Ohio Legislative Service Commission

Bill Analysis

Jeffery A. Bernard

Sub. S.B. 301

129th General Assembly
(As Reported by H. Health and Aging)

Sens. Burke and Cafaro, Lehner, Seitz, Jones, Tavares, Brown, Bacon, Balderson, Beagle, Gentile, Hite, Hughes, Kearney, LaRose, Manning, Obhof, Oelslager, Peterson, Schaffer, Schiavoni, Skindell, Smith, Turner

Reps. Garland, Hackett, Johnson, Smith, Yuko

BILL SUMMARY

- Modifies the professional disciplinary actions that may be taken by the State Board of Pharmacy, State Medical Board, and State Dental Board.
- Modifies the authority of the Dental Board to suspend without a prior hearing a license or certificate.
- Authorizes the Medical Board to inspect a pain management clinic or facility suspected of operating as a pain management clinic without a license.
- Expands the types of controlled substances that are not included in determining whether a prescriber has personally furnished a greater amount of controlled substances than allowed by law.
- Changes the criteria for determining whether a facility is subject to licensure as a pain management clinic.
- Modifies the laws governing submission to and requests for information from the Ohio Automated Rx Reporting System.
- Makes corrective and technical changes.

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CONTENT AND OPERATION

Disciplinary actions regarding health care professionals

The bill modifies the professional disciplinary actions that the State Board of Pharmacy, State Medical Board, and State Dental Board are authorized to take against their respective license or certificate holders and applicants for those licenses or certificates.

Pharmacy Board

Regarding terminal distributors of dangerous drugs, the bill permits the Board to refuse to grant a license to an applicant for a number of reasons, including making false claims, violating a Board rule, or violating any provision of federal drug law. The term

"terminal distributor of dangerous drugs" generally refers to a pharmacy or other retail seller of drugs and includes facilities required to be licensed as pain management clinics. The reasons for which the bill permits the Board to refuse to grant a license to an applicant are the same as the current law reasons for which the Board may suspend, revoke, or refuse to renew a license that has been issued or impose a monetary penalty or forfeiture against a license holder.[1]

Medical Board

The bill provides that the Medical Board has additional options for taking professional disciplinary action when the Board determines that a certificate holder or applicant has committed fraud during the administration of the examination for a certificate or committed fraud, misrepresentation, or deception in applying for or securing a certificate to practice. Under current law, if the Board takes action for these reasons, it may only revoke or refuse to grant the certificate. In addition to these options for disciplinary action, the bill permits the Board to limit, suspend, or refuse to reinstate the certificate or to reprimand, refuse to register, or place on probation the certificate holder or applicant.[2]

Among the reasons the Board currently is authorized to take disciplinary action against a certificate holder is the holder's failure to cooperate in an investigation, including failure to comply with a subpoena or order by the Board, and failure to answer truthfully questions presented by the Board at a deposition or in written interrogatories. The bill similarly permits the Board to take action for failure to answer truthfully a question presented by the Board in an investigative interview or an investigative office conference.[3]

Regarding pain management clinics, the bill permits the Board to take disciplinary action against a certificate holder if the holder does either of the following: (1) practices at a facility that is subject to licensure as a terminal distributor of dangerous drugs with pain management clinic classification if the person operating the facility has not obtained and maintained the license, or (2) owns a facility that is subject to that licensure without holding the license.[4]

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[1] R.C. 4729.57(A).

[2] R.C. 4731.22(A).

[3] R.C. 4731.22(B)(34).

[4] R.C. 4731.22(B)(45) and (46).

The bill provides that, at the request of the Board, a certificate holder must immediately surrender to the Board a certificate that the Board has suspended, revoked, or permanently revoked.[5]

Dental Board

The bill makes the modifications described below with regard to the professional disciplinary actions that may be taken by the Dental Board against license or certificate holders.

Summary suspension

The bill permits the Dental Board to suspend without a prior hearing a license or certificate if the Board's supervisory investigative panel determines both of the following: (1) that the holder has violated any action for which the Board is authorized to take disciplinary action and (2) that the person's continued practice presents a danger of immediate and serious harm to the public. This replaces the current procedure under which the Board, if it believes that a person's continued practice is a clear and immediate danger to the public health and safety, may apply to the court of common pleas for an order temporarily suspending a license or certificate without a prior Board hearing.

On review of the allegations, and on an affirmative vote of at least four dentist members of the Board and seven members in total, the Board may suspend a certificate or license without a prior hearing. The bill permits a telephone conference call to be utilized to review the allegations and vote on the suspension. The Board is to follow procedures for notification of the suspension without a hearing as provided in the Administrative Procedure Act (R.C. Chapter 119.). 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 75 days, the suspension is void on the 76th day after the suspension date.[6]

Misdemeanor or felony

Existing law provides that the Dental Board may take disciplinary action against a license or certificate holder who is convicted of either a misdemeanor in the course of practice or a felony. The bill provides that the misdemeanor or felony can occur in any jurisdiction (such as another state) for the Board to take action.

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[5] R.C. 4731.22(M).

[6] R.C. 4715.30(G).

For the Board to take the action under current law, the license or certificate holder must have been *convicted* of the misdemeanor in the course of practice or the felony. Conviction occurs after sentencing and final adjudication of a case; that is, a person may be found guilty of an offense but not convicted until after sentencing.[7] The bill provides that the Board may also take action for a plea of guilty to, a judicial finding of guilt resulting from a plea of no contest to, or a judicial finding of eligibility for intervention in lieu of conviction of a misdemeanor in the course of practice or a felony.[8] The bill therefore permits the Board to take disciplinary action against a license or certificate holder after a finding of guilt but prior to sentencing.

Federal or state drug offenses

Specifically for drug offenses, the Dental Board is currently authorized to take action if a license or certificate holder is *convicted* of a violation of any state or federal law regulating the possession, distribution, or use of any drug. As with a conviction of a misdemeanor in the course of practice or a felony discussed above, the bill permits the Board to take action for a plea of guilty to, a judicial finding of guilt resulting from a plea of no contest to, or a judicial finding of eligibility for intervention in lieu of conviction, of a violation of any federal or state law regulating the possession, distribution, or use of any drug.[9]

Action based on another licensing entity

The Dental Board is not authorized under current law to take disciplinary action against a license or certificate holder based on another entity taking disciplinary action against that person. The bill permits the Board to take such action if another entity responsible for regulating the practice of a health care occupation takes action against that license or certificate holder, other than for the nonpayment of a fee.

Cooperation in investigations

The bill authorizes the Dental Board to take disciplinary action against a license or certificate holder who fails to cooperate in an investigation conducted by the Board. It specifies that failure to cooperate includes failing to comply with a subpoena or order issued by the Board or failure to answer truthfully a question presented by the Board at a deposition or in written interrogatories. The bill provides, however, that a license or certificate holder is not subject to discipline for failure to cooperate in an investigation if

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[7] *State of Ohio v. Henderson* (58 Ohio St.2d 171).

[8] R.C. 4715.30(A)(4), (5), and (6).

[9] R.C. 4715.30(A)(8).

a court of competent jurisdiction has issued an order that either quashes a subpoena or permits the license or certificate holder to withhold the testimony or evidence.

Subpoenas

The Dental Board is currently authorized to issue subpoenas in any investigation. The bill lengthens the minimum amount of time a person must be given to comply with a subpoena for the production of papers to at least seven days, rather than the current minimum of three days.[10]

Dental Board authority to share investigation information

The bill authorizes the Dental Board to share any information it receives in an investigation, including patient records and information, with law enforcement agencies, licensing boards, and other governmental agencies that are prosecuting, adjudicating, or investigating a violation of any statute or administrative rule. The entity receiving the information is required to comply with the same confidentiality requirements that apply to the Dental Board regarding the information.[11]

In a judicial proceeding, the investigation information may be admitted into evidence under the Rules of Evidence, but the court must require that appropriate measures are taken to ensure that confidentiality is maintained with respect to any part of the information that contains names or other identifying information about patients or complainants whose confidentiality was protected by the Dental Board when it possessed the information. These measures may include sealing of records or deleting specific information from the records.

Medical Board investigation and inspection authority

The bill modifies the investigative and inspection authority of the Medical Board. Under current law, the Board has authority to investigate possible violations of the law governing the professionals it regulates. The bill expands this authority to include inspections of pain management clinics. Regarding both inspection and investigation authority, the bill expands the information gathering activities the Board currently may engage in during an inspection or investigation by providing that the Board may also question witnesses and conduct interviews.[12]

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[10] R.C. 4715.033.

[11] R.C. 4715.30(J).

[12] R.C. 4731.22(F).

Inspection of pain management clinics

For the purpose of ensuring compliance with the laws governing pain management clinics, the bill authorizes the Medical Board to inspect facilities that are licensed as terminal distributors of dangerous drugs with pain management clinic classification or facilities or physician practices that the Board suspects are illegally operating as such. The inspections are to be completed in the manner provided for under current law regarding Board investigations.[13] The bill specifies that, before conducting an on-site inspection, the Board must provide notice to the owner or other person in charge of the facility or practice. Prior notice, however, is not required if, in the Board's judgment, the notice would jeopardize an investigation being conducted by the Board.[14]

Service of subpoenas

Regarding the Medical Board's subpoena power, the bill permits a subpoena to be served by leaving it at the person's usual place of business or address on file with the Board, as well as leaving it at the person's usual place of residence as provided under current law. When choosing to deliver a subpoena by certified mail, as currently permitted, the bill provides that the Board is no longer required to do so by using restricted delivery.

The bill provides that if the person being served refuses to accept the subpoena or is not located, service may be made to an attorney who notifies the Board that the attorney is representing the person.[15]

Confidentiality of information collected in an inspection or investigation

Current law provides that information received by the Medical Board in an investigation is confidential and not subject to discovery. The bill extends this confidentiality provision to a report required to be submitted to the Board, a complaint, or information received by the Board under either an investigation or an inspection. Regarding inspections, the bill requires the Board to protect the confidentiality of patients and persons who file complaints with the Board, as it currently is required to do with regard to investigations.[16]

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[13] R.C. 4731.054(E) and 4731.22(F).

[14] R.C. 4731.054(E)(3).

[15] R.C. 4731.22(F)(3).

[16] R.C. 4731.22(F)(5).

Duties of the Secretary

The bill provides that the Secretary of the Medical Board is to enforce R.C. Chapter 4731. and the rules adopted under it, in place of the current law provision requiring the Secretary to enforce the laws relating to the practice of medicine and surgery. Under R.C. Chapter 4731., the Board regulates medical doctors, osteopathic doctors, podiatrists, massage therapists, and cosmetic therapists.[17]

Limits on prescriber-furnished controlled substances

Current law establishes limits on the amount of controlled substances that may be personally furnished by prescribers on a 30-day and 72-hour basis. Methadone, however, is not included in determining whether a prescriber has exceeded those limits. The bill modifies this exclusion for methadone by providing that the prescriber must meet conditions specified under federal law governing narcotic treatment programs.[18]

The bill also provides that, as with methadone, personally furnished controlled substances that meet the following requirements are not included in determining whether a prescriber exceeds the 30-day and 72-hour limits:

(1) Buprenorphine provided to patients for the purpose of treating drug addiction, if the prescriber is exempt from separate registration with the United States Drug Enforcement Administration;[19]

(2) Controlled substances provided to research subjects by a facility conducting clinical research in studies approved by a hospital-based institutional review board or an institutional review board accredited by the Association for the Accreditation of Human Research Protection Programs.[20]

Pain management clinic licensing and operation

The bill makes a number of revisions regarding the licensure of terminal distributors of dangerous drugs with pain management clinic classification.

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[17] R.C. 4731.39.

[18] 21 Code of Federal Regulations (C.F.R.) 1306.07.

[19] 21 C.F.R. 1301.28.

[20] R.C. 4729.291.

Facilities required to be licensed

The definition of a "pain management clinic," which specifies the facilities that are subject to licensure, is modified by the bill as follows:

- Eliminates the condition that a facility have, as its primary component of practice, the treatment of pain or chronic pain;[21]

- Removes a condition that a majority of patients of the prescribers at the facility be provided treatment for *pain* but maintains existing law's reference to *chronic pain*, and provides that the treatment must be *through* the use of controlled substances, tramadol, or other drugs (in place of the current law provision referring to treatment that *includes* the use of those drugs);[22]

- Removes a reference to a facility's treatment of pain with carisoprodol – a muscle relaxant and pain relieving drug[23] that, according to Pharmacy Board representatives, is now classified as a controlled substance and, therefore, no longer needs to be separately specified;[24]

- Adds the following two entities as facilities that are not considered pain management clinics: (1) a nursing home licensed by the Department of Health or certified by a local political subdivision and (2) a facility conducting only clinical research that may use controlled substances in studies approved by a hospital-based institutional review board or an institutional review board accredited by the Association for the Accreditation of Human Research Protection Programs.[25]

Compliance with Medical Board rules

The bill requires the holder of a license as a terminal distributor of dangerous drugs with a pain management clinic classification to comply with the requirements for the operation of a clinic that are adopted by the Medical Board. Under current law, the Medical Board may take professional disciplinary action against a physician for failure

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[21] R.C. 4731.054(A)(5)(a)(i).

[22] R.C. 4731.054(A)(5)(a)(ii) and (b)(ii).

[23] U.S. National Library of Medicine, PubMed Health, Carisoprodol (last visited May 23, 2012) available at <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000717/>.

[24] R.C. 4731.054(A)(5)(a).

[25] R.C. 4731.054(A)(5)(b)(viii) and (ix).

to comply with these rules, but the Pharmacy Board is not authorized to take action against the terminal distributor license holder. The bill provides that the Pharmacy Board may take disciplinary action against the terminal distributor for failure to comply with the rules adopted by the Medical Board.[26]

Pharmacy Board rules

The bill authorizes the Pharmacy Board to adopt rules it considers necessary to implement and administer the law governing the licensing of pain management clinics.[27]

Ohio Automated Rx Reporting System (OARRS)

The bill modifies the laws governing submission of information to and requests for information from the Ohio Automated Rx Reporting System (OARRS).

Submission of information

The bill makes the following adjustments in instances when a prescriber who personally furnishes a controlled substance or other dangerous drug is required to submit certain information through OARRS to the Pharmacy Board: (1) requires the prescriber to submit information when the prescriber personally furnishes a drug to any patient, rather than only when the drug is furnished to a patient in Ohio, (2) requires the prescriber to submit information identifying the owner of the drug furnished, and (3) provides that the information may be submitted on behalf of the prescriber by the owner of the drug being personally furnished or by a delegate approved by that owner (current law provides that only the prescriber may submit the information).[28]

Requests for information from OARRS

The bill modifies the circumstances when information from OARRS may be released by permitting the Pharmacy Board to provide patient information from the database on receipt of a request from all of the following:

(1) A prescriber's *delegate approved by* the Board, rather than an *agent registered with* the Board as provided under current law;

(2) A prescriber (or the prescriber's approved delegate) regarding a potential patient of the prescriber based on a referral of the patient to the prescriber;

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[26] R.C. 4729.552(B)(2).

[27] R.C. 4729.552(E).

[28] R.C. 4729.79.

(3) A pharmacist's delegate approved by the Board to receive OARRS information regarding a patient of the pharmacist.[29]

Misuse of OARRS information

The bill modifies the existing prohibition against disseminating a written or electronic document received from OARRS by providing that the prohibition applies to any such written or electronic OARRS *information*, rather than only a *document*. The bill specifies that the prohibition applies not only to *disseminating* the information, but also to *otherwise providing* another person access to the information that has been received. The bill establishes an exception to the prohibition that reflects the authority of prescribers, pharmacists, and their respective delegates to provide OARRS information to each other.[30]

The bill modifies the existing prohibition against providing false information to the Pharmacy Board relative to OARRS. Under the bill, the prohibition applies not only when providing false information with the intent to *obtain* OARRS information, as specified in current law, but also when providing false information with the intent to *alter* OARRS information.[31]

As under current law, a person who violates the bill's modified prohibitions is guilty of a misdemeanor of the third degree for a first offense. On subsequent offenses, including other offenses related to OARRS, the person is guilty of a misdemeanor of the first degree.[32]

Restrictions on further access to OARRS

The Pharmacy Board is currently authorized to restrict a person from obtaining further information from OARRS if the person is *convicted* of or *pleads guilty* to an offense related to the misuse of OARRS information. The bill provides that the Board may impose the restriction when a person *violates* the prohibitions, rather than when the action of conviction or pleading guilty has occurred.[33]

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[29] R.C. 4729.80.

[30] R.C. 4729.86(A)(1).

[31] R.C. 4729.86(A)(2).

[32] R.C. 4729.99 (not in the bill).

[33] R.C. 4729.86(C).

Corrective and technical changes

Drug names and categories

The bill corrects a misspelling of the schedule I controlled substance "methylenedioxypyrovalerone," a drug commonly known as "bath salts." The bill also moves this drug and a number of other controlled substances that are currently categorized as "hallucinogens" into the schedule I category of "stimulants."[34]

Pain management clinics

Regarding the requirements that must be met to obtain and maintain licensure as a pain management clinic, the bill removes references to meeting and remaining in compliance with applicable requirements under the law governing controlled substances. As a terminal distributor of dangerous drugs, a pain management clinic continues to be subject to any requirements that apply to terminal distributors.[35]

The bill corrects a reference to wholesale distributors of dangerous drugs in a provision of existing law specifying when drugs may be sold by the distributors to pain management clinics.[36]

Waiver of dental insurance cost-sharing

The bill makes technical changes to a provision of existing law that authorizes the Dental Board to take professional disciplinary actions when a person waives a copayment or deductible required under a patient's dental insurance.[37]

Cross references

The bill makes a number of technical corrections in statutory cross references. Among these corrections, the bill includes in the laws governing prescribers and pharmacists a reference to the provision of existing law that authorizes the release of OARRS information to prescribers and pharmacists when complying with their licensing boards' rules to review the information for particular patients.[38]

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[34] R.C. 3719.41.

[35] R.C. 4729.552.

[36] R.C. 4729.51(B)(2).

[37] R.C. 4715.30(A)(13) and (H).

[38] R.C. 4715.034, 4715.301, 4715.302, 4723.487, 4725.092, 4729.162, 4729.51(B), 4730.53, and 4731.055.

HISTORY

ACTION	DATE
Introduced	02-15-12
Reported, S. Health, Human Services & Aging	05-03-12
Passed Senate (32-0)	05-03-12
Reported, H. Health and Aging	05-23-12

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