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Substitute Bill Comparative Synopsis

Sub. H.B. 73

135th General Assembly

House Health Provider Services

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This table summarizes how the latest substitute version of the bill differs from the immediately preceding version. It addresses only the topics on which the two versions differ substantively. It does not list topics on which the two bills are substantively the same.

Previous Version (As Introduced)	Latest Version (I_135_0502-5)
Off-label drug dispensing – hospitals and inpatient facilities	
<p>Generally requires a pharmacist to dispense an off-label drug that is prescribed in accordance with the bill's provisions (<i>R.C. 3792.06(C)</i>).</p> <p>No provision.</p>	<p>Maintains this requirement, but also generally requires a hospital or inpatient facility to allow for such dispensing (<i>R.C. 3792.06(C)(1)</i>).</p> <p>When an in-house treating prescriber issues for a hospital or facility patient a prescription for an off-label drug and the drug is neither in stock at the hospital or facility pharmacy nor listed on the hospital's or facility's formulary, requires the hospital or facility pharmacist to 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 facility or another distributor (<i>R.C. 3792.06(C)(3)(a)</i>).</p>

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Hospital or inpatient facility patients – access to off-label drugs	
No provision.	<p>If (1) 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 distributor or (2) 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, provides for both of the following:</p> <ul style="list-style-type: none"> ▪ The hospital or facility must permit the drug to be brought in to be “identified,” or determined by the hospital or facility pharmacist as (1) in the original packaging or labeled from an outside retail pharmacy, (2) approved by the prescriber for use, and (3) not outside its beyond use date, 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 drug to the patient for a moral, ethical, or religious belief or conviction, authorizes another prescriber or prescriber’s delegate to administer the drug (<i>R.C. 3792.06(C)(3)</i>).
Outpatient physician prescriber and hospital or inpatient facility temporary privileges	
No provision.	<p>When a patient cannot be safely transported out of a hospital or inpatient facility 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, then all of the following apply:</p> <ul style="list-style-type: none"> ▪ Allows the patient’s outpatient physician prescriber, after a prompt consultation with the patient’s hospital or inpatient

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	<p>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;</p> <ul style="list-style-type: none"> ▪ Specifies that the temporary privileges approval process is not to exceed five days; ▪ Provides that if the outpatient physician prescriber does not meet the facility’s medical staff bylaw requirement, requires the denial to be reported to the Department of Health (ODH); ▪ 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 drug 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 (<i>R.C. 3792.06(C)(4)</i>).
Pharmacist dispensing	
No provision.	Exempts a pharmacist from dispensing an off-label drug prescribed under the bill’s provisions if the pharmacist has documented that the patient has a history of a life-threatening allergic reaction to the prescribed off-label drug or there is a life-threatening contraindication (<i>R.C. 3792.06(C)(1)(b)</i>).
No provision.	Specifies that the bill’s provisions do not prevent a pharmacist from discussing a prescription with the prescriber who issued it (<i>R.C. 3792.06(C)(6)</i>).

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Disciplinary actions	
<p>Prohibits the following licensing boards from considering any action taken by a prescriber or pharmacist under the bill to be unlawful, unethical, unauthorized, or unprofessional conduct: State Medical Board, Ohio Board of Nursing, State Dental Board, State Vision Professionals Board, and State Board of Pharmacy (<i>R.C. 3792.06(D)</i>).</p> <p>Prohibits a health professional licensing board from pursuing an administrative or disciplinary action against a prescriber, pharmacist, or other licensed health professional for publicly or privately expressing a medical opinion that does not align with the opinions of the board, a local board of health, or ODH (<i>R.C. 3792.06(D)</i>).</p>	<p>Maintains this prohibition, but also extends it to ODH and actions taken by a hospital or inpatient facility (<i>R.C. 3792.06(D)</i>).</p> <p>Maintains this prohibition, but also extends it to ODH and opinions expressed by a hospital or inpatient facility (<i>R.C. 3792.06(D)</i>).</p>
Denial of nutrition, fluids, and standard daily medications	
<p>Prohibits a hospital or other health care facility from denying nutrition or fluids to a patient who has refused a hospital's or facility's treatment intervention or standard protocol (<i>R.C. 3796.02(F)</i>).</p>	<p>Instead prohibits a hospital or inpatient facility patient from being denied sufficient means of fluids or nutrition, unless that wish is clearly stated in the patient's end of life health directive or the denial is necessary for a medical procedure and then only for the shortest amount of time medically possible and with informed consent (<i>R.C. 3792.06(F)</i>).</p>
Immunity from administrative or civil liability	
<p>No provision.</p>	<p>Grants immunity from administrative or civil liability to a pharmacist who must dispense an off-label drug or a hospital or inpatient facility that must allow the dispensing of an off-label drug, but has an objective, good faith, and scientific objection to the administration or dosage of the drug for the patient if both of the following conditions are met:</p> <ul style="list-style-type: none"> ▪ At the time of dispensing, the pharmacist, hospital, or inpatient facility documents in the patient's medical record the

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<p>No provision.</p>	<p>objective, good faith, and scientific objection, by stating with particularity the basis of the objection, which must be based on an individualized assessment of the patient and the off-label drug;</p> <ul style="list-style-type: none"> ▪ The pharmacist submits to the Board of Pharmacy or the hospital or inpatient facility submits to ODH the objective, good faith, and scientific objection, which must be based on an individualized assessment of the patient and the off-label drug <i>(R.C. 3796.02(C)(2))</i>. <p>Grants an in-house pharmacist, hospital, or inpatient facility and the in-house physician 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 <i>(R.C. 3792.06(C)(4)(c))</i>.</p>
Informed consent	
<p>Authorizes a prescriber to issue a prescription for a drug, including an off-label drug, if the prescriber has obtained the patient’s informed consent <i>(R.C. 3792.06(B))</i>.</p>	<p>Maintains this provision, but also permits consent from the person holding the patient’s health care power of attorney <i>(R.C. 3792.06(B))</i>.</p>
<p>No provision.</p>	<p>With respect to the denial of fluids or nutrition, requires the hospital or inpatient facility, when a denial is necessary for a medical procedure, to obtain the informed consent of the patient or person holding the patient’s health care power of attorney <i>(R.C. 3792.06(F))</i>.</p>

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Out-of-pocket costs and payment	
No provision.	Requires an off-label drug available from another hospital, inpatient facility, or distributor to be offered to a patient at an upfront out-of-pocket cost to the patient and also authorizes the hospital or facility to require payment prior to ordering the drug (<i>R.C. 3792.06(C)(3)(a)</i>).
No provision.	Specifies that a patient may be required to pay out-of-pocket for an off-label drug prescribed by an outpatient physician prescriber who has obtained temporary privileges at a hospital or inpatient facility (<i>R.C. 3796.02(C)(4)</i>).
Definitions	
Defines “hospital” to mean an institution or facility that provides inpatient medical or surgical services for a continuous period longer than 24 hours (<i>R.C. 3792.06(A)(2)</i> and <i>R.C. 3722.01</i> , not in the bill).	Same, but also specifies that a hospital includes one owned or operated by the U.S. Department of Veterans Affairs (<i>R.C. 3792.06(A)(2)</i>).
Throughout the bill, refers to a health care facility other than a hospital.	Instead refers to an inpatient facility and defines it to include either or both of the following: a skilled nursing facility or freestanding inpatient rehabilitation facility (<i>R.C. 3792.06(A)(4)</i>).