - meaning the right to select the pharmacist of one's choice.

The unit dose distribution system (also referred to as pharmacists measured medication dose system) is a relatively new concept for dispensing medication to the adult care home patient in Kansas. Several pharmaceutical companies in this country have developed and marketed unit dose systems in this state, which although differing somewhat mechanically function fundamentally along the same design: *i.e.*, unit dose packaging of prescription medication is prepared by a registered pharmacist in containers which preserve integrity and drug identity from the point of prescription through administration to the patient in the adult care facility. These systems, unique and somewhat complex in nature, utilize *inter alia* packaging and labeling methods which the Board believed should be carefully scrutinized for compliance with state and federal law. Accordingly, the Board issued what was officially entitled "Guidelines and Policy Statement of the State Board of Pharmacy of the State of Kansas Concerning Pharmacists Measured Medication Dose System or Unit Dose System in Adult Care Homes" on March 15, 1974, to all Kansas pharmacists.¹ This document became the so-called "guidelines" which precipitated the question here presented. Essentially these guidelines recognized the acceptability of unit dose systems to the extent they could meet the requirements of state and federal law which were delineated in the Board's requirements. As a practical matter the guidelines were designed to assist the Board in its investigatory capacity by requesting each pharmacist desiring to implement a unit dose system to apply to the Board for an informal hearing preferably before the system became operative (although this was not entirely feasible since several had begun operation at the time the guidelines were issued). We are advised that the Board in fact conducted a number of such hearings, and that each consisted of a factual presentation by the "applicant" of the proposed unit dose system. The Board was then to ascertain from the evidence whether the system complied with state and federal law. By making this determination the Board thus gave *de facto* approval of several unit dose systems now operating throughout the state.

¹ "Guidelines and Policy Statement of the State Board of Pharmacy of the State of Kansas Concerning Pharmacists Measured Medication Dose System or Unit Dose System in Adult Care Homes" is attached hereto for your convenience.

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Initially it should be understood that the guidelines did not, of course, carry the weight and authority of law. And, we have no knowledge that the Board ever attempted to enforce them as such. As the Board's Executive Secretary, Mr. Joseph Shalinsky, pointed out in his letter to the pharmacists,² the guidelines were drafted to assist the Board in controlling unit dose systems in the interim period while regulations were being prepared. We find nothing which would indicate that the Board exceeded its statutory authority by issuing the guidelines or by conducting the informal hearings. On the contrary, it appears that the Board, recognizing the technical problems presented by unit dose, acted propitiously in utilizing its investigative authority to protect the many nursing home patients who would be directly concerned. Accordingly, it is the opinion of this office that by examining and "approving" unit dose drug distribution systems as it has, the Board has exercised reasonably its statutory mandate to assure compliance with the Kansas Pharmacy Act.

Secondly, you inquire whether the unit dose system operates to deprive the patient of an adult care home the freedom to select a particular pharmacist for his or her medication, a privilege commonly referred to as "freedom of choice." "Freedom of choice" originally derives from a provision of the federal Social Security Act, 42 U.S.C.A. § 1395a which provides:

"Any individual entitled to insurance benefits under this subchapter may obtain health services from any institution, agency, or person qualified to participate under this subchapter if such institution, agency, or person undertakes to provide him such services." [§ 1802, Social Security Act]

"Freedom of choice" was subsequently referred to generally as such in 45 C.F.R. § 249.11. This proviso was replaced by 45 C.F.R. § 249.20 which in pertinent part provides:

"A State Plan for medical assistance under title XIX of the Social Security Act must provide that any individual eligible for medical assistance under the

² See, cover letter for "Guidelines and Policy Statement" prepared by Mr. Joseph Shalinsky, Executive Secretary for the Board, dated March 15, 1974, attached hereto.

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plan may obtain the services available under the plan from any institution, agency, pharmacy, or practitioner, including an organization which provides such services or arranges for their availability on a prepayment basis, which is qualified to perform such services. However, services provided on a prepayment basis may be limited in accordance with section 1902(a)(23) of the Social Security Act." * * * [See, 39 F.R. 2223, January 17, 1974]

We are advised however that the agency of the United States Department of Health, Education and Welfare responsible for the administration of the Medicaid program has not issued as of this date a definitive interpretation of this regulation which would provide an answer to your question.

Many nursing homes in this state employing the unit dose system require all patients within the home to utilize the system. Thus, it is argued that the systems' net effect deprives patients the "freedom of choice" specified by federal regulation. It is further suggested that this result is not in accordance with the desires of the Kansas Legislature. First, we find no constitutional provision or Kansas statute which would reflect any position taken by the legislature with regard to "freedom of choice." Second, we do not believe it is the implementation of the unit dose system *per se* which deprives a patient the opportunity to purchase his or her drugs from the pharmacy of his or her choice. The problem appears to pivot upon the immediate relationship between the patient and the nursing home. In other words it is the contractual arrangement between the patient and the facility which determines those "rights" the patient may have with respect to the services offered by the facility. Thus the critical element becomes the mutual understanding between the two contracting parties. And, we find nothing unlawful under Kansas law for a nursing home to require contractually that all patients be administered their prescribed medication via a unit dose system operated by a single pharmacy. The fact remains that if such an arrangement is not suitable to the patient or prospective patient he or she may still exercise the option of seeking the services of another institution. Parenthetically we add that the medical services section of the Division of Social Services of the Kansas Department of Social and Rehabilitation Services

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has for some time applied essentially this definition to the federal regulations requiring freedom of choice for providers of medical services.³

Thus it is my opinion that the Board of Pharmacy has acted within its statutory authority to investigate the unit dose distribution systems, both proposed and in operation; that the guidelines were an informal yet legitimate method of assisting the Board in performing that function; and, the decisions reached by the Board upon examination of the facts were well within its province. Further it is my opinion that the "freedom of choice" concept as provided by federal regulation is not violated by the unit dose systems used as above described by Kansas nursing homes insofar as the patient is never deprived of an alternative to seek service elsewhere, and absent applicable Kansas statutory provisions to the contrary we must conclude that such systems do not violate the law of this state.

Yours very truly,



CURT T. SCHNEIDER
Attorney General

CTS:JPS:kj

cc: Mr. Clarence J. Hamm
914 Clute
Kinsley, Kansas

Mr. Jacob W. Miller
2000 Collins Avenue
Topeka, Kansas

Mr. Hugh T. Polson
2332 Redbud
Wichita, Kansas

Ms. E. Marie Wyckoff
1138 North Anthony
Anthony, Kansas

Mr. Joseph Shalinsky
Board of Pharmacy
Post Office Box 6150, Argentine Station
Kansas City, Kansas

³ Advised via interview with Mr. William Newman, Director Medical Service Section, Division of Social Services, Department of Social and Rehabilitation Services, December 1, 1975.

MEMO

TO: ALL KANSAS PHARMACISTS

FROM: Joseph G. Shalinsky, Executive Secretary
Kansas State Board of Pharmacy

DATE: March 15, 1974

Gentlemen:

The State Board of Pharmacy of the State of Kansas has been studying an innovation in the drug distribution system within Adult Care Homes in the state of Kansas, commonly referred to as the pharmacists measured medication dose system or unit dose system. On October the 5th, 1973, a meeting was held by the Kansas State Board of Pharmacy for the purpose of discussing the use of such a system within this State. Invitations were forwarded to various agencies and during the course of that meeting, extensive testimony was received concerning the benefits and liabilities of said system. After full consideration by the State Board of Pharmacy of the State of Kansas of all testimony at said meeting and after independent study, the State Board of Pharmacy has adopted guidelines and policies relating to the use of such a system within Kansas. A copy of guidelines is attached to this letter for your information. Any questions pertaining to these guidelines should be directed to the Executive Secretary of the State Board of Pharmacy of the State of Kansas.

The guidelines require that any pharmacist, prior to adopting or initiating the use of such a system must notify the Executive Secretary of the State Board of Pharmacy and make written application to the State Board of Pharmacy of the State of Kansas prior to the initiation of that system. Those pharmacists presently operating such a system in the state of Kansas must make application on a written form provided by the Executive Secretary of the State Board of Pharmacy for continued use of said system. Upon receipt of the written application, time will be allotted at a regular meeting of the State Board of Pharmacy for discussion of the system presently being used or discussion of a system proposed to be used in the State of Kansas. [Your cooperation with reference to these guidelines is greatly appreciated and within a short period of time, regulations will be adopted concerning the pharmacist's measured medication dose system or unit dose system within Adult Care Homes in the State of Kansas.]

Sincerely,

JGS/ss

Joseph G. Shalinsky,
Executive Secretary of the
State Board of Pharmacy of
the State of Kansas

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KANSAS STATE BOARD OF PHARMACY
Office of the Executive Secretary
Box 6150
Argentine Station
Kansas City, Kansas 65106
913-362-1790

GUIDELINES AND POLICY STATEMENT OF THE STATE BOARD OF
PHARMACY OF THE STATE OF KANSAS CONCERNING
PHARMACISTS MEASURED MEDICATION DOSE
SYSTEM OR UNIT DOSE SYSTEM
IN ADULT CARE HOMES

I. DEFINITION OF SYSTEM: THAT DRUG DISTRIBUTION SYSTEM WHICH IS PHARMACY BASED AND WHICH INVOLVES UNIT DOSE PACKAGING OF PRESCRIPTION MEDICATION IN CONTAINERS WHICH PRESERVE DRUG INTEGRITY AND DRUG IDENTITY FROM THE POINT OF PRESCRIPTION THROUGH ADMINISTRATION OF SAID DRUG TO PATIENTS.

II. PHARMACY BASED:

A. Dispensing as that term is defined under Kansas Pharmacy Law and the Uniform Controlled Substances Act must be done within such system by a Kansas registered pharmacist or pharmacy intern as that term is defined under Kansas Pharmacy Law and Regulations.

B. Dispensing for the purposes of said system shall include the following:

- (1) Packaging of unit dose.
- (2) Labelling of unit dose.
- (3) Selection of unit dose package.
- (4) Placing unit dose into trays (for purposes of this system, container requirements of a prescription broaden to include trays, carts, locked cabinets, etc.)
- (5) Adding additional labelling information, e.g., name of patient, prescription number, pharmacy name, physician's name and date.

C. Label for unit dose container - must be complete in all details as required by present applicable federal and state law, included but not limited to, the following:

- (1) Patient's name and directions for use.
- (2) Physicians name and date.
- (3) The name of the pharmacy dispenser.
- (4) The name of the drug product and strength.
- (5) The prescription number.
- (6) The control number.

D. Packaging - Package must be a suitable container so as to preserve the drug integrity of such unit dose from the time of packaging to the point of administering the drug to the patient.

E. Medication order or prescription - All requirements relating to prescriptions under the present Uniform Controlled Substances Act of the State of Kansas and applicable regulations, the Pharmacy Act of the State of Kansas and all federal laws must be complied with insofar as the prescription or medication order is concerned.

F. Medication profile - Required for all patients (patient record card system). Patient record card system shall contain sufficient information to allow the pharmacist to monitor patient drug therapy, however, cards shall not be used in lieu of telephonic or written prescriptions.

G. Record keeping requirements - Inventory and record keeping requirements are the same as outlined in the present Uniform Controlled Substances Act of the State of Kansas and applicable regulations, Kansas Pharmacy Laws and Regulations and federal laws and regulations requiring inventory and record keeping by all pharmacists handling prescription drugs.

H. Written applications required - In order to insure compliance with guidelines and policies herein set forth, prior to the adoption or utilization of such systems falling within these guidelines, written application must be made to the Executive Secretary of the State Board of Pharmacy of the State of Kansas on forms provided by the Executive Secretary.

III. ADMINISTRATION OF DRUG TO PATIENT

SYSTEMS ABOVE REFERRED TO INVOLVE THE UNIT DOSE PACKAGING, AS THAT PROCEDURE IS OUTLINED ABOVE, IN A MANNER WHICH REMOVES TRADITIONAL DRUG STOCK FROM PATIENT CARE AREAS AND ENABLES SELECTION AND DISTRIBUTION OF INDIVIDUAL DOSES, TOGETHER WITH THE ADMINISTRATION OF THE DRUG TO THE PATIENT WITHIN THAT SYSTEM, ALL OF WHICH IS TO BE PHARMACY BASED AND CONTROLLED.

A. Each system, subject to those requirements set forth above, must require a "check" by a registered pharmacist from the physician's original order.

B. Within such systems, the integrity of free choice must be affirmed and maintained.