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H.B. 73
(I_135_0502-6)
135th General Assembly

Fiscal Note & Local Impact Statement

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

Version: In Senate Health

Primary Sponsors: Reps. Gross and Loychik

Local Impact Statement Procedure Required: No

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Highlights

- Occupational licensing boards could realize some savings related to disciplinary actions if less cases are investigated as a result of the bill's provisions.
- Government-owned hospitals will 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.
- The Ohio Department of Health (ODH) could experience an increase in costs to receive and review outpatient physician prescriber complaints permitted under the bill. Any costs will depend on the number of complaints received.

Detailed Analysis

Off-label drug dispensing

The bill authorizes a prescriber to prescribe any drug, including an off-label drug, and generally requires a pharmacist to dispense, and a hospital or inpatient facility to allow the dispensing of, the drug, including when a patient has not had a positive screen or test result for or exposed to a particular disease, illness, or infection. However, the bill specifies that an off-label drug does not include a controlled substance and, in the case of a drug that is subject to a federal Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategy (REMS), its usage for off-label purposes must be consistent with any requirements or recommendations the REMS establishes. Prior to issuing a prescription for any drug, including an off-label drug, a prescriber must obtain informed consent and provide all of the following information: the patient's diagnosis, if known; the nature and purpose of the recommended drug, treatment, or intervention; the burdens, risks, and expected benefits of all drug, treatment, or intervention options, including the option of forgoing treatment; and any conflicts of interest the physician

may have regarding the recommended drug, treatment, or intervention. The bill specifies that the ultimate decision to accept a drug prescribed is to be made by one of the following who has given informed consent: the patient, patient's parent or guardian, or person holding the patient's health care power of attorney.

The bill provides (1) an exception if a pharmacist, hospital, or inpatient facility has a moral, ethical or religious belief or conviction that conflicts with the drug's dispensing and (2) an exception 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. When an off-label drug must be dispensed and the pharmacist, hospital, or inpatient facility has an objection, the pharmacist or entity is immune from administrative or civil liability for any harm that may arise from the dispensing if the objection is documented in the patient's medical record. The bill also requires a pharmacist to make a good faith effort to find out if the drug is available from another hospital or inpatient facility or another United States distributor. If available, the drug must be offered to the patient at an upfront out-of-pocket cost 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 as required above.

If the hospital or inpatient facility pharmacist is unable to obtain an off-label drug prescribed by an in-house treating prescriber from another hospital, facility, or United States distributor or 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, or determined by the hospital or facility pharmacist as in the original packaging or labeled from an outside retail pharmacy, approved by the prescriber for use, and not outside its beyond use date, for the patient's use and administration within the hospital or facility, if identified, 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 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 or inpatient facility and the patient, 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 physician prescriber, after a prompt consultation with the patient's hospital or inpatient facility care team and a review of all of the patient's drugs, to immediately begin applying for temporary privileges with oversight, based on criteria within the hospital or facility medical bylaws, (2) specifies that the temporary privileges approval process is not to exceed five

days, (3) provides that if the outpatient physician prescriber does not meet the facilities medical staff bylaw requirement and the prescriber feels that temporary privileges were wrongfully denied, the bill permits the prescriber to file a complaint with the Ohio Department of Health (ODH), and (4) 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 or facility until the patient is in a condition where the patient can be safely transported to a hospital or inpatient facility where the outpatient physician prescriber is credentialed. The bill specifies that the patient may be required to pay out-of-pocket for the prescribed off-label drug before it is ordered. When an outpatient physician prescriber files a complaint with ODH, it must include the hospital's or facility's name, its stated reason for denying privileges, and the name of the drug the prescriber was seeking to prescribe. After a complaint is filed, ODH is required to keep a record of the complaint, with its information to be (1) kept on file for seven years and (2) made available to any Ohio citizen within ten days of the citizen's written request. Government-owned hospitals would experience an increase in costs to grant temporary privileges. The costs will depend on the frequency of this occurring. ODH may also incur costs to receive and review outpatient physician prescriber complaints permitted under the bill. Any costs will depend on the number of complaints received. Additionally, the bill provides immunity from administrative and civil liability for the in-house pharmacist, hospital, or inpatient facility and the in-house physician 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.

The bill also prohibits the following: (1) a licensing board or ODH from pursing a disciplinary action against a prescriber, pharmacist, hospital, or inpatient facility regarding the bill's off-label drug provisions, (2) disciplinary action against a prescriber, pharmacist, or other licensed health care professional or hospital or inpatient facility for expressing a medical opinion that does not align with those of the licensing board, a local board of health, or ODH, (3) a political subdivision, public official, or state agency from enforcing or using any state funding to implement any guideline, mandate, recommendation, or rule issued by the World Health Organization (WHO) that prohibits 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.

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