



www.lsc.ohio.gov

# OHIO LEGISLATIVE SERVICE COMMISSION

Office of Research  
and Drafting

Legislative Budget  
Office

H.B. 12  
136<sup>th</sup> General Assembly

## Bill Analysis

**Version:** As Introduced

**Primary Sponsors:** Reps. Gross and Swearingen

Emma Carroll, Research Analyst

### SUMMARY

- Generally authorizes a prescriber to prescribe any drug, including a drug for off-label use, and generally requires a pharmacist to dispense, and a hospital, inpatient facility, or pharmacy to allow the dispensing of, the drug.
- 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 an administrative action or professional discipline against a prescriber, pharmacist, hospital, inpatient facility, or pharmacy for actions taken under the bill.
- Prohibits a health-related licensing board, the Department of Health, or another state agency responsible for the licensure or regulation of health care professionals from infringing on free speech.
- Prohibits professional discipline, fines, or regulatory sanctions, or a threat thereof against a prescriber, pharmacist, or other 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

### Authority to prescribe drugs

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 informed consent of the patient or patient's personal representative.<sup>1</sup>

For purposes of the bill, a **prescriber** includes an advanced practice registered nurse, dentist, optometrist, physician, physician assistant, or certified mental health assistant,<sup>2</sup> while a **patient's personal representative** includes a minor patient's parent or other person acting in loco parentis, a court-appointed guardian, a person with durable power of attorney for health care for the patient, the executor or administrator of the patient's estate, or the person responsible for the patient's estate if it is not to be probated.<sup>3</sup>

### Informed consent

Under the bill, informed consent means communication between the patient or personal representative and prescriber that results in the patient or representative authorizing or agreeing to accept a specific drug. As part of that communication, the prescriber must provide the patient's diagnosis, if known; information about the drug consistent with current law and practices for on-label use; any known financial conflicts of interest the prescriber may have; and any other available information related to the risks and benefits of options pertaining to the drug's off-label uses, including the option of forgoing treatment with the drug.<sup>4</sup>

### Existing law prescriptive authority

Current Ohio law grants a prescriber the authority to prescribe drugs, with certain limitations or conditions.<sup>5</sup> Once the federal Food and Drug Administration (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.<sup>6</sup>

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,

---

<sup>1</sup> R.C. 3792.08(B).

<sup>2</sup> R.C. 4729.01, not in the bill.

<sup>3</sup> R.C. 3701.74, not in the bill.

<sup>4</sup> R.C. 3792.08(B).

<sup>5</sup> See e.g., R.C. 4715.01, 4723.481, and 4730.41.

<sup>6</sup> 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](http://fda.gov).

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.<sup>7</sup>

## **Duty to dispense drugs**

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

- The pharmacist, hospital, inpatient 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.<sup>8</sup>

## **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:<sup>9</sup>

- 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;<sup>10</sup>
- An abortifacient, when prescribed, dispensed, or administered to a patient known to be pregnant;
- A drug known to be used for the intent or purpose of euthanasia.

## **Pharmacist discussion**

The bill specifies that its provisions do not prevent a pharmacist from discussing a prescription or expressing any dosage recommendations or other concerns with the prescriber, patient, or patient's personal representative.<sup>11</sup>

## **Decision to accept or continue a drug**

The bill states that the ultimate decision to accept a prescribed drug must be made by the patient or the patient's personal representative.<sup>12</sup> The bill also includes a similar provision

---

<sup>7</sup> R.C. 3792.08(A).

<sup>8</sup> R.C. 3792.08(C) and 4743.10, not in the bill.

<sup>9</sup> R.C. 3792.08(G).

<sup>10</sup> R.C. 3129.01 and 3129.02, not in the bill.

<sup>11</sup> R.C. 3792.08(C)(7).

<sup>12</sup> R.C. 3792.08(C)(7).

regarding decisions about continuing to use drugs. In the event of a disagreement between a patient's in-house prescriber and other medical staff employed by a hospital or inpatient facility involved in the patient's care about whether to continue a drug, including one for off-label use, the bill specifies that the decision to continue the drug must be made by the patient or personal representative after discussing its risks and benefits with the prescriber and other medical staff.<sup>13</sup>

## 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 prescriber has a conflicting moral, ethical, or religious belief or conviction about it being prescribed, dispensed, or used.<sup>14</sup>

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.<sup>15</sup>

### Good faith effort to locate drug

Under the bill, when an in-house prescriber issues for a hospital or inpatient facility patient a prescription for a drug, including one for off-label use, 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 distributor located in the United States.<sup>16</sup>

### Access to and administration of drugs

If (1) the hospital or inpatient facility pharmacist is unable to obtain the drug 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 the patient has access to the drug through a pharmacy outside the hospital or facility or has the drug available at home, the bill provides for both of the following:

- The hospital or facility must permit the drug to be brought in to be **identified**, or determined by the hospital or facility pharmacist as prescribed for the patient, in its original packaging or labeled from an outside retail pharmacy for the patient, approved by the prescriber for the patient's use, and not outside its beyond-use or expiration date, for the patient's use and administration within the hospital or facility;
- If the patient's in-house prescriber is unavailable and other hospital medical staff involved in the patient's care are unwilling to administer the identified drug to the patient due to a moral, ethical, or religious belief or conviction, the prescriber may designate a delegate

---

<sup>13</sup> R.C. 3792.08(C)(5).

<sup>14</sup> R.C. 3792.08(C).

<sup>15</sup> R.C. 3792.08(A).

<sup>16</sup> R.C. 3792.08(C)(3)(a).

to administer the drug who meets the hospital or facility's guidelines and accreditation standards for drug administration.<sup>17</sup>

### **Absent prescriber**

When the patient's in-house prescriber is absent from the hospital or facility, the prescriber's orders for a drug must not be modified or discontinued unless one of the following applies: (1) the prescriber is consulted and agrees to the modification or discontinuation, (2) the patient or personal representative requests in writing to discontinue the drug or consents to the modification, or (3) in an emergency when there is not time, or it is not possible, to contact the prescriber, in which case the hospital or facility must follow its existing protocol for patient care.<sup>18</sup>

### **Right to try**

When there is no in-house prescriber willing to prescribe a drug that a patient or 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.<sup>19</sup>

### **Out-of-pocket payments**

With respect to an outpatient pharmacy setting or a hospital or inpatient facility pharmacy, 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 prescriber or pharmacist must notify the patient of the estimated out-of-pocket costs of the drug. The pharmacist also must offer the drug to the patient at an upfront, out-of-pocket cost.

In the case of a hospital or inpatient facility, the hospital or facility may require payment before ordering the drug. And in the case of an outpatient pharmacy, the prescriber or pharmacist must notify the patient of the option to pay for the drug out-of-pocket.<sup>20</sup>

### **Immunity**

The bill includes two provisions relating to immunity – one specifying that a prescriber is not immune from civil liability and another granting immunity from civil liability, professional discipline, and other regulatory sanctions to a pharmacist, hospital, inpatient facility, or pharmacy in a specified circumstance.

Under the first immunity provision, a prescriber is not immune from civil liability under the bill if harm comes to a patient.<sup>21</sup>

---

<sup>17</sup> R.C. 3792.08(C)(3)(b).

<sup>18</sup> R.C. 3792.08(C)(4).

<sup>19</sup> R.C. 3792.08(C)(6).

<sup>20</sup> R.C. 3792.08(D).

<sup>21</sup> R.C. 3792.08(E).

Under the second immunity provision, when the bill requires a drug to be dispensed, a pharmacist, hospital, inpatient facility, or pharmacy is immune from civil liability, professional discipline, or other regulatory sanctions for any harm that may arise from the patient's use of a drug, starting from the date it was dispensed, in the following circumstance:

- The pharmacist, hospital, inpatient facility, or pharmacy has an objective, good faith, and scientific objection to the administration or dosage of the drug for the patient or patient's condition;
- The pharmacist, hospital, inpatient facility, or pharmacy explains and discusses the objection with the prescriber; and
- As soon as practicable and within 24 hours after dispensing, the pharmacist, hospital, inpatient facility, or pharmacy documents in the patient's medical record that the objection was explained and discussed with the prescriber before the drug's dispensing.<sup>22</sup>

### **Disciplinary actions and sanctions**

The bill 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, 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 prescriber, pharmacist, hospital, inpatient facility, or pharmacy, except in cases where prescribing, dispensing, or administering the drug to that patient was done with recklessness or gross negligence.<sup>23</sup>

### **Medical opinions**

The bill declares that free speech is a protected right under the United States and Ohio Constitutions and that health care professionals are not exempt from constitutional protections. It prohibits a health-related licensing board, ODH, or another state agency responsible for the licensure or regulation of health care professionals from infringing on free speech or pursuing or threatening to pursue professional discipline, fines, or other regulatory sanctions against a prescriber, pharmacist, or other licensed health professional 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 the board, ODH, another state agency, a local board of health, or other health authority.<sup>24</sup>

---

<sup>22</sup> R.C. 3792.08(C)(2).

<sup>23</sup> R.C. 3792.08(E).

<sup>24</sup> R.C. 3792.08(F).

---

---

## HISTORY

Action	Date
Introduced	01-23-25

---