



OHIO COUNCIL OF
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June 20, 2023

**TESTIMONY IN OPPOSITION TO SUBSTITUTE HOUSE BILL 73
BEFORE THE HOUSE HEALTH PROVIDER SERVICES COMMITTEE**

Lora Miller, Director of Governmental Affairs & Public Relations

Good afternoon, Chairman Cutrona, Vice Chair Gross, Ranking Member Somani and members of the Committee. Thank you for the opportunity to share our deep concerns regarding Substitute House Bill 73.

Along with my testimony, you will find a legal memorandum prepared by our outside counsel, Vorys, Sater, Seymour & Pease. I will attempt to summarize the legal concerns along with comments received from our members.

Sub. H.B. 73 proposes to eliminate the checks and balances of safe and effective medication use, which includes the professional judgement of a pharmacist. Discriminatory refusals are already unlawful, abandoning patients is malpractice, and professional judgment necessarily involves the subjective knowledge and experience of the individual pharmacist. This bill would move us away from the checks and balances the legislature purposefully created to keep the citizens of Ohio safe, including the laws currently in place to fight opioid addiction and diversion.

Sub. H.B. 73 contemplates *any* off-label use – not just those which are generally-accepted by the medical community, which presents a legitimate safety issue for patients and could conceivably allow prescribers to prescribe drugs that may be dangerous to patients, in any way they see fit, regardless of the general acceptance by the rest of the medical community. Despite the fact that the off-label use may not be indicated, may not be safe, and may not be accepted by the medical community, Sub. H.B. 73 requires pharmacists to dispense the off-label drugs prescribed unless they have a religious objection or are aware of some other life-threatening contraindication.

The potential impact of Sub. H.B. 73 on the health and safety of the people of Ohio is very concerning as a matter of public policy. Simply put, Sub. H.B. 73, which is written very broadly, potentially makes it easier for controlled substances and other drugs to be abused and diverted into the hands of people who should not have them in the first place by undercutting barriers specifically enacted to address the ongoing drug crisis and promote greater patient safety, including the role of pharmacists in that process.

The requirements included in Sub. H.B. 73 directly conflict with existing requirements obligating Ohio pharmacists to determine the legitimacy of, and exercise their professional judgment when dispensing each and every prescription, including declining to dispense prescriptions in some circumstances. The direct conflict in the law which would be created by enacting the bill is completely unworkable because it would be impossible for pharmacists to comply with both the requirements of Sub. H.B. 73 and their existing legal obligations. The bill effectively negates a pharmacist's professional judgment and could require, among other things, the dispensing of illegitimate or questionable prescriptions, which could be very harmful to individual patient safety and the community as a whole. Sub. H.B. 73 does not take into account the guardrails that exist under current law to protect patients from harm. There are legitimate safety reasons why pharmacists may not feel it is safe to dispense certain drugs for off-label use, and Sub. H.B. 73 requires them to dispense them anyway, even if they have concern that the patient will be harmed.

While the bill purports to provide some level of civil and administrative immunity for pharmacists complying with Sub. H.B. 73, such immunity does not expressly extend to a pharmacist's failure to comply with other conflicting legal mandates to which the pharmacist is subject, and the immunity is civil and administrative only, suggesting that criminal prosecution may still be possible. While the bill provides for civil and administrative immunity for both the pharmacist and the prescriber, this immunity does not extend to a failure to comply with other conflicting laws applicable to the pharmacist or prescriber. Further, the civil and administrative immunity proposed in this legislation does not seem to extend to all health care professionals who would be involved in the provision of off-label drugs to patients. For example, pharmacy technicians assisting with off-label prescriptions or nurses who might be forced to administer an off-label drug in a hospital or inpatient facility setting do not appear to have any immunity at all. Additionally, dispensing prescriptions when inconsistent with the generally accepted standard of care, or otherwise when not indicated or not considered safe, opens pharmacists up to potential criminal liability.

Lastly, proposed section 3792.06 (E) states that "(a) political subdivision, public official, or state agency shall not enforce any rule or order issued by a federal agency that prohibits issuing a prescription for or dispensing an off-label drug." Article VI of the United States Constitution, commonly referred to as the Supremacy Clause, makes clear that the Constitution, federal laws, federal regulations, and treaties take superiority over similar state laws. To the extent that federal law regulates the prescribing or dispensing of off-label drugs, compliance with federal law is paramount. State law cannot supersede federal law. Accordingly, proposed section 3792.06 (E) is likely unconstitutional, violates current state law and is unenforceable.

I appreciate your time and thoughtful consideration of our significant concerns with Sub. H.B. 73. Although I am not a health care attorney, I will attempt to answer any questions you may have.