OHIO LEGISLATIVE SERVICE COMMISSION

www.lsc.ohio.gov

Office of Research and Drafting

Legislative Budget Office

H.B. 73
135th General Assembly

Fiscal Note & Local Impact Statement

Click here for H.B. 73's Bill Analysis

Version: As Reported by Senate Health

Primary Sponsors: Reps. Gross and Loychik

Local Impact Statement Procedure Required: No

Jacquelyn Schroeder, Senior Budget Analyst

Highlights

- Government-owned hospitals could experience an increase in costs to search for a drug's availability, to grant temporary privileges to out-of-house practitioners, 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 authorizes a prescriber to issue for a human patient a prescription for an off-label drug that is approved for human use, if the prescriber has obtained the patient's informed consent or the consent of the person holding the patient's health care power of attorney. The bill also requires a pharmacist practicing in a hospital or inpatient facility to dispense an off-label drug, and the hospital or inpatient facility to allow its dispensing, during a public health emergency or period in which a local or state public health order or rule remains in effect. The bill provides an exception (1) if a pharmacist, hospital, or inpatient facility has a moral, ethical, or religious belief or conviction that conflicts with the off-label drug's dispensing, (2) if the pharmacist has documented that the patient has a history of a life-threatening allergic reaction to the off-label drug or there is a life-threatening contraindication or drug interaction, and (3) if the pharmacist, hospital, or inpatient facility has an objective, good faith, and scientific objection to the administration or dosage of the off-label drug for that patient or that patient's condition. It is possible that government-owned hospitals may have some administrative costs to make any necessary updates to hospital procedures.

Prohibited off-label drugs

However, the bill specifies that no person can prescribe, dispense, or administer an off-label drug if the person knows that the drug is (1) a controlled substance that is not intended for a medical purpose, (2) a drug that is subject to a federal Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategy (REMS), (3) a cross-sex hormone or puberty blocking drug to be used in violation of section 3129.02 of the Revised Code, or (4) a drug to be used for euthanasia. However, the bill does not specify a penalty for violating these provisions.

Hospitals and inpatient facilities

When an in-house prescriber issues for the hospital or inpatient facility patient a prescription for an off-label drug 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 or inpatient facility or another United States distributor. If available, but the off-label drug is not authorized under insurance, or the patient does not want to wait for 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 an off-label 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 hospital or inpatient facility or the patient's in-house treating prescriber or other in-house treating clinician is unwilling to administer the drug to the patient for a moral, ethical, or religious belief or conviction, the bill authorizes another prescriber or prescriber's delegate to administer the drug. 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.

Temporary privileges

When a patient's condition is so serious that the patient cannot be safely transported out of a hospital and the patient, minor patient's parent/guardian, or person holding the patient's health care power of attorney wishes to try an off-label drug to treat the patient's condition, but there is no in-house prescriber willing to prescribe the drug, the bill: (1) allows the patient's outpatient Ohio-licensed physician prescriber, after a prompt consultation with the patient's hospital care team and a review of all of the patient's drugs, to immediately begin applying for temporary privileges, based on criteria within the hospital medical staff bylaws, to treat that patient only, and (2) immediately allows the outpatient physician prescriber who meets the

bylaw requirements to participate in the patient's care in the narrowed scope of practice regarding the administering and monitoring of the prescribed off-label within the hospital until the patient is in a condition where the patient can be safely transported to a hospital or inpatient facility that is willing to provide that off-label drug, or discharge home, or within the maximum number of days temporary privileges are allowed within the hospital's bylaws, whichever comes first. The bill specifies that in such a case, if the off-label drug is not covered by insurance, or the patient does not want to wait for authorization, then the patient is required to be offered the option to pay out-of-pocket for the prescribed off-label drug before it is ordered, and be notified of estimated costs prior to ordering. The outpatient physician with temporary privileges must make a good faith effort to maintain ongoing consultation with the patient's care team while those privileges are in effect. Government-owned hospitals would experience an increase in costs to grant temporary privileges. The costs will depend on the frequency of this occurring under the circumstances of the bill.

Additionally, the bill provides immunity from administrative and civil liability for the in-house pharmacist, hospital, or inpatient facility and the in-house physician or other licensed health care professionals responsible for the patient's care for any harm that may arise from the patient's use of the off-label drug prescribed by the outpatient physician prescriber. 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: (1) a licensing board or ODH from pursuing an administrative or disciplinary action against a prescriber, pharmacist, or other licensed health care professional, hospital, or inpatient facility regarding the bill's off-label drug provisions, (2) a licensing board or ODH from infringing on medical free speech, a threat to pursue, or pursue administrative or disciplinary action against a prescriber, pharmacist, or other licensed health care professional or hospital or inpatient facility for expressing a medical opinion about off-label prescribing that does not align with those of the licensing board, a local board of health, ODH, or other health authority, (3) a political subdivision, public official, or state agency from enforcing or using any state funding to implement or incentivize any health policy guideline, mandate, recommendation, or rule issued by the World Health Organization (WHO), including the prohibition of issuing a prescription for or dispensing of an off-label drug, and (4) a hospital or inpatient facility patient from being denied sufficient means of nutrition or fluids unless that wish is clearly stated in the patient's end of life health directive, or the denial is necessary for a medical procedure. 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.