OHIO LEGISLATIVE SERVICE COMMISSION

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Office of Research and Drafting

Legislative Budget Office

H.B. 12
(I_136_0239-4)
136th General Assembly

Fiscal Note & Local Impact Statement

Click here for H.B. 12's Bill Analysis

Version: In House Health

Primary Sponsors: Reps. Gross and Swearingen

Local Impact Statement Procedure Required: No

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Highlights

- Government-owned hospitals could experience an increase in costs to identify drugs brought into the hospital in accordance with the bill's provisions and possibly to update any hospital policies.
- Occupational licensing boards could realize some savings related to disciplinary actions if fewer cases are investigated as a result of the bill's provisions.

Detailed Analysis

Off-label drug dispensing

The bill requires a pharmacist to dispense a drug prescribed by a physician, including for off-label use, and a hospital, inpatient or outpatient facility, or pharmacy to allow its dispensing. The bill provides an exception (1) if a pharmacist, hospital, inpatient or outpatient facility, or pharmacy has a moral, ethical, or religious belief or conviction that conflicts with the drug's dispensing, and (2) if the pharmacist has documented that the patient has a history of a life-threatening allergic reaction to the drug, there is a life-threatening contraindication or drug interaction for that patient, or the drug has a high probability of causing serious disability or serious injury to that patient. It is possible that government-owned hospitals may have some administrative costs to make any necessary updates to hospital procedures.

Hospitals and inpatient facilities

In the case of a hospital or inpatient facility pharmacist and where an in-house physician issues a prescription for a drug, including for off-label use, that is neither in stock nor listed on the hospital's or facility's formulary, and the patient can obtain the drug at an outpatient pharmacy, then the hospital or facility must permit the drug to be brought in to be identified. If

it is able to be identified according to the hospital or facility's drug identification procedure, the off-label drug will be administered to the patient. If there is no in-house physician willing to prescribe a drug, the hospital or inpatient facility must not obstruct or intentionally delay the transfer of that patient to another hospital, facility, or hospice that is willing to accept and treat the patient. Similarly, the hospital or facility must not prevent the patient's discharge, if that is the patient's or representative's wish. When there is a safety concern regarding a prescription for a drug, including a drug for off-label use, a pharmacist should discuss any prescription dosage recommendations or other clinical concerns with the physician, the patient, or the patient's personal representative, including risk-benefit discussions. Government-owned hospitals may experience an increase in costs to identify such drugs in these instances. Costs will depend on how many instances this occurs under the circumstances of the bill and the difficulty in identifying each drug.

Immunity

Additionally, the bill provides immunity from professional discipline, criminal liability, civil liability and damages, or other licensing or regulatory sanctions for a pharmacist, hospital, inpatient or outpatient facility, or pharmacy for any harm that may arise from the dispensing or administration of a drug, starting from the date it was prescribed, if there is an objective, good faith, and scientific objection to the administration or dosage of the drug, if the physician was informed of the objection, if the objection to the named drug is documented in the patient's medical record, and if the objection is documented within 24 hours of dispensing the drug. This may reduce the number of cases being brought forward in local courts or being brought before the Ohio Department of Health (ODH) or occupational licensing boards.

Prohibitions

The bill also prohibits the following from considering the action of prescribing, dispensing, or administering a drug for off-label use taken by a physician, pharmacist, hospital, or inpatient or outpatient facility under the bill to be unlawful, unethical, unauthorized, or unprofessional conduct: a health-related licensing board, ODH, or another state agency responsible for the licensure or regulation of health care professionals or health care facilities. It further prohibits such an entity from pursuing professional discipline, fines, or other regulatory sanctions, except in cases where prescribing, dispensing, or administering the drug to that patient was not done in accordance with the minimal standard of care. The State Medical Board is prohibited from determining that the prescribing, dispensing, or administering of a drug for off-label use is considered below the minimal standard of care because it is being used to treat a particular condition that is not commonly treated with that drug. The bill also prohibits regulatory entities from pursuing, or threatening to pursue, such actions for (1) publicly expressing an opinion regarding the safety, risks, benefits, or efficacy of a drug or other medical intervention that does not align with the opinions of a board, ODH, another state agency, a local board of health, or other health authority, or (2) informing a patient of safety concerns or risks that may be associated with a drug or other medical intervention. ODH and occupational licensing boards, including the State Medical Board, Ohio Board of Nursing, State Dental Board, State Vision Professionals Board, and the State Board of Pharmacy, could realize some savings related to disciplinary actions if less cases are investigated as a result of the bill's provisions.

Synopsis of Fiscal Effect Changes

The substitute bill, l_136_0239-4, makes changes to the bill's immunity provisions by also including immunity from criminal liability and damages, which could reduce the number of cases and related costs to local courts compared to the previous substitute bill (l_136_0239-2).

The substitute bill applies the prohibition against professional discipline and regulatory sanctions only to the prescribing, dispensing, or administering of a drug for off-label use. The previous substitute bill applied the prohibition against discipline and sanctions to the prescribing, dispensing, or administering of a drug to a consenting patient. This modification would allow regulatory entities to investigate and take action regarding other cases, other than those involving drugs for off-label use, compared to the previous substitute bill.

The substitute bill also modifies an exception to a provision prohibiting regulatory entities from professional discipline, fines, or other regulatory sanctions. The substitute bill (1) makes an exception in cases where prescribing, dispensing, or administering the drug to a patient was not done in accordance with the minimal standard of care, and (2) prohibits the State Medical Board from determining that the prescribing, dispensing, or administering of a drug for off-label use is considered below the minimal standard of care because it is being used to treat a particular condition that is not commonly treated with that drug. The previous substitute bill instead provided an exception in cases where a court has determined that prescribing, dispensing, or administering the drug was done with recklessness or gross negligence. This modification would allow these actions to occur in cases that have not been adjudicated in court. This could reduce court costs, but enable licensing entities to review more cases.

The substitute bill also makes various other changes regarding decision making, compliance with existing law, and professional discipline which should not have a noticeable fiscal impact.

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