Ohio Legislative Service Commission

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Fiscal Note & Local Impact Statement

Bill: S.B. 319 of the 131st G.A. (LSC 131 2372-4) **Date**: December 5, 2016

Status: In House Finance **Sponsor**: Sen. Eklund

Local Impact Statement Procedure Required: No

Contents: Drug law regulations, practice of pharmacy, provision of addiction services

State Fiscal Highlights

- The annual operating expenses of the State Board of Pharmacy will increase by an uncertain degree to register and regulate approximately 42,000 registered pharmacy technicians, certified pharmacy technicians, and pharmacy technician trainees plus approximately 1,000 additional licensed office-based opioid treatment facilities.
- The fees to be collected by the State Board of Pharmacy are estimated to generate between $1.2 million and $2.3 million in the first year and will be deposited in the state's existing Fund 4K90, the Occupational Licensing and Regulatory Fund. Most of the money needed to cover the Board's annual operating expenses is appropriated from this fund.
- There could be a decrease in Medicaid prescription drug costs if the Medicaid prior authorization requirements or utilization review measures for opioid analgesics result in fewer prescriptions of opioid analgesics filled. There could also be an increase in administrative costs to the Ohio Department of Medicaid to process additional prior authorizations received.
- The requirement that health insurers apply prior authorization requirements or utilization review measures as conditions of providing opioid analgesics could decrease the costs for the state to provide health benefits to workers and their dependents.
- The State Medical Board could experience an increase in costs to take certain disciplinary actions if a certificate holder is found to practice at or own a facility or clinic subject to licensure as a category III terminal distributor of dangerous drugs with an office-based opioid treatment classification. Any increase will depend on the number of disciplinary actions taken. However, certain disciplinary actions could result in some fine revenues being collected.

- The Ohio Department of Mental Health and Addiction Services (OMHAS) may realize an increase in administrative costs to adopt rules regarding methadone provider licensure requirements.
- OMHAS will realize an increase in administrative costs to analyze the unmet needs for methadone treatment in Ohio and to publish a report regarding its findings.
- OMHAS could realize an increase in costs to establish a waiver process regarding continuum of care essential elements.
- Violations of the bill's minor misdemeanor prohibition against the dispensing of an opioid analgesic under certain circumstances may generate, at most, a minimal amount of locally collected court cost revenue annually for deposit into the Indigent Defense Support Fund (Fund 5DY0) and the Victims of Crime/Reparations Fund (Fund 4020).

Local Fiscal Highlights

- Pharmacists and terminal distributors of dangerous drugs will generally comply with the bill's minor misdemeanor prohibition against the dispensing of an opioid analgesic under certain circumstances, making violations infrequent. It is likely that revenues collected from violators (fines, court costs, and fees) will offset to some degree the costs that counties and municipalities incur to process minor misdemeanors.
- The requirement that health insurers apply prior authorization requirements or utilization review measures as conditions of providing opioid analgesics could decrease the costs for local governments to provide health benefits to workers and their dependents.
- A local board of health could experience an increase in administrative costs if it chooses to establish a naloxone distribution or administration protocol or to authorize individuals to furnish or administer naloxone.
- A county board of health that currently receives state grant funding to enhance naloxone access across the state can also, as a result of the bill, use grant funds to provide naloxone through a Project DAWN Program within the county under certain conditions.[1]

[1] Project DAWN (Deaths Avoided with Naloxone) is a community-based overdose education and naloxone distribution program.

Detailed Fiscal Analysis

State Board of Pharmacy

Pharmacy technician licensing

The bill requires pharmacy technicians to register with the State Pharmacy Board, establishes a process for those registrations, and creates three professional registration categories: registered pharmacy technician, certified pharmacy technician and pharmacy technician trainee. The Board is required to adopt rules governing registration and regulation of pharmacy technicians. Pharmacy technicians and pharmacy technician trainees who violate those rules will be subject to the Board's disciplinary procedures.[2]

To process and regulate what they estimate to be over 42,000 new registrations, the Board will need to hire additional licensing and compliance staff and at least one hearing officer. The Board's annual costs to register and regulate pharmacy technicians are not known, but increased revenues noted immediately below may offset some, if not all, of the expense increase.

Applicants for registration as a registered or certified pharmacy technician are required to pay a $50 fee and applicants for registration as a pharmacy technician trainee are required to pay a $25 fee. All registrants are required to pay a renewal fee at a time and cost to be determined by the Board. Based on the Board's estimate of over 42,000 new registrants, the total amount of money that could be generated in the first year by these fees will be in the range of $1.1 million to $2.1 million. The money generated from these fees will be deposited in the state's existing Fund 4K90, the Occupational Licensing and Regulatory Fund. Most of the money needed to cover the Board's annual operating expenses is appropriated from this fund.

Operations generally

The bill permits the Board: (1) to keep electronic books to include records of its proceedings, and a register of all identification cards, licenses and registrations granted, renewed, suspended, or revoked, (2) to adopt rules requiring reporting of violations of state and federal laws, and (3) to hire one or more attorneys at law to serve as hearing examiners. These examiners may hear and consider evidence and send findings to the Board for a final decision in an administrative hearing.

[2] The disciplinary actions the Board of Pharmacy may take include revoking, suspending, or limiting the pharmacy technician or trainee's registration; placing the pharmacy technician or trainee's registration on probation; refusing to grant or renew the pharmacy technician or trainee's registration; or imposing a monetary penalty or forfeiture not to exceed $500. Any forfeiture collected would be deposited to the credit of Fund 4K90, the Occupational Licensing and Regulatory Fund.

Opioid prescription limitations

The bill prohibits pharmacists, pharmacy interns, and terminal distributors of dangerous drugs from dispensing an opioid analgesic in an amount greater than a 90-day supply (based on prescription instructions) and from dispensing an opioid analgesic for any prescription older than 14 days with certain exceptions. A violation of that prohibition is a minor misdemeanor. Under current law, unchanged by the bill, law enforcement can only issue a citation for a minor misdemeanor; the person being cited generally cannot be arrested. If the person pays the associated fine of up to $150, court costs, and fees, that person is in effect pleading guilty and waiving the requirement that they make a court appearance.

Presumably, once the bill's prohibition is enacted, pharmacists, pharmacy interns, and terminal distributors will discontinue dispensing opioid analgesics in a way that would violate the prohibition. Most violations will be first-time offenders and subsequent violations will be relatively few in number.

The amount of locally collected state court costs that might be forwarded to the state treasury annually is likely to be no more than minimal. The state court costs for a misdemeanor conviction generally total $29, with $20 of that amount being deposited in the state treasury to the credit of the Indigent Defense Support Fund (Fund 5DY0) and the remainder, or $9, being credited to the Victims of Crime/Reparations Fund (Fund 4020).

The time and cost to process a minor misdemeanor is relatively low, with most persons cited typically opting to pay the fine, court costs, and fees, and waive a court appearance. This likely means that in many cases the fines, court costs, and fees collected will offset some, if not all, of the cost associated with processing citations.

Office-based opioid treatment classification

The bill requires any facility which provides office-based opioid treatment to more than 30 patients to hold a category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification. The Board estimates that just over 1,000 facilities statewide will require licensing, including paying a fee of $150 annually. The additional amount of money that will be generated annually from the fee is estimated at $150,000 and will be deposited in Fund 4K90.

The Board is required to adopt rules to administer this new licensing classification and is authorized to impose a fine of up to $5,000 per day of violation on any person who operates an office-based opioid treatment facility without the proper licensing or fails to remain in compliance with other statutory requirements. The amount of fine revenue that may be generated annually for deposit in Fund 4K90 is uncertain.

Community addiction services

The bill removes the requirement that a community addiction services provider: (1) be operated by a private, nonprofit organization or by a government entity, and (2) that the provider has been fully certified by the Ohio Department of Mental Health and Addiction Services (OMHAS) for at least two years immediately preceding the date of application in order to be licensed to maintain methadone treatment. The bill specifies that the provider meet any additional requirements established under rules. The bill requires OMHAS to adopt rules that revise the requirements governing licensure of methadone treatment providers. In addition, the bill specifies what the rules must require for licensure. The bill specifies that if OMHAS has not adopted the rules to revise the requirements, or if the rules are not in effect on, June 1, 2017, OMHAS is not to issue any methadone treatment licenses. There could be administrative costs to adopt rules and to modify the licensure process if the rules are different than the current process.

OMHAS waivers

The bill permits, beginning on July 1, 2017, the OMHAS Director to issue to an alcohol, drug addiction, and mental health services board (ADAMHS board) a time-limited waiver of the requirement that the board's continuum of care include all of the specified essential elements if the Director determines that the board has made reasonable efforts to include in the continuum the elements being waived. The bill also permits, beginning July 1, 2017, the OMHAS Director to issue to an ADAMHS board a waiver of a requirement that addiction services and recovery supports for opioid and co-occurring drug addiction include ambulatory detoxification and medication-assisted treatment if the Director makes certain determinations. As a result, OMHAS could experience an increase in administrative costs to establish the waiver process and to review waiver requests. However, if a waiver is granted, an ADAMHS board would not be penalized for not providing an essential element as they would have been starting July 1, 2017.

Withholding of ADAMHS board funds

The bill requires OMHAS, beginning on July 1, 2017, to withhold in whole or in part an ADAMHS board's allocated funds if the board's use of state and federal funds fails to comply with the board's approved budget. Current law requires, beginning on July 1, 2017, OMHAS to withhold all of a board's allocated funds in this scenario.

Other OMHAS changes

The bill makes several changes to behavioral health statutes. These include, among others: (1) adding recovery supports to many provisions of law regarding addiction services and mental health services, (2) requiring ADAMHS boards to make recovery supports available, (3) requiring OMHAS to perform the same types of administrative functions for recovery supports that OMHAS performs for addiction services and mental health services, (4) revising and providing for the consistent use of

terminology, (5) requiring addiction services providers to submit reports about the waiting lists for addiction services and recovery supports to OMHAS instead of ADAMHS boards and revising the contents of the reports, (6) requiring the compilation of statistics regarding gambling addiction, and (7) provisions regarding class two residential facilities. According to OMHAS, all of these changes either clarify existing practice or codify existing practice or modify law that has not yet taken effect in a few instances. Thus, these provisions should have no fiscal effect.

The bill requires that OMHAS conduct an analysis of unmet needs for methadone treatment in Ohio and the impact of the abovementioned changes on the overall treatment capacity in Ohio within two years of the bill's effective date. OMHAS must also complete a report of its finding within 180 days after beginning the analysis and must publish a copy of the report on its website. There would be a cost to OMHAS to conduct the analysis and to complete the report.

The bill permits a community addiction services provider providing services for a drug court in the Medication-Assisted Treatment Drug Court Program for Specialized Docket Programs to provide access to time-limited recovery supports.

State Medical Board

The bill requires the State Medical Board, by an affirmative vote of at least six of its members, to limit, revoke, or suspend an individual's certificate to practice; refuse to issue a certificate to an individual, refuse to renew a certificate; refuse to reinstate a certificate; or reprimand or place on probation the holder of a certificate if the certificate holder is found by the Board to practice at or own a facility, clinic, or other location that is subject to licensure as a category III terminal distributor of dangerous drugs with an office-based opioid treatment classification unless the person operating that place has obtained and maintains the license with the classification. The Board may experience an increase in costs to take disciplinary action. Any increase will depend on the number of disciplinary actions taken. However, certain disciplinary actions could result in some fine revenues being collected.

Naloxone exemption

Under the bill, an individual who is an employee, volunteer, or contractor of a public or private entity that provides services to individuals who may be at risk of an opioid-related overdose[3] and has been authorized to administer naloxone to a person who is apparently experiencing such an overdose is exempt from civil damages, criminal prosecution, or disciplinary action based on the administration of naloxone.

[3] Such entities include colleges, universities, schools, local health departments, addiction treatment facilities, courts, probation departments, halfway houses, prisons, jails, community residential centers, homeless shelters, or similar locations.

Civil immunity for naloxone use by peace officers

Under current law, a peace officer who obtains naloxone from his or her law enforcement agency and administers it in good faith to someone who is apparently experiencing an opioid-related drug overdose is not subject to administrative action or criminal prosecution. Current law also provides immunity from civil damages for the administration of emergency care in an emergency situation.[4] The bill adds immunity from civil liability for any injury, death, or loss to person or property that allegedly arises from an officer's acts or omissions in obtaining and administering the naloxone.

This change makes it even less likely that a person will file a civil action against a peace officer related to the administration of naloxone, or if an action is filed, for that person to prevail. There will be no discernible fiscal effect on the courts with jurisdiction over such matters, most likely courts of common pleas, as cases of this nature are relatively infrequent.

Naloxone protocol

The bill specifies that a board of health, through a physician serving as the board's health commissioner or medical director, may establish a protocol for personally furnishing naloxone. The bill specifies what must be included in the protocol. Additionally, the bill specifies that a board that establishes a naloxone distribution protocol may, through a physician serving as the board's health commissioner or medical director, authorize one or more individuals to personally furnish a supply of naloxone pursuant to the protocol to certain individuals. The bill also specifies that an authorized individual may personally furnish naloxone to an individual as long as certain conditions are met, including completion of training required under the established naloxone distribution protocol.

Additionally, the bill specifies that a board of health that has established a naloxone administration protocol may authorize an individual who is an employee, volunteer, or contractor of a service entity to administer naloxone to an individual who is apparently experiencing an opioid-related overdose. These individuals may administer naloxone if certain conditions are met.

The bill also permits a physician who has established a naloxone administration protocol to authorize an individual who is an employee, volunteer, or contractor of a service entity to administer naloxone to an individual who is apparently experiencing an opioid-related overdose if certain conditions are met.

The bill specifies that a board of health is not liable for damages in any civil action for any act or omission of the individual to whom the naloxone is furnished. The bill also specifies certain individuals under the bill are not liable for or subject to damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action related to the administration of naloxone.

[4] R.C. 2305.23.

A local board of health could experience an increase in administrative costs to establish a naloxone distribution or administration protocol and to authorize individuals to furnish or administer naloxone. However, the provision is permissive, so any costs would be due to a board's decision to establish such a protocol.

County boards of health – grant funds

In Am. Sub. H.B. 64 of the 131st General Assembly, up to $500,000 of GRF line item 336504, Community Innovations, is to be allocated by the Ohio Department of Mental Health and Addiction Services in each of FYs 2016 and 2017 to enhance naloxone access across the state for county health departments to disburse through a grant program to local law enforcement, emergency personnel, and first responders. The bill permits the county health department to use grant funding to provide naloxone through a Project DAWN Program within the county if these entities are not making use of the naloxone grant.

Prior authorization requirement for certain opioids

The bill requires certain health insurers, including public employee benefit plans, and the Medicaid Program to apply prior authorization requirements or utilization review measures as conditions of providing coverage of opioid analgesics. When implementing the required prior authorization or utilization review, the bill requires the health insurer or the Medicaid Program to consider all of the following: (1) if the course of treatment with the drug continues for more than 90 days, the current law requirements regarding physician management of chronic pain, and (2) if the morphine equivalent daily dose for the drug exceeds 80 milligrams or the individual is being treated with a benzodiazepine at the same time the opioid analgesic is prescribed, the current opioid prescribing guidelines established by the Governor's Cabinet Opiate Action Team. The bill specifies when prior authorization requirements or utilization review measures are not required.

As a result, there could be a decrease in Medicaid prescription drug costs if the prior authorizations result in fewer prescriptions of opioid analgesics filled. There could also be an increase in administrative costs to the Ohio Department of Medicaid to process additional prior authorizations received.

Because the requirement applies to public employee benefit plans, it applies to self-insured government-sponsored health plans, like the plan for state employees. Thus, the bill's requirement to do so could reduce the state's costs of providing health benefits to employees and their dependents. Similarly, any local government-sponsored health plan that does not currently employ prior authorization or utilization review measures for opioid analgesic drug products may experience a decrease in costs of providing health benefits to employees and their dependents.

Synopsis of Fiscal Effect Changes

The substantive differences in the fiscal effects between the substitute bill (LSC 131 2372-4) and the previous version (As Passed by the Senate) are described below.

Prior authorization requirement for certain opioids

The substitute bill requires certain health insurers, including public employee benefit plans, and the Medicaid Program to apply prior authorization requirements or utilization review measures as conditions of providing coverage of opioid analgesics except in certain circumstances. This provision was not included in the As Passed by the Senate version of the bill. As a result, there could be a decrease in Medicaid prescription drug costs if the prior authorizations result in fewer prescriptions of opioid analgesics filled. There could also be an increase in administrative costs to the Ohio Department of Medicaid to process additional prior authorizations received. Additionally, because the requirement applies to public employee benefit plans, it applies to self-insured government-sponsored health plans, like the plan for state employees. Thus, the bill's requirement to do so could reduce the state's costs of providing health benefits to employees and their dependents. Similarly, any local government-sponsored health plan that does not currently employ prior authorization or utilization review measures for opioid analgesic drug products may experience a decrease in costs of providing health benefits to employees and their dependents.

OMHAS waivers

The substitute bill permits, beginning on July 1, 2017, the OMHAS Director to issue to an ADAMHS board a time-limited waiver of the requirement that the board's continuum of care include all of the specified essential elements if the Director determines that the board has made reasonable efforts to include in the continuum the elements being waived. The substitute bill also permits, beginning July 1, 2017, the OMHAS Director to issue to an ADAMHS board a waiver of a requirement that addiction services and recovery supports for opioid and co-occurring drug addiction include ambulatory detoxification and medication-assisted treatment if the Director makes certain determinations. These provisions were not in the As Passed by the Senate version of the bill. As a result, OMHAS could experience an increase in administrative costs to establish the waiver process and to review waiver requests. However, if a waiver is granted, an ADAMHS board would not be penalized for not providing an essential element as they would have been starting July 1, 2017.

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The substitute bill requires OMHAS, beginning on July 1, 2017, to withhold in whole or in part an ADAMHS board's allocated funds if the board's use of state and federal funds fails to comply with the board's approved budget. Current law requires, beginning on July 1, 2017, OMHAS to withhold all of a board's allocated funds in this scenario. This provision was not in the As Passed by the Senate version of the bill.