Mike DeWine, Governor Jim Tressel, Lt. Governor Steven W. Schierholt, Executive Director

HB 12 - Testimony - Ohio Board of Pharmacy

May 7, 2025

Chair Schmidt, Vice-Chair Deeter, Ranking Member Somani, and members of the House Health Committee, my name is Steven W. Schierholt, and I serve as the Executive Director for the Ohio Board of Pharmacy. On behalf of the Board, thank you for the opportunity to express our concerns with HB 12 and its potential impact on the practice of pharmacy. This legislation has far-reaching repercussions that will negatively impact patient care and ignores the extensive training and knowledge of pharmacists.

For my testimony, I would like to highlight the following concerns:

<u>Concern 1: Removes Authority of the Pharmacist to Participate in the Provision of</u> Healthcare Services

One of the Board's primary concerns is that the bill fails to recognize the education and expertise of a pharmacist in ensuring safe patient care. In general, HB 12 would require a pharmacist to dispense most medications even if the pharmacist has an "objective, good faith, and scientific objection to the administration or dosage of the drug for that patient."

As written, the only exceptions a pharmacist can use to refuse to dispense a prescription are as follows:

- (1) A moral, ethical, or religious belief or conviction that conflicts with the drug's dispensing;
- (2) The patient has a documented 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.

The bill does allow a pharmacist to refuse to dispense medication if there is a life-threatening contraindication or life-threatening drug interaction. However, such limitations imply that a pharmacist practicing in this state must accept a level of patient harm that is just below life-

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threatening or risk sanctions. In pharmacy, we have varying levels of medication harm related to medication errors.[†] At which point, using the index below, does it meet the definition of "life-threatening" (e.g., temporary harm, permanent harm, hospitalization, or death)?

Table 1. NCC MERP Index for Categorizing Medication Errors

Category	Description
Α	No error, capacity to cause error
В	Error that did not reach the patient
С	Error that reached patient but unlikely to cause harm (omissions
	considered to reach patient)
D	Error that reached the patient and could have necessitated
	monitoring and/or intervention to preclude harm
E	Error that could have caused temporary harm
F	Error that could have caused temporary harm requiring initial or
	prolonged hospitalization
G	Error that could have resulted in permanent harm
Н	Error that could have necessitated intervention to sustain life
I	Error that could have resulted in death

Additionally, a pharmacist has the existing authority under ORC 4743.10 to object to dispensing a drug on ethical, moral, or religious terms. If the pharmacist questions the efficacy of a treatment and feels the patient is being taken advantage of – would this be a moral or ethical consideration that would prohibit dispensing? For example, let's say an elderly patient consented to receiving medications to treat a condition that the pharmacist knows is not effective and that this patient may be spending their limited resources on an ineffective treatment. Is the pharmacist able to deny a prescription based on a moral or ethical consideration if the patient is being defrauded?

Concern 2: Defining Gross Negligence

While there are some standards in which to discipline individual providers in the bill, such as recklessness and gross negligence, these raise additional implementation concerns. For example, the legislation uses the term "gross negligence" as a standard for disciplinary action. However, this standard is not defined in the Ohio Revised Code nor is it a standard currently applied to healthcare licensing Boards. Will agencies responsible for enforcement be required

to develop this definition? Is it expected we will use case law to determine this standard? Without a clear standard, this makes any attempt at enforcement difficult.

Concern 3: Definition of Off-Label Drug

The bill defines an off-label drug as follows:

- (a) The drug is approved by the United States food and drug administration to treat or prevent a disease, illness, or infection, but prescribed for or used by a patient to treat or prevent another disease, illness, or infection.
- (b) The drug is legal for use in this state.

This definition is not limited to drugs that are approved for human-use. Under the bill, a physician could prescribe clenbuterol (which is used to treat horses with reactive airway disease) as a weight loss medication (it is often abused by athletes and other body builders). Or prescribers could take advantage of patients by providing drugs of abuse that are not controlled substances. For example, there have been recent reports of the abuse of a non-controlled sedative used in veterinary and human medicine, medetomidine (dexmedetomidine in humans). Additionally, the Board has seen recent cases of prescribers utilizing animal supplements for human injections.

Concern 4: Additional Free Speech Provisions May Come at the Expense of Patient Safety

The bill prohibits a licensing authority from engaging in professional discipline against a prescriber, pharmacist, or other licensed health care professional for publicly or privately expressing an opinion regarding the safety, risks, benefits, or efficacy of a drug or other medical intervention. Therefore, if we have pharmacists or prescribers who are actively and aggressively making claims that are hurting patients, Ohio's healthcare regulatory Boards are unable to act to safeguard the public.

At what point should healthcare providers be held accountable for claims that result in the deaths of individuals? Does this apply to prescribers who encourage patients to take opioids for high blood pressure, as long as the prescriber doesn't issue the prescription? Additionally, how does this provision impact a Board's ability to address any underlying mental health concerns that a licensee may be experiencing?

Concern 5: Ability to Attract and Retain Pharmacists

Lastly, the Board is generally concerned about the impact this legislation will have on the ability to attract and retain pharmacists in Ohio. By ignoring the expertise of the pharmacist and eliminating any standard of care, this legislation is removing the ability of the pharmacist to be an active participant in the care of their patients. If given the option, most pharmacists will not want to practice in a state that ignores their training and value as part of a patient's care team.

In closing, the Board opposes the passage of HB 12. Prescribers are already afforded ample latitude to issue prescriptions for off-label use and, unlike in other states, can already order and personally furnish (e.g., prescriber dispense) medications in a similar manner to pharmacies. Ultimately, this legislation undermines patient safety, places pharmacists in an impossible situation, and encourages unscrupulous healthcare providers who seek to profit by peddling misinformation and unproven remedies.

Chair Schmidt and members of the House Health Committee, thank you for the opportunity to provide opposition testimony to HB 12. Should you or the committee members have any questions or need any additional information, please do not hesitate to contact the Board's Director of Policy and Communications, Cameron McNamee, at cameron.mcnamee@pharmacy.ohio.gov.

Sincerely,

Steven W. Schierholt

Executive Director

Ohio Board of Pharmacy

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iii https://www.chicagohan.org/alert-detail/-/alert-details/46684184?p_r_p_categoryId=undefined

iv https://hip.phila.gov/document/4421/PDPH-HAN-0441A-05-13-24.pdf/