13. MEDICAL PRODUCT SAFETY

Goal

Ensure the safest and most effective use of medical products.

Terminology

Controlled substance: A drug or chemical listed in KRS Chapter 218A. These drugs or chemicals have the potential to cause addiction or are subject to abuse. They are divided into five schedules. Schedule I substances are illegal, i.e. they have no currently accepted medical use in the United States. Substances listed in schedules II-V are prescription drugs because they have a currently accepted medical use in treatment in the United States.

Dispenser: A person who delivers a controlled substance to or for the use of a patient.

Electronic data transfer: The transfer of prescription data by electronic means such as modem, diskette or magnetic tape.

Prescription drug: A drug that is required by federal law to be labeled "Rx only."

Triplicate prescription blank: A special form for writing prescriptions for certain drugs. The practitioner completes the form, retains the back copy, and gives the original and first copy to the patient. The patient presents the original and first copy to a pharmacy in order to receive the drug. The pharmacy retains the original and mails the copy to a state agency.

Overview

In addition to federal initiatives, the state of Kentucky can develop several programs to help ensure safe and effective use of medical products.

An electronic database for controlled substance prescription drugs that are dispensed to Kentuckians is a priority. It is estimated that approximately 5 million prescriptions for controlled substances are dispensed in Kentucky each year. Since these drugs have a proven potential for abuse or addiction, the risk to the public health is higher than for other prescription drugs. In the past, regulatory and law enforcement agencies that investigated violations of the Kentucky Controlled Substances Act had to guess where the evidence might be and then search the entire area. The result was an inefficient and labor-

intensive process of investigations. Other states have implemented various monitoring systems ranging from triplicate prescription blanks to electronic data transfer systems; all of which result in an electronic database. Kentucky's first system will build on the experience of the other states and will include all schedules of controlled substances. This will eliminate the incentive for a practitioner to prescribe a drug that may be less effective but is not monitored by the system. (Many states do not monitor all schedules.) Kentucky's system also attempts to close the gap created by dispensing practitioners and out-of-state pharmacies by requiring all dispensers to report. Thus the only way a patient can avoid inclusion in Kentucky's system is to go in person to an out-of-state pharmacy or out-of-state dispensing practitioner to obtain controlled substances.

The electronic monitoring system is currently being implemented and should be fully operational by January 1, 2000.

Other state level programs could further federal objectives by supplementing the efforts of the federal agencies. The current system of drug recalls has not proven to be as timely as would be desirable. The Department for Public Health may be able to facilitate communication with health professionals by using the Internet. A web site that provides updated information about drug recalls or drug warnings could alert heath professionals to information that will assist them in making medical judgments. A fax or e-mail network could also be developed that would not require the health professional to initiate the search for information but would automatically notify them whenever new information is posted.

Drug interactions and patient prescription information go hand-in-hand with better use of drugs and medical products. The Kentucky Board of Pharmacy monitors the practice of pharmacy throughout the state and seeks to insure that pharmacists provide current information to patients. The Department for Public Health should cooperate with the Board in any area where assistance can be provided.

2010 Objectives

13.1. Maintain an electronic database of 90 percent of all prescription controlled substances dispensed to citizens of the Commonwealth.

The Department for Public Health (DPH) is currently in the process of implementing an electronic monitoring system for prescription controlled substances. The enabling legislation was passed during the 1998 General Session and administrative regulations were promulgated. All dispensers of prescription controlled substances are required to report the drugs dispensed to a vendor on contract with the DPH. Health care professionals may utilize the database as source of information for making health-medicine decisions.

The database is a highly secure system for which the statute provides very strict access limitations. Furthermore, illegal disclosure of the information is a felony.

13.2. (Developmental) **Expand the electronic monitoring system described in Objective 13.1.**

Implementation Strategy:

- Incorporate sales/distribution information from wholesalers and manufacturers into the database.
- Decrease the lag time for reporting to the database by dispensers.
- Increase accessibility of the data to health professionals.

When sales and distribution information are incorporated into the database, the computer can search for discrepancies between quantity of drugs being received by a dispenser and the quantity dispensed. This will facilitate the Department's duty to monitor the use of controlled substances. As technology progresses, dispensers may be able to report to the database more frequently and with greater ease. If the data is more current, it will be more useful to practitioners, pharmacists and law enforcement officers. In addition, improvements in security may eventually permit authorized individuals to access the database directly. However, the system will need to verify that the individuals who seek information are legally permitted to obtain it.

13.3. (Developmental) **Develop a system to disseminate drug information such as safety alerts or drug recalls that is available to 85 percent of health professionals.**

The DPH is providing a web site for the Drug Control Branch. Safety alerts or drug recalls could be posted, if staff and funds are available, and accessed by anyone with Internet capability.

Implementation Strategy:

Update the Branch's web site when staff and funds are available.

13.4. (Developmental) **Increase to 98 percent the proportion of pharmacies using drug alert/drug interaction systems that have been updated within the past 3 months.**

Implementation Strategy:

- The Kentucky Board of Pharmacy can survey pharmacies about whether their current system of obtaining drug alert/drug interaction information is up-to-date.
- The Department of Public Health can assist the Pharmacy Board in designing such a survey to conduct.

13.5. Increase to 99 percent the proportion of patients receiving, at the time their prescription is first dispensed, oral or written information related to name of drug, dose, side effects, warnings, and drug or food interactions.

The Kentucky Board of Pharmacy requires patient counseling about any prescription that is dispensed. Currently, the level of counseling is inadequate, or patients do not perceive that they have received counseling. The DPH could assist the Board by disseminating information that would be helpful to pharmacists. However, the Board of Pharmacy is responsible for insuring that patients receive the required information.

Implementation Strategy:

If the Pharmacy Board requests assistance, the Department for Public Health will comply.

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