

## 13. Medical Product Safety

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### Goal

Ensure the safest and most effective use of medical products.

### Overview

Over the last two to three decades, several federal programs and initiatives have been developed to assure the safe and effective use of medical products. Many states including Kentucky have implemented programs designed to complement or enhance these federal initiatives. For example, in 1998, Kentucky implemented a Controlled Substances Act and promulgated corresponding regulations. In the last 5-6 years Kentucky has also developed a uniform electronic database which captures information on prescriptions for controlled substances. This database has proven to be a significant enhancement in assuring the safe use of controlled substances.

Misuse and abuse of controlled drugs is a serious problem in Kentucky. Over the last two years, articles have appeared in the *Lexington Herald Leader* concerning abuse of controlled substances by both Medicaid and non-Medicaid individuals particularly in the mountains of Eastern and Southeastern Kentucky. Abuse of controlled substances is harmful to individuals and families as well as to communities and the state at large. The individual, family, and society all bear the consequences of addiction. An electronic data system which captures prescriptions for controlled substances is essential in determining the extent of the problem and in creating solutions to curb continued abuse.

### Summary of Progress

On July 1, 1999 the KASPER (Kentucky All Schedule Prescription Electronic Reporting) database was implemented statewide. This electronic database was designed to capture information on prescriptions for controlled substances that are dispensed within Kentucky. The database is quite comprehensive in that it captures information on all schedules of controlled substances for which there is a legitimate medical use-- Schedules II-V. Information on out of state dispensing to Kentucky residents (via mail order) is also captured provided the patient does not visit the dispensing agent in person. This informational system facilitates targeting of individuals (prescribers, dispensers, and end users) who are in violation of Kentucky's Controlled Substances Act. The electronic information system also provides valuable information to prescribing health care professionals on other controlled substances that the patient may be using.

In 2002 duties associated with the Department for Public Health's Drug Control Branch including responsibility for the KASPER reporting system were transferred to the Office of the Inspector General (OIG), Cabinet for Health and Family Services. Through this

transfer increased emphasis was placed on investigation, follow-up, and enforcement of regulations in situations involving controlled substance abuse. Because of the transfer to an investigational/enforcement unit, there are no plans at this time to pursue some of the preventive measures originally developed by Department for Public Health staff (Objectives 13.3-13.5).

## **Progress toward Achieving Each HK 2010 Objective**

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

**Data Source:** Drug Control Program, Office of the Inspector General (OIG); KASPER Reporting System

**Baseline:** Prior to FY 2000, a uniform electronic database for capturing prescriptions for controlled substances did not exist in Kentucky.

**HK Target:** Implement and maintain a reporting system/database which will capture at least 90% of all prescriptions for controlled substances dispensed in Kentucky

**Mid-Decade Status:** The HK Target has been exceeded. KASPER was implemented in Kentucky in FY 1999-2000. In FY 2004-2005, information was captured by KASPER on approximately 95 percent of controlled substance prescriptions filled in the state. (In FY 2005 8,371,504 prescriptions for controlled substances were prescribed in Kentucky.)

#### **Strategies to Achieve Objective:**

- Continue funding for KASPER operations
- Continue to provide education/information to dispensers and health care professionals on KASPER

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

**Data Source:** Drug Control Program, OIG; KASPER Reporting System

**Baseline:** In FY 2000, information on sales and distribution of controlled substances from wholesalers and manufacturers was not a component of KASPER; lag time for reporting by dispensers averaged 16 days; and the controlled substance data was not readily available to practitioners, pharmacists and law enforcement personnel.

**HK 2010 Target:** Expand the electronic monitoring system (Incorporate sales/distribution information from wholesalers and manufacturers in the reporting system; decrease lag time for reporting by dispensers; and increase accessibility of the data to health professionals)

**Mid-Decade Status:**

--The Drug Control Program in the OIG does not have any plans to include sales and distribution information in the data system; therefore, this target will be omitted.

--Lag time for reporting has not been decreased so a new strategy/strategies will be implemented.

--Data availability to health professionals has been maximized through development of an online database (eKASPER) which issues reports within 15 minutes of request. All persons permitted access by Kentucky statute to the database have access either by internet, fax, or mail. This target has been met/exceeded.

**Strategies to Achieve Objective:**

- Promulgate a regulation which will require dispensers to report within a specified period of time (Lag time for reporting could be decreased by an estimated 50%)
- Provide information/updates to dispensers concerning the new regulatory requirements

**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. (DELETED)**

**Reason for Deletion:** The Drug Control Program in OIG is not pursuing this targeted objective.

**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. (DELETED)**

**Reason for Deletion:** The Drug Control Branch in OIG has no plans to pursue this objective.

**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. (DELETED)**

**Reason for Deletion:** The Drug Control Program in OIG has no plans to pursue this objective.

**References**

- KASPER Program data (FY 2005)

## **Contributors**

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## 13. Medical Product Safety – Summary Table

| Summary of Objectives for Medical Product Safety   | Baseline  | HK 2010 Target   | Mid-Decade Status                       | Progress        | Data Source |
|--|---|--|---|-----------------|-------------|
| 13.1. Maintain an electronic database of 90 percent of all prescription controlled substances dispensed to citizens of the Commonwealth. | Database first implemented in FY 2000   | ≥90%   | 95% (2005)                              | Target Achieved | KASPER      |
| 13.2. Expand the electronic monitoring system described in Objective 13.1  | a) Lag time in reporting averaged 16 days; b) Data not readily available to professionals | Decrease lag-time in reporting; b) Expand availability | Lag time in reporting not decreased;    | No              | KASPER      |
|  | b) Data not readily available to professionals  | Expand availability                                    | Expanded access to health professionals | Yes             | KASPER      |
| 13.3. – 13.5. (DELETED)  |   |  |   |                 |             |