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Bill Analysis

Version: As Introduced

Primary Sponsors: Reps. Cutrona and Reynolds

Emma Carroll, Research Analyst

SUMMARY

- Generally requires a pharmacist to dispense any drug, including a drug for off-label use, prescribed by a physician.
- Authorizes, under certain circumstances, a drug, including one for off-label use, to be brought into a hospital or inpatient facility for administration to a patient.
- Prohibits a health-related licensing board, the Department of Health, or another state agency from pursuing professional discipline, fines, or other regulatory sanctions against a physician, pharmacist, hospital, inpatient facility, outpatient health care facility, or pharmacy for actions taken under the bill.
- Prohibits professional discipline, fines, or regulatory sanctions, or a threat thereof against a licensed health care professional for expressing an opinion about a drug or other medical intervention that does not align with that of a health-related licensing board, the Department of Health, another state agency, a local board of health, or other health authority.
- Names the act the Jeff, Dave, and Angie Patient Right to Try Act.

DETAILED ANALYSIS

Off-label use

Current Ohio law grants a prescriber the authority to prescribe drugs, with certain limitations or conditions.[1] Once the federal Food and Drug Administration (FDA) approves a drug

[1] *See e.g.*, R.C. 4715.01, 4723.481, and 4730.41.

for a specific indication, it may be prescribed for any indication, absent state law to the contrary, if the prescriber judges it medically appropriate. This is often referred to as off-label use.[2]

The bill defines ***off-label use*** as the use of a drug that meets both of the following conditions: (1) the drug is approved by the FDA to treat or prevent a disease, illness, or infection, but is prescribed for, or used to treat or prevent, another disease, illness, or infection and (2) the drug is legal for use in Ohio.[3]

Duty to dispense drugs

The bill requires a pharmacist to dispense a drug prescribed by a physician in accordance with the bill, including for off-label use, and requires a hospital, inpatient facility, outpatient health care facility, or pharmacy to allow the drug to be dispensed, except in either of the following circumstances:

- The pharmacist, hospital, facility, or pharmacy has a moral, ethical, or religious belief or conviction that conflicts with the drug's dispensing;
- 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 life-threatening drug-interaction for that patient, or that the drug has a high probability of causing serious disability or serious injury to that patient.[4]

The bill states that the dispensing requirement does not prevent compliance with existing federal laws or state pharmacy laws, but it establishes that the final decision on whether a prescribed drug is dispensed must be made by the physician.[5]

Drugs not subject to the bill

The bill specifies that it does not apply to, repeal, or supersede existing law regarding prescribing, dispensing, or administering a drug that is any of the following:[6]

- A controlled substance, including an opioid;
- A drug subject to an FDA risk evaluation and mitigation strategy;
- A cross-sex hormone or puberty-blocking drug to be used in violation of statutory law regarding gender transition services for minors;[7]

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[2] 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.

[3] R.C. 3792.08(A).

[4] R.C. 3792.08(B)(1) and 4743.10, not in the bill.

[5] R.C. 3792.08(B)(3).

[6] R.C. 3792.08(F).

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

- An abortifacient, when prescribed, dispensed, or administered to a patient believed to be pregnant;
- A drug known to be used for the intent or purpose of euthanasia.

Safety concern discussions

The bill specifies that a pharmacist should discuss any prescription dosage recommendations or other clinical concerns with the physician, patient, or patient's personal representative when there are safety concerns regarding a prescription. There should be risk-benefit discussions between the physician, the patient or the patient's personal representative, and other inpatient and outpatient medical staff directly involved in the patient's care.[8]

Decision to accept or continue a drug

The bill states that, outside of emergency situations, the ultimate decision to accept a prescribed drug should be made by the consenting patient or the patient's personal representative.[9]

Hospitals and inpatient facilities

Some of the bill's provisions relate to the prescribing, dispensing, or use of a drug in a hospital or inpatient facility, including those that address when the drug is not in stock or the hospital, facility, in-house pharmacist, or the in-house physician has a conflicting moral, ethical, or religious belief or conviction about it being prescribed, dispensed, or used.[10]

For purposes of the bill, 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 Department of Health (ODH) or a skilled nursing facility. An ***in-house physician*** is a physician who is employed or contracted by the hospital or inpatient facility where a patient is being treated or who has hospital privileges at the hospital where a patient is being treated.[11]

Access to and administration of drugs

In the case of a pharmacist who practices within a hospital or inpatient facility's pharmacy where an in-house physician prescribes a drug that is neither in stock nor listed on the hospital or facility's formulary, and the patient has access to the drug through a pharmacy outside the hospital or facility, the hospital or facility must permit the drug to be brought in to be ***identified***, or determined by the hospital or facility pharmacist to be prescribed for the patient, in its original packaging or labeled from an outside retail pharmacy for the patient, approved by the physician

[8] R.C. 3792.08(B)(6).

[9] R.C. 3792.08(B)(6).

[10] R.C. 3792.08(B).

[11] R.C. 3792.08(A).

for the patient's use, and not outside its beyond-use or expiration date. Once identified, it must be administered to the patient in the hospital or facility.[12]

Right to try

When there is no in-house physician willing to prescribe a drug that a patient or patient's personal representative wishes to try to treat the patient's condition, 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.[13]

Out-of-pocket payments

With respect to an outpatient pharmacy setting, if a drug prescribed under the bill is not covered by a patient's health benefit plan or the patient does not want to wait for prior authorization, the physician or pharmacist must notify the patient of the option to pay for the drug out-of-pocket, as well as the estimated out-of-pocket costs for the drug. The pharmacist also must offer the drug to the patient at an upfront, out-of-pocket cost.[14]

Immunity

The bill specifies that it does not provide a physician immunity from civil liability.[15]

Additionally, when the bill requires that a drug be dispensed or that dispensing be allowed, a pharmacist, hospital, inpatient facility, outpatient health care facility, or pharmacy subject to that requirement is immune from civil liability, professional discipline, and sanctions or fines imposed by a regulatory authority for any harm that may arise from the dispensing or administration of the drug, starting from the date it was dispensed, if all of the following conditions are met:

- The pharmacist, hospital, facility, or pharmacy has an objective, good faith, and scientific objection to the administration or dosage of the drug for that patient or that patient's condition;
- The pharmacist, hospital, facility, or pharmacy explains and discusses the objection with the physician; and
- Within 24 hours after dispensing the drug, the pharmacist, hospital, facility, or pharmacy documents the objection in the patient's medical record, including the date of the discussion with the physician, although the discussion does not have to be described in detail.[16]

[12] R.C. 3792.08(B)(4).

[13] R.C. 3792.08(B)(5).

[14] R.C. 3792.08(C).

[15] R.C. 3792.08(D).

[16] R.C. 3792.08(B)(2).

Except as described above, the bill states that it does not provide a pharmacist, hospital, inpatient facility, outpatient health care facility, or pharmacy immunity from civil liability.[17]

Disciplinary actions and sanctions

The bill prohibits the following from considering prescribing, dispensing, or administering a drug, including for off-label use, to a consenting patient or with the consent of the patient's personal representative by a physician, pharmacist, hospital, outpatient health care facility, or inpatient 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 against the physician, pharmacist, hospital, facility, or pharmacy, except in cases where a court has determined that the prescribing, dispensing, or administering was done with recklessness or gross negligence.[18]

Medical opinions

The bill declares that a health care professional should be free to engage in scientific debate. It prohibits a health-related licensing board, ODH, or another state agency responsible for the licensure or regulation of health care professionals from pursuing or threatening to pursue professional discipline, fines, or other regulatory sanctions against a physician, pharmacist, or other licensed health professional for doing either of the following:

- 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 the board, ODH, another state agency, a local board of health, or other health authority;
- Informing a patient or a patient's personal representative of safety concerns or risks that may be associated with a drug or other medical intervention.

These provisions do not provide a health care professional immunity from civil liability to a patient under the health care professional's care in a private care setting.[19]

HISTORY

Action	Date
Introduced	05-27-25

ANSB0209IN-136/ks

[17] R.C. 3792.08(D).

[18] R.C. 3792.08(D).

[19] R.C. 3792.08(E).