The Ohio Senate
Senate Health Committee
Senator Steve Huffman, Chair

Substitute House Bill 73
Written Opposition Testimony

Chairman Huffman, Vice Chairman Johnson, Ranking Member Antonio, and Members of the Senate Health Committee, thank you for the opportunity to provide opponent testimony on Substitute House Bill 73 ("Sub. H.B. 73").

Founded in 1866, University Hospitals ("UH") serves the needs of patients through an integrated network of 21 hospitals (including five joint ventures), more than 50 health centers and outpatient facilities, and over 200 physician offices in 16 counties throughout northern Ohio. The system's flagship quaternary care, academic medical center, University Hospitals Cleveland Medical Center, is affiliated with Case Western Reserve University School of Medicine and Northeast Ohio Medical University. The main campus also includes the UH Rainbow Babies & Children's Hospital, ranked among the top children's hospitals in the nation; UH MacDonald Women's Hospital, Ohio's only hospital for women; and UH Seidman Cancer Center, part of the NCI-designated Case Comprehensive Cancer Center. UH is home to some of the most prestigious clinical and research programs in the nation, with more than 3,000 active clinical trials and research studies underway. UH Cleveland Medical Center is perennially among the highest performers in national ranking surveys, including "America's Best Hospitals" from U.S. News & World Report. UH is also home to 19 Clinical Care Delivery and Research Institutes. UH is one of the largest employers in Northeast Ohio with more than 30,000 employees.

First, we would like to state there is no opposition to the provisions within Sub. H.B. 73 that codify the practice of prescribing off-label medications. This is a common practice that has been successfully utilized by providers for decades to increase the quality of patient care and improve outcomes. However, UH is opposed to Sub. H.B. 73 in its current form, especially as it creates conflict and confusion surrounding the professional judgment of pharmacists.

While off-label prescribing is not a new practice, Sub. H.B. 73 poses a significant risk to patients by requiring use of any off-label medications (minus controlled substances) requested by a patient, even those that may lack evidence of benefit or cause potential harm to the patient. This broad rule opens up potential safety concerns as it circumvents both the supervising provider and pharmacists' deliberate and collaborative clinical review and years of extensive training. Should Sub. H.B. 73 pass as is, even if the off-label use may not be indicated, safe, nor accepted by the overall medical community; requiring pharmacists to dispense the off-label drug prescribed undermines the clinical expertise and professional judgement of pharmacists, effectively eliminating them as the last line of defense between a patient and potentially harmful or deadly medication.

I. Standard of Care and Existing Law

Ohio law[1] requires pharmacists to conduct a prospective drug utilization review prior to dispensing any prescription for the purpose of identifying: over-utilization or under-utilization; therapeutic duplication;

[1] OAC 4729:5-5-08

drug-disease state contraindications; drug-drug interactions; incorrect drug dosage; drug-allergy interactions; abuse and/or misuse; inappropriate duration of drug treatment; and food-nutritional supplements-drug interactions. Pharmacists often go beyond this to optimize therapy to improve clinical outcomes and to ensure safe prescribing practices.

Pharmacists are crucial to health care as they are often one of the few practitioners that have a full picture of the various medications a patient may be taking in the hospital and across various transitions of care. Federal quality standards require hospitals to complete medication reconciliation at every transition of care in which new medications are ordered or existing orders are rewritten. This reconciliation is done to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions. It is extremely common during this process for a hospital pharmacist to contact a prescriber after a prescription is written and discuss with the prescriber some of the potential adverse impacts a particular drug may have on a patient. Though the bill allows the pharmacist to discuss a prescription with a prescriber, it does not allow the pharmacist to engage in their statutorily required professional practice, as it would require the pharmacist to dispense the drug as prescribed, regardless of any professional concerns the pharmacist may have. For a prescription to be valid, it must be issued for a "legitimate medical purpose" where the responsibility lies upon the prescriber, however, Ohio law details a corresponding responsibility to ensure legitimacy resting with the pharmacist who dispenses the prescription. The bill negates a pharmacist's professional judgment which is protected by Ohio law[2].

When concerns in clinical care arise, there are mechanisms in place to resolve these safely and effectively through various ethics or physician committees whose sole priority is ensuring timely and efficient patient care and safety.

II. Temporary Privileges

Though the requirement that hospitals grant temporary medical staff privileges has been limited in the revised bill, it could undermine the existing hospital quality and safety structure. Hospitals grant temporary privileges to fulfill important patient care, treatment, and service needs. As it is currently written, granting temporary privileges for off-label prescribing does not meet the criteria, especially if the hospital provider team does not support the medical need for the patient's care. Rather, the temporary privilege allowing for such prescribing is likely to pose more harm than benefit. This legislation would give a provider denied these privileges the novel remedy of filing a complaint with the Ohio Department of Health (ODH) that is available to the public without the context of clinical decision-making by the hospital's care team for the benefit of the patient and the clinical standards to which the medical staff and the hospital are required to adhere. Sub. H.B. 73 eliminates the interdisciplinary and patient-oriented committees and standard procedures rendering the actions required by Sub H.B. 73 untenable in today's hospital practice.

III. Liability

While the bill purports to provide some level of civil/administrative immunity for pharmacists, such immunity does not expressly extend to a pharmacist's failure to comply with other conflicting legal mandates to which the pharmacist is subject. Hospitals would risk being able to care effectively for patients while attempting to comply with this state law that is in direct conflict with federal requirements, such as pharmacist review as detailed above, maintenance of a formulary required by CMS, and storage/procurement of medications, for example. On top of this, the language of Sub. H.B. 73 states that the immunity is civil and administrative only, leaving hospitals and pharmacists to interpret this as suggesting that criminal prosecution may still be possible.

Continuing with issues in this section, the civil and administrative immunity proposed in this legislation does not seem to extend to all healthcare professionals who would be involved in the provision of off-label

[2] OAC 4279:5-5-15

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.

In conclusion pertaining to liability, as OHA mentioned in a previous testimony, we ascertain if the law requires a pharmacist or hospital to violate other laws, professional practice standards, and ethical standards, then liability protection should be broad and unconditional. It should also provide immunity from suit, so that pharmacists, hospitals, and all other clinicians such as nurses, cannot be sued, rather than having to incur the expense of defending a suit to obtain immunity.

IV. Unverified Medications, Cost, and Drug Shortages

Sub. H.B. 73 states a pharmacist must make a good faith effort to obtain a drug regardless of appropriateness for the patient and document such efforts when an in-hospital or temporary privileged prescriber issues a prescription for a drug that is either not in stock or not on the hospital's formulary. Further, if the drug is available, it must be given.

Sub. H.B. 73 overlooks the efforts of hospitals and health systems to maintain medications that are safe and effective. The interventions of pharmacists is critical not only to optimizing clinical outcomes, but also in stewardship of medication resources, especially when a medication is on shortage, to ensure patients receive essential medications they require. Sub. H.B. 73 would require health systems to dispense these medications regardless of mitigation strategies in crucial supply chain disruptions, introducing unnecessary and avoidable harm to patients.

Beyond this, this law requires a pharmacy to dispense a medication regardless of reimbursement or therapeutic value. Hospitals and pharmacies should not be required to bear the burden for a patient preference with lack of efficacy and safety data for the medication requested. This could further drive up the cost of care for not only health systems, but also state-supported health plans and patients. As such, introducing medications into hospitals poses a plethora of risks to patient safety, medication supply chain, and financial standing of the state, patients, and hospitals.

V. CONCLUSION

Thank you Chairman Huffman, Vice Chairman Johnson, Ranking Member Antonio, and members of the Senate Health Committee, for this opportunity to provide feedback on this important legislation. We appreciate the work done by the sponsors, committee chairman and others to understand the nuances of prescribing drugs in a hospital setting.

For the reasons above, we have serious concern with the bill as written and we look forward to continued discussions throughout this process on how to continue to protect our patients and caregivers.

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