Department of Legislative Services
Maryland General Assembly
2003 Session

FISCAL AND POLICY NOTE

Senate Bill 48 (Senator DeGrange, *et al.*)
Judicial Proceedings

Controlled Dangerous Substances - Dispensing Monitoring Program

This bill requires the Department of Health and Mental Hygiene (DHMH) to establish a program for the electronic monitoring of certain controlled dangerous substances that are dispensed in the State by an authorized provider, or dispensed to an address in the State by a pharmacy licensed by the State Board of Pharmacy.

Fiscal Summary

State Effect: DHMH general fund expenditures could increase by $350,900 in FY 2004. Future year expenditures reflect annualization, inflation, and periodic computer software and hardware replacement and upgrades. The civil and criminal penalty provisions of this bill are not expected to significantly affect State finances or operations.

(in dollars)	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008
Revenues	$0	$0	$0	$0	$0
GF Expenditure	350,900	262,500	278,000	294,800	313,000
Net Effect	($350,900)	($262,500)	($278,000)	($294,800)	($313,000)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate effect

Local Effect: The civil and criminal penalty provisions of this bill are not expected to significantly affect local finances or operations.

Small Business Effect: Potential minimal. Small business prescription drug dispensers could incur additional administrative expenses to comply with the bill's electronic reporting requirements.

Analysis

Bill Summary: Each dispenser licensed by the Board of Pharmacy must report data to DHMH for each controlled dangerous substance (CDS) that is dispensed, including: (1) the patient identifier; (2) the drug dispensed; (3) the dispensing date; (4) the dispensed quantity; (5) the prescriber; (6) the dispenser; and (7) other information DHMH requires. The dispenser must provide the data in the electronic format specified by DHMH unless a waiver has been granted by DHMH to an individual dispenser.

A dispenser does not have to report these data to DHMH if a drug is administered directly to a patient or is dispensed by a practitioner at a facility licensed by DHMH, provided the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of 48 hours.

DHMH may provide data: (1) to a designated representative of an appropriate health occupation board that licenses a provider or another person who is authorized to prescribe, administer, or dispense CDS; (2) to another person who is authorized to prescribe, administer, or dispense CDS and who is involved in an investigation involving a specific person; (3) to a State, federal, or local officer responsible for law enforcement relating to drugs and who is engaged in an investigation; (4) to a State-operated Medicaid program; (5) in response to a properly issued subpoena in a criminal investigation or prosecution; or (6) to an authorized provider for the purpose of providing medical or pharmaceutical treatment to a patient.

A person who receives data from DHMH may not provide it to another except by order of a court of competent jurisdiction. The data and any report obtained from the data are confidential information and not a public record. DHMH, law enforcement officers, courts, and regulatory agencies who use the data for investigative or prosecutorial purposes must consider the nature of the authorized provider's practice and the condition for which the patient is being treated.

A dispenser that knowingly fails to transmit data to the department as required by the bill is guilty of a misdemeanor and subject to a fine not exceeding $500 for each failure to submit data. A person who knowingly discloses transmitted data to an unauthorized person or who knowingly obtains data not relating to an investigation is guilty of a felony and subject to imprisonment not exceeding five years.

Current Law: Drug manufacturers, distributors, and dispensers must register with the Board of Pharmacy to dispense controlled dangerous substances. Dispensers include licensed pharmacists and licensed health care practitioners such as physicians, dentists, veterinarians, or other health care practitioners authorized to prescribe controlled

dangerous substances within the scope of their practice. All registrants must maintain inventory records of controlled dangerous substances. In addition, registrants must provide effective controls and procedures to guard against theft and unlawful diversion of controlled substances. In the case of theft or loss of controlled dangerous substances, registrants must notify the regional office of the Drug Enforcement Administration and DHMH's Division of Drug Control upon discovery of the loss or theft.

A person may not possess or administer a CDS to another person unless obtained directly or by prescription or order from an authorized provider acting in the course of professional practice. A person may not obtain or attempt to obtain a CDS by: (1) fraud, deceit, misrepresentation, or subterfuge; (2) the counterfeiting or alteration of a prescription or written order; (3) the concealment of a material fact; (4) the use of a false name or address; (5) falsely assuming the title of or representing to be a manufacturer, distributor, or authorized provider; or (6) making, issuing, or presenting a false or counterfeit prescription or written order. A person may not pass, issue, make, or possess a false, counterfeit, or altered prescription for a CDS with the intent to distribute the CDS. Applicable criminal penalties vary depending on the nature of the violation.

Background: All states have laws and regulations that govern the distribution and handling of controlled substances and other drugs. State laws must balance the safe use of controlled substances for medical care with the need to prevent illegal and harmful activities involving these drugs. For many years, states have struggled with the diversion and abuse of certain drugs.

Some states have taken such proactive measures as implementing prescription monitoring programs as tools to combat prescription drug abuse. As of October 2002, 18 states have instituted some type of prescription monitoring program and more states are seeking legislation to do so. Prescription monitoring programs collect prescription data from pharmacies either in paper or electronic format. Data are reviewed and analyzed for educational, public health, and investigative purposes.

The National Alliance for Model State Drug Laws has developed the Model Prescription Accountability Act. The Act is intended to improve a state's ability to stop illegal diversion of prescription drugs in an efficient and cost-effective manner that will not impede the appropriate medical utilization of legal controlled substances. In an effort to impede drug diversion and abuse, the federal Drug Enforcement Agency's Office of Diversion Control encourages states to implement prescription monitoring programs by adopting the Model Prescription Accountability Act.

State Fiscal Effect: DHMH general fund expenditures could increase by an estimated $350,861 in fiscal 2004, which accounts for the bill's October 1, 2003 effective date.

This estimate reflects the cost of five new positions (one database specialist, one data entry clerk, one office secretary, and two pharmacists within the Division of Drug Control to collect and distribute data on controlled dangerous substances). It includes salaries, fringe benefits, one-time start-up costs, ongoing operating expenses, and computer hardware and software development.

Salaries and Fringe Benefits	$177,672
Computer Hardware and Software Development	134,000
Other Operating Expenses	39,189
Total FY 2004 State Expenditures	**$350,861**

Future year expenditures reflect: (1) full salaries with 4.5% annual increases and 3% employee turnover; (2) 1% annual increases in ongoing operating expenses; and (3) periodic computer software and hardware upgrades and replacements. Revenues would not be affected.

Additional Information

Prior Introductions: A similar bill, SB 44, was introduced in 2002 but was reported unfavorably by the Senate Finance Committee.

Cross File: HB 60 (Delegate Bromwell, *et al*.) –Judiciary.

Information Source(s): National Association of State Controlled Substances Authorities, U.S. Department of Justice (Drug Enforcement Agency), Kentucky Cabinet for Health Services (Drug Control Office – KASPER), National Alliance for Model State Drug Laws, Department of Health and Mental Hygiene (Division of Drug Control, Office of Health Care Quality, Boards and Commissions), Department of Public Safety and Correctional Services, Department of Legislative Services

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