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October 4, 1999

Elizabeth Robinson
Chairman, Opinions Committee
Office of the Attorney General
P.O. Box 12548
Austin, Texas 78711-2548

Dear Ms. Robinson:

ML-41039-99

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RQ-0121-JC

The Texas State Board of Pharmacy (Board) requests an 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.

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.

Thus, the question posed by the Board is two-fold:

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?

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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?

Currently, dangerous drugs and controlled substances for a patient in a nursing home are handled as follows:

Prescription Drug Orders Dispensed by a Licensed Pharmacy

Most dangerous drugs and controlled substances in a nursing home are drugs that a pharmacy has dispensed and labeled for a specific patient of the nursing home. Generally the nursing home obtains these drugs as follows:

- (1) A prescription drug order is called or faxed to a pharmacy.
- (2) The order is filled by a pharmacist in the pharmacy and the medication is placed in an appropriate container which is labeled for the specific patient.
- (3) The order is then delivered to the nursing home where it is placed in a secured medication cart or area.
- (4) The medication is then administered to the patient according to the physician's instruction by a nurse or medication aid.

Bulk Controlled Substances or Dangerous Drugs for Emergency Use

- (1) Controlled Substances: Section 242.161 of the Health and Safety Code allows a nursing home (Long-Term Care Facility) to maintain a supply of bulk controlled substances for a resident's emergency medical needs in an emergency medication kit. The facility is required to obtain a controlled substance registration with the Texas Department of Public Safety and comply with rules adopted by the Texas Department of Health which specify the amount, type and procedure for use of the controlled substances in the emergency medication kit.
- (2) Dangerous Drugs: Section 19.1510 of Title 40 of the Texas Administrative Code allows a physician to maintain a supply of bulk dangerous drugs for the emergency medical needs of the residents in a nursing home facility. These drugs are considered the physician's drugs but are kept for use in an emergency.


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A lawsuit has been filed against the Board by KVM Technologies, Inc., the manufacturer of the Envoy Automated Medication System, a machine which operates according to the above-mentioned process, and by Charles Ashy, R.Ph., a licensed pharmacist. The plaintiffs request that the applicable regulations of the Board be declared as invalid or alternatively not applicable to plaintiffs in their operation of the Envoy System. However, the parties have agreed to abate the proceedings for a period of approximately 60 days and allow for an Attorney General's opinion. In light of the abatement, the Board and KVM Technologies and Mr. Ashy jointly request the Attorney General to render an opinion as expeditiously as possible.

I have attached a letter written by the former General Counsel of the Board, Cynthia Villareal-Reyna, which outlines in detail the applicable statutory provisions and rules governing this issue.

Please do not hesitate to contact me at 302-8026, or Kerstin Arnold, General Counsel, at 305-8035 if you have any further questions.

Sincerely,


Gay Dodson, R.Ph.
Executive Director/Secretary

c: Board Members

Steve Dillawn, Attorney for KVM Technologies, Inc.