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PRESCRIPTION REQUIREMENTS FOR CONTROLLED SUBSTANCES

House Bill 5260

Sponsor: Rep. Thomas M. George

House Bill 5261

Sponsor: Paul N. DeWeese

House Bill 5262

Sponsor: Stephen Ehardt

Committee: Health Policy

Complete to 10-19-01

A SUMMARY OF HOUSE BILLS 5260, 5261, AND 5262 AS INTRODUCED 10-17-01

Article 7 of the Public Health Code regulates controlled substances and, among other things, provides for an “official prescription form program,” or “OPP.” Article 15 of the code regulates health care occupations, and the general provisions of Article 15 set forth several legislative findings and directives concerning the OPP, controlled substances, and the treatment of “intractable” pain. Among other things, the general provisions of Article 15 state that the OPP “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. It is the intent of the legislature to permit and facilitate adequate treatment for intractable pain by licensed health professionals, including, but not limited to, the prescription or dispensing of controlled substances included in schedule 2 . . . , when medically appropriate.”

House Bills 5260 - 5262 would amend various provisions in Articles 7 and 15 of the Public Health Code. House Bill 5260 would replace the official prescription form program for schedule 2 controlled substances with an electronic reporting system. House Bill 5261 would amend Article 15 to abolish the Official Prescription Form Program Fund and create a Pain Management Education and Controlled Substances Antidiversion Fund. House Bill 5262 would revise several definitions relating to prescriptions in the general provisions of Article 7. House Bills 5260 and 5262 are tie-barred.

House Bill 5260 would amend Articles 7 and 15 of the Public Health Code (MCL 333.7333 et al.) to eliminate the official prescription form program. The bill would retain the statement of the legislature’s intent to permit and facilitate adequate pain management, but would eliminate the explicit justification for creating the OPP. In place of the OPP, the bill would direct the Department of Community Health to establish an electronic reporting system for the monitoring and prescribing of schedule 2 controlled substances. The bill would eliminate references to the official prescription form and the OPP throughout Articles 7 and 15. Moreover, the bill would eliminate a definition of “intractable pain” and various references to intractable pain in the general provisions of Article 15. (House Bill 5263 would eliminate other references to intractable

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pain in the code.) Finally, the bill would repeal the code's provisions for, and thus dissolve, the Controlled Substances Advisory Commission.

Electronic reporting system. The Department of Community Health would have to establish, by rule, an electronic system for monitoring schedule 2, 3, 4, and 5 controlled substances dispensed by pharmacists and dispensing "prescribers." The rules would have to provide an appropriate electronic format for the reporting of data including patient identifiers, the name of the drug dispensed, date of dispensing, quantity dispensed, prescriber, and dispenser. The Michigan Board of Pharmacy, or its designated or established authority, in conjunction with the department, would have to determine which controlled substances and controlled substance schedules it was appropriate to monitor. The bill would specify, however, that the rules would exempt from the reporting requirements the administration of a controlled substance directly to a patient. Moreover, a prescriber dispensing a controlled substance in a quantity adequate to treat a patient for up to 48 hours from a licensed health facility would be exempt from the reporting requirements. Otherwise, reporting would be mandatory for a pharmacist, veterinarian, and dispensing prescriber. However, the department could issue a written waiver for use of the electronic system to any pharmacist, veterinarian, or dispensing prescriber who established grounds for inability to use the electronic system.

Controlled substances and androgenic anabolic steroids. Currently, the code prohibits, with some exceptions, the dispensing of a schedule 2 controlled substance or an androgenic anabolic steroid without the written prescription of a licensed practitioner. The prescription must be written on an official prescription form. The bill would change this qualified prohibition so that a schedule 2, schedule 3, schedule 4, or schedule 5 controlled substance or an androgenic anabolic steroid could not be dispensed without the prescription of a licensed practitioner "on a prescription form or format." (See below House Bill 5262's proposed revision to the code's definition of "prescription form.") The bill would also prohibit a practitioner from issuing more than one prescription for a schedule 2 controlled substance on a single form. Finally, the bill would repeal a section of the law specifying which androgenic anabolic steroids would be exempt from the general requirement that such steroids be prescribed on an official prescription form.

Refills of certain prescriptions. Currently, the code prohibits the refilling of prescriptions for a schedule 2 controlled substance and for an androgenic anabolic steroid, other than methyltestosterone, testosterone, or fluoxymensterone. The bill would eliminate this prohibition.

Schedule 3 or 4 controlled substances. Currently a prescription for a schedule 3 or 4 controlled substance may not be filled or refilled later than six months after the date of the prescription or be refilled more than five times, unless renewed by the *practitioner* in accordance with rules promulgated by the Michigan Board of Pharmacy or its designated or established authority. The bill would state that such a prescription could not be filled or refilled more than five times in that time frame, unless renewed by the "prescriber." (See below the definition of "prescriber" that would be added by House Bill 5262.)

Expansion of provision specific to written prescriptions. In general, controlled substances must be prescribed in writing, but the code does provide for cases in which a prescriber may

need to prescribe a controlled substance orally—e.g., emergency situations. Currently, the code requires that a prescription that must be written must contain the quantity of the controlled substance or androgenic anabolic steroid prescribed, in both written and numerical terms. The bill would state instead that if a prescription was required, the prescription would have to contain the quantity of the controlled substance prescribed in both written and numerical terms.

Postdating prescription forms. Currently, the code prohibits a prescribing practitioner from postdating an official prescription form or from signing an official prescription form on a day other than the day the prescription is issued. The bill would eliminate these references to the official prescription form and specify instead that a prescribing practitioner could not postdate a prescription form for a controlled substance.

House Bill 5261 would amend the Article 15 of the Public Health Code (MCL 333.16315) to abolish the Official Prescription Form Program Fund and create a Pain Management Education and Controlled Substances Antidiversion Fund. The state treasurer would be directed to transfer the money remaining in the Official Prescription Form Program Fund on the bill's effective date to the Health Professions Regulatory Fund.

The bill would create the Pain Management Education and Controlled Substances Antidiversion Fund within the state treasury. The treasurer would direct the investment of the newly created fund, and all interest and earnings from such investment would be credited to the fund. The unencumbered balance in the fund at the close of the fiscal year would remain in the fund and would not revert to the general fund. The fund could receive gifts and devises and other money as provided by law. Currently, the law states that the Department of Consumer and Industry Services is to deposit \$20 of the license fee to engage in manufacturing, distributing, prescribing, dispensing, or conducting research on controlled substances with the state treasurer, who is directed to credit it to the Official Prescription Form Program Fund. The bill would direct the treasurer to deposit the \$20 to the Pain Management Education and Controlled Substances Antidiversion Fund instead. The department could only use this fund in connection with programs relating to pain management education for health professionals and preventing the diversion of controlled substances.

House Bill 5262 would amend Article 7 of the Public Health Code (MCL 333.7104 et al.) to revise several definitions. First, the bill would eliminate the definition of “official prescription form,” in conjunction with House Bill 5260’s elimination of the OPP, and modify the definition of “prescription form.” Currently a prescription form is defined as a printed form that is authorized and intended for use by a prescribing practitioner to prescribe controlled substances or prescription drugs. The bill would recognize a printed form, the facsimile of a printed form, or electronic format, as long as these forms were not prohibited under federal law. The bill would retain the current requirement that the prescription form meet requirements of rules promulgated by the Michigan Board of Pharmacy or its designated or established authority.

In addition, the bill would incorporate a definition of “prescriber” by reference to the part of Article 15 that regulates occupations involving pharmacy practice and drug control. (As defined in that part, “prescriber” means “a licensed dentist, a licensed doctor of medicine, a licensed doctor of osteopathic medicine and surgery, a licensed doctor of podiatric medicine and

surgery, a licensed optometrist certified . . . to administer and prescribe therapeutic pharmaceutical agents, a licensed veterinarian, or another licensed health professional acting under the delegation and using, recording, or otherwise indicating the name of the delegating licensed doctor of medicine or licensed doctor of osteopathic medicine and surgery.”)

The bill also would revise the definition of “counterfeit prescription form” by eliminating reference to the official prescription form and recognizing as counterfeit a prescription form that had been electronically transmitted without the prescriber’s knowledge or permission.

Finally, the bill would revise the definition of “controlled substance analogue.” Currently, the definition of “controlled substance analogue” includes a substance whose chemical structure is substantially similar to the structure of a schedule one or schedule two controlled substance. The definition also includes a substance that has a narcotic, stimulant, depressant, or hallucinogenic effect on the central nervous system that is similar to or greater than the effect of a schedule one or schedule two controlled substance. In other words, either type of substance is considered to be a controlled substance analogue. The bill would recognize as a controlled substance analogue only those substances whose chemical structure was substantially similar to a schedule one or schedule two controlled substance *and* whose effect on the central nervous system was similar to or greater than the effect of a schedule one or schedule two controlled substance.

Analyst: J. Caver

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