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OHIO LEGISLATIVE SERVICE COMMISSION

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Office

H.B. 12
136th General Assembly

Fiscal Note & Local Impact Statement

[Click here for H.B. 12's Bill Analysis](#)

Version: As Introduced

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 search for a drug's availability and to identify drugs brought into the hospital in accordance with the bill's provisions.
- 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 generally authorizes a prescriber to issue for a patient a prescription for any drug, including for off-label use, if the prescriber has obtained the patient's informed consent or the consent of the patient's personal representative. The bill also requires a pharmacist to dispense a drug, including for off-label use, and the hospital, inpatient facility, or pharmacy to allow its dispensing. The bill provides an exception (1) if a pharmacist, hospital, inpatient 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 or there is a life-threatening contraindication or drug interaction for 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

When an in-house prescriber issues for the 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 must 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. If available, but the 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 to the patient. The hospital or inpatient facility may require payment prior to ordering the drug. A health care provider can generally already prescribe off-label medications, so there should not be any direct impacts to the state or to local health plans. However, if this increases off-label usage, there could be impacts. However, under the bill, drugs ordered would be offered at an upfront cost to the patient. Additionally, government-owned hospitals may experience an increase in costs to search for a drug's availability under the circumstances outlined in the bill.

If the hospital or inpatient facility pharmacist is unable to obtain the drug from another hospital, facility, or United States distributor or if the hospital, facility, or pharmacist declines to fill the prescription for a moral, ethical, or religious belief or conviction and the patient has access to the drug through an outside pharmacy or has the drug available at home, the bill provides for both of the following: (1) the hospital or facility must permit the drug to be brought in to be identified, and 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, and (2) when the patient's in-house prescriber or other medical staff are unwilling to administer the drug to the patient for a moral, ethical, or religious belief or conviction, the bill authorizes a prescriber's delegate to administer the drug. Additionally, if there is no in-house prescriber 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. 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 facility, or pharmacy for any harm that may arise from the patient's use 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, this is explained and discussed with the prescriber, and, this is documented in the patient's medical record. This may reduce the number of cases being brought forward in local courts or being brought before ODH or occupational licensing boards.

Prohibitions

The bill also prohibits the following from considering any action taken by a prescriber, pharmacist, hospital, or inpatient facility under the bill to be unlawful, unethical, unauthorized, or unprofessional conduct: a health-related licensing board, the Ohio Department of Health (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 done with recklessness or gross negligence. The bill also prohibits these entities from infringing on free speech, pursuing, or threatening to pursue, such actions for publicly or privately 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. 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.