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H.B. 73*
135th General Assembly

Bill Analysis

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Version: As Reported by Senate Health

Primary Sponsors: Reps. Gross and Loychik

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SUMMARY

- Generally authorizes a prescriber to prescribe an off-label drug and generally requires a pharmacist practicing in a hospital or inpatient facility to dispense, and the hospital or inpatient facility to allow the dispensing of, the off-label drug.
- Authorizes, under certain circumstances, the off-label drug to be brought into a hospital or inpatient facility for administration to a patient.
- Establishes a process by which an outpatient Ohio-licensed physician prescriber may obtain temporary hospital privileges to participate in the hospital patient's care in the narrowed scope of practice regarding the administering and monitoring of the prescribed off-label drug.
- Grants the in-house pharmacist, physician, or other licensed health care professional and the hospital or inpatient facility qualified immunity from administrative and civil liability for harm resulting from the use of the off-label drug prescribed by the outpatient physician prescriber.
- Generally prohibits a licensing board from pursuing an administrative or disciplinary action against a licensed health care professional or a hospital or inpatient facility for actions taken under the bill.
- Prohibits an administrative or disciplinary action against a licensed health care professional or a 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, or the Ohio Department of Health.

* This analysis was prepared before the report of the Senate Health Committee appeared in the Senate Journal. Note that the legislative history may be incomplete.

- Generally prohibits the denial of nutrition or fluids to a patient.
- Prohibits a political subdivision, public official, or state agency from enforcing or using any state funding to implement or incentivize any guideline, mandate, recommendations, or rule issued by the World Health Organization, including one that prohibits issuing a prescription for, or dispensing, an off-label drug.
- Names the act the Dave and Angie Patient and Health Provider Protection Act.

DETAILED ANALYSIS

Off-label drugs – prescribing and 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.[1]

The bill also requires a pharmacist practicing in a hospital or inpatient facility to dispense the 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 is in effect, except in the following circumstances:

- The pharmacist, hospital, or inpatient facility has a moral, ethical, or religious belief or conviction that conflicts with the off-label drug's dispensing;
- 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;
- 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.[2]

The bill does not specifically address the dispensing of off-label drugs by pharmacists practicing in other settings.

Prohibited off-label drugs

In certain circumstances, some off-label drugs cannot be prescribed, dispensed, or administered under the bill.[3] It prohibits a person from prescribing, dispensing, or administering an off-label drug if the person knows, or has reasonable cause to know, that the off-label drug is any of the following:

- A controlled substance that is not intended for a medical purpose;

[1] R.C. 3792.06(B).

[2] R.C. 3792.06(C) and R.C. 4743.10, not in the bill.

[3] R.C. 3792.06(G).

- A drug subject to a federal Food and Drug Administration (FDA) risk evaluation and mitigation strategy;
- A cross-sex hormone or puberty-blocking drug to be used in violation of the law regarding gender transition services for minors;[4]
- A drug to be used for euthanasia.

The bill, however, does not specify a penalty for violating these provisions.

Definitions

- A "prescriber" includes a physician, advanced practice registered nurse, physician assistant, optometrist, or dentist.[5]
- An "off-label drug" means a drug that is both of the following: (1) approved by the FDA to treat or prevent a disease, illness, or infection, but prescribed for or used to treat or prevent another disease, illness, or infection and (2) legal for use in Ohio.[6]
- A "hospital" includes one owned or operated by the U.S. Department of Veterans Affairs, while an "inpatient facility" means a freestanding inpatient rehabilitation facility licensed by the Ohio Department of Health (ODH) or a skilled nursing facility.[7]
- "Gross negligence" is defined under the bill to mean intentional failure to perform an apparent duty in reckless disregard of the consequences concerning the life or property of another.[8]

Authority to prescribe off-label

In general, once the FDA approves a drug for a specific indication, it may be prescribed by a health care provider for any indication, absent state law to the contrary, if the provider judges it medically appropriate. This is often referred to as "off-label" use.[9] The bill codifies that authority.

Pharmacist discussion

The bill specifies that its provisions do not prevent the pharmacist from discussing a prescription with the prescriber who issued it.[10]

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[4] R.C. 3129.01 and 3129.02, not in the bill.

[5] R.C. 4729.01, not in the bill.

[6] R.C. 3792.06(A).

[7] R.C. 3792.06(A).

[8] R.C. 3792.06(A).

[9] U.S. Food and Drug Administration, Understanding Unapproved Use of Approved Drugs "Off Label" (February 5, 2018), which is also available by conducting a keyword "off label" search on the FDA's website: fda.gov.

[10] R.C. 3792.06(C).

Decision to accept an off-label drug

The bill states that the ultimate decision to accept an off-label drug prescribed by the prescriber must be made by any of the following who has given informed consent – the patient, minor patient's parent or guardian, or person holding the patient's health care power of attorney.[11]

Hospitals and inpatient facilities

Most of the bill's provisions relate to the prescribing, dispensing, or use of an off-label drug in a hospital or inpatient facility only, including those that address when the off-label drug is not in stock or the hospital, facility, in-house pharmacist, or treating prescriber has a conflicting moral, ethical, or religious belief or conviction about its being prescribed, dispensed, or used.[12]

Good faith effort to locate off-label drug

Under the bill, where an in-house treating prescriber issues for a hospital or inpatient facility patient a prescription for an off-label drug and the drug is neither in stock nor listed on the hospital's or facility's formulary, the hospital or facility 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 another United States distributor.[13]

Out-of-pocket costs – in-house off-label prescribing

If the off-label drug is available from another hospital, facility, or U.S. distributor, but the off-label drug is not authorized under insurance or the patient does not want to wait for its authorization, the bill requires the patient to be notified of estimated out-of-pocket costs and the drug to be offered to the patient at an upfront, out-of-pocket cost to the patient. Under the bill, the hospital or inpatient facility may require payment prior to ordering the off-label drug.[14]

Access to and administration of off-label drugs

If (1) the hospital or inpatient facility pharmacist is unable to obtain the off-label drug prescribed by an in-house treating prescriber from another hospital, facility, or distributor or (2) the hospital or facility or its pharmacist declines to fill the prescription for a moral, ethical, or religious belief or conviction, and (3) the patient has access to the off-label drug through a pharmacy outside the hospital or facility or has the off-label drug available at home, the bill provides for both of the following:

- The hospital or facility must permit the off-label drug to be brought in to be "identified," or determined by the hospital or facility pharmacist as in its original packaging or labeled

[11] R.C. 3792.06(C).

[12] R.C. 3792.06(C).

[13] R.C. 3792.06(C).

[14] R.C. 3792.06(C).

from an outside retail pharmacy, approved by the prescriber for use, and not outside its beyond use date,[15] for the patient's use and administration within the hospital or facility;

- 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 off-label drug to the patient for a moral, ethical, or religious belief or conviction, another prescriber or prescriber's delegate may administer the drug.[16]

Temporary privileges – hospitals only

When a patient's condition is so serious that the patient cannot be safely transported out of the hospital and the patient 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, all of the following apply under the bill:

- 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, must be allowed to immediately begin applying for temporary privileges, based on criteria within the hospital medical staff bylaws used to determine the issuance of temporary privileges to treat that patient only;
- The hospital bylaws must not be more restrictive for outpatient physicians than for other physicians seeking temporary privileges;
- The physician applicant is not prevented by the bill from withdrawing the application during the process and the hospital is not prevented by the bill from revoking temporary privileges if at any point the physician's license is found not to be in good standing;
- If the outpatient physician prescriber meets the bylaw requirements for temporary privileges, the outpatient physician prescriber must immediately be allowed to participate in the patient's care in the narrowed scope of practice regarding the administering and monitoring of the prescribed off-label drug 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.[17]

  In such a case, both of the following provisions apply:

- The hospital or facility must permit the off-label drug to be brought in to be identified, as described above in "**Access to and administration of off-label drugs**";
- 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 off-label drug to the patient

[15] R.C. 3792.06(A).

[16] R.C. 3792.06(C).

[17] R.C. 3792.06(C).

for a moral, ethical, or religious belief or conviction, another prescriber or prescriber's delegate may administer the off-label drug.[18]

Outpatient physician – patient care team

The bill requires an outpatient physician with temporary privileges to make a good faith effort to maintain ongoing consultation with the patient's care team during the duration that the privileges are in effect.

And in a case where there is a disagreement between the care team and the outpatient physician on the continued use of the off-label drug, the decision to continue the use of the off-label drug prescribed by the outpatient physician must be made by the patient, minor patient's parent or guardian, or person holding the patient's health care power of attorney. The bill provides that this decision is to be made after (1) having a discussion with the outpatient physician and hospital care team on the risks and benefits of continuing the off-label drug and (2) giving informed consent.

Out-of-pocket costs – outpatient off-label prescribing

If the off-label drug prescribed by the outpatient physician with temporary privileges is not authorized under the patient's insurance or the patient does not want to wait for its authorization, the bill requires the patient to be offered the option to pay out-of-pocket, upfront before it is ordered. It also requires the patient to be notified of estimated out-of-pocket costs prior to ordering.[19]

Immunity

The bill grants the in-house pharmacist, hospital, or inpatient facility and the in-house physicians or other licensed health care professionals responsible for the patient's care immunity from administrative and civil liability for any harm that may arise from the patient's use of the off-label drug prescribed by an outpatient physician prescriber starting from the date of dispensing.[20] The bill neither defines nor describes administrative liability.

Disciplinary actions

The bill prohibits the following from considering any action taken by a prescriber, pharmacist, other licensed health care professional, hospital, or inpatient facility under the bill to be unlawful, unethical, unauthorized, or unprofessional conduct: the State Medical Board, Ohio Board of Nursing, State Dental Board, State Vision Professionals Board, State Board of Pharmacy, and ODH.[21] It further prohibits such an entity from pursuing an administrative or disciplinary action against the prescriber, pharmacist, health care professional, hospital, or inpatient facility, except in cases of recklessness or gross negligence.[22]

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[18] R.C. 3792.06(C).

[19] R.C. 3792.06(C).

[20] R.C. 3792.06(C).

[21] R.C. 3792.06(D).

[22] R.C. 3792.06(D).

Medical opinions

The bill prohibits a board that licenses or regulates a health care professional or ODH from infringing on medical free speech or from threatening to pursue, or pursuing, an administrative or disciplinary action against a prescriber, pharmacist, or other licensed health professional or a hospital or inpatient facility for publicly or privately expressing a medical opinion about off-label prescribing that does not align with the opinions of the board, a local board of health, or ODH.[23]

Denial of fluids or nutrition

The bill prohibits a hospital or inpatient facility patient from being denied sufficient means of fluids or nutrition, unless (1) that wish is clearly stated in the patient's end of life health directive, as that directive is defined by the patient or patient's health care power of attorney or (2) the denial is necessary for a medical procedure, including a diagnostic or surgical procedure. The denial must be for the shortest amount of time medically possible and with the informed consent of the patient or person holding the patient's health care power of attorney.[24]

Enforcement of World Health Organization guidelines or rules

The bill prohibits 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, including one that prohibits issuing a prescription for or dispensing an off-label drug.[25]

Severability

If any portion of the bill is determined by a court to be illegal or unconstitutional, the bill specifies that its remaining portions must remain in effect.[26]

HISTORY

Action	Date
Introduced	02-27-23
Reported, H. Health Provider Services	06-21-23
Passed House (75-17)	06-21-23
Reported, S. Health	---

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[23] R.C. 3792.06(D).

[24] R.C. 3792.06(F).

[25] R.C. 3792.06(E).

[26] R.C. 3792.06(H).