



HB 73 – Testimony – Ohio Board of Pharmacy

June 12, 2024

Chair Huffman, Vice-Chair Johnson, Ranking Member Antonio, and members of the Senate 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 continued concerns with substitute HB 73 and its potential impact on the pharmacy community. This legislation has far-reaching repercussions that will negatively impact patient care and ignores the role and expertise of pharmacists.

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

Concern 1: No Standard of Care Can Be Applied to Off-Label Prescribing

The bill, as drafted, allows for the use of off-label prescribing without needing to perform any testing or screening. A patient is not required to have any disease exposure and may receive an off-label prescription for a non-controlled drug for prophylactic purposes.

This language generally eliminates any standard of care for off-labeling prescribing. Is it the General Assembly’s intent to permit the use of any drug as a prophylactic? Is a physician who writes for propofol (an intravenous anesthetic) to treat high cholesterol permitted to do so under this law? Without any standard of care based in objective fact, it makes it extremely difficult for regulators to differentiate between well-meaning prescribers and those who are engaged in fraudulent activity that can hurt patients.

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. 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 2: Removes Authority of the Pharmacist to Participate in the Provision of Healthcare Services

In general, HB 73 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 fill 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.*

Would a pharmacist who knows the drug is contraindicated for the patient and could lead to patient harm be able to utilize one of these exemptions? Does this only apply in the case of a life-threatening allergy? Can a pharmacist refuse to fill a prescription for a drug for a pregnant patient if that drug would harm that patient’s child? Currently, the exception listed in the bill is for life-threatening allergic reactions and does not account for other contraindications (such as drugs listed in Category X for pregnancyⁱ). *If not, how does the state force a pharmacist to dispense a medication that could harm a patient or their unborn child?*

In addition, 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.

Concern 3: Definition of Off-Label Drug

The bill defines an off-label drug as follows:

- (a) *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) *Legal for use in this state.*
- (c) *The drug is not a controlled substance as defined in section 3719.01 of the Revised Code.*

While updates to the bill removed controlled substances as drugs that can be prescribed off-label, the removal of the standard of care can still lead to dangerous consequences for drugs of abuse that are non-controlled. For example, 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).ⁱⁱ 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).^{iii iv}

In closing, the Board opposes the passage of HB 73 as proposed. 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., physician 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 Huffman and members of the Senate Health Committee, thank you for the opportunity to provide opposition testimony to HB 73. I would be happy to answer any questions you may have at this time.

ⁱ Studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits.
<https://chemm.hhs.gov/pregnancycategories.htm#:~:text=Category%20D.pregnant%20women%20despite%20potential%20risks>.

ⁱⁱ https://www.deadiversion.usdoj.gov/drug_chem_info/clenbuterol.pdf

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/>