Ohio Hospital Association
Ohio House Health Provider Services Committee
Sub. House Bill 73 - Opponent Testimony
June 20, 2023

Chairman Cutrona, Vice Chair Gross, Ranking Member Somani and members of the House Health Provider Services Committee, on behalf of the Ohio Hospital Association (OHA) thank you for the opportunity to provide opponent testimony on Substitute House Bill 73.

First, OHA 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, the Ohio Hospital Association is opposed to Substitute House Bill 73 in its current form, as **it creates a framework that requires the dispensing of drugs upon the issuance of a prescription, without the ability of health care providers to perform their role in a patient's clinical care. OHA believes this framework to be particularly unsafe for hospitalized patients and contrary to numerous other laws and regulations currently in place with which hospitals, and practitioners working in hospitals, are required to comply.**

The majority of patients in hospital settings are Ohio's most acutely sick patients. Oftentimes, those patients are treated with up to a dozen, or even two dozen drugs while in a hospital. Maintaining a clinical balance regarding their drug treatment plans requires open lines of communication and respect for clinical perspectives among providers. The balance, communication, and professional respect is vital to patients' well-being and compliance regarding numerous laws governing the treatment of hospitalized patients.

It is only in very rare circumstances that there are disputes between prescribers and pharmacists in a hospital setting regarding drugs prescribed for a patient. In cases when questions are raised by a pharmacist in the hospital setting, the issue is resolved professionally between clinicians and in the best interest of patients. In the rare circumstances where there is an impasse in the discussions between providers, there are professional mechanisms in place to quickly resolve them. These mechanisms are led by physicians and other clinicians.

Sub. H.B. 73 upsets these existing mechanisms, which are required by law, professional practice standards, and professional ethics. Additionally, the newest version of the bill also creates a new regulatory structure. OHA appreciates the bill sponsors efforts to address circumstances that are extremely rare in hospitals, but ultimately this regulatory structure has the potential to disrupt the operations of hospitals regarding virtually all patients, not just an extremely small number of patients who may be seeking care in a hospital but desire to have a non-hospital physician direct their care. This bill is not only dangerous to hospitalized patients but will result in hospitals, pharmacists, and other providers having to choose which laws to comply with – the laws set forth in Sub. H.B. 73 or the laws that continue to govern the practice of medicine.

Specific Concerns within Sub. House Bill 73

Conflict with Existing Laws and Standard Practice of Care

Under the current version of Sub. H.B. 73, a hospital pharmacist is required to dispense (and requires the hospital to allow the dispensing of) any drug prescribed for off-label use, with exceptions for moral, ethical, or religious belief that conflicts with the drug's dispensing, or if a pharmacist has documented that the patient has a history of life-threatening allergic reaction to the drug or there is a life-threatening contraindication. While OHA appreciates the efforts of the sponsors to address concerns around requiring clinicians to administer drugs that could potentially harm patients, this provision still conflicts with current state and federal laws governing the practice of pharmacy and federal medical reconciliation requirements.

For example, the language does not contemplate that a large part of a pharmacist's practice is ensuring that prescribed drugs do not adversely impact a patient. Ohio law (OAC 4729:5-5-08) 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; 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.

The role of a pharmacist is extremely important in a hospital because the pharmacist is often one of the few practitioners that has a full picture of the various drugs that a patient may be taking in the hospital. 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 to discuss with the prescriber some of the potential adverse impacts a particular drug may have on a patient that the prescriber may not have known. It is very common for those conversations in a hospital to result in an alternate drug prescription or alternate care plan. This dialogue prevents harm from happening to patients and reduces the opportunities for medication errors. Though section (C)(6) of 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.

In the rare instances when prescriber and pharmacist are at an impasse regarding the appropriate drug regimen for a hospitalized patient, there are mechanisms to resolve those disputes quickly and professionally. Those mechanisms are physician-led executive committees or ethics committees whose priority is ensuring the best care for patients. Sub. House Bill 73 would not allow for these well-established processes as the bill mandates the prescription be filled as written. That is untenable in hospitals and could result in unsafe care and potential harm to patients, as well as violations of current law.

Liability Protection for Healthcare Providers

Section (C)(2) attempts to provide liability protection to a pharmacist or hospital who objects to dispensing a drug, but only if the pharmacist or hospital documents in the medical record the basis for the objection and submits to the Pharmacy Board or ODH a document detailing the basis of the objection. Again, we appreciate the bill sponsors hearing OHA's concerns around liability for providers under Sub. H.B. 73, but this section still raises questions as many pharmacists will not have access to a patient's full medical record and will be unable to comply with this requirement. For example, retail pharmacies do not have access to patient medical records.

OHA strongly believes if the law requires a pharmacist or hospital 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 and hospitals cannot be sued, rather than having to incur the expense of defending a suit to obtain immunity.

Unverified Medications in Hospitals

Section (C)(3) of Sub. H.B. 73 states that a pharmacist must make a good faith effort to obtain the drug and document such efforts if an in-hospital 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. If the pharmacist or hospital is not able to source the drug, but the patient has access to the drug at home or through another source, the bill requires the hospital to allow the patient to bring the drug into the hospital and use it.

OHA is not able to support a requirement to dispense a drug brought from home to be used in the hospital because it could be dangerous, even if requiring the drug be "identified", as defined in the bill. Unfortunately, there is no way to ensure a drug provided by the patient is what they say it is, or if the packaging accurately labels the drug. Requiring a drug to be used in the hospital without regard to clinical contraindications, allergies, drug interactions, dosage checks, and other regularly performed patient safety steps required by law will result not only in violations of existing law but could also result in adverse outcomes for patients. Requiring a hospital to dispense a drug without allowing for legally required patient safety processes and professional practice by highly trained clinicians is not in the best interest of patients.

Temporary Credentialing

Section (C)(4) of Sub. H.B. 73 provides that if there is not a prescriber in the hospital willing to prescribe a particular drug, then the patient's outpatient prescriber must be allowed to immediately apply for "temporary privileges with oversight." If the outpatient prescriber is not granted privileges, the hospital must report the denial to ODH. If the outpatient prescriber is granted privileges, they must be authorized to participate in the patient's care to administer and monitor the prescribed off-label drug until the patient can be transferred to a hospital where the outpatient prescriber is credentialed.

Some hospitals may not have a category of "temporary privileges" in their medical staff bylaws. Nor is the term defined in the bill or within Ohio law. Additionally, the process for granting such privileges may take more than 5 days depending on the documentation needed or references to be checked, and the speed with which the physician responds to requests for information.

It is also unclear under this section how the Ohio Department of Health would utilize this report indicating a physician's application for temporary privileges was denied. OHA also questions the concept under which the bill requires hospitals to report when they choose to deny a physician credentials. Hospitals deny credentials for physicians and other providers for a variety of reasons that are not reported to regulators.

CONCLUSION

The Ohio Hospital Association would like to thank committee members for their consideration of the above concerns. We appreciate the work done by the sponsors, committee chairman and others to understand the nuances of prescribing drugs in a hospital setting. However, for the reasons outlined throughout this testimony, we respectfully request the committee modify the scope Sub. H.B. 73 to only the outpatient and retail pharmacy setting.

Patient care in hospitals is complex and providers need to be able to practice their profession to the fullest extent of their training. Sub. H.B. 73 impairs providers' ability to do that in a hospital and is both unsafe for patients and will cause hospitals, pharmacists, and other providers to choose whether to violate Sub. H.B. 73 or other laws governing their practice.

Thank you for your time and consideration. We look forward to continued discussions as the bill moves through the legislative process.