Senate Fiscal Agency
P. O. Box 30036
Lansing, Michigan 48909-7536

SFA BILL ANALYSIS

Telephone: (517) 373-5383
Fax: (517) 373-1986
TDD: (517) 373-0543

House Bill 5260 (Substitute H-3 as passed by the House)
House Bill 5261 (Substitute H-2 as passed by the House)
House Bill 5262 (Substitute H-3 as passed by the House)
Senate Bill 827 (as introduced 11-27-01)
Sponsor: Representative Thomas M. George (H.B. 5260)
Representative Paul N. DeWeese (H.B. 5261)
Representative Stephan Ehardt (H.B. 5262)
Senator Dale L. Shugars (S.B. 827)
House Committee: Health Policy
Senate Committee: Health Policy

Date Completed: 11-28-01

CONTENT

The bills would amend the Public Health Code to do the following:

-- Require the Department of Consumer and Industry Services (DCIS) to establish, by rule, an electronic system for monitoring dispensed controlled substances.
-- Require certain prescribers and pharmacists to use the electronic system.
-- Eliminate current provisions that require official prescription forms for Schedule 2 prescriptions.
-- Require a prescription form to include additional information.
-- Abolish the Official Prescription Form Program Fund, transfer its balance to a proposed "Controlled Substances Electronic Monitoring Fund", and create a "Pain Management Education and Controlled Substances Antidiversion Fund".

House Bill 5260 (H-3) is tie-barred to House Bill 5262. House Bill 5261 (H-2) is tie-barred to House Bills 5260 and 5262. House Bill 5262 (H-3) is tie-barred to House Bill 5260. Senate Bill 827 is tie-barred to the House bills.

House Bill 5260 (H-3)

Controlled Substances Monitoring

The bill would require the DCIS to establish, by rule, an electronic system for monitoring Schedule 2, 3, 4, and 5 controlled substances (described in **BACKGROUND**, below) dispensed in Michigan by veterinarians, and by licensed pharmacists and dispensing prescribers (doctors and dentists who dispense prescription drugs to their own patients); or dispensed to a Michigan address by a pharmacy licensed in the State. The rules would have to provide an appropriate electronic format for the reporting of data, including patient identifiers, the name of the controlled substance dispensed, date of dispensing, quantity dispensed, prescriber, and dispenser. The DCIS would have to require a veterinarian, pharmacist, or prescribing dispenser to use the electronic data transmittal process developed by the Department's contractor.

A veterinarian, pharmacist, or dispensing prescriber could not be required to pay a new fee dedicated to the operation of the electronic monitoring system, or incur any additional costs for the transmission of data to the Department. The rules promulgated under the bill would have to exempt from the reporting requirements the administration of a controlled substance directly to a patient; and the dispensing from a licensed health facility or agency of a controlled substance by a dispensing prescriber, in a quantity adequate to treat a patient for no more than 48 hours.

The DCIS could provide data to all of the following:

-- A designated representative of a board responsible for the licensure, regulation, or

discipline of practitioners, pharmacists, or other person who was authorized to prescribe, administer, or dispense controlled substances, and who was involved in a bona fide specific investigation involving a designated person.

-- A State, Federal, or municipal officer whose duty was to enforce the laws of the State or the United States relating to drugs, and who was engaged in a bona fide specific investigation involving a designated person.
-- A State-operated Medicaid program.
-- A properly convened grand jury pursuant to a subpoena properly issued for the records.
-- A practitioner or pharmacist who requested information and certified that the information was for the purpose of providing medical or pharmaceutical treatment to a bona fide current patient.

A person who received data or any report containing any patient identifiers of the system from the DCIS could not provide it to any other person or entity, except by order of a court of competent jurisdiction. The DCIS, all law enforcement officers, all officers of the court, and all regulatory agencies and officers, in using the data for investigative or prosecution purposes, would have to consider the nature of the prescriber's and dispenser's practice and the condition for which the patient was being treated. The data and any report containing any patient identifiers obtained from them would not be a public record or subject to the Freedom of Information Act.

The DCIS could issue a written waiver of the electronic reporting requirement to a veterinarian, pharmacist, or dispensing prescriber who established grounds that he or she was unable to use the electronic monitoring system. The DCIS would have to require the applicant for the waiver to report the required information in a manner approved by the DCIS.

Under the Code, the Controlled Substances Advisory Commission is required to monitor consumption of controlled substances in Michigan, and issue an annual report to the Governor, Legislature, and Board of Pharmacy on the status of the abuse and diversion of controlled substances. The bill would require the Commission to include in its annual report information on the implementation and effectiveness of the electronic monitoring system. In consultation with the Commission, the Michigan Board of Pharmacy, the Michigan Board of Medicine, the Michigan Board of Osteopathic Medicine and Surgery, and appropriate medical professional associations, the DCIS would have to examine the need for the production of a prescription form on paper that minimized the potential for forgery. The DCIS could promulgate rules for the production of the form, but the rules could not include any requirement that sequential numbers, bar codes, or symbols be affixed, printed, or written on a prescription form, or that the form be produced by the State. In examining the need for rules for the production of a form, the DCIS would have to consider and identify the cost, benefits, and barriers; the overall cost-benefit analysis; and compatibility with the electronic monitoring system.

The DCIS would have to report its findings on the need for a prescription form to the members of the House and Senate standing committees having jurisdiction over health policy issues, at least 120 days before the electronic monitoring system became operational.

Official Prescription Form/Prescription Form

Section 7334 of the Code requires official prescription forms to be used for prescriptions for Schedule 2 controlled substances; requires the DCIS to issue the forms to practitioners; prescribes certain requirements for the content of the forms; and requires prescribers to follow specified procedures when using the forms. The bill would repeal Section 7334. Further, the bill would delete references to "official prescription form" in various sections of the Code, and would retain references to "prescription form".

The bill also would repeal Section 17766b, which requires a prescription for an androgenic anabolic steroid to be recorded on an official prescription form in the manner that is required for Schedule 2 prescriptions.

The bill would retain provisions that prohibit a practitioner from issuing more than one prescription for a Schedule 2 controlled substance on a single form, and prohibit a prescribing practitioner from postdating a prescription form that contains a prescription for a controlled substance.

Currently, except for a terminally ill patient, a prescription for a Schedule 2 controlled substance may not be filled more than five days after the prescription was issued. The bill would allow up to 60 days.

The bill would allow a prescriber to transmit a prescription by facsimile of a printed prescription form, and by electronic transmission of a printed prescription form, if not prohibited by Federal law. If a prescription were electronically transmitted, it would have to be transmitted directly to the pharmacy, and the data could not be altered, modified, extracted, viewed, or manipulated in the transmission process.

Penalties

The Code provides that a person who manufactures, creates, delivers, or possesses with intent to manufacture, create, or deliver an official prescription form, or counterfeit official prescription form, is guilty of a felony punishable by imprisonment for up to 20 years, a fine up to $25,000, or both. The bill would delete this provision, but retain a provision that makes it a felony, punishable by up to seven years' imprisonment, up to a $5,000 fine, or both, to manufacture, create, or deliver (or possess with the intent to manufacture, create, or deliver) a prescription form or counterfeit prescription form.

Further, the Code provides that a person who knowingly or intentionally possesses an official prescription form (unless obtained in a valid manner from a practitioner) is guilty of a felony punishable by imprisonment for up to one year, a fine up to $2,000, or both. The bill would delete this provision, but retain a provision that makes it a misdemeanor, punishable by imprisonment for up to one year, a fine of up to $1,000, or both, to possess a prescription form knowingly or intentionally (unless it was validly obtained).

Legislative Findings

Section 16204b of the Code contains statements of legislative findings regarding the treatment of intractable pain. The bill would remove "intractable" from the statements, and remove a reference to the definition of intractable pain.

Section 16204c of the Code contains statements of legislative findings regarding the use of controlled substances in the medical

treatment of intractable pain. The bill would remove the references to "intractable". Further, the current provision states, in part, that "...efforts to control diversion or improper administration of controlled substances should not interfere with the legitimate, medically recognized use of those controlled substances to relieve pain and suffering." The language also provides that, based on these findings, "...the legislature states that the official prescription form program...was created to prevent the abuse and diversion of controlled substances included in schedule 2...and not to prevent or inhibit the legitimate, medically recognized use of those controlled substances to treat patients with cases of intractable pain, especially long-term treatment." The bill would delete this statement.

In addition, Section 16204c states that it is the intent of the Legislature to permit and facilitate adequate treatment for pain by licensed health professionals, including the prescription or dispensing of Schedule 2 controlled substances when medically appropriate. The bill would add, "and to enable regulatory and law enforcement agencies to prevent the abuse and diversion of controlled substances by creating an electronic monitoring system".

Informational Booklet

The Code requires the DCIS, in consultation with the Department of Community Health, to develop, publish, and distribute an informational booklet on intractable pain. The Code prescribes the content of the booklet, and requires that it include the definition of "intractable pain"; information on the history and purpose of the official prescription form program; and information on how the DCIS collects, processes, and compiles official prescription form information. The bill would delete the requirements that the booklet contain this information.

Effective Date

The provisions in the bill that would remove requirements for, and references to, the official prescription form, and those that would delete the penalties for manufacturing, creating, delivering, or possessing official prescription forms, would not take effect until the DCIS promulgated rules required to implement the proposed electronic monitoring system for dispensed controlled substances, and the Secretary of State received written notice from the DCIS Director that the electronic monitoring system was operational. The notice would have to include a statement that the DCIS was able to receive data from at least 80% of those required to report under the bill, and was able to respond to requests for data from persons authorized to make such requests and to review and use the data.

House Bill 5261 (H-2)

The bill would abolish the Official Prescription Form Program Fund and create a "Controlled Substances Electronic Monitoring Fund" as well as a "Pain Management Education and Controlled Substances Antidiversion Fund".

Currently, the Program Fund is established in the Department of Treasury and is administered by the DCIS. The Fund receives $20 from each $75 annual licensing fee paid to the DCIS for persons licensed to manufacture, distribute, prescribe, dispense, or conduct research with controlled substances. Money in the Fund may be used only for programs relating to official prescription forms, and any unspent balance at the end of a fiscal year is carried forward to the next fiscal year. The bill provides that money in the Program Fund on the bill's effective date would have to be transferred to the Monitoring Fund. The $20 from the annual licensing fees would have to be deposited in the Antidiversion Fund. Both of the proposed Funds would be established in the Department of Treasury. The DCIS could use the Monitoring Fund only in connection with developing and maintaining the electronic system for the monitoring of controlled substances data required under House Bill 5260 (H-3). The DCIS could use the Antidiversion Fund only in connection with programs relating to pain management education for health professionals, preventing the diversion of controlled substances, and maintenance of the electronic monitoring system.

The bill would require the State Treasurer to direct the investment of the Funds. Interest and earnings from the investments would have to be credited to the Funds. The unencumbered balance in the Funds at the close of the fiscal year would have to remain in the Funds and would not revert to the General Fund. The Funds could receive gifts and devises and any other money as provided by law.

House Bill 5262 (H-3)

The bill would delete from the Code the definition of "official prescription form", and revise the definition of "prescription form".

Currently, "official prescription form" means a prescription form for a Schedule 2 controlled substance that meets the requirements of Section 7334 and is issued to practitioners by the DCIS. (Section 7334 would be repealed by House Bill 5260 (H-3).)

"Prescription form" currently means a printed form, that is authorized and intended for use by a prescribing practitioner to prescribe controlled substances or other prescription drugs and that meets the requirements of rules promulgated by the administrator (the Board of Pharmacy). The bill also would require a prescription form to include the following:

-- The preprinted, stamped, typed, or manually printed name, address, and telephone number or pager number of the prescribing practitioner.
-- The manually printed name of the patient, the address of the patient, the prescribing practitioner's signature, and the prescribing practitioner's Drug Enforcement Administration registration number.
-- The quantity of the prescription drug prescribed, in both written and numerical terms.
-- The date the prescription drug was prescribed.

In addition, a prescription form would have to meet the requirements of any rules promulgated by the Department (pursuant to House Bill 5260 (H-3)).

The bill provides that an "electronic signature" would be an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record. Further, "sign" would mean to affix one's signature manually to a document or to use an electronic signature.

The bill would take effect upon the promulgation of the rules by the DCIS under House Bill 5260 (H-3), and the Secretary of State's receipt of written notice from the DCIS Director that the required electronic monitoring system was operational. The notice to the Secretary of State would have to include a statement that the DCIS was able to receive data from at least 80% of those persons required to report under House Bill 5260 (H-3), and able to respond to requests for data from persons authorized to make such requests and to review and use the data.

Senate Bill 827

The Code provides that a person who manufactures, creates, delivers, or possesses with intent to manufacture, create, or deliver an official prescription form, or counterfeit official prescription form, is guilty of a felony punishable by imprisonment for up to 20 years, a fine up to $25,000, or both. The bill would delete this provision, but retain a provision that makes it a felony, punishable by up to seven years' imprisonment, up to a $5,000 fine, or both, to manufacture, create, or deliver (or possess with intent to manufacture, create, or deliver) a prescription form or counterfeit prescription form.

Further, the Code provides that a person who knowingly or intentionally possesses an official prescription form (unless obtained in a valid manner from a practitioner) is guilty of a felony punishable by imprisonment for up to one year, a fine of up to $2,000, or both. The bill would delete this provision, but retain a provision that makes it a misdemeanor, punishable by imprisonment for up to one year, a fine of up to $1,000, or both, to possess a prescription form knowingly or intentionally (unless it was validly obtained).

The bill would take effect upon the promulgation of the rules by the DCIS under House Bill 5260 (H-3), and the Secretary of State's receipt of written notice from the DCIS Director that the required electronic monitoring system was operational. The notice to the Secretary of State would have to include a statement that the DCIS was able to receive data from at least 80% of those persons required to report under House Bill 5260 (H-3), and able to respond to requests for data from persons authorized to make such requests and to review and use the data.

MCL 333.7333 et al. (H.B. 5260)
333.16315 (H.B. 5261)
333.7104 et al. (H.B. 5262)
333.7401 et al. (S.B. 827)

BACKGROUND

The Public Health Code classifies controlled substances under one of five schedules. By definition, all scheduled drugs have the potential for abuse and are either illegal and without any medically accepted use in the United States (all Schedule 1 drugs) or prescription drugs with medically accepted uses in the U.S. but that have a potential for psychological or physical dependence (Schedules 2, 3, 4, and 5). Schedules 1 and 2 drugs are both defined as having a "high risk" of abuse, and drugs on Schedule 2-5 have successively reduced potential for leading to dependence.

Schedule 2 prescription drugs include opium and its derivatives (e.g., codeine, morphine, and oxycodone), opium poppy and straw, other opiates, methadone, and pethidine, coca leaves and derivatives, such as cocaine, and methylphenidate. Schedule 2 also includes substances containing any quantity of such drugs as amphetamine and methamphetamine, methaqualone, and barbiturates.

Schedule 3 includes, among other things, substances with any quantity of a derivative of barbituric acid and drugs containing limited quantities of opium, codeine, or morphine. Schedule 4 includes drugs such as diazepam, barbital, chloral hydrate, lorazepam, meprobamate, and phenobarbital.

Legislative Analyst: G. Towne

FISCAL IMPACT

House Bills 5260 (H-3) & 5261 (H-2) and Senate Bill 827

These bills would require the Department of Consumer and Industry Services to create an electronic database to monitor prescriptions of Schedules 2, 3, 4, and 5 controlled substances. According to the Department, the creation of this system would cost approximately $1.3 million, which would be covered by the balance being transferred from the Official Prescription Form Program Fund. The operation of the system is estimated to cost $1 million annually, which would be covered by the annual revenue currently being collected from the $20 license fee. Therefore, there would be no real fiscal impact on the Department.

According to the Department of Corrections (DOC) Statistical Report, in both 1998 and 1999, only one offender was convicted of violating or attempting to violate MCL 333.7401 with regard to manufacturing, creating, delivering (or possessing with intent to manufacture, create, or deliver) an official prescription form. If one assumes that as in previous years, one offender would commit this offense but instead would be convicted for violating this section without the distinction of an "official" prescription form, and would receive the maximum sentence, which would be seven years rather than 20, then the State would save $286,000. The maximum penal fine also would be $5,000, instead of $25,000, which would decrease the amount of funds available for libraries.

The DOC Statistical Report also says that no offenders in 1998 or 1999 were convicted for violating MCL 333.7403 with regard to possessing either an official prescription form or prescription form. The bill would eliminate the distinction between the two offenses, leaving one offense punishable as a misdemeanor with a maximum fine of $1,000, which would shift the responsibility for incarceration and probation costs from the State to local units of government and decrease the amount of funds available for libraries.

House Bill 5262 (H-3)

The bill would have no fiscal impact on State or local government.

Fiscal Analyst: M. Tyszkiewicz
B. Wicksall