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Substitute House Bill 73 – Opponent Testimony
Senate Health Committee
June 12, 2024

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Chair Huffman, Vice Chair Johnson, Ranking Member Antonio, and members of the Ohio Senate Health Committee, thank you for allowing us to provide opponent testimony for Substitute House Bill 73 (Sub. HB 73), legislation regarding off-label prescribing. Our names are Donald Malone (Executive Vice President, Cleveland Clinic) and Lindsey Amerine (Chief Pharmacy Officer, Cleveland Clinic) and we are jointly providing testimony on behalf of Cleveland Clinic.

Cleveland Clinic is a not-for-profit, integrated healthcare system dedicated to patient-centered care, teaching, and research. Cleveland Clinic Health System operates 23 hospitals with more than 6,600 staffed beds, including a main campus near downtown Cleveland and 15 Northeast Ohio regional hospitals, as well as 276 outpatient locations. Cleveland Clinic employs over 5,700 physicians and scientists and over 16,500 nurses. Last year, our system cared for 3.3 million patients, including 13.7 million outpatient visits and 323,000 hospital admissions and observations. Cleveland Clinic is proud to be Ohio's largest private employer and is dedicated to being a leader in patient experience, clinical outcomes, research, and education for patients.

To begin, both physicians and pharmacists have long supported safe and effective off-label use of FDA approved medications. It is a practice that we value and will continue to support, regardless of whether Sub. HB 73 becomes law. Therefore, this proposed legislation is unnecessary, as existing laws already permit the prescribing and dispensing of off-label treatments.

Unfortunately, as currently written, HB 73 would introduce a myriad of unintended consequences and harm Ohioans. The potential impact of Sub. HB 73 on the health and safety of the people of Ohio is very concerning as a matter of public policy.

The bill would mandate that pharmacists dispense prescribed off-label medications without the ability to exercise professional judgment to ensure all dispensed prescriptions are safe and effective, eliminating vital safeguards that prevent inappropriate and harmful medication use. This not only endangers patients but also provides cover for bad faith actors who may prescribe medications without proper oversight or patient safety considerations. The review by the dispensing pharmacist is the final check in the medication use process to ensure the safe and appropriate use of prescription medications. The pharmacist is the last line of defense for patients to prevent medication-related adverse events from drug-drug interactions, drug-disease interactions, or even medications which require dosing changes when new medications are started.

The bill also states that the provider prescribing for off-label medication use does not need to obtain or document a test result for a specific diagnosis or condition. This provision contradicts

the basic safety requirements for medicine administration: the right drug to the right patient for the right condition in the right dosage form. The medical necessity of hospital admission indicates that a patient needs acute care and may already be administered drugs or other treatments that may have interactions with the off-label medication.

Further, hospitals routinely require lab tests before using particular drugs for patient safety purposes. For instance, hospitals require tests for indications before providing broad-spectrum antibiotics to make sure the medication will be effective and help reduce antibiotic resistance; their ability to do so would be called into question if this law were enacted.

Additionally, requiring pharmacies to dispense every non-formulary medication would likely worsen patient safety interventions and bypass safety processes, thereby potentially compromising patient safety. Cleveland Clinic routinely reviews evidence on safety and efficacy of medications; based on this review, we have approved formulary restrictions for use of particular medications and have decided based on lack of efficacy and/or potential safety concerns to not add certain medications to our formulary. If this were to become law, hospitals would have to provide whatever medication is requested by a provider or patient, no matter the evidence or patient safety considerations.

The language requiring hospitals to exercise a “good faith effort” to obtain the drug is ambiguous and would create confusion and concern about how to meet this standard. Hospitals already have an existing and often sparingly used policy for patients’ access to or bringing in outside medications. It is a slippery slope to go beyond established protocols because there is no way to ensure the externally obtained medication was properly stored and transported. Storage and transportation issues are of great concern because they can impact the safety and efficacy of the medication. There also remains confusion about the proposed requirement that hospitals “identify” the drugs brought from outside for patient use; it is unclear what this process would entail.

In addition, while the requirement that hospitals grant temporary medical staff privileges has been limited in the substitute version of the bill, it could still undermine the existing hospital quality and safety structure. Hospitals grant temporary privileges to fulfill important patient care, treatment, and service needs; it is not clear that access to off-label drugs meets these criteria. This legislation would give a provider denied these privileges the novel remedy of filing a complaint with the Ohio Department of Health (ODH); these complaints would be available to the public without the full 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.

Another issue is that the bill would grant eligible providers civil and administrative immunity, but not criminal immunity, and this is a real concern as the bill would potentially compel hospitals and pharmacists to act outside of the standards of professional practice and counter to established norms of clinical judgment. Further, Sub. HB 73 could expose providers to liability for using off-label drugs if they do not comply with the new “informed consent” definition in the bill. Many doctors currently prescribe off-label without an informed consent requirement: off-label use of drugs is estimated to constitute up to 33% of overall prescriptions in the United States and up to 97% in certain populations. This occurs under current practice standards of physician-pharmacist-nurse checks to ensure evidence-based therapy is upheld. Creating this entirely new, undue, and highly administratively burdensome requirement is unnecessary and an overreach.

Another issue to note is that the bill does not provide specific liability protections for a nurse. If an outside physician is granted temporary privileges and the pharmacist cannot refuse to dispense

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the medication, it is unclear what responsibility lies with the hospital-employed nurse when the medication is administered. The nurse is also not given the ability to file a good faith objection as outlined for others in the bill. He or she would be required to refuse based on conscience or practice standards to fulfill his or her responsibilities.

Further, it is unclear what the implications would be for the attending physician or specialist caring for the patient who has received medication from an outside provider. We also question and have concerns with how an outside provider would be held accountable when they write the medication to be administered to a patient they have not seen, examined, or treated in the hospital.

In summary, there remain too many concerns to allow this legislation to move forward, and we ask that the committee members oppose Sub. HB 73.

Thank you again for allowing us to provide opponent testimony on behalf of Cleveland Clinic.