Ohio Legislative Service Commission

Bill Analysis

Jeffery A. Bernard

Sub. H.B. 93

129th General Assembly
(As Reported by S. Health, Human Services and Aging)

Reps. Burke and Johnson, Batchelder, Bubp, J. Adams, Boose, Grossman, Hackett, Hottinger, Huffman, Peterson, Pillich, Rosenberger, Ruhl, Uecker, Balderson, Gardner, McKenney, Gonzales, Goodwin, R. Hagan, Garland, Fende, Sears, Schuring, Wachtmann, Barnes, Duffey, Antonio, R. Adams, Amstutz, Anielski, Ashford, Baker, Beck, Blair, Blessing, Brenner, Buchy, Budish, Butler, Carey, Carney, Celeste, Clyde, Coley, Combs, Damschroder, DeGeeter, Derickson, Dovilla, Driehaus, Fedor, Foley, Gerberry, Goyal, C. Hagan, Hall, Hayes, Heard, Henne, Kozlowski, Landis, Letson, Luckie, Lundy, Mallory, Martin, McClain, McGregor, Mecklenborg, Milkovich, Murray, Newbold, O'Brien, Patmon, Phillips, Ramos, Reece, Roegner, Slaby, Slesnick, Sprague, Stautberg, Stebelton, Stinziano, Szollosi, Thompson, Weddington, Williams, Winburn, Young, Yuko

BILL SUMMARY

PAIN MANAGEMENT CLINICS

- Requires the State Board of Pharmacy (the Pharmacy Board) to license pain management clinics.
- Provides for pain management clinics to be licensed as terminal distributors of dangerous drugs with a pain management clinic classification.
- Delays, until 30 days after the bill's effective date, the prohibition on operating a pain management clinic without holding a terminal distributor of dangerous drugs with a pain management clinic classification.
- Requires the State Medical Board (the Medical Board) to adopt rules establishing standards for physician operation of pain management clinics and standards to be followed by physicians who provide care at pain management clinics.
- Authorizes the Pharmacy Board to impose a fine of up to $5,000, and the Medical Board to impose a fine of up to $20,000, for failure to follow the rules of operation or standards for pain management clinics.

WHOLESALERS AND TERMINAL DISTRIBUTORS

- Authorizes the Pharmacy Board to suspend, without prior hearing, the license of a wholesaler of controlled substances or terminal distributor of dangerous drugs if the Board determines there is danger of immediate and serious harm to others.

- Provides that an application for a terminal distributor of dangerous drugs license may not be withdrawn without the approval of the Pharmacy Board.

LIMITS ON PRESCRIBER-FURNISHED CONTROLLED SUBSTANCES

- Limits the amount of controlled substances that a prescriber, other than a veterinarian, may personally furnish to a patient and provides for a $5,000 per instance fine for surpassing those limits.

DRUG TAKE-BACK PROGRAM

- Requires the Pharmacy Board, Attorney General, and Department of Alcohol and Drug Addiction Services to develop a program under which drugs are collected from the community for destruction or disposal.

OHIO AUTOMATED Rx REPORTING SYSTEM (OARRS)

- Modifies the review, reporting, and retention of information in OARRS.

- Establishes criminal penalties for improperly disseminating, seeking to obtain, or obtaining information from OARRS.

- Prohibits the use of a document obtained from OARRS in a civil or administrative proceeding.

- Requires the applicable licensing agency to adopt rules specifying when a prescriber or pharmacist is required to review information in OARRS.

PHARMACY BOARD CONTRACTS

- Authorizes the Pharmacy Board to enter into contracts with private entities to fulfill any of the Board's duties, including duties related to OARRS.

OHIO LAW ENFORCEMENT GATEWAY

- Expands Ohio Law Enforcement Gateway access to the Medical Board and Board of Nursing.

MEDICAL BOARD DISCIPLINARY ACTIONS

- Specifies criteria for the Medical Board to issue a summary suspension of a license.
- Permits the Medical Board to take disciplinary actions based on actions of other regulatory entities involving any health care profession or service.
- Allows the Medical Board to use a telephone conference call to (1) ratify a consent agreement for the revocation or suspension of a license or (2) accept the surrender of a license.

BOARD OF NURSING INFORMATION

- Expands access to information collected by the Board of Nursing in an investigation.

CORONER NOTIFICATIONS

- Authorizes a coroner to notify the Medical Board about a death caused by a drug overdose.

COORDINATED SERVICES PROGRAMS

- Requires each Medicaid managed care organization and the Medicaid fee-for-service system to establish a coordinated services program for Medicaid recipients who obtain prescription drugs at a frequency or in an amount that is not medically necessary.
- Requires the Bureau of Workers' Compensation to establish a coordinated services program that is substantially the same as the programs to be established under Medicaid.

CHRONIC PAIN

- Replaces existing provisions dealing with treatment of intractable pain by physicians with provisions on treatment of chronic pain, and requires the Medical Board to approve continuing education courses and procedures to be followed by physicians in treating chronic pain rather than intractable pain.

MEDICAL BOARD EDUCATION AND PATIENT SAFETY PROGRAMS

- Establishes the Drug Database Fund and the Medical Board Education and Patient Safety Fund.

EMERGENCY CLAUSE

- Declares an emergency.

TABLE OF CONTENTS

CONTENT AND OPERATION

PAIN MANAGEMENT CLINICS

Overview

The bill requires that a facility operating as a pain management clinic be licensed by the State Board of Pharmacy (the Pharmacy Board) as a terminal distributor of dangerous drugs with a pain management classification, even if it is operated by a business entity that is not otherwise required to be licensed as a terminal distributor of dangerous drugs. The operation of a pain management clinic must comply with rules to be adopted by the State Medical Board (the Medical Board).[1]

"Pain management clinic" is defined by the bill as a facility to which all of the following apply:

(1) A primary component of practice is treatment of pain or chronic pain.

(2) The majority of patients of the prescribers at the facility are provided treatment for pain or chronic pain that includes the use of controlled substances, tramadol, carisoprodol, or other drugs specified by the Medical Board. Tramadol is a controlled substance used to relieve pain, but is not a narcotic drug. Carisoprodol is a non-controlled substance used to relieve pain.

[1] R.C. 4729.51, 4729.54, 4729.541, and 4731.054.

(3) The facility meets any other identifying criteria established by the Medical Board.

Under the bill, the following are not included as a pain management clinic: (1) a hospital registered with the Ohio Department of Health or facility owned in whole or in part by a hospital, (2) an educational institution or program to the extent that it provides instruction to individuals preparing to practice as physicians, podiatrists, dentists, nurses, physician assistants, optometrists, or veterinarians, or any affiliated facility, (3) a facility affiliated with such a medical or dental school, (4) a hospice program licensed by the Ohio Department of Health, or (5) an ambulatory surgical facility.[2]

The prohibition on operating a pain management clinic without holding a terminal distributor of dangerous drugs license with a pain management clinic classification is delayed until 30 days after the bill's effective date.[3]

Licensure requirements for pain management clinics

General requirements for terminal distributor licensure

Possession and distribution of dangerous drugs, including controlled substances, is strictly controlled under state law. Current law provides, with exceptions, that to legally possess, have custody or control of, or distribute dangerous drugs at retail a person or entity must be licensed by the Pharmacy Board as a terminal distributor of dangerous drugs.[4] To obtain the license, an applicant must meet a number of requirements, including requirements dealing with supervision of employees and safeguarding of drugs. A wholesale distributor may sell drugs, at wholesale, only to licensed terminal distributors and licensed health professionals authorized to prescribe drugs (prescribers).[5]

Specific requirements for pain management clinic licensure

The bill establishes a "pain management clinic" classification for terminal distributors of dangerous drugs.[6] Pain management clinics are required to apply for

[2] R.C. 4731.054.

[3] Section 4.

[4] R.C. 4729.551.

[5] R.C. 4729.51.

[6] R.C. 4729.51 and 4729.54.

licensure in the same way as other terminal distributors and meet the same requirements.[7]

The bill's licensure requirements for pain management clinics extend to certain business entities that are otherwise exempt under current law from licensure as terminal distributors. Specifically, these requirements apply to a business entity that is a pain management clinic, or is operating a pain management clinic, if the entity is a corporation, limited liability company, partnership, or professional association composed solely of individuals who are authorized to provide the professional services being offered by the business entity. Unless the business entity is licensed, it cannot receive drugs from wholesale distributors.[8]

Operation of the clinic

In addition to meeting the general requirements for licensure as a terminal distributor, an applicant for licensure as a terminal distributor with a pain management clinic classification must submit evidence satisfactory to the Pharmacy Board that the clinic will be operated in accordance with the bill's requirements for the operation of such clinics. These requirements, which apply to the holder of the license, are as follows:[9]

(1) Be in control of a facility that is owned and operated solely by one or more physicians authorized by the Medical Board to practice medicine or osteopathic medicine;

(2) Ensure that any person employed by the facility complies with requirements established by the Medical Board for the operation of pain management clinics;

(3) Require any person with ownership of the facility to submit to criminal records check and send the results directly to the Pharmacy Board for review;[10]

(4) Require all employees of the facility to submit to a criminal records check and ensure that no person is employed who has previously been convicted of, or pleaded guilty to, any felony in Ohio, another state, or the United States;

---

[7] R.C. 4729.54 and 4729.55.

[8] R.C. 4729.51(B)(2) and 4729.541.

[9] R.C. 4729.552(A) and (B).

[10] R.C. 4776.01 to 4776.04.

(5) Maintain a list of each person with ownership of the facility and notify the Pharmacy Board of any changes.

Criminal records check

To obtain a criminal records check, a person must submit a request to the Bureau of Criminal Identification and Investigation (BCII). The request must be accompanied by the appropriate form, a set of fingerprint impressions, and the fee established by BCII. The person must also request that BCII obtain from the Federal Bureau of Investigation (FBI) any information it has on the person. The results of the criminal records check and any information provided by the FBI are to be made available only to the person who requested the records check and the employer or potential employer specified in the request.[11]

License issuance

If the Pharmacy Board determines that an applicant meets the requirements for operation of pain management, the Board is required by the bill to issue a category III terminal distributor of dangerous drugs license and specify on the license that the terminal distributor is classified as a pain management clinic.[12] A category III license authorizes the license holder to possess, have custody or control of, or distribute any controlled substance contained in schedule I, II, III, IV, or V. These schedules consist of categories of dangerous drugs that are scheduled based on their potential for abuse.[13] As under current law, the license fee is $150.[14]

Medical Board rules for pain management clinics

The bill requires the Medical Board to adopt rules in accordance with the Administrative Procedure Act that establish all of the following:

(1) Standards and procedures for the operation of pain management clinics by physicians;

(2) Standards and procedures to be followed by physicians who provide care at pain management clinics;

---

[11] R.C. 4729.071, 4776.02, and 4776.04.

[12] R.C. 4729.552(A).

[13] R.C. 3719.41.

[14] R.C. 4729.54.

(3) The other drugs used to treat pain or chronic pain that identify a facility as a pain management clinic for the purpose of requiring licensure as a clinic;

(4) Other criteria that identify a facility as a pain management clinic for the purpose of requiring licensure as a clinic;

(5) Standards and procedures to be followed by a clinic owner in providing supervision, direction, and control of the activities of employees, volunteers, or individuals under contract who provide care at the clinic.[15]

Sanctions for illegal or improper operation of a pain management clinic

Administrative fines and criminal penalties

The bill authorizes the Pharmacy Board to impose a fine of no more than $5,000 on a terminal distributor that fails to comply with the requirements for operation of a pain management clinic. A separate fine may be imposed for each day of violation.

The bill also provides that failure to comply with pain management clinic requirements is a misdemeanor of the first degree. If the offender has previously been convicted of or pleaded guilty to the same offense, the offense is a felony of the fifth degree. Failure to obtain the required license carries the same criminal penalties.[16]

The bill authorizes the Medical Board to fine physicians at pain management clinics. The Board may impose a fine of no more than $20,000 on any physician who fails to comply with the Board's rules on pain management clinic operating standards and standards to be followed by physicians providing care at the clinics.

The bill provides that a physician subject to a fine may also be subject to other disciplinary action by the Board. In the case of a pain management clinic owner, the Board may take disciplinary action against the clinic owner for failing to provide supervision, direction, and control of individuals providing services at the clinic. Disciplinary action includes a summary suspension of a license (see "**Medical Board summary suspensions**," below).

Summary suspension of clinic licenses

As discussed below (see "**Summary suspension of distributor licenses**"), the bill permits the Pharmacy Board to suspend the license of a terminal distributor of dangerous drugs without a prior hearing under certain circumstances. If a terminal

[15] R.C. 4731.054.

[16] R.C. 4729.552 and 4729.99.

distributor is classified as a pain management clinic and the person who holds the terminal distributor license also holds a certificate to practice as a physician, the bill provides that, prior to suspending the license without a prior hearing, the Pharmacy Board must consult with the secretary of the Medical Board or, if the secretary is unavailable, another physician member of the Medical Board.[17]

Annual report on pain management clinic requirements

The Pharmacy Board is required to prepare and submit a report on the pain management clinic requirements established by the bill. The report is to include all of the following:

(1) The total number of applications received by the Board for a terminal distributor of dangerous drugs license with pain management clinic classification;

(2) The total number of licenses with a pain management clinic classification granted or denied by the Board;

(3) Any disciplinary actions taken by the Board against holders of licenses with a pain management clinic classification;

(4) Total revenues generated from fees for licenses with a pain management clinic classification, fines and penalties paid by license holders, or other disciplinary actions taken against license holders;

(5) Any other relevant information regarding the implementation of the bill.

The report is to be completed annually for five years and made available according to the existing law requirements that apply to agency reports, including submission to the Governor and members of the House of Representatives and Senate.[18]

WHOLESALERS AND TERMINAL DISTRIBUTORS

Summary suspension of distributor licenses

The bill permits the Pharmacy Board to suspend without a prior hearing the license of a wholesaler of controlled substances or a terminal distributor of dangerous drugs if the Board determines that there is clear and convincing evidence that the method used by the wholesaler or distributor to distribute controlled substances presents a danger of immediate and serious harm to others. The Board is to follow

[17] R.C. 4729.571.

[18] Section 8 of the bill.

procedures for the notification of the suspension without a hearing as provided under the Administrative Procedure Act. The suspension is to remain in effect, unless removed by the Board, until a final order is issued through an administrative hearing. If the Board does not issue a final order within 90 days, the suspension is to be void on the 91st day after the date of the suspension.[19]

Application withdrawal

The bill provides that, once submitted, an application for licensure as a terminal distributor of dangerous drugs may not be withdrawn by the applicant without the approval of the Pharmacy Board.[20]

LIMITS ON PRESCRIBER-FURNISHED CONTROLLED SUBSTANCES

The bill establishes limits on the amount of controlled substances that may be personally furnished by prescribers on a monthly and 72-hour basis. Although "personally furnish" is not defined in current law or the bill, it is a term that is used to describe the action of a prescriber who provides a whole or partial supply of drugs to a patient for the patient's personal use. This is in contrast to the action of directly administering a drug to a patient.

The bill applies the limits to all types of prescribers, other than veterinarians. In effect, however, the limits apply only to prescribers who are physicians, podiatrists, or dentists. According to the Pharmacy Board, this is because the remaining types of prescribers (i.e., advanced practice nurses, physician assistants, and optometrists) currently do not have authority to personally furnish supplies of controlled substances to patients.

The bill's specific limits on personally furnishing controlled substances are as follows:

--Monthly: In any 30-day period, an amount of all controlled substances combined that exceeds a total of 2,500 dosage units;

--72-hour period: In any 72-hour period, an amount of a controlled substance provided to or for a patient that exceeds the amount necessary for the patient's use in a 72-hour period.

---

[19] R.C. 3719.031 and 4729.571.

[20] R.C. 4729.54.

Any amount of methadone personally furnished to a patient for the purpose of treating drug addiction does not count toward the limits.

If a prescriber violates the bill's limits, the prescriber is subject to a $5,000 administrative fine. Each instance of a violation is subject to an additional fine.[21]

DRUG TAKE-BACK PROGRAM

Implementation

In collaboration with the Attorney General and Department of Alcohol and Drug Addiction Services (ODADAS), the Pharmacy Board is to establish and administer a drug take-back program that collects drugs from the community for the purpose of destruction or disposal. The first collection of drugs must occur no later than one year after the bill's effective date.

Under the bill, the office of the Attorney General is solely responsible for the costs incurred in establishing and administering the program. The Attorney General, ODADAS, and the Pharmacy Board are authorized by the bill to accept grants, gifts, or donations for the program. The money received is to be deposited in the Drug Take-Back Program Fund established by the bill.

The program is to comply with any state or federal laws regarding the collection, destruction, or disposal of drugs. The program must maintain the confidentiality of individuals who surrender drugs to the program.

The bill specifies that failure to participate in the program is not grounds for civil liability or a basis for disciplinary action.[22]

Rules for operation

The Board, in consultation with the Attorney General and ODADAS, is required by the bill to adopt rules that specify the following: (1) who may participate in the program, (2) guidelines and responsibilities for participation, (3) drugs that may be collected, (4) record-keeping requirements, (5) proper methods to destroy unused drugs, (6) privacy protocols and security standards, (7) drug transportation procedures, (8) the schedule, duration, and frequency of the collections of drugs, (9) any other standards and procedures the Board considers necessary.

---

[21] R.C. 4729.29, 4729.291, and 4729.99.

[22] R.C. 109.90, 3793.22, and 4729.69.

The bill permits the Pharmacy Board to adopt rules allowing a participant in the program to return any unused drugs to the pharmacy that dispensed the drugs. The rules must include procedures to be followed to maintain the confidentiality of the person for whom the drug was dispensed. The Board's rules for returning drugs must be in accordance with state and federal law.

The rules adopted by the Pharmacy Board are not permitted to do any of the following: (1) require that an entity establish, fund, or operate a drug take-back program, (2) establish any new licensing requirement or fee, (3) require an entity to collect any data on drugs collected.[23]

Data compilation

The Pharmacy Board is authorized to compile data on the amount and type of drugs collected under the program. The Board may cooperate with a public or private entity to assist in the compilation of data, but the entity cannot be reimbursed for any assistance provided.

If the Board chooses to collect and compile data, the Board is required to submit a report to the Governor, Speaker of the House of Representatives, and President of the Senate. The report, to the extent possible, must include all of the following:

(1) Total weight of drugs collected, both with and without packaging;

(2) The total weight of controlled substances;

(3) The amount of all of the following as a per cent of total drugs collected:

--Controlled substances;

--Brand name drugs;

--Generic drugs;

--Prescription drugs;

--Non-prescription drugs;

(4) The amount of vitamins, herbal supplements, and personal care products collected;

[23] R.C. 4729.69(C) to (E).

(5) If provided by the person who submitted the drugs, the reason why the drugs were returned or unused.[24]

OHIO AUTOMATED Rx REPORTING SYSTEM (OARRS)

OARRS modifications

The bill modifies the operation of OARRS and establishes criminal penalties for failing to comply with certain requirements of the system. OARRS, which was established and is maintained by the Pharmacy Board, is a drug database used to monitor the misuse and diversion of controlled substances and other dangerous drugs.

Those required to report to or review information in OARRS

Rules adopted by the Pharmacy Board require wholesale distributors and certain terminal distributors of dangerous drugs to report information to OARRS regarding the delivery and dispensing of dangerous drugs.[25] In the case of wholesale distributors, current statute refers to reports being required only when drugs are sold to prescribers. The bill, as under the current Pharmacy Board rule, requires wholesale distributors to make reports also when drugs are delivered to terminal distributors (i.e., pharmacies).[26]

The bill establishes an OARRS reporting requirement for prescribers who personally furnish to a patient a controlled substance or other dangerous drug specified by the Pharmacy Board.

Specifically, a prescriber must submit the following information:

(1) Prescriber identification;

(2) Patient identification;

(3) Date drug was personally furnished by the prescriber;

(4) Indication of whether the drug is new or a refill;

(5) Name, strength, and national drug code of drug furnished;

(6) Quantity of drug furnished;

---

[24] R.C. 4729.69(F) to (H).

[25] Ohio Administrative Code 4729-37-03.

[26] R.C. 4729.78.

(7) Number of days' supply of drug furnished.[27]

Prescribers who fail to report information to OARRS may be subject to disciplinary action.

Current law includes a specific statement that prescribers and pharmacists are not required to obtain information about a patient from OARRS. The bill eliminates this statement and requires all of the following to review information in OARRS according to rules adopted by the applicable licensing entity: (1) dentists, (2) nurses, (3) optometrists, (4) pharmacists, (5) physicians, and (6) physician assistants.[28]

Those permitted to obtain information in OARRS

Data contained in OARRS, any information obtained from it, and information contained in the records of requests for information from OARRS are not public records.[29] Only the following are permitted to obtain data from OARRS under current law: (1) prescribers and pharmacists, (2) licensing board personnel, (3) law enforcement personnel, (4) grand juries, and (5) individuals seeking information about themselves.

The bill modifies who may receive information from OARRS as follows:

(1) In addition to licensing entities that govern prescribers, an entity may receive information if it licenses individuals who administer or dispense drugs.

(2) Law enforcement officers who receive information are limited to those investigating drug abuse offenses, rather than those involved in any active investigation, as permitted under current law. These officers, however, are required to be given the OARRS information.

(3) Information must be provided pursuant to a subpoena issued by a grand jury.

(4) Information must be provided pursuant to a subpoena, search warrant, or court order in connection with the investigation or prosecution of a possible or alleged criminal offense.

(5) A "prescriber's agent registered with the board," as well as a prescriber, may receive information from OARRS.

---

[27] R.C. 4729.79.

[28] R.C. 4729.79 and 4715.30, 4723.487, 4725.092, 4729.161, 4730.53, and 4731.055.

[29] R.C. 4729.79(C).

(6) A licensing entity, law enforcement officer, prescriber, prescriber's agent, or pharmacist from another state's prescription monitoring program, may receive information if there is a written agreement under which the information is to be used and disseminated according to Ohio laws.

(7) A pharmacist may receive information for the purpose of "the practice of pharmacy involving the patient" rather than for "providing pharmaceutical treatment" as under current law.

(8) A prescriber may receive information relating to a current patient.

(9) A medical director of a Medicaid managed care organization may receive information relating to a Medicaid recipient enrolled in the organization, but only if the organization has entered into a data security agreement with the Pharmacy Board. For purposes of this provision, each Medicaid managed care organization is required to enter into a data security agreement with the Board not later than one year after the bill's effective date.[30]

(10) The Director of Job and Family Services may receive information relating to a recipient of a program administered by the Department.

(11) The Administrator of Workers' Compensation may receive information relating to a Bureau of Workers' Compensation claimant.[31]

Retention of OARRS information

As under current law, the bill provides that information collected in OARRS is to be retained for at least two years. The bill eliminates the provision of existing law that generally requires OARRS information to be destroyed after two years. Instead, the bill requires information to be destroyed after two years only if it would identify a patient. Patient-identifying information may be retained longer than two years, however, if a law enforcement agency or licensing entity has submitted a written request to the Board for retention of the identifying information in the database.[32]

Criminal penalties

The bill establishes the following prohibitions and penalties for misuse of the information contained within OARRS:

---

[30] R.C. 5111.1710 and Section 3(C).

[31] R.C. 4729.80 and 4729.84.

[32] R.C. 4729.82.

(1) Prohibits a person authorized to receive information from OARRS from disseminating any written or electronic document received from the database to a person not authorized to receive the document. A person violating this prohibition is guilty of a misdemeanor of the third degree. If the offender has previously been convicted of or pleaded guilty to the same or other OARRS-related offense, the offense is a misdemeanor of the first degree.

(2) Prohibits a person from providing false information to the Pharmacy Board with the intent of obtaining OARRS information. A person violating this prohibition is guilty of a misdemeanor of the first degree. If the offender has previously been convicted of or pleaded guilty to the same or other OARRS-related offense, the offense is a felony of the fifth degree.

(3) Prohibits a person from obtaining OARRS information by any means other than those permitted by law. A person violating this prohibition is guilty of a felony of the fifth degree. If the offender has previously been convicted of or pleaded guilty to the same or other OARRS-related offense, the offense is a felony of the fourth degree.[33]

Restrictions due to using OARRS data in legal proceedings

The bill prohibits a person from using a document obtained from the database as evidence in any civil or administrative proceeding or improperly disseminating, submitting, or obtaining OARRS information. The Pharmacy Board is authorized under the bill to restrict a person who fails to comply with these requirements from obtaining further information from OARRS. The Board is to determine the extent to which the person is restricted access.[34] Unauthorized dissemination of information in OARRS, under the bill, does not include dissemination as necessary in the investigation or prosecution of a possible or alleged offense.

Funding acceptance

The bill permits the Board to accept grants, gifts, or donations to operate OARRS. Any grants, gifts, or donations are to be deposited in the Drug Database Fund, which is created in the state treasury by the bill. The money in the Fund is to be used solely for the operation of OARRS.[35]

---

[33] R.C. 4729.86 and 4729.99.

[34] R.C. 4729.86.

[35] R.C. 4729.83.

OARRS improvements

The bill requires the Pharmacy Board, in consultation with prescribers and pharmacists, to consider improvements to Ohio's method of monitoring through OARRS the misuse and diversion of controlled substances. The Board is to submit a report not later than six months after the bill's effective date. The report must include the following:

(1) Recommendations on the establishment of a "real time" drug database;

(2) Recommendations on improvements to OARRS, including (a) improvements necessary to facilitate information exchange between OARRS and users and (b) improvements that allow a drug utilization review for monitoring use of controlled substances;

(3) The potential cost of upgrading OARRS or creating a new database;

(4) Information on the availability of, and methods to secure, federal grants to implement the Board's recommendations;

(5) Other matters the Board considers relevant.[36]

PHARMACY BOARD CONTRACTS

Contracts with private entities

The bill authorizes the Pharmacy Board to enter into contracts with private entities for the furtherance of its duties. The Board may give consideration to entities based in Ohio when entering in the contracts. The funds collected under the contracts may be used for any purpose determined by the Board to be relevant to its duties, including the establishment and maintenance of OARRS.[37]

Any money received by the Board as revenue under the contracts is to be deposited to the credit of the Occupational Licensing and Regulatory Fund. That fund is the repository for license fees and other assessments collected by multiple licensing boards and is used to fund the activities of the boards.

---

[36] Section 4.

[37] R.C. 4729.021.

OHIO LAW ENFORCEMENT GATEWAY

Access

Access to the Ohio Law Enforcement Gateway (OLEG) is extended by the bill to the Medical Board and Board of Nursing. OLEG, established and operated under current law by the Superintendent of the Bureau of Criminal Identification and Investigation, is a statewide communications network to gather and disseminate information, data, and statistics for the use of law enforcement agencies, known as OLEG. The Attorney General is permitted to adopt rules establishing guidelines for the operation and participation in OLEG.

The bill requires the Attorney General to permit the Medical Board and the Board of Nursing to access and view, but not alter, information gathered and disseminated through OLEG. It also expressly permits the boards to access and view, but not alter, the OLEG information.[38]

MEDICAL BOARD DISCIPLINARY ACTIONS

Medical Board summary suspensions

The bill specifies that, to summarily suspend a license, the Medical Board is to find that both of the following apply: (1) that there is clear and convincing evidence that a physician has violated a provision for which a physician is subject to disciplinary action, and (2) that the person's continued practice presents a danger of immediate and serious harm to the public. This provision applies to a summary suspension imposed for any reason; it is not limited to issues involving pain management clinics.[39]

Discipline based on actions of other regulatory entities

The bill expands the situations under which the Medical Board may take action against a license holder based on disciplinary actions taken by another entity. Under current law allows the Medical Board to take disciplinary actions against a license holder based on another state's licensing board's disciplinary actions. For the Medical Board to be authorized to take any disciplinary action, the action taken by the other entity must be directed at the same professions the Medical Board regulates (i.e., medicine, podiatry, massage therapy, etc.). The bill expands the Medical Board's authority to take action against a license holder based on actions taken by another entity to cases where the disciplinary action pertains to other "health care professions,"

[38] R.C. 109.57, 4723.064, and 4731.391.

[39] R.C. 4731.054 and 4731.22.

whether in Ohio or in another state, instead of only actions against the same professions the Medical Board regulates.

Telephone conference calls

When taking certain disciplinary actions against a license holder, the bill permits the Medical Board to do so through a telephone conference call.[40] Specifically, the bill authorizes a conference call to be used to (1) ratify a consent agreement that revokes or suspends a certificate to practice or (2) accept an individual's surrender of a certificate to practice. The conference call is required to comply with current law's notification requirements that apply to a special meeting.[41]

BOARD OF NURSING INFORMATION

Access to investigatory information

The bill expands access to information collected by the Board of Nursing in an investigation. Existing law provides that information received by the Board in an investigation is confidential and not subject to discovery in any civil action. An exception to this confidential status of information applies to law enforcement officers and government entities investigating a "registered nurse, licensed practical nurse, or dialysis technician or a person who may have engaged in the unauthorized practice of nursing." The bill expands the exception for which the Board may disclose information to include information regarding any "licensed health care professional."

If the Board does provide information to a law enforcement officer or government entity, current law prohibits the law enforcement officer or government entity from divulging the information to any other person or government entity except "for the purpose of an adjudication by a court or licensing or registration board or officer to which the person to whom the information relates is a party." The bill specifies that the law enforcement officer or government entity is permitted to divulge the information for the purpose of "a government investigation, a prosecution, or an adjudication by a court or government entity."[42]

---

[40] R.C. 4731.22.

[41] R.C. 121.22 (not in the bill).

[42] R.C. 4723.28.

CORONER NOTIFICATIONS

Notification of drug overdoses

The bill permits a coroner to notify the Medical Board if the coroner determines that a drug overdose is the cause of a person's death. The coroner is authorized to include in the notice any information relating to the overdose, including the physician who prescribed the drug to the decedent.[43]

COORDINATED SERVICES PROGRAMS

Medicaid

The bill requires each Medicaid managed care organization and the fee-for-service component of the Medicaid program to implement a coordinated services program for Medicaid recipients who are found to have obtained prescription drugs at a frequency or in an amount that is not medically necessary. The program must be consistent with federal law that allows states to restrict Medicaid recipients to designated providers when they are found to have over-utilized Medicaid services.[44]

In the case of Medicaid managed care, the requirement to establish a coordinated services program is to be included in a managed care organization's contract with ODJFS. Because Medicaid managed care currently does not include coverage of outpatient prescription drugs, it appears that the contract requirement to establish a coordinated services program will have limited effect unless coverage of outpatient prescription drugs is added to the Medicaid managed care system.

Bureau of Workers' Compensation

The bill requires that the administrator of Workers' Compensation implement a coordinated services program for all workers' compensation claimants. The program is to apply to each claimant who is found to have obtained prescription drugs at a frequency or in an amount that is not medically necessary. The program must be operated in a manner that is substantially similar to the Medicaid program's coordinated services programs.[45]

---

[43] R.C. 313.212.

[44] R.C. 5111.085, 5111.172(B), 5111.179, 42 U.S.C. 1396n(a)(2), and 42 C.F.R. 431.54(e).

[45] R.C. 4121.50.

Implementation date

The bill requires Medicaid fee-for-service and the Workers' Compensation Program to each include a coordinated services program by July 1, 2012. For Medicaid managed care, ODJFS is to begin including the coordinated services program requirement in contracts with managed care organizations not later than July 1, 2012. Once ODJFS implements the contract requirement, the bill provides that the requirement extends to any contract renewal, amendment, or modification after the implementation date.[46]

CHRONIC PAIN

Standards for diagnosis and treatment

With respect to the Medical Board's existing duty to adopt rules establishing standards for physicians who treat patients with intractable pain, the bill replaces the term "intractable pain" with "chronic pain" and redefines the term. As a result, the Board will be required to adopt new rules regarding the standards and procedures to be followed by physicians in the diagnosis and treatment of chronic, rather than intractable pain.[47]

Similarly, the Board will be required to approve continuing medical education courses in chronic pain, rather than intractable pain.[48]

Terminology

Under the bill, "chronic pain" is defined as "pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically for longer than three continuous months." Specifically excluded from the definition of "chronic pain" is pain associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.

In contrast to the bill's definition of "chronic pain," existing law defines "intractable pain" as a state of pain that is determined, after reasonable medical efforts have been made to relieve the pain or cure its cause, to have a cause for which no treatment or cure is possible or for which none has been found.

---

[46] Section 3(B).

[47] R.C. 4731.052.

[48] R.C. 4731.283.

MEDICAL BOARD EDUCATION AND PATIENT SAFETY PROGRAMS

The bill permits the State Medical Board to solicit and accept grants and services from public and private sources for the purpose of developing and maintaining programs that address patient safety and education, supply and demand of health care professionals, and information sharing with the public and individuals regulated by the Board. The Board is prohibited from soliciting or accepting a grant or service that would interfere with the Board's independence or objectivity, as determined by the Board.

All money received by the Board is to be deposited in the Medical Board Education and Patient Safety Fund, which the bill creates in the state treasury.[49]

SUMMARY OF ADMINISTRATIVE FINES

The following table provides a summary of the fines that may be imposed under the bill by the Pharmacy Board and Medical Board.

Enforcement agency	Potential offenders	Offense	Maximum fine
Pharmacy Board	Pain management clinics	Failure to comply with any of the requirements for operation of a pain management clinic, including failing to be appropriately licensed	$5,000 for each day of violation
Pharmacy Board	Physicians, dentists, and any other prescribers with authority to personally furnish drugs (excluding veterinarians)	Personally furnishing a controlled substance in an amount that exceeds the bill's limits	$5,000 for each violation of the limitation
Medical Board	Physicians at pain management clinics	Failure to comply with the Board's rules for the provision of physician care at a pain management clinic or failure as a clinic owner to comply with the	$20,000

[49] R.C. 4731.241.

Enforcement agency	Potential offenders	Offense	Maximum fine
		Board's rules for providing supervision, direction, and control of individuals who provide treatment	

HISTORY

ACTION	DATE
Introduced	02-08-11
Reported, H. Health & Aging	03-03-11
Passed House (97-0)	03-09-11
Reported, S. Health, Human Services & Aging	05-12-11

h0093-rs-129.docx/ks