Legislative Fiscal Bureau
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March 16, 2010

TO: Members
Joint Committee on Finance

FROM: Bob Lang, Director

SUBJECT: Assembly Substitute Amendment 1 to 2009 Assembly Bill 227: Pharmacy Examining Board, Dispensing Prescription Drugs

Assembly Substitute Amendment 1 (ASA 1) to 2009 Assembly Bill 227 (AB 227) would require the Pharmacy Examining Board (PEB) to monitor the dispensing of certain prescription drugs.

Assembly Bill 227 was introduced on April 4, 2009, and referred to the Assembly Committee on Public Health. On September 9, 2009, the Committee recommended ASA 1 for passage on a 7-0 vote. On September 22, 2009, the Assembly rejected referral to the Committee on Public Privacy on a 43-52 vote, and ASA 1 was passed by the Assembly on an 89-6 vote. On September 24, 2009, ASA 1 was referred to the Senate Committee on Health, Health Insurance, Privacy, Property Tax Relief, and Revenue. On January 27, 2010, the Committee recommended concurrence on a 7-0 vote. On February 10, 2010, ASA 1 was referred to the Joint Committee on Finance.

CURRENT LAW

The Controlled Substances Board is attached to the Department of Regulation and Licensing (DRL) and consists of the Attorney General, the secretaries of the Department of Health Services and the Department of Agriculture, Trade and Consumer Protection, or their designees; the chairperson of the Pharmacy Examining Board or a designee; and one psychiatrist and one pharmacologist appointed for 3-year terms.

The Pharmacy Examining Board (PEB) is also located within DRL and consists of seven members appointed by the Governor for staggered four-year terms. Five of the members must be licensed to practice pharmacy in this Wisconsin and two members must be members of the

public. The board is responsible for issuing pharmacist, pharmacy and wholesale distributor licenses.

Currently, individuals may not manufacture, distribute, or deliver a controlled substance or controlled substance analog unless authorized under the uniform controlled substances act [Chapter 961 of the statutes]. Individuals may not possess or attempt to possess a controlled substance or controlled substance analog unless it is obtained through a valid prescription or order of a practitioner who is acting within the scope of their license.

Pharmacists, practitioners and any other federally-authorized controlled substance registrant must maintain complete and accurate records of each controlled substance which is received, manufactured, distributed, dispensed or disposed. Records must be maintained and available for inspection by an authorized person for at least five years at the location where drugs are received, manufactured, distributed or dispensed.

Records of controlled substance prescription orders must be maintained for at least five years and must be readily accessible by enforcement personnel. These orders must be dated and contain the full name and address of the patient, the drug name, strength, dosage, quantity prescribed, directions for use, and the name and address of the prescriber.

Pharmacists and pharmacies must report certain occurrences to a local health organization (a municipal health department), including: (a) an unusual increase in the number of prescriptions dispensed or nonprescription drug products sold for the treatment of conditions specified by the Department of Health Services; (b) an unusual increase in antibiotic drug prescriptions; (c) dispensing drugs for treatment of an uncommon disease; and (d) dispensing drugs that may be used for bioterrorism.

SUMMARY OF SUBSTITUTE AMENDMENT

Assembly Substitute Amendment 1 to AB 227 would require PEB to establish by rule a program for monitoring the dispensing of prescription drugs. The program would require pharmacists and practitioners to create a record documenting each dispensing of a prescription drug and deliver that record to the PEB, except no record could be generated for drugs administered directly to a patient. The Board would have to specify a deadline for the delivery of a record and a penalty for non-compliance.

Under the substitute amendment, the PEB would have to identify specific data that would be contained in the records generated by pharmacists and practitioners. The Board would have to consider data collected in other states and ensure, to the extent possible, that data may be shared with other states. The substitute amendment would also specify that information provided to relevant agencies in other states would not be limited by patient confidentiality statutory limitations.

The substitute amendment would specify that PEB develop of a secure electronic format for the delivery of generated records and allows PEB to grant a pharmacists and practitioners a waiver

from using that specified format. Further, a pharmacist or practitioner would be immune from civil or criminal liability or professional discipline arising from their compliance in good faith with the provisions of the substitute amendment or rules. The substitute amendment would also specify that nothing under provisions of ASA 1 should be construed to require a pharmacist or practitioner to obtain information about the patient that was collected pursuant to passage of ASA 1.

Under ASA 1, records generated or disclosed pursuant to PEB rules, regarding monitored prescription drugs, would be added to the current list of confidential patient records. Under current law, certain health care records are confidential and only persons listed under statute, the patient, or persons so authorized by patient may have access to that patient's records.

Records generated under ASA 1 provisions would not be subject to inspection or copying under the open records law. The Board would also be responsible for ensuring that the program complies with state statutes related to patient confidentiality laws and privacy of health information of federal regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA).

The Board would be required to seek the maximum potential funding from federal sources for the operation of the program. The Department of Regulation and Licensing would be required, under ASA 1, to submit a timely application under the National All Schedules Prescription Electronic Reporting Grant (42 US Code 280g-3) and the Harold Rogers Prescription Drug Monitoring Program to fund the establishment of the program. If DRL is unable to obtain federal funding before January 1, 2015, the program would by void.

Prescription drugs would be defined to include any drug under Schedule II [s. 961.16 of the statutes] or Schedule III [s. 961.18 of the statutes]. These drugs are identified in the attachment to this memorandum.

FISCAL EFFECT

The Department completed a fiscal estimate for AB 227, which indicated that there would be one-time costs of $356,400, which would include $56,400 for rule making and $300,000 for planning and development of a data collection system. The Department also estimated ongoing costs of $288,600, including $52,500 annually for Division of Board services for consumer assistance in operating the program, $236,100 for grant writing, system maintenance, and contract services for system operation.

It should be noted that there are several changes between the substitute amendment and the bill, including:

1. The bill would have specified that an "electronic record" be created, while ASA 1 states that a "record" would be created.

2. The bill would have required PEB to specify, by rule, the specific format of the

electronic record that would be generated, while ASA 1 would specify that a secure format for delivery of the record and authorize PEB to grant a waiver.

3. The amendment would add a requirement that rules developed by the PEB are compliant with HIPAA and state statutes regarding the confidentiality of patient records.

4. The amendment would add a provision that would state that the records created would not be subject to state open records laws.

5. The amendment would add liability immunity to pharmacists and practitioners that complied in good faith with statutes and rules under the ASA 1 regarding their actions in complying.

6. The amendment would add a provision that would specify that pharmacists and practitioners would not be required to obtain information from a patient that had been collected before the provision took effect.

The substitute amendment generally does not make substantive changes in areas relating to costs. Costs under the bill and the substitute amendment mainly relate to creation and ongoing operation of an electronic data collection system. One potential difference however, is that there may be some additional costs under the substitute amendment related to accepting non-electronic files, which DRL would have to enter in order to complete the data collection. The extent of these costs is unknown.

The substitute amendment does not provide any expenditure authority, but instead requires DRL to make grant requests to the federal government. If the federal government provides the state with any funding for this purpose by January 1, 2015, PEB and the Department would be required to operate the program.

Under provisions of ASA 1, the federal grant programs which DRL would have to apply are:

1. *National All Schedules Prescription Electronic Reporting Grant* has a stated goal of fostering the establishment of state-administered controlled substances monitoring programs. It is a formula grant for states that is appropriated at $2 million in federal fiscal year (FFY) 2010. The amount awarded includes a minimum payment per applicant, plus a weighted payment based on the number of pharmacies located in the state. In FFY 2009, 13 grantees were approved, with payments ranging from approximately $40,000 to $400,000. If all eligible applicants applied, assistance would range from approximately $21,000 to $113,000. The FFY 2010 request for applications has not been released, but would have to include a budget estimate and a plan to ensure that the state's controlled substance monitoring program is in compliance with certain federal criteria and penalty requirements, including: criteria for securely handling data and developing a state-maintained data base; an agreement to adopt interoperability standards and the ability to develop system that can interact with the federal electronic system used by the Substance Abuse and Mental Health Services Administration (SAMHSA); criteria for availability of information and limitation on access to

program personnel; criteria for access to the database and procedures to ensure accuracy of information; and criteria for the certification process for allowing requests of information contained in the database; and penalties for unauthorized use.

2. *Harold Rogers Prescription Drug Monitoring Program.* In FFY 2009, the federal Bureau of Justice Assistance provided grants to 15 of 28 applicants totaling $4,944,600 and an additional $1,457,000 to Brandeis University for planning regional and national meetings, providing technical assistance, maintaining and updating a website for the federal prescription drug monitoring program, and acting as a clearinghouse for information for best practices. The remaining 15 grants ranged from $50,000 to $400,000. Applications for FFY 2010 are due April 1, 2010, and allow requests of up to $50,000 for planning (18 month grant) and up to $400,000 for either implementation or enhancement (two year grant).

Under normal administrative rule procedures it could take 12 to 18 months for writing and approval of rules associated with the program. If the substitute amendment were to be signed into law by May 1, 2010, it could be estimated that the rules would be completed near the end of the 2010-11 fiscal year. Under provision of ASA 1, the Department would have to promulgate rules as well as create and implement an electronically accessible data collection system between the time of bill passage and at least January 1, 2015. State funding for the cost of the drug monitoring program, if any, would depend upon the amount of the grant that the state might receive from the federal government. If the cost of the program is funded by the amount of the federal grant, no state funding would be needed.

The author of the bill (Representative Sherman) has informed the Secretary of DRL and the Chair of the Pharmacy Examining Board that it was his intent "that no state funds be expended on rulemaking until after federal funds has been secured." The Department has acknowledged this letter, stating that DRL "would not move forward unless federal funds are available."

It should be noted that the rule making procedure would only become an issue if the state did not receive federal funding from either the National All Schedules Prescription Electronic Reporting Grant or the Harold Rogers Prescription Drug Monitoring Program before the completion of drug monitoring rule making. It should also be noted that all 13 applicants for the National All Schedules Prescription Electronic Reporting Grant received a grant in 2009. While the granting agency cannot state that Wisconsin would definitively receive a grant upon application, they indicate that states that attempt to improve their drug monitoring capabilities and meet the federal application guideline criteria would be highly considered. It is likely that the Department of Regulation and Licensing would receive some amount of federal funding for a drug monitoring program such as the one proposed under 2009 Assembly Bill 227. Therefore, it is very unlikely that the program would sunset due to a lack of federal funds and it is likely that some federal funds would be provided to the Department by the time rules would be completed.

Prepared by: Darin Renner
Attachment

ATTACHMENT

Prescription Drugs Included Under ASA 1 to AB 227

Schedule II [s. 961.16]

Schedule II includes materials, compounds, mixtures or preparations of the following:

1. Plant based materials including opium and substances derived from opium, and any salt, compound, derivative or preparation of opium or substances derived from opium excluding apomorphine, dextrorphan, nalbuphine, butorphanol, nalmefene, naloxone and naltrexone and their respective salts and the isoquinoline alkaloids of opium and their respective salts. The opiate materials that would be included are: (a) opium, including raw opium, opium extracts, opium fluid extracts, powdered opium, granulated opium and tincture of opium; (b) opium poppy and poppy straw; (c) concentrate of poppy straw, which is the crude extract of poppy straw in either liquid, solid or powder form containing the phenanthrene alkaloids of the opium poppy (d) codeine; (e) dihydrocodeine; (f) dihydroetorphine; (g) ethylmorphine; (h) etorphine hydrochloride; (i) hydrocodone, also known as dihydrocodeinone; (j) hydromorphone, also known as dihydromorphinone; (k) metopon; (l) morphine (m) oxycodone; (n) oxymorphone; and (o) hebaine.

2. Coca leaf materials except extractions which do not contain cocaine or ecgonine, but including: (a) cocaine; (b) ecgonine; (c) synthetic opiates.

3. Synthetic opiates, including any of their isomers, esters, ethers, esters and ethers of isomers, salts and salts of isomers, esters, ethers and esters and ethers of isomers that are theoretically possible within the specific chemical designation, including: (a) alfentanil; (b) alphaprodine; (c) anileridine; (d) bezitramide; (e) carfentanil;(f) diphenoxylate; (g) fentanyl; (h) isomethadone; (i) levo-alphacetylmethadol; (j) levomethorphan; (k) levorphanol; (l) meperidine, also known as pethidine; (m) meperidine — Intermediate — A, 4-cyano-1-methyl-4-phenylpiperidine; (n) meperidine — Intermediate — B, ethyl-4-phenylpiperidine- 4-carboxylate; (o) meperidine — Intermediate — C, 1-methyl-4-phenylpiperidine-4-carboxylic acid; (p) metazocine; (q) methadone; (r) methadone — Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenylbutane; (s) moramide — Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropanecarboxylic acid; (t) phenazocine; (u) piminodine; (v) racemethorphan; (w) racemorphan; (x) remifentanil; and (y) sufentanil.

4. Stimulants that effect on the central nervous system, including any of their salts, isomers and salts of isomers that are theoretically possible within the specific chemical designation, including: (a) amphetamine; (b) methamphetamine (c) phenmetrazine; and (d) methylphenidate.

5. Substances that have a depressant effect on the central nervous system, including any of their salts, isomers and salts of isomers that are theoretically possible within the specific

chemical designation: (a) amobarbital; (b) glutethimide; (c) pentobarbital; and (d) secobarbital.

6. An immediate precursor to amphetamine or methamphetamine [Phenylacetone].

7. Hallucinogenic substances, including nabilone.

Schedule III [s. 961.18]

Schedule III includes the following controlled substances:

1. Stimulants that effect the central nervous system, including any of their salts, isomers and salts of isomers that are theoretically possible within the specific chemical designation. including: (a) benzphetamine; (b) chlorphentermine; (c) clortermine; and (d) phendimetrazine.

2. Substances having a depressant effect on the central nervous system, including any of their salts, isomers and salts of isomers that are theoretically possible within the specific chemical designation, including: (a) any substance which contains a derivative of barbituric acid; (b) chlorhexadol; (c) lysergic acid; (d) lysergic acid amide; (e) methyprylon; (f) sulfondiethylmethane; (g) sulfonethylmethane; (h) sulfonmethane; (i) tiletamine and zolazepam in combination; (j) any substance containing amobarbital, secobarbital, and pentobarbital and one or more other active medicinal ingredients not included in any schedule; (k) amobarbital, secobarbital, and pentobarbital in suppository dosage form that is approved by the federal Food and Drug Administration (FDA) in that form; and (l) gamma−hydroxybutyric acid. [The Controlled Substances Board may accept, by rule, a compound, mixture, or preparation that contain a depressant or stimulant from all or part of this schedule, if the substance contains one or more active medicinal ingredient not having a depressant or stimulant effect on the central nervous system and the combined substance is unlikely to have a potential for abuse.]

3. Ketamine and nalorphine and any of their salts, isomers and salts of isomers that are theoretically possible within the specific chemical designation.

4. Hallucinogenic substances, including dronabinol in sesame oil and encapsulated in a soft gelatin capsule that has been approved by the federal FDA.

5. Narcotic drugs or their salts, isomers or salts of isomers, calculated as the free anhydrous base or alkaloid, in limited quantities as follows: (a) not more than 1.8 grams of codeine per 100 milliliters or per 100 grams or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium; (b) not more than 1.8 grams of codeine per 100 milliliters or per 100 grams or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts; (c) not more than 300 milligrams of hydrocodone per 100 milliliters or per 100 grams or not more than 15 milligrams per dosage unit, with a four−fold or greater quantity of an isoquinoline alkaloid of opium; (d) not more than 300 milligrams of hydrocodone per 100 milliliters or per 100 grams or not more than 15

milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts; (e) not more than 1.8 grams of dihydrocodeine per 100 milliliters or per 100 grams or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts; (f) not more than 300 milligrams of ethylmorphine per 100 milliliters or per 100 grams or not more than 15 milligrams per dosage unit, with one or more ingredients in recognized therapeutic amounts; (g) not more than 500 milligrams of opium per 100 millilitersor per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts; and (h) not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

6. Buprenorphine [a narcotic] in unspecified amounts.

7. Anabolic steroids, including any of their esters, isomers, esters of isomers, salts and salts of esters, isomers and esters of isomers that are theoretically possible within the specific chemical designation, including: (a) boldenone; (b) 4−chlorotestosterone; (c) dehydrochloro-methyltestosterone; (d) 4−dihydrotestosterone; (e) drostanolone; (f) ethylestrenol; (g) fluoxymesterone; (h) formebulone; (i) mesterolone; (j) methandienone; (k) methandriol; (l) methenolone; (m) methyltestosterone; (n) mibolerone; (o) nandrolone; (p) norethandrolone; (q) oxandrolone; (r) oxymesterone; (s) oxymetholone; (t) stanozolol; (u) testolactone; (v) testosterone; and (w) trenbolone.