SFA BILL ANALYSIS

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Senate Bill 75 (Substitute S-3 as passed by the Senate)
Senate Bill 76 (as passed by the Senate)
Sponsor: Senator Robert Geake
Committee: Health Policy

Date Completed: 7-24-87

RATIONALE

During the 1980s, Michigan ranked first in the nation in the consumption of several Schedule 2 prescription drugs, which are considered the most highly addictive of the controlled substances. In 1983, for example, Michigan reportedly received 35% of the methamphetamine ("speed") consumed in the United States. The State in the same year also was the top consumer of Preludin, Ritalin, and Dilaudid. After two years of special enforcement activity and revised rules, the consumption in Michigan of certain Schedule 2 drugs, such as methamphetamine (Dexosyn) and phenmetrazine (Preludin), dropped considerably, but consumption of other Schedule 2 drugs still remains high. Reportedly, many of these drugs are diverted from legal channels to illegal and abusive distribution channels through forged and stolen prescription pads and forms; dishonest doctors, pseudo doctors, and pharmacists who prescribe and/or dispense these drugs for illegitimate purposes; and duped, troubled, and out-of-date practitioners who write prescriptions for abusing patients. A triplicate prescription system, some people contend, would decrease the use of fraudulent and forged prescriptions to obtain these drugs as well as greatly increase the effectiveness of identifying and investigating dishonest and incompetent prescribers and dispensers of Schedule 2 drugs.

CONTENT

Senate Bill 75 (S-3) would amend the Public Health Code to do the following:

- Create a Controlled Substances Advisory Commission within the Department of Licensing and Regulation and prescribe the duties of the Commission.
- Require the use of triplicate prescription forms for the dispensing of certain controlled substances.
- Prohibit the creation and sale of a "controlled substance analogue".
- Provide penalties for violations.
- Establish a sunset date of September 30, 1993, for the Commission and triplicate prescription program.

The bill would take effect April 1, 1989.

Senate Bill 76 would amend the State License Fee Act to raise the fees for a person who is licensed or seeking licensure to manufacture or distribute controlled substances. The fee for a controlled substance license and a controlled substance license renewal would be raised from $30 to $40 per license or license renewal.

MCL 338.2251

The bills are tie-barred.

A more detailed description of Senate Bill 75 (S-3) follows.

Controlled Substances Advisory Commission

The Controlled Substances Advisory Commission, created within the Department of Licensing and Regulation, would consist of 13 voting members appointed by the Governor with the advice and consent of the Senate: three would be public members, one of whom would serve as chairperson; one would be from the field of psychiatry, one from the field of pharmacology, one representing pharmaceutical manufacturers, and one each from the boards of medicine, dentistry, pharmacy, osteopathic medicine and surgery, podiatric medicine and surgery, veterinary medicine, and nursing. The Directors, or their designees, of the following Departments would be nonvoting members: State Police, Licensing and Regulation, Public Health, Social Services, Education, and Attorney General. The drug control administrator from the Department of Licensing and Regulation also would be a nonvoting member and would serve as secretary to the Commission.

Advisory Commission members would receive per diem compensation, as established annually by the Legislature, and would be reimbursed for expenses for travel, etc., in performance of official functions. Members would serve for two-year terms, with an individual not serving more than two terms, consecutive or otherwise. A vacancy would be filled for the balance of the unexpired term in the same manner as the original appointment. The Commission would be required to meet at least once every three months, to report at least annually to the administrator (the Michigan Board of Pharmacy or its designated or established authority), the Governor, and the Legislature on the current status of the abuse and diversion of controlled substances, and to make recommendations for legislative, administrative, and interagency activities.

The Commission would be required to monitor indicators of controlled substance abuse and diversion, and if the data showed that the State exceeded the national average per capita consumption of a controlled substance, the Commission would have to investigate to determine if there was a legitimate reason for the excess consumption. If such a reason were not found, the Commission would have to develop a plan to "overcome the problem".

Within one year after the effective date of the bill, the Commission, in conjunction with the Department and the Michigan Pharmacists Association, would be required to establish a standardized data base format which could be used by dispensing pharmacies to transmit electronically the prescription-related information required in the bill to the Department or on storage media including, but not limited to, disks, tapes, and cassettes. Within two years after having established electronic or storage media transmissions of data, the Commission would be required

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to evaluate the continued need for triplicate prescription forms and report to the Legislature.

In addition, the administrator could promulgate rules relating to the prescribing of Schedule 2 controlled substances.

Prescription Forms and Requirements

Currently, a controlled substance that is listed on Schedule 2 of the Code cannot be dispensed without the written prescription of a licensed practitioner. (Inclusion of a substance on the Schedule 2 list indicates that it has currently accepted medical uses but also has a high potential for abuse of a kind that could lead to severe psychic or physical dependence.) The bill provides that Schedule 2 substances could not be dispensed without an official prescription form, and only one prescription could be recorded on a form. A prescription for a person who was admitted to a hospital at the same time the prescription was written and filled at the hospital or a prescription that was administered to a patient on the premises of a licensed health facility or agency, would not have to be on an official prescription form. In addition, an official prescription form would not have to be used by a practitioner who resided adjacent to the land border between Michigan and an adjoining state, who was authorized under the laws of that state to practice a health profession, and whose practice could extend into Michigan but who did not maintain an office or designate a place to meet patients or receive calls in Michigan.

An "official prescription form" would be defined as a prescription form issued at no charge to practitioners by the Department of Licensing and Regulation that was numbered serially, was in triplicate, and contained spaces for the following information: the date the prescription was written and the date filled; the controlled substance prescribed, the dosage, and instructions; the name, address, and Federal Drug Enforcement Administration (DEA) number of the dispensing pharmacy and the initials of the pharmacist who filled the prescription; the name, address, and age of the person for whom the substance was prescribed; and, the name, address, and age of the authorized agent, if any, for the ultimate user.

A person who prescribed Schedule 2 controlled substances would be required to fill in all three copies of a prescription form and include the following information: the date the prescription was written; the controlled substance prescribed, the dosage, and instructions; the name, address, and age of the patient, or in the case of an animal its owner, for whom the substance was prescribed; and, the name, address, and age of the authorized agent for the ultimate user, or "none", if applicable. The prescriber would have to sign copies one and two of the form (or sign copy one and in doing so produce a carbon copy of the signature on copy two), except for an oral prescription, and give those copies to the patient or person authorized to receive the prescription, and keep copy three with the prescriber's records for at least five years from the date the prescription was written.

A pharmacist dispensing a Schedule 2 controlled substance would be required to take the following actions: record on copies one and two of the prescription (which the prescriber had given to the patient or authorized person) the information not required to be filled in by the Department or the prescriber; keep copy two with the pharmacy's records for at least five years; and, sign copy one and send it to the Department by the 15th of the month following the month it was written.

If a prescribing practitioner had failed to fill in all of the information required in the bill (such as the date of the prescription, the controlled substance prescribed, and the name and address of the patient, etc.), the dispensing pharmacist could fill in the correct information. If the dispensing pharmacist did fill in the correct information, the dispensing pharmacist would be required to note on the back of copy one that a correction had been made. If the Department determined that a prescribing practitioner was consistently failing to fill in the required information, the Department would be required to notify the prescribing practitioner.

The bill would prohibit a prescriber from using a prescription form for a purpose other than prescribing. A prescribing practitioner would not be allowed to postdate an official prescription form, or to sign an official prescription form on a day other than the day on which the prescription was issued. A person in possession of prescription forms issued by the Department whose license to dispense or practice, or whose DEA number had been suspended or revoked, would be required to return to the Department all unused prescription forms within seven days of the suspension or revocation. An individual who violated this provision would be guilty of a misdemeanor.

Oral Prescriptions

Currently, a Schedule 2 drug can be prescribed upon an oral prescription in an emergency situation, if the prescription is promptly put into writing and filed by the pharmacy. Under the bill, a Schedule 2 drug could be dispensed upon oral prescription of a practitioner if the prescribing practitioner promptly filled out an official prescription form and forwarded the first and second copies of the official prescription form to the dispensing pharmacy within 72 hours after the oral prescription was issued. The prescribing practitioner would be required to give the dispensing pharmacy the information needed by it to fill the prescription. If the dispensing pharmacist did not receive the first and second copies of the official prescription form within the 72-hour period, the dispensing pharmacist would be required to notify immediately the Department of Licensing and Regulation. The bill would prohibit the filling of an oral prescription more than three days following the day on which it was issued.

Penalties

The bill would prohibit persons from manufacturing, delivering, or possessing with intent to manufacture or deliver, a controlled substance prescription form, an official prescription form, or counterfeit prescription form, except as authorized by the Code. A person who violated this provision regarding an "official" prescription form or counterfeit prescription form would be guilty of a felony punishable by imprisonment for up to 20 years, a fine of to $25,000, or both. (An "official prescription form" would be one issued by the Department for Schedule 2 drugs.) A person who violated this provision regarding a nonofficial prescription form or counterfeit nonofficial prescription form would be guilty of a felony punishable by imprisonment for up to seven years, a fine of up to $5,000, or both. (A nonofficial prescription form would be used for a prescription drug or controlled substance not on Schedule 2, which was authorized and intended for use by a prescriber and met the requirements of rules promulgated by the board of controlled substances.)

The bill would prohibit a person from knowingly or intentionally possessing a prescription form, unless it was obtained directly from or pursuant to a valid prescription form or order of a practitioner acting in the course of the practitioner's practice. A person who violated these provisions regarding an official prescription form would be guilty of a felony punishable by imprisonment for up to one year, a fine of up to $2,000, or both. A person who violated these provisions regarding a prescription form other than an official prescription form would be guilty of a misdemeanor, punishable by imprisonment for up to one year, a fine of up to $1,000, or both.

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The bill would prohibit a person from knowingly or intentionally giving, permitting, or obtaining access to information submitted to the Department regarding issued prescription forms, except as authorized; or possessing counterfeit prescription forms, except as a government agent while engaged in enforcement of the bill's provisions. A person who violated this provision would be guilty of a felony punishable by imprisonment for up to four years, a fine of up to $30,000, or both.

Controlled Substance Analogue

The bill would prohibit the creation, delivery, or possession with intent to deliver, a controlled substance analogue intended for human consumption. Violation of this provision would be a felony punishable by imprisonment for up to 15 years, a fine up to $250,000, or both. A "controlled substance analogue" would be defined as a substance, other than a controlled substance, that had a chemical structure substantially similar to that of a controlled substance in Schedule 1 or Schedule 2, or that was specifically designed to produce an effect substantially similar to that of a Schedule 1 or Schedule 2 controlled substance. Controlled substance analogues would include, but not be limited to, the following chemical classes: phenethylamines, N-substituted piperdines, morphinans, ecogenines, quinazolinones, substituted indoles, and arylcycloalkylamines. The bill's provisions regarding a controlled substance analogue would not apply to the manufacture or distribution of a substance under an approved new drug application, or for investigational use under the Federal Food, Drug and Cosmetic Act.

Confidential Information

The Director of the Department would be required to permit access to information submitted to the Department regarding issued prescriptions only to Department employees and agents authorized by the Director, and employees of the Department of State Police who were authorized by the administrator to cooperate and assist a governmental agency responsible for the enforcement of controlled substances laws, or a prescribing practitioner concerning an individual suspected of attempting to obtain a controlled substance by fraud, deceit, or misrepresentation. The system for retrieval of such information would have to be designed to preclude improper access to information. Information submitted to the Department would be confidential, but could be released to persons authorized by the Department Director to conduct research studies or to other persons authorized by the Director. Information released under this provision could not allow identification of the individuals to whom the information pertained, and could be released for statistical purposes only. Upon written request, the Department would be required to provide an individual practitioner with a computer printout, at no cost, that summarized all prescriptions written by the individual practitioner on official prescription forms during the 12 months that immediately preceded the receipt of the request.

Information submitted to the Department could be used only for bona fide drug-related criminal investigatory or evidentiary purposes or for the investigatory or evidentiary purposes in connection with the functions of one or more of the licensing boards. The identity of the patient submitted to the Department would have to be removed from the retrieval system and destroyed and rendered irretrievable no later than the end of the calendar year following the year in which the information was submitted to the Department. An individual patient identity that was necessary for use in a specific ongoing investigation conducted in accordance with the bill could be retained in the system until the end of the year in which the necessity for retention of the identity ended. The bill would not prohibit access to prescription information otherwise allowed by law. The Department could contract for the administration of this section.

Progress Report

On or before October 1, 1993, a public report would have to be submitted by the Department and Commission to the Legislature on the effectiveness of the triplicate prescription program. The report would have to include a recommendation on whether the program had been a cost effective method of controlling the diversion of controlled substances.

MCL 333.7103 et al.

FISCAL IMPACT

Senate Bill 75

The bill would result in a cost increase for the Department of Licensing and Regulation of approximately $900,000 GF/GP in FY 1987-88 and $700,000 GF/GP in subsequent years through FY 1992-93, assuming that there was no change in the number of prescriptions issued. If the number of prescriptions issued decreased in subsequent years, as has happened in other states, then the annual cost would fall. However, unanticipated costs could significantly increase the cost of the program over these estimates.

The bill could also increase costs for the Attorney General if there were an increase in license actions. In addition, the bill could increase expenditures for State and local law enforcement agencies by an indeterminate amount if those agenices increased their investigations as the result of the information provided from this program.

Senate Bill 76

The bill would increase fee revenues by approximately $400,000 per year if there were no decline in the number of licenses renewed; however, the fee increase alone would not be sufficient to cover the cost of the triplicate prescription program (proposed by Senate Bill 75) without affecting the General Fund dollars available for other programs. That is, although the cost of operating the existing pharmacy program and the anticipated cost of a triplicate prescription program combined would be less than the revenue generated at the current fee of $30 per year, the fee increase by itself would be less than the anticipated cost of the triplicate prescription program. Thus, it would be necessary to increase the fee to at least $50 per year per license to generate sufficient additional revenue to cover the cost of the program fully and avoid a reduction in the amount of General Fund dollars available for other programs.

ARGUMENTS

Supporting Argument

The State triplicate prescription program would decrease fraudulent and forged prescriptions; help to identify and investigate dishonest prescribers and dispensers; and aid in identifying and educating physicians who are out of date in prescription practices or have been duped by their patients to write prescriptions for dependence-producing substances. The printing of controlled substance prescription blanks is virtually unregulated in the State. Anyone can legally print and possess prescription forms. An activity becomes illegal only when those forms are used to obtain a prescription fraudulently. Michigan law enforcement agencies report that totally fraudulent prescriptions are a large part of Michigan's drug diversion problem. In recent actions by the DEA against Detroit-area pharmacies, 40% to 75% of the controlled substances prescriptions were phony. Dishonest practitioners also are part of the problem. Controlled substances are regulated only at the wholesale and pharmacy levels — there is no

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regular monitoring of prescribing practices. To investigate a practitioner, law enforcement personnel usually have to go to a number of pharmacies and actually count the prescriptions that were prescribed by the doctor, which is a time-consuming and expensive task. Often by the time a dishonest doctor is identified, investigated, and charged, he or she has made a large profit and no longer is practicing in the same location. Therefore, identifying and investigating dishonest practitioners is an expensive, inefficient, and somewhat ineffective process. Despite some progress in law enforcement, a triplicate prescription program would greatly enhance efforts at eliminating fraudulent and dishonestly prescribed prescriptions.

Supporting Argument

Prescription drugs are abused or misused by more Americans than cocaine, hallucinogens, or heroin. In fact, prescription drugs are identified in drug-related deaths more often than all illegal drugs combined. While Schedule 2 drugs, such as narcotic analgesics and amphetamines, have legitimate purposes, they are highly habit forming and have a high potential for abuse and dependence. Michigan ranks in the top one-third of all the states in the per capita purchase and consumption of Schedule 2 drugs, and the diversion of drugs contributes to the size of the problem. The most effective way to curtail the flow of drugs is to attack the weak points in the prescription and distribution system. A triplicate prescription program would develop more reliable evidence and facilitate successful criminal prosecutions against dishonest professional practitioners and their collaborators.

Supporting Argument

Data currently is available from the Federal Drug Enforcement Administration on the amount of Schedule 2 drugs delivered by manufacturers to wholesalers, pharmacies, and physicians who purchase in quantity from wholesalers. No information is readily available on amounts prescribed by health care practitioners, however, without law enforcement officials either auditing the records of all pharmacies in the State, which can be very time-consuming, or collecting data from all third party payers, which does not reflect prescriptions that are paid for in cash. A multiple prescription program would provide information that is needed to give a complete picture of the distribution and use of Schedule 2 drugs in the State.

Supporting Argument

Officials in states where multiple copy prescription systems are in effect see their systems as an effective and efficient method for attacking prescription drug abuse and diversion at the state level. In addition to providing law enforcement and regulatory benefits in dealing with criminal practitioners, these systems supply the only "tool" available that has an impact in identifying prescription forgers, professional patients, and "doctor shoppers". California, New York, and Texas have implemented a triplicate prescription system and, as a result, have experienced a decrease in the average per capita consumption of Schedule 2 drugs. In Texas, where the triplicate system was implemented in 1982, there was a 63% reduction in consumption from the date of implementation to 1985. New York implemented a triplicate prescription program in 1977 and reported a 53% reduction from 1978 to 1984. Several multiple copy states, according to the Drug Enforcement Administration, have reported that only 21% to 35% of these states' authorized prescribers order prescription blanks or actually prescribe the affected drugs. California reported that only 21% of its registered practitioners issued multiple copy prescriptions for patients during 1982. In Rhode Island, another state with a multiple copy system, between February 1979 and June 1984, 24% of the practitioners never reordered prescription blanks; only 30% reordered blanks once; 16% ordered once a year and 2% more than twice a year. Yet, there reportedly were no significant complaints from patients or physicians in any states with multiple copy prescription programs regarding interference with legitimate prescribing decisions or an inability to obtain medication, according to the DEA. The experiences in these states illustrate that a triplicate prescription program can reduce the number of prescriptions written for Schedule 2 drugs. This is a positive method to decrease fraudulent and forged prescriptions and to identify and investigate dishonest prescribers efficiently and effectively.

Supporting Argument

The Drug Enforcement Administration reported in 1984 that for some amphetamine drugs, 90% of the usage in the United States occurred in Michigan; 90% of the misuse in Michigan occurred in metropolitan Detroit åd 90% of metro Detroit's misuse took place within the City of Detroit, according to the Detroit Health Department. Steps have been taken to reduce the rate of abuse in the State. In 1985, for example, the Boards of Medicine and Osteopathic Medicine and Surgery issued rules restricting the prescribing, dispensing, and administering of amphetamines for "exogenous obesity". As a result, the State dropped from first place to 51st place in the per capita distribution of methamphetamine, according to a representative of the Department of Licensing and Regulation. In addition to the revised amphetamine rules, drug accountability audits completed by pharmacy inspectors have netted more than 85 pharmacies and pharmacists for drug diversion. While these actions have had an impact, a problem still remains with the use of methylphenidate (Ritalin) and hydromorphone (Dilaudid).

Supporting Argument

Millions of dollars are lost every year in the direct costs of diversion to third party carriers and their clients. This includes the cost of reimbursing for the diverted drugs as well as the costs of caring for the acute medical emergencies and chronic dependency that result from the availability of these drugs. In 1986, the Drug Enforcement Administration noted that officials for the automobile industry said the drug abuse-induced undependable work and workmanship added $350 to the cost of every automobile manufactured in the country. Responding to Michigan's prescription drug problem would have positive effects on the pocketbooks and health of the State's citizens.

Supporting Argument

The Controlled Substances Advisory Commission, proposed in Senate Bill 75, would provide an accountable, interdisciplinary body that would have the responsibility for monitoring the overall drug problem and developing a plan to overcome the problem. Currently, there are boards in the Department of Licensing and Regulation that monitor and regulate individual practitioners. Yet, these boards are not charged with monitoring and developing policies to deal with problems, such as drug diversion and abuse.

Supporting Argument

Senate Bill 76 would raise the annual fees paid by Schedule 2 prescribing and dispensing practitioners from $30 to $40, in order to fund the triplicate prescription program. Implementation of the program actually could produce an overall savings to the State because the program could increase the effectiveness of each field investigator, through the combination of triplicate forms and computer record keeping, which then could more effectively accomplish the goal of identifying and investigating dishonest and incompetent prescribers and dispensers of Schedule 2 drugs.

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Response: The cost of operating the existing pharmacy program and the anticipated cost of operating the triplicate prescription program would be less than the revenue that was generated as a result of the current $30 fee. Thus, there is no need to increase fees to a select group of licensees for a program that would benefit the State as a whole.

Supporting Argument

Law enforcement officials have reported that certain substances, included among controlled substances under State law, are being processed in such a way as to develop one or two analogues different from the original controlled substance. As a result, these newly developed substances, while having a chemical structure substantially similar to that of a controlled substance, are not illegal under current law. The bill would prohibit the creation, delivery, or possession with intent to deliver these controlled substance analogues.

Opposing Argument

While there is a need to control the production, dispensing, and distribution of Schedule 2 drugs, the triplicate prescription program represents a broad brush approach that would affect legitimate practitioners and dispensers, rather than targeting abusers. Instead of relying on the triplicate prescription program, which some consider to be a quick fix to a difficult problem, there should be an increase in personnel and support for the investigative efforts of the Department of Licensing and Regulation.

Opposing Argument

The fee increase proposed in Senate Bill 76 would not be sufficient to cover the cost of the triplicate prescription program without affecting the General Fund monies available for other programs. Although the cost of operating the existing pharmacy program and the cost of the proposed prescription program combined would be less than the revenue generated at the current $30 per year fee, a portion of that revenue currently lapses to the General Fund and is used to fund other programs. Therefore, the fee should be increased sufficiently to cover fully the cost of the triplicate prescription program and avoid a reduction in the General Fund dollars available for other programs.

Opposing Argument

The triplicate prescription program would not be the most effective solution to the Schedule 2 drug problem. Proponents of this program cite reductions in usage of Schedule 2 drugs, but, in many cases, the abuse was shifted to Schedule 3 and 4 drugs. The abuse continued, but only the types of drugs that were abused had changed.

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This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.