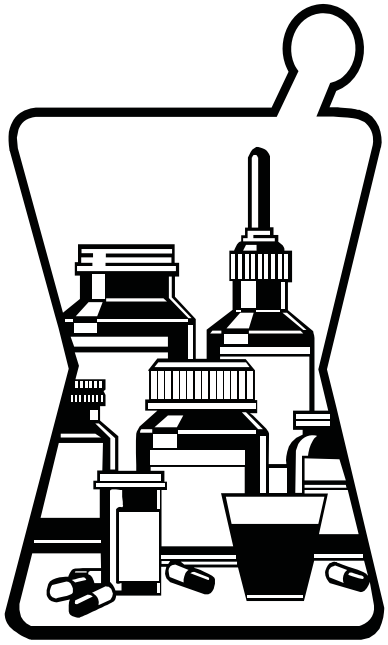
Improving Kentucky's Prescription Drug Monitoring Program:

Ideas and Recommendations



Prescription Drug Abuse Task Force
Final Report
(House Bill 303)

Research Report No. 313

Legislative Research Commission
Frankfort, Kentucky
October 1, 2003

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Improving Kentucky's Prescription Drug Monitoring Program

Prescription Drug Abuse Task Force

Membership

Area Represented	Senate Appointees	House Appointees
Kentucky State Police Division of Police Services	Capt. Mike Reichenbach	Capt. Mitch Bailey
Drug Enforcement Agency Office of Diversion Control	Gary Oetjen	Mark Caverly
Cabinet for Health Services, Dept. for Public Health	Dave Sallengs	Mike Townsend
County Attorney or Commonwealth Attorney	Brian Wright	Steve O'Connor
Kentucky Bar Association Member – Criminal Defense	John West	Jerry Cox
Kentucky Board of Medical Licensure or Board of Pharmacy	Danny Clark, M.D.	Georgina Kindall-Jones
Drug Treatment Program Representative	Randa Simpson	Dave Matthews
Citizens Group	Kay Dignan	Donna Herndon

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FOREWORD

The Prescription Drug Abuse Task Force was established by the Kentucky General Assembly in 2003 to examine prescription drug abuse and the illegal diversion of prescription drugs in Kentucky. The task force charge was to review the Kentucky All Schedule Prescription Electronic Reporting (KASPER) system and propose legislation to the Interim Joint Committee on Judiciary to improve and enhance the effectiveness of the KASPER system. Legislative Research Commission staff prepared this report at the direction of the task force to accompany and explain the proposed legislation.

Special thanks to Susan Hubbard Gitzinger who provided invaluable assistance in her role as intern to the task force. The task force co-chairmen also wish to thank the citizen members of the task force and all the individuals who took the time to attend the task force meetings and provide testimony.

Robert Sherman
Director

The Capitol
Frankfort, Kentucky
October 1, 2003

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Summary

The Prescription Drug Abuse Task Force was established by the Kentucky General Assembly in 2003 to examine prescription drug abuse and the illegal diversion of prescription drugs in Kentucky. The specific charge to the task force was to review the Kentucky All Schedule Prescription Electronic Reporting (KASPER) system and propose legislation to the Interim Joint Committee on Judiciary to improve the effectiveness of the system. The 19-member task force included representation from the legislature, federal and state law enforcement, public health, prosecutors, defense attorneys, the Kentucky Medical Licensure Board, the Kentucky Board of Pharmacy, drug treatment programs, and citizens groups. The task force met five times over a three-month period to hear testimony, gather information, formulate recommendations, and prepare draft legislation.

The primary work product of the task force, as directed by House Bill 303, is proposed legislation included in this report as Appendix B. This report was prepared in addition to the draft legislation because the members of the task force developed several recommendations that do not require legislative change for implementation. The report also helps to explain the basis for the recommended legislative changes.

A summary of the 16 recommendations made by the task force follows. Additional detail regarding the basis for each recommendation is in Chapter 2.

Recommendations Relating to KASPER Data

1. **Submission of Data by Dispensers -**
   (a) Dispensers should be required to report data to KASPER at least weekly.
   (b) The Cabinet for Health Services should continue to develop more efficient and effective methods for the transmission of point-of-sale data.
   (c) The Cabinet for Health Services should request currently, and should require upon contract renewal, that the third-party vendor:
      - Provide a more timely and thorough response to dispensers submitting data;
      - Verify that the data was received;
      - Verify the month, day and year of the submitted data; and
      - Verify that the data was correct and complete.

2. **Accuracy of Data** - Dispensers reporting data to the KASPER system should be required to report the data accurately and should be required to correct errors in the data when notified by the Cabinet for Health Services that corrections are needed.

3. **Unique Patient Identifier** - The Cabinet for Health Services should amend its regulation to strengthen the requirement for a standard patient identifier such as a driver's license number or Social Security number.

4. **Additional Data Fields** - The Cabinet for Health Services should work with the dispensing community to explore the possibility of adding data fields to the KASPER database, particularly a field identifying the method of payment.

5. **Active Database** - The Cabinet for Health Services should be given the authority to limit the length of time that patient information remains in the active KASPER database.

Recommendations Relating to Expanded and Enhanced Access

6. **Improved Response Time** - The lag time between the request and receipt of a KASPER report should be reduced.

7. **Multistate Sharing** - The Cabinet for Health Services should enter into agreements with other states that have prescription drug monitoring systems to allow the sharing of information with appropriate safeguards.

8. **Shared Investigations** - Law enforcement agencies and officers should be permitted to share KASPER reports and information when working on joint or related investigations with other law enforcement agencies or officers. Any agency or officer sharing information should complete and maintain an administrative disclosure form identifying all individuals with whom the information was shared, and the date information was shared.

9. **Board of Medical Licensure** - The Board of Medical Licensure should be authorized to receive a KASPER report on:
   (a) Any physician who is associated in a partnership or other business entity with a physician who is already under investigation by the board for inappropriate prescribing practices;
   (b) Any physician in a particular community when a KASPER trend report indicates that inappropriate prescribing may be occurring in that community; and
   (c) Any physician in a particular community when a KASPER report on another physician in the community indicates that inappropriate prescribing may be occurring in that community.

10. **KASPER and Medicaid Investigations** - The Medicaid program should be given the authority to share KASPER reports and other information regarding overutilization of scheduled drugs by Medicaid recipients with regulatory boards and law enforcement as a part of the existing referral process.

11. **Access for Judges and Probation and Parole Officers of Drug Courts** - Judges and probation and parole officers of Drug Courts should be permitted to request KASPER reports.

Recommendations Relating to Analysis, Research, and Education

12. **Proactive Use of KASPER Data** - The Cabinet for Health Services should be required to use the data available from the KASPER system, based on available funding, for

research, statistical, and educational purposes, to proactively identify trends and potential problem areas, and to produce and disseminate aggregate reports on a quarterly basis.

(a) The circumstances under which specified employees of the Cabinet for Health Services may access and analyze KASPER data should be clarified.
(b) The Cabinet for Health Services should be required to make referrals to licensing boards when potentially actionable issues are identified.
(c) Authorized law enforcement officers should be able to request trend reports that do not provide individually identifiable information.
(d) The Cabinet for Health Services should solicit input from the provider community in determining the most effective and meaningful methods to use the data available from the KASPER system.

13. **Education About the KASPER System** - The Board of Pharmacy, Board of Medical Licensure, the Kentucky Bar Association, and the Justice Cabinet should work with the Cabinet for Health Services, Drug Control Branch to develop and deliver continuing education programs for doctors, pharmacists, attorneys, and law enforcement officers regarding the purposes and appropriate use of the KASPER system.

14. **Evaluation and Oversight of KASPER** - The Cabinet for Health Services should convene a multidisciplinary work group to assess the effectiveness of the KASPER system. The work group should, at a minimum, assess the effectiveness of investigations using KASPER data and the coordination among regulatory and law enforcement agencies. The work group should also identify ways in which KASPER data can be used for educational and training purposes. The work group should report annually to the Legislative Research Commission.

General Recommendations

15. **Treatment Resources** - The General Assembly is strongly encouraged to increase the treatment resources available to address drug abuse.

16. **Sentencing Recommendations** - The Legislative Research Commission should undertake a study of whether sentencing recommendations are actually being imposed in prescription drug cases.

Introduction

"29 Plead Guilty to Buying, Selling Prescription Drugs – Oxycontin Linked to 59 Deaths in Past 15 Months"[1]

"Eastern Kentucky: Painkiller Capital – Investigation Reveals Narcotics Flood Mountain Counties at Highest Rate in the Nation"[2]

"Oxycontin use in Ky. Doubled – Drug Involved in 69 Deaths Across State"[3]

These headlines are but a few examples of those that have appeared in Kentucky media sources over the past three years related to the abuse and illegal diversion[4] of prescription drugs. Although these media headlines are recent, the abuse and diversion of prescription drugs in Kentucky are not new. For nearly 20 years, Kentucky policy makers have considered how to address these issues.

- In 1984, the Kentucky General Assembly passed House Concurrent Resolution 110, petitioning Governor Martha Layne Collins to establish a task force on prescription drug abuse. The preamble to that resolution noted that "the diversion of prescription drugs by licensed practitioners has become a major drug enforcement problem in the United States."

- In February 1994, the legislatively established Substance Abuse and Pregnancy Work Group recommended to the Secretary of the Cabinet for Human Resources and the Legislative Research Commission that additional study of prescription drug abuse in Kentucky be initiated.

- In 1997, Attorney General Ben Chandler established the Prescription Drug Abuse Task Force that produced a report with recommendations that resulted in substantial changes to Kentucky's law, including implementation of the Kentucky All Schedule Prescription Electronic Reporting (KASPER) program.

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[1] The Courier-Journal
[2] The Herald-Leader
[3] The Cincinnati Enquirer
[4] The federal Controlled Substances Act (21 U.S.C. Sec. 801 *et seq*) establishes a closed system for the distribution of "controlled substances." Controlled substances are drugs that have been determined to have a potential for abuse. Entities and individuals authorized to manufacture, prescribe, distribute, and dispense controlled substances are required to register with the Drug Enforcement Administration and maintain records, which, when combined from all levels, track all controlled substances from manufacture to dispensing. Drugs that are in any way transferred outside this closed system are "diverted" drugs.

- In 2001, Governor Paul Patton established the Oxycontin®[5]/Prescription Drug Abuse Task Force in response to a dramatic increase in the illegal use of Oxycontin®. This task force also issued a report including recommended legislative and administrative changes intended to limit the abuse of prescription drugs.

Through these initiatives, issues were identified, new laws were enacted, and new technologies were implemented that improved Kentucky's ability to address prescription drug abuse and diversion. However, the diversion and abuse of prescription drugs continues to be one of the most serious and pressing issues facing Kentucky.

In recognition of the seriousness of this issue, the 2003 General Assembly enacted HB 303 directing the President of the Senate and the Speaker of the House to establish a 19-member task force to examine prescription drug abuse and the illegal diversion of prescription drugs in Kentucky. The specific charge to the task force was as follows:

> "The task force shall review the Kentucky All Schedule Prescription Electronic Reporting (KASPER) program and propose legislation to the General Assembly on:
> (a) Improving the KASPER program's efficiency in recording information and responding to requests for information;
> (b) Increasing the enforcement of reporting requirements of dispensers and prosecution for violations thereof;
> (c) The use of data compiled by KASPER to isolate illegal drug diversion trends and to identify patterns of illegal drug diversion; and
> (d) Enhancing the overall utility of KASPER for law enforcement and drug prevention purposes."

The legislation directed the task force to report its recommendations as proposed legislation to the Interim Joint Committee on Judiciary no later than October 1, 2003.

The task force included representation from the legislature, federal and state law enforcement, public health, prosecutors, defense attorneys, the boards of Medical Licensure and Pharmacy, drug treatment programs, and citizens groups.

The task force met five times over a three-month period. The first three meetings were devoted to gathering information about the KASPER system and how it might be improved. The task force heard testimony from the Drug Control Branch of the Cabinet for Health Services about the current operation of the KASPER system and how additional funding provided by the General Assembly in 2003 will be used to improve KASPER. The task force also heard testimony and recommendations from individuals representing state and local law enforcement, the Medicaid program, the Kentucky Board of Medical Licensure, the Kentucky Board of Pharmacy, practicing

[5] "Oxycontin® tablets are a controlled-release form of oxycodone hydrochloride that is prescribed for the management of moderate to severe pain when continuous relief is needed over an extended period of time. Oxycontin® is a Schedule II controlled substance with an abuse liability similar to morphine." Oxycontin® package insert obtained from http://www.pharma/com/html/Our_products/Our_products.htm (Accessed on 8/20/03).

physicians and pharmacists, treatment providers, and legislators who were involved in past legislative efforts to address prescription drug abuse. In addition, the task force learned about the UNITE initiative,[6] the privacy rules under the Health Insurance Portability and Accountability Act of 1996, prescription drug monitoring programs in other states, the investigative process used by the federal Drug Enforcement Administration, investigations undertaken by the Office of the Inspector General in Medicaid fraud and abuse cases, and the national initiatives being implemented by Purdue Pharma L.P. to address prescription drug abuse.

During its fourth and fifth meetings, the task force reviewed the testimony and information from the initial three meetings and developed recommendations and proposed legislation to be presented to the Interim Joint Committee on Judiciary.

This report was prepared at the direction of the task force to supplement and support the draft legislation. The report includes two chapters. The first chapter provides an overview of the KASPER system. The second chapter sets forth the recommendations of the task force. The legislation creating the task force is attached as Appendix A. The draft legislation recommended by the task force is attached as Appendix B.

[6] Unlawful Narcotics Investigations, Treatment and Education, known as Operation UNITE, is a new federally funded comprehensive community-focused program to address drug abuse in eastern and southern Kentucky. The program incorporates law enforcement, treatment, and education under one organizational umbrella.

CHAPTER 1

Overview of the KASPER System[7]

Prior to 1999, Kentucky did not have a centralized prescription monitoring system. Investigations of prescription drug abuse often took several months to complete because investigators had to collect computer printouts from individual pharmacies and providers that a suspected drug abuser might have used. A doctor had no way to determine whether a patient seeking pain medication had recently sought treatment and medication from other practitioners. There was no way to review or track trends in the prescribing or dispensing of prescription medications. There were, however, growing concerns among law enforcement agencies, practitioners, and legislators that prescription drug abuse in Kentucky was growing.

To address these issues, Attorney General Ben Chandler established a Prescription Drug Abuse Task Force in 1997. The task force included 45 members representing the judicial system; legislators; prosecutors; pharmacists; doctors; nurses; federal, state, and local law enforcement; executive branch agency administrators; educators; researchers; and substance abuse treatment providers. The task force focused primarily on the lack of legal remedies that hindered identifying and prosecuting crimes related to prescription drug abuse. The report produced by the task force resulted in the introduction and passage of House Bill 115 during the 1998 Regular Session of the Kentucky General Assembly. HB 115 amended existing laws to clarify terms, established new crimes to facilitate investigating and prosecuting prescription drug abuse, and required that all prescriptions for controlled substances be written on security paper.

HB 115 also required the Cabinet for Health Services (CHS) to establish a system to monitor the dispensing of schedules II-V controlled substances.[8]

Implementation of KASPER

In response to the provisions of HB 115, the Kentucky All-Schedule Prescription Electronic Reporting system (KASPER) was established on July 1, 1999. KASPER was designed to be a source of information for practitioners and pharmacists to provide the most appropriate medical treatment. KASPER was also designed to serve as an investigative tool for law enforcement by making information already available to law enforcement officers more accessible. According to a 2002 report prepared by the United States General Accounting Office, prior to the implementation of KASPER, state drug control investigators took an average of 156 days to complete an investigation of alleged doctor shoppers. Following the implementation of KASPER, the average investigation time dropped to 16 days (GAO Report p. 15).

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[7] To gather information for this report, LRC staff conducted interviews with representatives of the Drug Enforcement and Professional Services Branch of the Department for Public Health and the Special Investigations Division of the Office of the Attorney General.

[8] The Federal Controlled Substances Act of 1970 establishes five schedules into which drugs are placed according to their potential for abuse and whether they are accepted for medical use. Drugs with the greatest potential for abuse are placed in schedules I and II. Schedule I drugs are those for which there is no known acceptable medical use. Kentucky's scheduling system is codified in KRS Chapter 218A.

Currently, 18 states have some form of prescription drug monitoring system in place, while several other states, including West Virginia and Virginia, are developing new monitoring systems. KASPER is operated and administered by the Drug Enforcement and Professional Practices Branch of the Kentucky Department for Public Health of the Cabinet for Health Services.

Reporting Requirements

All pharmacies, dispensing physicians, dispensing veterinarians, and other licensed dispensers in Kentucky who dispense schedules II-V controlled substances are required to complete a record for each schedule II-V prescription dispensed.[9] Records must be submitted to a private contractor responsible for collecting and compiling the data within 16 days of the date the prescription was provided to the patient. Approximately 2,100 entities report to KASPER, including approximately 1,300 pharmacies. The data is usually submitted electronically, and is stored in a secure database. All data submitted is confidential. Reporting dispensers receive a postcard from the third-party vendor acknowledging receipt of data and the date range covered each time data is submitted. These cards are retained by the dispenser and may be reviewed by the licensing agency during regular inspections to ensure compliance with the reporting requirements. The third-party vendor reviews, compiles, and edits the data, then forwards it to the Drug Enforcement and Professional Practices Branch every two weeks. The new data is added to the database within two days of receipt. The lag time between receipt of data by the third-party vendor and conveyance of the data to the Drug Enforcement and Professional Practices Branch is about two weeks, making the average amount of time between the dispensing of the medication and receipt of the data by CHS about four weeks. Dispensers who knowingly fail to submit data as required by KRS 218A.202 could be charged with a Class A misdemeanor.[10]

Information required to be submitted to KASPER includes the following:

- Patient identifier (full name, address including zip code, date of birth, and Social Security or alternative identification number);
- National drug code of the drug dispensed;
- Metric quantity of the drug dispensed;
- Date of dispensing;
- Estimated days of supply dispensed;
- Drug Enforcement Administration (DEA) registration number of the prescriber;[11]
- Serial number assigned by the dispenser; and
- DEA registration number of the dispenser.

Availability of Information

The primary reports generated from KASPER include all available information on individuals, such as an individual patient, doctor, or pharmacy.[12] For example, a report on an individual shows

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[9] Mail order pharmacies delivering prescription medication in Kentucky are required to register and are therefore required to report to KASPER. Generally, out-of-state pharmacies are not required to register or report.

[10] A Class A misdemeanor is punishable by up to 12 months' imprisonment and/or a fine up to $500 if an individual and $10,000 if a corporation.

[11] The Controlled Substances Act of 1970 authorizes the DEA to regulate transactions involving the sale and distribution of controlled substances. All legitimate handlers of controlled substances, including manufacturers, distributors, hospitals, practitioners, pharmacies, and researchers, are required to have DEA registration numbers, which they must use in all transactions involving controlled substances.

each prescription for a controlled substance that was received, including name of the drug, the prescribing physician, the dispensing pharmacy or physician, the date of the dispensing, and quantity dispensed. A report on a physician or pharmacy contains similar information for all schedule II-V controlled substances that were prescribed or dispensed.

KRS 218A.202 limits the availability of KASPER data to practitioners, pharmacists, regulatory bodies, law enforcement entities, Medicaid, and grand juries. KASPER reports must be requested in writing and signed by the requester. If the requester is a practitioner, the DEA number must also be included (905 KAR 55:110, Section 4). Authorized persons who receive information from KASPER are advised by the CHS against sharing that information with any other individual outside their agency or practice group, including other authorized users who may be collaborating in an investigation or the person who is the subject of the request. Law enforcement officers and regulatory agency representatives may access KASPER data only if they are involved in a bona fide, specific investigation of a designated person. Practitioners and pharmacists may request information only for the purpose of providing medical or pharmaceutical treatment to a bona fide current patient. An authorized person who knowingly discloses KASPER data to an unauthorized person or who obtains information for other than permitted purposes may be charged with a Class D felony.[13]

Due to the specific investigation requirements, current law does not permit KASPER data to be used to initiate investigations or to confirm general suspicions about illegal drug activity in certain geographical areas.

Responses to Requests

Because requests must be made in writing, all KASPER requests are received by fax or mail. Responses requested by fax are typically responded to by fax. KASPER staff indicated that a request can usually be completed and returned within four hours, although the requested information is often provided more quickly. Responses received by mail are returned by mail, usually on the same day the request was received. KASPER staff report that they sometimes receive 400-500 requests at one time from doctors specializing in the treatment of chronic pain. These doctors request reports several days in advance for patients with appointments. These responses are prepared and mailed back to the requesting doctors. The KASPER staff currently includes three pharmacists who run reports. KASPER staff report that they each can run about 150 reports a day in addition to fulfilling other duties.

Requests for KASPER reports have increased significantly each year since the system was implemented. In 1998, when the KASPER system was proposed, it was estimated that the system would produce 1,500 reports each year. That number was surpassed in the first six months of operation with annual report volume increasing to 96,510 by the end of 2002. The numbers of requests by requester category are illustrated below.

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[12] Pharmacies, rather than individual pharmacists, have DEA numbers. Therefore, KASPER information is available for pharmacies rather than individual pharmacists.

[13] A Class D felony is punishable by up to five years of imprisonment and/or fine up to $10,000 if an individual or $20,000 if a corporation.

Table 1. KASPER reports requested by requester and year 1999-2002.

Requester	1999[14]		2000		2001		2002	
	Total Number	% of total	Total Number	% of total	Total Number	% of total	Total Number	% of total
Physician	2,301	74%	28,892	80%	60,307	84%	83,503	87%
Pharmacist	42	1%	1,593	4%	3,985	6%	3,967	4%
Law Enforcement	742	24%	4,568	13%	5,784	8%	5,586	6%
Licensure Boards	18	1%	1,098	3%	1,571	2%	2,150	2%
Grand Jury Subpoena	0	0%	0	0%	3	0%	2	0%
Court Order	0	0%	3	0%	4	0%	8	0%
ARNP[15]	0	0%	0	0%	156	0%	1,294	1%
TOTAL	3,103	100%	36,154	100%	71,810	100%	96,510	100%

Source: Cabinet for Health Services Drug Control Branch, May 7, 2003.

Monitoring Data

The database used by the KASPER staff also has the capacity to run reports that could be used to identify trends or questionable practices. These reports would not focus on individuals, but might identify areas of the state with relatively high use of certain controlled substances or an increase in the general use of certain drugs. At the present time, reports are not run and analyzed on a regular basis. KASPER staff testified that running reports on individuals utilizes all of their available resources. Current law does not allow authorized users other than the KASPER staff to request and utilize reports not related to a specific investigation of a named individual. Legislation (2002 HB 26) was proposed during the 2002 Regular Session of the General Assembly to allow law enforcement officers to request KASPER reports "where there is an identifiable trend of illegal diversion in a geographical area"; however, the language was removed before the bill was finally passed by the General Assembly.

Data Limitations

The KASPER database has some limitations that may reduce its effectiveness. The first limitation is the time it takes from when a prescription is filled until the data is available in KASPER. As stated earlier, it may take up to four weeks for a new prescription to appear in KASPER. Therefore, reports may be missing the most recent activity. This may not present a serious problem for law enforcement, as the data will eventually become available. Staff with the Attorney General's office indicated that the time delay did not substantially affect their investigations because they look for long-term trends. The time lag may be of greater concern for doctors, as they may use the data for the immediate detection of possible prescription drug abuse and "doctor-shopping" by patients. With the most recent prescribing data unavailable from KASPER, it may be difficult for a physician to identify a patient who recently started doctor-shopping. However, if the patient has been receiving excessive prescriptions for several months, and if the doctor requests information about the patient going back several months, the information will be available through KASPER.

The time it takes to receive a report from the KASPER system could potentially limit a physician's ability to review a patient's record. Although Department for Public Health staff indicated that the reports are usually returned in about four hours, in some cases this may be considered too long if a patient has to wait for a report in order to receive a prescription. The extent to which this limits

[14] This represents six months of data for 1999. Reports were not run until July of that year.

[15] Nurse practitioners (ARNPs) were not permitted to request reports until a ruling in 2001 determined that they are prescribers under the law even though they are not permitted to write prescriptions for controlled substances.

the effectiveness of the system is not clear. Physicians may be able to accommodate the four-hour wait by ordering reports in advance.

A final limitation is that the data collected by KASPER may not accurately identify an individual patient. Although a unique identifying number for the patient, such as a Social Security number, is requested, the information is not always collected, verified, or accurately recorded. KASPER staff is often able to compensate for this limitation by using combinations of addresses and birth dates.

Investigations

The Drug Enforcement and Professional Practices Branch staff includes three field investigators who are pharmacists, in addition to the three pharmacists who review and respond to requests for KASPER reports. If a complaint is filed with the branch and no law enforcement agency is involved, a branch investigator may initiate an investigation. These Department for Public Health investigators also work collaboratively on investigations with the Kentucky State Police, the Attorney General's office, and local law enforcement.

KRS 218A.240 requires all law enforcement agencies, the Cabinet for Health Services, Commonwealth's attorneys, and the Attorney General to enforce the provisions of KRS Chapter 218A within their jurisdictions and to cooperate with other agencies in the enforcement of controlled substances laws. KRS 218A.240 also vests designated agents of the CHS and the Kentucky Board of Pharmacy with the full power and authority of peace officers, including the power to arrest, administer oaths, bear arms, enter any premises at any time for the purpose of making inspections, seize evidence, interrogate any person, require the production of prescriptions, books, papers, documents, or other evidence, employ special investigators, and to expend funds to obtain evidence.

Agents of the Cabinet for Health Services and the Kentucky Board of Pharmacy are also granted the authority to remove from the files of a pharmacy any controlled substance prescription or other controlled substance record upon providing a receipt containing sufficient detail to identify the record.

KASPER Budget

Start-up costs for KASPER were approximately $415,000 and were provided through a federal grant. Ongoing annual expenditures are approximately $600,000. KASPER received additional one-time funding of $1,474,000 from coal severance funds in FY 2003 to upgrade and enhance the system. In addition, $225,000 in supplemental funding was provided in FY 2004 from KY-ASAP.[16]

KASPER Pilot Project - Real-Time Access

In 2002, the General Assembly amended KRS 218A.202 to require the Governor's Office of Technology (GOT), in consultation with the Cabinet for Health Services, to submit an application to the U.S. Department of Justice for a grant to fund a pilot project to study a real-time electronic monitoring system for schedules II-V controlled substances. The legislation dictated that the project be conducted in two rural counties that have an interactive, real-time electronic

[16] KY-ASAP is the Kentucky Agency for Substance Abuse Policy, established by KRS 12.330-12.334. KY-ASAP is directed by a board and is responsible for coordinating and organizing efforts to fight alcohol and drug abuse in Kentucky. KY-ASAP is funded through tobacco settlement money.

information system in place through a federally funded community access program. The legislation also required that the study use an interactive system with a relational database and query capability.

The GOT submitted the grant application to the Bureau of Justice Assistance in July 2002 and was awarded $240,000 to implement a pilot project in Harlan and Perry counties, where the federally funded Southeast Kentucky Community Access Program (SKYCAP) is already in place.[17] The request for proposals to operate the program has been issued, responses have been reviewed, and a vendor selected. It is anticipated that work on the project will begin soon.

The pilot project described in the grant application will require doctors to use a computer connected to a real-time database to write prescriptions. The computer will check the system for all drugs prescribed within the pilot area to the patient and will then produce a bar-coded prescription. The patient will take the prescription to a participating pharmacy, where the prescription will be scanned and matched back to the prescription entered by the doctor. A consultant will be hired to monitor the project and to advise on the feasibility of expanding the scope of the project. The project, as proposed, involves a start-up period of six months, the collection of data for 90 days, and a follow-up report and analysis.

It should be noted that Purdue Pharma L.P., the manufacturer of Oxycontin®, has promised to provide up to $2 million to the state of Florida to finance the development of software needed to operate a real-time prescription drug-monitoring system. Once developed, the computer program will be made available for free to any other state that requests it (Robeznieks).

National Efforts Toward Prescription Drug Monitoring Programs

One of the primary problems identified with all state prescription drug monitoring programs is that no matter how thorough they are and how much data they include, they only include data from one state. It is therefore very easy for prescription drug abusers to avoid detection by simply crossing state lines to have their prescriptions filled. This is especially true in Kentucky, where, until recently, five of the seven bordering states did not have prescription monitoring programs, and the two that did only monitored Schedule II drugs and did not allow pharmacists or doctors to access the information. Because this is not an issue that a state can address unilaterally, efforts are ongoing at the federal level to encourage more states to develop prescription drug-monitoring programs and to determine how information can be shared among states that already have programs.

Federal funding is currently available through the "Hal Rogers Prescription Drug Monitoring Program." This program provides grants through the Department of Justices Bureau of Justice Assistance to assist states in establishing or enhancing prescription drug-monitoring systems. In FY 2002, $2 million was available. The Kentucky pilot project described above was funded

[17] SKYCAP was initiated by the University of Kentucky Center For Rural Health in 2000. The purpose of SKYCAP is to identify collaborative partners in rural communities to demonstrate ways to develop systems to provide sustainable health care to the medically indigent. SKYCAP uses "family navigators" who are trained to assist clients in accessing health services, mental health services, housing and environmental assistance and other necessary services. As part of the program, SKYCAP has implemented a management information system that allows health providers and agencies in Harlan and Perry counties to share information about clients and services. SKYCAP is a rural demonstration and evaluation program funded by the Health Resources and Services Administration, U.S. Department of Health and Human Services.

through this initiative. Other states receiving funding included Ohio,[18] Pennsylvania, Virginia, and West Virginia to initiate prescription drug monitoring programs, and California, Massachusetts, Nevada, and Utah to enhance their programs. Congress provided additional funding for the program in the amount of $7.5 million for fiscal year 2003.

In addition to the funding available to establish and enhance state prescription drug-monitoring programs, there are also efforts in Congress to establish a national prescription drug-monitoring system. On September 4, 2003, H.R. 3015 was filed "To amend the Public Health Services Act to establish an electronic system for practitioner monitoring of the dispensing of any schedule II, III, or IV controlled substance…" The bill has 11 co-sponsors and has been referred to the House Committee on Energy and Commerce.

There are several national groups, including the Alliance of States with Prescription Drug Monitoring Programs, the National Association of State Controlled Substances Authorities, and the National Alliance of Model State Drug Laws, that are working to make it easier for states to implement and improve prescription drug-monitoring programs. Two model acts have been developed, and technical assistance is available for states considering the implementation or expansion of a prescription drug-monitoring program.

[18] Although Ohio received funding to develop a prescription drug-monitoring program, the Ohio legislature failed to pass necessary enabling legislation. (See House Bill 475 from the 124th Ohio General Assembly, which passed the House of Representatives but failed to pass the Senate.)

CHAPTER 2

Task Force Recommendations

The task force used a facilitated discussion process to identify and discuss the 16 recommendations included in this report. Many other recommendations were discussed that are not included in this report because consensus could not be reached. For ease of review, the recommendations have been grouped under four headings: KASPER Data; Enhanced and Expanded Access to KASPER Data; Analysis, Education, and Research; and General Recommendations.

Recommendations Relating to KASPER Data

1. **Submission of Data by Dispensers -**
   - **(a) Dispensers should be required to report data to KASPER at least weekly.**
   - **(b) The Cabinet for Health Services should continue to develop more efficient and effective methods for the transmission of point-of-sale data.**
   - **(c) The Cabinet for Health Services should request currently, and should require upon contract renewal, that the third-party vendor:**
     - **Provide a more timely and thorough response to dispensers submitting data;**
     - **Verify that the data was received;**
     - **Verify the month, day and year of the submitted data; and**
     - **Verify that the data was correct and complete.**

Task force members learned through testimony provided by the Cabinet for Health Services (CHS) that the current reporting schedule for KASPER requires that data be reported within 16 days of the date the prescription was dispensed to the patient. This lag, combined with the time it takes the third-party vendor to transfer the data to the CHS, results in a delay of 17 to 31 days from the time a prescription is filled until it becomes part of the KASPER database. Changing the reporting requirement from every 16 days to every seven days as recommended by the task force will cut the lag time to 10-26 days. Task force members recognize that under ideal circumstances, data would be transmitted instantaneously from the point of dispensing to the KASPER system without an intervening third party; however, current resources are not sufficient to support this type of system.

Because it is important for the KASPER database to be as current as possible, the CHS is encouraged to continue to explore and identify other methods for decreasing the time between the dispensing of a prescription and including the information in the KASPER database. Options to further explore include determining whether the CHS can serve as the primary point of collection for KASPER data, rather than working through a third-party vendor, or if this is not feasible, whether information can be transmitted from the third party vendor more quickly.

Because this recommendation may impose an additional burden on dispensers, it is recommended that the CHS meet with dispensers to develop an implementation process and timeline that provides dispensers with sufficient time to make necessary adjustments.

The Cabinet for Health Services is also encouraged to develop a new notification process for dispensers after data is submitted. Currently dispensers receive a postcard in the mail a few weeks after data is submitted acknowledging receipt of the data. It is recommended that this notification be provided more quickly, and that it also include details about the data received, including the day, month, and year for which data was submitted, and confirmation that the data is complete and correct or identification of what is missing if the data is not complete and correct.

Action Required: This recommendation can be implemented by the CHS through regulatory amendment.

2. **<u>Accuracy of Data</u> - Dispensers reporting data to the KASPER system should be required to report the data accurately, and should be required to correct errors in the data when notified by the Cabinet for Health Services that corrections are needed.**

   The current law governing the operation of the KASPER system does not include a requirement that the data be reported accurately and does not require the correction of data identified as erroneous. Cabinet for Health Services staff testified that the existing system does include some edit checks that will identify inaccurate data and that additional edit checks could be implemented. The intent of this recommendation is to improve the accuracy of KASPER data, which will improve the database integrity. It is recommended that the dispenser submitting the data make any needed corrections to avoid the appearance of impropriety and to ensure that corrections are made at the source.

   Action Required: This recommendation is incorporated in draft legislation.

3. **<u>Unique Patient Identifier</u> - The Cabinet for Health Services should amend its regulation to strengthen the requirement for a standard patient identifier such as a driver's license number or Social Security number.**

   The task force heard testimony about the difficulties created because the information submitted to KASPER sometimes does not include a unique patient identifier, such as a Social Security or drivers license number. Under the current CHS regulation, zeros or nines can be entered in this field if the patient either does not have or refuses to provide a Social Security number or driver's license number. Lack of this type of information can make it more difficult for the Drug Control Branch staff preparing a report to ensure that all data regarding a patient is included, and that it is accurate, especially for patients with more common names. The goal of this recommendation is to improve the accuracy of KASPER data.

   Action Required: This recommendation can be implemented by the CHS through regulatory amendment.

4. **<u>Additional Data Fields</u> - The Cabinet for Health Services should work with the dispensing community to explore the possibility of adding data fields to the KASPER database, particularly a field identifying the method of payment.**

   Many of the individuals who testified before the task force recommended including additional data fields in the KASPER database. In particular, they recommended the addition of a field identifying the payment source. The availability of this information would help the Department of Medicaid Services identify Medicaid recipients. In addition, several law enforcement officers testified that it would be helpful for them to have information regarding cash transactions because individuals abusing or diverting prescription drugs often pay with cash. Initially it was believed that implementation of this recommendation would not be difficult because all pharmacies use a standard reporting format developed by the American Society for Automation of Pharmacy (ASAP) that already includes a field for the method of payment. However, there are different versions of the ASAP form, and concerns were expressed by representatives from the dispensing community that many of the pharmacies may be using an older version of the ASAP form that does not include the payment field. If dispensers were required to begin submitting information on the method of payment, many would have to update their existing software, which could be costly. To address these concerns, the recommendation is that the CHS work with the dispensing community to resolve this issue.

   Action Required: This recommendation can be implemented by the CHS through regulatory amendment.

5. **<u>Active Database</u> - The Cabinet for Health Services should be given the authority to limit the length of time that patient information remains in the active KASPER database.**

   The KASPER system was implemented in 1999. Since that time, data on more than 35 million prescriptions has been collected. Under current law, there is no provision allowing the CHS to archive data files after a specified amount of time or to limit the number of years back a request can cover. The intent of this recommendation is to address the practical issue that will soon arise regarding the ability to maintain an active database that is so large. In addition, this recommendation is also intended to give the Cabinet for Health Services the ability to determine a time after which data is so dated that it is no longer relevant.

   Action Required: This recommendation is incorporated in draft legislation.

Recommendations Relating to Expanded and Enhanced Access

6. **<u>Improved Response Time</u> - The lag time between the request and receipt of a KASPER report should be reduced.**

   It currently takes the Drug Control Branch approximately four hours to respond to a request for a KASPER report. Practitioners and law enforcement testified that they would benefit from receiving reports more quickly. The CHS has recognized this need and is utilizing $1.474 million provided by the General Assembly in FY 2003 to enhance the KASPER system. The enhancements are expected to allow the CHS to:

   - Make reports available to requesters 24 hours a day, seven days a week;
   - Cut response time from approximately four hours to 15 minutes for requests received electronically; and
   - Automate report requests so that CHS pharmacists can be re-deployed to analyze KASPER information on a proactive basis.

   The task force supports and encourages these efforts.

   Action Required: This recommendation can be implemented by the Cabinet for Health Services under existing law.

7. **<u>Multistate Sharing</u> - The Cabinet for Health Services should enter into agreements with other states that have prescription drug monitoring systems to allow the sharing of information with appropriate safeguards.**

   The task force heard testimony from several witnesses in support of allowing the sharing of KASPER reports and information across state lines. Witnesses noted that individuals abusing prescription drugs often cross state lines to fill prescriptions because they know that the information will not appear in the KASPER system. Likewise, individuals from other states may come to Kentucky to avoid their states' monitoring systems because they know that the information is not shared. The task force recommends that the CHS be given the authority to enter into agreements with other states to share information and that the agreements include sufficient safeguards to protect and limit the use of the information in the same manner as provided under Kentucky law.

   Action Required: This recommendation is incorporated in draft legislation.

8. **<u>Shared Investigations</u> - Law enforcement agencies and officers should be permitted to share KASPER reports and information when working on joint or related investigations with other law enforcement agencies or officers. Any agency or officer sharing information should complete and maintain an administrative disclosure form identifying all individuals with whom the information was shared and the date the information was shared.**

Virtually every law enforcement officer providing testimony before the task force recommended that law enforcement officers be permitted to share KASPER reports and information when they are working on a joint investigation. The officers testified that drug investigations by nature usually take several months to complete and often involve multiple law enforcement agencies at the local, state, and federal level. Under current law, if one of the partner agencies requests a KASPER report, the report and information included in the report cannot be shared with other partner agencies; however, each partner agency can request a separate report.

Concern was expressed that if law enforcement agencies are permitted to share the reports among themselves, then the Drug Control Branch will no longer have an accurate record of who has the information. To address this concern, it is also recommended that any law enforcement agency or officer disclosing a KASPER report or information contained in a KASPER report be required to complete an administrative disclosure report, listing all individuals with whom the information was shared. The report should be maintained by the disclosing agency and should be available for inspection upon request.

Action Required: This recommendation is incorporated in draft legislation.

9. **<u>Board of Medical Licensure</u> - The Board of Medical Licensure should be authorized to receive a KASPER report on:**
   - **(a) Any physician who is associated in a partnership or other business entity with a physician who is already under investigation by the board for inappropriate prescribing practices;**
   - **(b) Any physician in a particular community when a KASPER trend report indicates that inappropriate prescribing may be occurring in that community; and**
   - **(c) Any physician in a particular community when a KASPER report on another physician in the community indicates that inappropriate prescribing may be occurring in that community.**

The intent of this recommendation is to provide the Board of Medical Licensure with additional tools to address suspected inappropriate prescribing practices more quickly. The task force heard testimony that in many cases the Board of Medical Licensure is not aware of inappropriate prescribing practices until after an arrest is made. In addition, testimony was received that if one doctor in a practice group or community is inappropriately prescribing medication, then other practitioners in the practice group or community are likely also acting inappropriately. This recommendation expands the authority of the Board of Medical Licensure to request KASPER reports on doctors in a particular practice group or community based on known information relating to one doctor in the practice group or community. It would also allow the board to request KASPER reports on individual practitioners in a specific community based on information included in KASPER data trend reports.

Action Required: This recommendation is incorporated in draft legislation.

10. **<u>KASPER and Medicaid Investigations</u> - The Medicaid program should be given the authority to share KASPER reports and other information regarding overutilization of scheduled drugs by Medicaid recipients with regulatory boards and law enforcement as a part of the existing referral process.**

    This recommendation is similar to the recommendation allowing law enforcement officers to share KASPER reports and information when conducting joint investigations. If enacted into law, this recommendation would allow Medicaid investigators to pass KASPER information along to a licensing board or law enforcement when making a referral.

    Action Required: This recommendation is incorporated in draft legislation.

11. **<u>Access for Judges and Probation and Parole Officers of Drug Courts</u> - Judges and probation and parole officers of drug courts should be permitted to request KASPER reports.**

    The task force heard testimony that it may be a problem for probation and parole officers affiliated with drug courts to request KASPER reports. Under current law, probation and parole officers with law enforcement powers may request reports under that authority. The task force recommends that the law be clarified to include judges and probation and parole officers administering drug courts among the individuals who may request KASPER reports.

    Action Required: This recommendation is incorporated in draft legislation.

A Note About the Health Insurance Portability and Accountability Act of 1996 (HIPAA)[19] and KASPER

The above six recommendations relate to expanding and enhancing access to KASPER information. Task force members expressed concern about HIPAA, the Privacy Rule established thereunder,[20] and how the rule may impact the collection and dissemination of KASPER data. A representative from the Cabinet for Health Services Office of General Counsel testified that the cabinet is still evaluating how the HIPAA Privacy Rules apply to the KASPER system. Because the privacy rules are so new, there is still a great deal of uncertainty about how they will be implemented and interpreted. For this reason, it is recommended that all proposed changes in the collection, use, or dissemination of KASPER data be reviewed to ensure that the HIPAA Privacy Rule requirements are met.

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[19] Pub. L. 104-191. Enacted August 21, 1996. According to the Office of Civil Rights' "Summary of the HIPAA Privacy Rule," sections 261 through 264 of HIPAA require the Secretary of HHS to establish standards for the exchange, privacy, and security of electronic health information.

[20] As mandated by HIPAA, the U.S. Department of Health and Human Services (HHS) issued "Standards for Privacy of Individually Identifiable Health Information" (the "Privacy Rule") to establish, for the first time, a set of national standards for the protection of certain health information. The privacy rules became effective on April 14, 2003. The Privacy Rule standards address the use and disclosure of individuals' health information called "protected health information" by organizations subject to the Privacy Rule, called "covered entities." One of the primary goals of the Privacy Rule is to ensure that individuals' health information is protected while allowing the flow of health information needed to provide and promote health care. Violation of the privacy rules can result in heavy civil penalties and fines. The privacy rules are implemented and enforced by the Office of Civil Rights in the Department of Health and Human Services.

Recommendations Relating to
Analysis, Research, and Education

12. **<u>Proactive Use of KASPER Data</u> - The Cabinet for Health Services should be required to use the data available from the KASPER system, based on available funding, for research, statistical, and educational purposes, to proactively identify trends and potential problem areas, and to produce and disseminate aggregate reports on a quarterly basis.**
    - **(a) The circumstances under which specified employees of the Cabinet for Health Services may access and analyze KASPER data should be clarified.**
    - **(b) The Cabinet for Health Services should be required to make referrals to licensing boards when potentially actionable issues are identified.**
    - **(c) Authorized law enforcement officers should be able to request trend reports that do not provide individually identifiable information.**
    - **(d) The Cabinet for Health Services should solicit input from the provider community in determining the most effective and meaningful methods to use the data available from the KASPER system.**

    The task force heard testimony from several speakers that one of the capabilities of the KASPER system that is currently underutilized is its ability to provide aggregate and trend data for analysis. The cabinet provided the task force with examples of the types of information that the analysis of KASPER data could provide, including information about risk factors for the inappropriate use of scheduled drugs and prescribing patterns by specialty area or geographic location.

    Existing law is unclear regarding the ability of CHS staff to use the available KASPER data to produce and disseminate informational reports based upon aggregate data. Representatives from the CHS testified that the KASPER system has the capability to produce the type of statistical information noted above, as well as other types of reports; however, any reports produced cannot be shared under existing law.

    Cabinet representatives also testified that they do currently have the authority to proactively analyze KASPER data and to investigate any situations that are of concern; however, due to the volume of reports requested, there is not enough time for the existing staff to engage in these types of activities. Further, it is unclear whether the CHS can make referrals to licensing boards based on KASPER data. Cabinet representatives testified that one of the goals of the implementation of the enhanced KASPER system is to automate the report request function so that Drug Control Branch employees will have more time to engage in the proactive use of KASPER data.

    Some task force members expressed concern about the identification of prescribing patterns or parameters for different specialty groups without the involvement and input of practitioners. Therefore, it is recommended that the CHS seek this input in identifying patterns and parameters in each specialty area. It is also recommended that family practitioners be included in the list of specialties for which prescribing patterns are identified.

    Action Required: This recommendation is incorporated in draft legislation.

13. **<u>Education About the KASPER System</u> - The Board of Pharmacy, Board of Medical Licensure, the Kentucky Bar Association, and the Justice Cabinet should work with the Cabinet for Health Services, Drug Control Branch to develop and deliver continuing education programs for doctors, pharmacists, attorneys, and law enforcement officers regarding the purposes and appropriate use of the KASPER system.**

    The task force heard testimony from several witnesses indicating that there is a lack of knowledge among dispensers, practitioners, attorneys, and law enforcement officers about the KASPER system and how reports should be requested and used. Representatives from the Cabinet for Health Services testified that they have conducted more than 100 training events since the inception of KASPER but that there are still many dispensers and practitioners who have not participated in the training. The task force strongly encourages the Board of Medical Licensure, the Board of Pharmacy, the Kentucky Bar Association, and the Justice Cabinet to provide outreach and training to their members and associates about the KASPER system and how it can assist in identifying and preventing prescription drug abuse.

    Action Required: This recommendation is incorporated in draft legislation.

14. **<u>Evaluation and Oversight of KASPER</u> - The Cabinet for Health Services should convene a multidisciplinary work group to assess the effectiveness of the KASPER system. The work group should, at a minimum, assess the effectiveness of investigations using KASPER data and the coordination among regulatory and law enforcement agencies. The work group should also identify ways in which KASPER data can be used for educational and training purposes. The work group should report annually to the Legislative Research Commission.**

    The purpose of this recommendation is to make sure that the Cabinet for Health Services continually assesses the effectiveness of the KASPER system and that the CHS continues to regularly seek input from the various disciplines providing and using KASPER information. It is important for the CHS to know in a concrete way whether or not the KASPER system is effective. It is also important for this information to be conveyed to the General Assembly on a regular basis.

    Action Required: This recommendation can be implemented by the Cabinet for Health Services under existing law.

General Recommendations

15. **<u>Treatment Resources</u> - The General Assembly is strongly encouraged to increase the treatment resources available to address drug abuse.**

    Task force members and witnesses noted several times over the course of the task force meetings that one of the primary barriers to effectively addressing prescription drug abuse is the lack of available treatment options for drug abusers. Practicing physicians and treatment providers testified that it is not uncommon for an individual needing assistance with drug addiction to participate in a brief detoxification program, only to be released pending

admission to a long-term treatment program—most of which have waiting lists of six to eight months. In the intervening time period, individuals often relapse and have to start over, often going through the court system again. One physician testifying before the task force noted that providing effective treatment is much less costly than handling drug-addicted individuals through the criminal justice system. The task force recognized that both KY-ASAP and the House Bill 843 Commission are working on this issue and should be supported to the fullest extent by the General Assembly.

Action Required: Additional resources provided for treatment through the budgeting process. Preparation of a resolution encouraging the General Assembly to devote sufficient resources to drug abuse treatment is suggested.

16. **<u>Sentencing Recommendations</u> - The Legislative Research Commission should study whether sentencing recommendations are actually being imposed in prescription drug cases.**

The task force heard testimony that in many cases, prescription drug abusers and dealers are being arrested and prosecuted, but the sentencing recommendations are not being imposed as recommended, resulting in drug offenders serving little or no jail time. Law enforcement officers serving on the task force and providing testimony before the task force expressed frustration and dismay with the situation, noting that drug investigations can take up to 24 months to complete. These long-term investigations require many hours and resources and often result in the arrest of multiple offenders. Officers reported that in many cases, offenders were allowed to plea bargain for substantially reduced sentences or that sentencing recommendations were not adhered to by judges, resulting in offenders being back on the street, often within days. The officers testified that this is frustrating because of the time and resources used in making arrests when in the end, the offenders return to the streets having suffered few consequences. The task force recognized that this is a serious issue that is beyond the scope of the mission of the task force. For this reason, the task force recommends that further study be conducted in this area.

Required Action: Recommendation to the Interim Joint Committee on Judiciary.

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Appendix A

House Bill 303

AN ACT relating to programs of significant importance to the citizens of the Commonwealth and declaring an emergency.

Be it enacted by the General Assembly of the Commonwealth of Kentucky:

SECTION 1. A NEW SECTION OF KRS CHAPTER 158 IS CREATED TO READ AS FOLLOWS:

All public high schools shall observe Veterans Day under this section.

(1) On Veterans Day, or one (1) of the five (5) school days preceding Veterans Day, one (1) class period shall be devoted to the observance of Veterans Day.

(2) Students shall assemble in one (1) or more groups, as decided by the school principal, to attend the Veterans Day program.

(3) The program shall be approved by the principal and, at a minimum, shall consist of a teacher and a veteran speaking on the meaning of Veterans Day.

(4) To develop a Veterans Day program, Kentucky public high schools are encouraged to seek advice from the Kentucky Department of Military Affairs and veterans' service organizations, including but not limited to the American Legion and the Veterans of Foreign Wars.

Section 2. (1) The Speaker of the House and the President of the Senate are directed to establish a nineteen (19) member task force on prescription drug abuse and the illegal diversion of prescription drugs in the Commonwealth and to select two co-chairs from among its members no later than thirty (30) days from the effective date of this Act. The task force shall initially meet no later than thirty (30) days after its co-chairs are selected, and shall report its recommendations as proposed legislation in accordance with subsection (2) of this section to the Interim Joint Committee on Judiciary no later than October 1, 2003. The task force shall cease to exist upon the making of its report.

(2) The task force shall review the Kentucky All Schedule Prescription Electronic Reporting (KASPER) program and propose legislation to the General Assembly on:

(a) Improving the KASPER program's efficiency in recording information and responding to requests for information;

(b) Increasing the enforcement of reporting requirements of dispensers and prosecution for violations thereof;

(c) The use of data compiled by KASPER to isolate illegal drug diversion trends and to identify patterns of illegal drug diversion; and

(d) Enhancing the overall utility of KASPER for law enforcement and drug abuse prevention purposes.

(3) The task force shall consist of the following members:

(a) Two (2) members from the Kentucky State Police, Division of Police Services, one (1) each to be selected by the Speaker of the House and the President of the Senate;

(b) Two (2) members from the United States Department of Justice, Drug Enforcement Administration, Office of Diversion Control, one (1) each to be selected by the Speaker of the House and the President of the Senate;

(c) Two (2) members from the Kentucky Cabinet for Health Services, Department for Public Health, one (1) each to be selected by the Speaker of the House and the President of the Senate;

(d) Two (2) members who are a Commonwealth's attorney, a full-time county attorney, or combination thereof, to be selected by the Speaker of the House and the President of the Senate;

(e) Two (2) members of the Kentucky Bar Association whose primary practice is devoted to criminal defense, one (1) each to be selected by the Speaker of the House and the President of the Senate from one (1) list of five (5) submitted to those legislators upon a vote of the Criminal Law Section of the Kentucky Bar Association;

(f) Two (2) members from the Kentucky Board of Medical Licensure, the

Kentucky Board of Pharmacy, or combination thereof, one (1) each to be selected by the Speaker of the House and the President of the Senate;

(g) Two (2) members representing drug treatment programs licensed pursuant to KRS 222.231, one (1) each to be selected by the Speaker of the House and the President of the Senate;

(h) Two (2) members from citizen groups in the Commonwealth devoted to preventing drug abuse, one (1) each to be selected by the Speaker of the House and the President of the Senate;

(i) One (1) member of the Kentucky House of Representatives to be selected by the Speaker of the House;

(j) One (1) member of the Kentucky Senate to be selected by the President of the Senate; and

(k) The secretary of the Justice Cabinet, or a designee.

(4) Except as provided in KRS 18A.200, members of the task force shall receive actual travel expenses while attending meetings.

(5) The task force may employ consultants if approved by the Legislative Research Commission, request and hear testimony, and take other steps to ensure a thorough and reasonable study of the issue. The task force shall be staffed by the Legislative Research Commission.

(6) Provisions of this section to the contrary notwithstanding, the Legislative Research Commission shall have the authority to alternatively assign the issues identified herein to an interim joint committee or subcommittee thereof, and to designate a study completion date.

Section 3. Whereas prescription drug abuse and the illegal diversion of prescription drugs have become both an epidemic disease and the fastest growing crime trend in the Commonwealth, an emergency is declared to exist, and Section 2 of this Act takes effect upon its passage and signature by the Governor or upon its otherwise

becoming law.

Appendix B

Draft Legislation

Note: Identical drafts of this legislation have been prepared for introduction in the House and the Senate. The drafts are BR 336 and BR 337.

AN ACT relating to drug control.

Be it enacted by the General Assembly of the Commonwealth of Kentucky:

Section 1. KRS 218A.202 is amended to read as follows:

(1) The Cabinet for Health Services shall establish an electronic system for monitoring Schedules II, III, IV, and V controlled substances that are dispensed within the Commonwealth by a practitioner or pharmacist or dispensed to an address within the Commonwealth by a pharmacy ***that has obtained a license, permit, or other authorization to operate from*** ~~[licensed by]~~ the Kentucky Board of Pharmacy.

(2) A practitioner or a pharmacist shall not have to pay a fee or tax specifically dedicated to the operation of the system.

(3) Every dispenser within the Commonwealth or ***any other dispenser*** who ***has obtained a license, permit, or other authorization to operate from*** ~~[is licensed by]~~ the Kentucky Board of Pharmacy shall report to the Cabinet for Health Services the data required by this section in a timely manner as prescribed by the cabinet except that reporting shall not be required for:

(a) A drug administered directly to a patient; or

(b) A drug dispensed by a practitioner at a facility licensed by the cabinet provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of forty-eight (48) hours.

(4) Data for each controlled substance that is dispensed shall include but not be limited to the following:

(a) Patient identifier;

(b) Drug dispensed;

(c) Date of dispensing;

(d) Quantity dispensed;

(e) Prescriber; and

(f) Dispenser.

(5) The data shall be provided in the electronic format specified by the Cabinet for Health Services unless a waiver has been granted by the cabinet to an individual dispenser. ***Incomplete or inaccurate data shall be corrected upon notification by the cabinet.***

(6) The Cabinet for Health Services shall be authorized to provide data to:

(a) A designated representative of a board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other person who is authorized to prescribe, administer, or dispense controlled substances and who is involved in a bona fide specific investigation involving a designated person;

(b) A state, federal, or municipal officer whose duty is to enforce the laws of this ***Commonwealth, of another*** state, or ***of*** the United States relating to drugs and who is engaged in a bona fide specific investigation involving a designated person;

(c) A state-operated Medicaid program;

(d) A properly convened grand jury pursuant to a subpoena properly issued for the records;

(e) A practitioner or pharmacist who requests information and certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide current patient;~~[or]~~

(f) ***In addition to the purposes authorized under paragraph (a) of this subsection, the Kentucky Board of Medical Licensure, for any physician who is:***

1. Associated in a partnership or other business entity with a physician who is already under investigation by the Board of Medical Licensure for improper prescribing practices;

2. In a designated geographic area for which a trend report indicates a substantial likelihood that inappropriate prescribing may be occurring; or

3. In a designated geographic area for which a report on another physician in that area indicates a substantial likelihood that inappropriate prescribing may be occurring in that area; or

(g) A judge or a probation or parole officer administering a diversion or probation program of a criminal defendant arising out of a violation of this chapter or of a criminal defendant who is documented by the court as a substance abuser who is eligible to participate in a court-ordered drug diversion or probation program.

(7) A person who receives data or any report of the system from the cabinet shall not provide it to any other person or entity except by order of a court of competent jurisdiction***, except that:***

(a) A law enforcement officer who is authorized to receive data or a report may share that information with other law enforcement officers authorized to receive data or a report, if the law enforcement officers are working on a bona fide specific investigation involving a designated person. Both the person providing and the person receiving the data or report under this paragraph shall document in writing each person to whom the data or report has been given or received and the day, month, and year that the data or report has been given or received. This document shall be maintained in a file by each law enforcement agency engaged in the investigation; and

(b) A representative of the Department for Medicaid Services may share data or reports regarding overutilization by Medicaid recipients with a board designated in paragraph (a) of subsection (6) of this section, or with a

law enforcement officer designated in paragraph (b) of subsection (6) of this section.

(8) ~~[(7)]~~ The Cabinet for Health Services, all law enforcement officers, all officers of the court, and all regulatory agencies and officers, in using the data for investigative or prosecution purposes, shall consider the nature of the prescriber's and dispenser's practice and the condition for which the patient is being treated.

(9) ~~[(8)]~~ The data and any report obtained therefrom shall not be a public record.

(10) ~~[(9)]~~ Knowing failure by a dispenser to transmit data to the cabinet as required by subsection (3), (4), or (5) of this section shall be a Class A misdemeanor.

(11) ~~[(10)]~~ Knowing disclosure of transmitted data to a person not authorized by subsection (6) ***or (7)*** of this section or authorized by KRS 315.121, or obtaining information under this section not relating to a bona fide specific investigation, shall be a Class D felony.

(12) ~~[(11)]~~ The Governor's Office for Technology, in consultation with the Cabinet for Health Services, shall submit an application to the United States Department of Justice for a drug diversion grant to fund a pilot project to study a real-time electronic monitoring system for Schedules II, III, IV, and V controlled substances. The pilot project shall:

(a) Be conducted in two (2) rural counties that have an interactive real-time electronic information system in place for monitoring patient utilization of health and social services through a federally funded community access program; and

(b) Study the use of an interactive system that includes a relational data base with query capability.

(13) ~~[(12)]~~ Provisions in~~[subsections (1) to (10) of]~~ this section that relate to data collection, disclosure, access, and penalties shall apply to the pilot project

authorized under subsection ***(12)***[~~(11)~~] of this section.

(14) The Cabinet for Health Services may limit the length of time that data remain in the electronic system. Any data removed from the system shall be archived and subject to retrieval within a reasonable time after a request from a person authorized to review data under this section.

(15) (a) The Cabinet for Health Services shall work with each board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other persons who are authorized to prescribe, administer, or dispense controlled substances for the development of a continuing education program about the purposes and uses of the electronic system for monitoring established in this section.

(b) The cabinet shall work with the Kentucky Bar Association for the development of a continuing education program for attorneys about the purposes and uses of the electronic system for monitoring established in this section.

(c) The cabinet shall work with the Justice Cabinet for the development of a continuing education program for law enforcement officers about the purposes and users of the electronic system for monitoring established in this section.

Section 2. KRS 218A.240 is amended to read as follows:

(1) All police officers and deputy sheriffs directly employed full-time by state, county, city, or urban-county governments, the State Police, the Cabinet for Health Services, their officers and agents, and of all city, county, and Commonwealth's attorneys, and the Attorney General, within their respective jurisdictions, shall enforce all provisions of this chapter and cooperate with all agencies charged with the enforcement of the laws of the United States, of this state, and of all other states relating to controlled substances.

(2) For the purpose of enforcing the provisions of this chapter, the designated agents of the Cabinet for Health Services shall have the full power and authority of peace officers in this state, including the power of arrest and the authority to bear arms, and shall have the power and authority to administer oaths, to enter upon premises at all times for the purpose of making inspections, to seize evidence, to interrogate all persons, to require the production of prescriptions, of books, papers, documents or other evidence, to employ special investigators, and to expend funds for the purpose of obtaining evidence.

(3) The Kentucky Board of Pharmacy, its agents and inspectors, shall have the same powers of inspection and enforcement as the Cabinet for Health Services.

(4) Designated agents of the Cabinet for Health Services and the Kentucky Board of Pharmacy are empowered to remove from the files of a pharmacy or the custodian of records for that pharmacy any controlled substance prescription or other controlled substance record upon tendering a receipt. The receipt shall be sufficiently detailed to accurately identify the record. A receipt for the record shall be a defense to a charge of failure to maintain the record.

(5) Notwithstanding the existence or pursuit of any other remedy, civil or criminal, any law enforcement authority may maintain, in its own name, an action to restrain or enjoin any violation of this chapter, or to forfeit any property subject to forfeiture under KRS 218A.410, irrespective of whether the owner of the property has been charged with or convicted of any offense under this chapter.

(a) Any civil action against any person brought pursuant to this section may be instituted in the Circuit Court in any county in which the person resides, in which any property owned by the person and subject to forfeiture is found, or in which the person has violated any provision of

this chapter.

(b) A final judgment rendered in favor of the Commonwealth in any criminal proceeding brought under this chapter shall estop the defendant from denying the essential allegations of the criminal offense in any subsequent civil proceeding brought pursuant to this section.

(c) The prevailing party in any civil proceeding brought pursuant to this section shall recover his costs, including a reasonable attorney's fee.

(d) Distribution of funds under this section shall be made in the same manner as in KRS 218A.435, except that if the Commonwealth's attorney has not initiated the forfeiture action under this section, his percentage of the funds shall go to the agency initiating the forfeiture action.

(6) The Cabinet for Health Services shall make or cause to be made examinations of samples secured under the provisions of this chapter to determine whether any provision has been violated.

(7) (a) The Cabinet for Health Services shall use the data compiled in the electronic system created in Section 1 of this Act for investigations, research, statistical analysis, and educational purposes, and shall proactively identify trends in controlled substance usage and other potential problem areas. Only cabinet personnel who have undergone training for the electronic system and who have been approved to use the system shall be authorized access to the data and reports under this subsection. The cabinet shall notify a board responsible for the licensure, regulation, or discipline of each practitioner, pharmacist, or other person who is authorized to prescribe, administer, or dispense controlled substances, if a report or analysis conducted under this subsection indicates that further investigation about inappropriate or unlawful prescribing or dispensing may be necessary by the board.

(b) The cabinet shall develop criteria, in collaboration with the Board of Medical Licensure and the Board of Pharmacy, to be used to generate trend reports from the data obtained by the system. Meetings at which the criteria are developed shall be meetings, as defined in KRS 61.805, that comply with the open meetings laws, KRS 61.805 to 61.850.

(c) The cabinet shall, on a quarterly basis, publish trend reports from the data obtained by the system.

(d) Law enforcement officers authorized to receive data under Section 1 of this Act may request trend reports not specifically published pursuant to paragraph (c) of this subsection. A report under this paragraph may be based upon the criteria developed under paragraph (b) of this subsection or upon any of the data collected pursuant to subsection (4) of Section 1 of this Act, except that the report shall not identify an individual prescriber, dispenser, or patient.

(e) No trend report generated under this subsection shall identify an individual prescriber, dispenser, or patient.

SECTION 3. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO READ AS FOLLOWS:

(1) The secretary of the Cabinet for Health Services may enter into reciprocal agreements with any other state or states of the United States to share prescription drug monitoring information if the other state's prescription drug monitoring program is compatible with the program in Kentucky. If the secretary elects to evaluate the prescription drug monitoring program of another state as authorized by this section, priority shall be given to a state that is contiguous with the borders of the Commonwealth.

(2) In determining compatibility, the secretary shall consider:

(a) The essential purposes of the program and the success of the program in

fulfilling those purposes;

(b) The safeguards for privacy of patient records and its success in protecting patient privacy;

(c) The persons authorized to view the data collected by the program;

(d) The schedules of controlled substances monitored;

(e) The data required to be submitted on each prescription;

(f) Any implementation criteria deemed essential for a thorough comparison; and

(g) The costs and benefits to the Commonwealth in mutually sharing particular information available in the Commonwealth's database with the program under consideration.

(3) The secretary shall review any agreement on an annual basis to determine its continued compatibility with the Kentucky prescription drug monitoring program.

(4) The secretary shall prepare an annual report to the Governor and the Legislative Research Commission that summarizes any agreement under this section and that analyzes the effectiveness of that agreement in monitoring the dispensing of controlled substances in the Commonwealth.

(5) Any agreement between the cabinet and another state shall prohibit the sharing of information about a Kentucky resident, practitioner, pharmacist, or other prescriber for any purpose not otherwise authorized by this section or Section 1 of this Act.

Section 4. KRS 315.0351 is amended to read as follows:

(1) Every pharmacy located outside this Commonwealth which, other than on an incidental basis, does business within this Commonwealth within the meaning of KRS Chapter 315, shall hold a current pharmacy permit as provided in KRS 315.035(1) and (4) issued by the Kentucky Board of Pharmacy. The pharmacy

shall be designated an "out-of-state pharmacy" and the permit shall be designated an "out-of-state pharmacy permit." The fee for the permit shall not exceed the current in-state pharmacy permit fee as provided under KRS 315.035.

(2) Every out-of-state pharmacy granted an out-of-state pharmacy permit by the board shall disclose to the board the location, names, and titles of all principal corporate officers and all pharmacists who are dispensing prescription drugs to residents of the Commonwealth. A report containing this information shall be made to the board on an annual basis and within thirty (30) days after any change of office, corporate officer, or pharmacist.

(3) Every out-of-state pharmacy granted an out-of-state pharmacy permit shall comply with all statutorily-authorized directions and requests for information from any regulatory agency of the Commonwealth and from the board in accordance with the provisions of this section. The out-of-state pharmacy shall maintain at all times a valid unexpired permit, license, or registration to conduct the pharmacy in compliance with the laws of the ***jurisdiction***~~[state]~~ in which it is a resident. As a prerequisite to seeking a permit from the Kentucky Board of Pharmacy, the out-of-state pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the ***jurisdiction***~~[state]~~ in which it is located. Thereafter, the out-of-state pharmacy granted a permit shall submit to the Kentucky Board of Pharmacy a copy of any subsequent inspection report on the pharmacy conducted by the regulatory or licensing body of the ***jurisdiction***~~[state]~~ in which it is located.

(4) Every out-of-state pharmacy granted an out-of-state pharmacy permit by the board shall maintain records of any controlled substances or dangerous drugs or devices dispensed to patients in the Commonwealth so that the records are

readily retrievable from the records of other drugs dispensed.

(5) Records for all prescriptions delivered into Kentucky shall be readily retrievable from the other prescription records of the out-of-state pharmacy.

(6) Each out-of-state pharmacy shall, during its regular hours of operation, but not less than six (6) days per week and for a minimum of forty (40) hours per week, provide a toll-free telephone service directly to the pharmacist in charge of the out-of-state pharmacy and available to both the patient and each licensed and practicing in-state pharmacist for the purpose of facilitating communication between the patient and the Kentucky pharmacist with access to the patient's prescription records. A toll-free number shall be placed on a label affixed to each container of drugs dispensed to patients within the Commonwealth.

(7) Each out-of-state pharmacy shall have a pharmacist in charge who shall be responsible for compliance by the pharmacy with the provisions of this section.