OHIO LEGISLATIVE SERVICE COMMISSION

www.lsc.ohio.gov

Office of Research and Drafting

Legislative Budget Office

H.B. 12
(I_136_0239-2)
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

Jacquelyn Schroeder, Senior Budget Analyst

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, civil liability, or other 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 objection was discussed and 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 any action 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 a court has determined that prescribing, dispensing, or administering the drug to that patient was done with recklessness or gross negligence. The bill also prohibits these 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_0239-2, removes a provision which authorizes the prescription of any drug, including a drug for off-label use, with the informed consent of the patient or the patient's representative. The substitute bill also addresses prescribing only by physicians, whereas the As Introduced version of the bill also addressed prescribing by dentists, advanced practice registered nurses, optometrists, physician assistants, and certified mental health

assistants. Any fiscal impacts related to prescribing off-label may be minimized due to these removed provisions; however, prescribing off-label is generally already permitted.

The substitute bill also removes provisions that require, when an in-house prescriber issues for a hospital or inpatient facility patient a prescription for a drug, including one for off-label use, that is neither in stock nor listed on the hospital's or facility's formulary, the pharmacist to document in the patient's medical record that a good faith effort was made to find out if the drug is available from another hospital, facility, or United States distributor. Additionally, the substitute bill removes a provision specifying that, if available, but a drug is not covered by a patient's health benefit plan, or the patient does not want to wait for prior authorization, then the patient must be notified of estimated out-of-pocket costs and offered the drug. The substitute bill also removes a provision that allowed a hospital or inpatient facility to require payment before ordering the drug. Any related costs, including costs to conduct this search by government-owned hospitals, would no longer be realized under the substitute bill.

The substitute bill modifies the provisions regarding outside drugs, in that the patient must obtain the drug at an outpatient pharmacy and also prohibits a patient from bringing in a drug from home, which the As Introduced version of the bill permitted. This could reduce costs for government-owned hospitals if this makes identifying drugs brought in easier.

The substitute bill also makes various changes regarding professional discipline, immunity, and medical opinions, which should not have a significant fiscal impact.

FNHB0012H1-136/zg