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# OHIO LEGISLATIVE SERVICE COMMISSION

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## Substitute Bill Comparative Synopsis

### Sub. H.B. 12

### 136<sup>th</sup> General Assembly

### House Health

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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_136_0239-2)
<b>Prescriptive authority</b>	
Authorizes the prescription of any drug, including a drug for off-label use, with the informed consent of the patient or the patient's personal representative (which under current law includes a minor patient's parent or other person acting <i>in loco parentis</i> , a guardian, a person with a patient's health care power of attorney, the executor or administrator of a patient's estate, or the person responsible for a patient's estate if it is not to be probated) ( <i>R.C. 3792.08(A)(6) and (B), and 3701.74(A)(11), not in the bill</i> ).	No provision.
Defines informed consent to mean communication between the patient or the patient's personal representative and prescriber that results in authorizing or agreeing to accept a specific drug and requires the prescriber to provide information about (1) the patient's diagnosis, if known, (2) informed consent consistent with current law and practices for on-label use, (3) any other available information regarding the risks and benefits of the drug,	No provision.

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treatment or intervention options pertaining to its off-label uses, including the option to forgo treatment, and (4) any financial conflicts of interest ( <i>R.C. 3792.06 (B)</i> ).	
<b>Applicable types of prescribers</b>	
Addresses prescribing by dentists, advanced practice registered nurses, optometrists, physicians, physician assistants, and certified mental health assistants ( <i>R.C. 3792.08(A)(8) and 4729.01(I), not in the bill</i> ).	Instead, addresses prescribing only by physicians ( <i>R.C. 3792.08(A)(8)</i> ).
Specifies that an <i>in-house prescriber</i> is a prescriber who is employed or contracted by a hospital or inpatient facility where a patient is being treated ( <i>R.C. 3792.08(A)(3)</i> ).	Instead, refers to an <i>in-house physician</i> , and also includes physicians with hospital privileges at the hospital where a patient is being treated ( <i>R.C. 3792.08(A)(3)</i> ).
<b>Dispensing</b>	
Generally requires a pharmacist in any setting to dispense, and a hospital, inpatient facility, or pharmacy to allow the dispensing of, a drug, including for off-label use ( <i>R.C. 3792.08(C)(1)(a)</i> ).	Same, and adds outpatient health care facilities to the dispensing requirement ( <i>R.C. 3792.08(B)(1)(a)</i> ).
Exempts a pharmacist, hospital, or inpatient facility from the dispensing requirement if the pharmacist documents that the patient has a history of a life-threatening allergic reaction to the drug or there is a life-threatening contraindication or drug interaction for that patient ( <i>R.C. 3792.08(C)(1)(b)</i> ).	Same, but expands the exemption to include: <ul style="list-style-type: none"> <li>▪ If the pharmacist documents that the drug has a high probability of causing serious disability or serious injury to that patient;</li> <li>▪ Outpatient health care facilities (<i>R.C. 3792.08(B)(1)(b)</i>).</li> </ul>
No provision.	States that nothing in the bill prevents compliance with existing pharmacy law, but it establishes that the final decision on whether a prescribed drug is dispensed must be made by a physician ( <i>R.C. 3792.08(B)(3)</i> ).

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<b>Decision to accept or continue drug</b>	
States that the ultimate decision to accept a prescribed drug must be made by the patient or the patient's personal representative ( <i>R.C. 3792.08(C)(7)</i> ).	Same, specifies that the ultimate decision to take a prescribed drug must be made by the <i>consenting</i> patient or the patient's personal representative ( <i>R.C. 3792.08(B)(6)</i> ).
States that when there is a disagreement about whether to continue a drug, including for off-label use, between a patient's in-house provider and other medical staff employed by the hospital or inpatient facility involved with the patient's care, the risks and benefits of continuing the drug must be discussed with the patient or the patient's personal representative, who must make the decision to continue or discontinue the drug ( <i>R.C. 3792.08(C)(5)</i> ).	No provision.
<b>Pharmacist discussion</b>	
States that the bill does not prevent a pharmacist from discussing a prescription or expressing any dosage recommendations or other concerns with the prescriber, the patient, or the patient's personal representative ( <i>R.C. 3792.08(C)(7)</i> ).	Instead, specifies that a pharmacist <i>should</i> discuss any prescription dosage recommendations or other clinical concerns with the physician, the patient, or the patient's personal representative when there are safety concerns regarding a prescription ( <i>R.C. 3792.08(B)(6)</i> ).
No provision.	States that 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 ( <i>R.C. 3792.08(B)(6)</i> ).
<b>Absent prescriber</b>	
Specifies that if a patient's in-house prescriber is absent from the hospital or inpatient facility, the prescriber's orders may not be modified or discontinued unless (1) the prescriber is consulted and agrees, (2) the patient or the patient's personal representative requests in writing to discontinue the drug or consents to the modification, or (3) there is an emergency in	No provision.

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which it is not possible to contact the prescriber ( <i>R.C. 3792.08(C)(4)</i> ).	
<b>Locating a drug and out-of-pocket costs</b>	
If a drug is neither in stock nor listed on a hospital or inpatient facility's formulary, requires a pharmacist to document that a good faith effort was made to find the drug at another hospital or facility or from another distributor in the United States ( <i>R.C. 3792.08(C)(3)(a)</i> ).	No provision.
If the drug is not covered by the patient's insurance or the patient does not want to wait for prior authorization, a hospital or facility is required to offer the drug to the patient at an upfront out-of-pocket cost for which payment may be required before ordering the drug ( <i>R.C. 3792.08(D)(2)</i> ).	No provision.
<b>Outside drugs</b>	
Permits a drug that is not available at a hospital or inpatient facility but that the patient has access to through a pharmacy outside the hospital or facility or has available at home to be brought into the hospital or facility if it is (1) in the original manufacturer's packaging or labeled from an outpatient retail pharmacy for the patient, (2) has been approved by the prescriber for the patient's use, and (3) is not outside of its beyond use date ( <i>R.C. 3792.08(C)(3)(b)(i)</i> ).	Same, but specifies that the patient must obtain the drug at an outpatient pharmacy, and does not permit a drug to be brought in from the patient's home ( <i>R.C. 3792.08(B)(4)</i> ).
If an in-house prescriber at a hospital or facility is unwilling to administer the drug brought in from a pharmacy outside the hospital or facility or the patient's home for moral, ethical, or religious reasons, another prescriber or the prescriber's delegate may administer the drug ( <i>R.C. 3792.08(C)(3)(b)(ii)</i> ).	No provision.
<b>Professional discipline</b>	
Prohibits a health-related licensing board, the Ohio Department of Health (ODH), or another state agency from taking disciplinary action or	Same, except:

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<p>imposing regulatory sanctions against a prescriber, pharmacist, hospital, inpatient facility, or pharmacy for taking action under the bill, except in cases of recklessness or gross negligence (<i>R.C. 3792.08(E)</i>).</p> <p>Prohibits a health-related licensing board, ODH, or another state agency from infringing on free speech or taking, or threatening to take, disciplinary action against a prescriber, pharmacist, or other health care 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, agency, a local board of health, or other health authority (<i>R.C. 3792.08(F)</i>).</p>	<ul style="list-style-type: none"> <li>▪ Refers to actions against a physician, rather than a prescriber, to conform to the rest of the bill;</li> <li>▪ Also prohibits such actions against an outpatient health care facility;</li> <li>▪ Specifies that recklessness or gross negligence must be determined by a court (<i>R.C. 3792.08(D)</i>).</li> </ul> <p>Same, except:</p> <ul style="list-style-type: none"> <li>▪ Does not address infringement on free speech;</li> <li>▪ Does not address privately expressing such an opinion;</li> <li>▪ Additionally prohibits professional discipline for informing a patient of safety concerns or risks associated with a drug or other medical intervention (<i>R.C. 3792.08(E)</i>).</li> </ul>
Immunity	
<p>Grants immunity from civil liability, professional discipline, and sanctions or fines to a pharmacist, pharmacy, hospital, or inpatient facility subject to the bill's dispensing requirement if the pharmacist, pharmacy, hospital, or facility has an objective, good faith, and scientific objection that is discussed with the prescriber and documented in the patient's medical record within 24 hours of dispensing (<i>R.C. 3792.08(C)(2)</i>).</p> <p>States that a prescriber is not immune from civil liability if harm comes to a patient (<i>R.C. 3792.08(E)</i>).</p> <p>No provision.</p>	<p>Same, except:</p> <ul style="list-style-type: none"> <li>▪ Specifies that this provision applies only if after discussing the objection with the physician it is still in the clinical judgment of the physician to dispense the drug;</li> <li>▪ Additionally provides immunity to outpatient health care facilities;</li> <li>▪ Requires the discussion and date of the discussion with the physician to be documented in the patient's medical record, and states that the objection does not have to be described in detail (<i>R.C. 3792.08(B)(2)</i>).</li> </ul> <p>Instead, states that the bill does not provide a physician immunity from civil liability (<i>R.C. 3792.08(D)</i>).</p> <p>States that, except as provided in regard to objective, good faith, and scientific objections,</p>

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<p>States that the bill's provision regarding expressing medical opinions does not limit liability for a medical act that causes actual patient harm <i>(R.C. 3792.08(F))</i>.</p>	<p>the bill does not provide a pharmacist, hospital, inpatient facility, outpatient health care facility, or pharmacy immunity from civil liability <i>(R.C. 3792.08(D))</i>.</p> <p>States that the bill's provision regarding expressing medical opinions does 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 <i>(R.C. 3792.08(E))</i>.</p>
<b>Medical opinions</b>	
<p>Recognizes that free speech is a protected right under the United States and Ohio Constitutions from which health professionals are not exempt <i>(R.C. 3792.08(F))</i>.</p> <p>No provision.</p>	<p>No provision.</p> <p>States that a health care professional should be free to engage in scientific debate <i>(R.C. 3792.08(E))</i>.</p>
<b>Excluded drugs</b>	
<p>Specifies that (except for its medical opinion provision) the bill does not apply to, repeal, or supersede existing law regarding the prescribing, dispensing, or administering abortifacients for patients <i>known</i> to be pregnant <i>(R.C. 3792.08(G)(4))</i>.</p>	<p>Instead, applies this provision when a patient is <i>believed to be pregnant (R.C. 3792.08(F)(4))</i>.</p>