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Testimony before the Ohio Senate Health Committee
Opposing Substitute House Bill 73
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Chairman Huffman, Vice Chairman Johnson, Ranking Member Antonio, and members of the Senate Health Committee, thank you for the opportunity to provide written testimony in opposition to Substitute House Bill 73.

As one of the nation's leading academic health centers, The Ohio State University Wexner Medical Center (OSUWMC) offers health care services in virtually every specialty and subspecialty in medicine. Providing access to health care information is central to our research, education and patient care mission. At Ohio State Wexner Medical Center, we're dedicated to improving health in Ohio and across the world through innovation in research, education and patient care.

I appreciate the opportunity to submit testimony in writing regarding Sub. H.B. 73.

First, OSUWMC has no opposition to the provisions of the bill that codify the practice of prescribing off-label medications. Off-label prescribing is a common practice that has been successfully utilized by providers for decades and involves a provider writing a prescription for a medication whose use is approved by the U.S. Food and Drug Administration (FDA) but the prescription is for an indication that is not currently approved. While this bill supports the practice of off-label prescribing, it should be noted that there will be no negative impact on the current practice of off-label prescribing if this bill is **not** passed and signed into law.

However, OSUWMC has significant concerns about multiple provisions in Sub. H.B. 73 and we are opposed to it in its current form.

One of the most concerning provisions in Sub H.B.73 would **require** a pharmacist to fill off-label prescriptions without regard for their own professional judgment. The practice of off-label prescribing has an appropriate double check by having the pharmacist who is dispensing the medication also be responsible for reviewing the prescription to ensure that the drug is safe for the patient. Sub. H.B. 73 would set an uncommon precedent by forcing a pharmacist to fill any prescription for an off-label indication, even when dispensing that drug goes against the pharmacist's professional judgement. This provision will significantly jeopardize patient safety. This proposed bill is in direct conflict with OAC

4729:5-9-02.7 (I) which places corresponding responsibility on both prescribers and pharmacists for ensuring the safety and efficacy for medication prescriptions.

In addition, Sub. H.B.73 creates a new requirement for hospitals to provide temporary privileges to any provider who requests them solely for the purpose of allowing the provider in question to prescribe an off-label drug. This provision in the bill has significant safety implications by causing chaos within the facility by an unknown, individual provider attempting to enter a medication order on patients who they have not been caring for and have not examined while in the hospital. The medical staff credentialing process is a key element in the administrative process to ensure that safe care is provided within a hospital. Based on national accreditation and regulatory requirements, the credentialing process requires primary source verification of a provider's license, their previous training, any previous malpractice lawsuits, a review of their National Practitioner Databank file, etc. This process is quite costly in terms of staff time and usually takes a minimum of 30-45 to complete.

If a hospital were to allow an unknown provider who has not established a pre-existing relationship to a patient to obtain temporary credentials solely for the purposes of prescribing a medication that the hospital's providers and pharmacists have determined is not safe or if the dispensing of that medication would be prohibited by the hospital's policies, the hospital would be in serious jeopardy of a disciplinary action by either the Centers for Medicare and Medicaid Services (CMS) under the Conditions of Participation or by The Joint Commission (or similar accrediting agency) regardless of what the Ohio Revised Code might allow. This disciplinary action would be based on the blatant disregard of basic patient safety practices and principles for safe medication prescribing within a hospital setting.

If an individual did obtain temporary privileges at a hospital, that practitioner would still be required to abide by medical staff bylaws, rules and regulations, and hospital and medical staff policies. Forcing a pharmacist to dispense a medication against their own professional judgement would not be consistent with the ethical and professional expectations for a provider under most medical staff bylaws and hospital policies.

In summary on this topic, our concern is that this provision would essentially nullify the long-standing authority of hospital boards and hospital medical staffs to determine criteria for membership on a medical staff and to develop programs and processes to ensure patient safety within their institution.

In addition, we are concerned that there are insufficient guardrails in Sub. H.B. 73 that would further define when this process may apply. For example:

- There is not a provision in Sub H.B. 73 that would require the patient and provider to have a pre-existing patient-provider relationship prior to the off-label prescribing.
- There is not a provision in Sub. H.B. 73 that would require the provider to perform a physical exam of the patient prior to prescribing the off-label medication. Even in situations when there is a pre-existing patient-provider relationship, the patient's physical and medical condition may be significantly different in the hospital than the last time the provider examined the patient.

Prescribing an off-label medication in opposition to the judgement of the patient's current treating physician without examining the patient would not be safe.

- There is not a provision in Sub. H.B.73 that would require the provider to review the patient's medical record – including the patient's clinical course in the hospital -- prior to prescribing the off-label medication.
- There is not a provision in Sub. H.B. 73 that would require the provider to use the hospital's electronic medical record to prescribe the medication. Electronic medical record systems contain a variety of safety screens and double-checks that help reduce the risk of unsafe prescribing.
- There is not a provision in Sub. H.B. 73 that would require the provider to document their medical decision making about why they are prescribing the medication. The electronic medical record is an important communication mechanism between providers and other hospital staff. This communication would be even more important in these situations when the provider caring for the patient (and the pharmacist assigned to that patient) are not in support of the use of the off-label medication.

Beyond the mention of "controlled substances" in Sub. H.B.73, there are no additional limitations on which classes of medications a provider could prescribe off-label. As written, HB73 would permit a pathologist or radiologist to write a prescription for a chemotherapeutic agent without restrictions. For medications like chemotherapy or other drugs with significant side effects/risks, many hospitals have specific privileging criteria that allow only certain providers with specialized training or experience to prescribe these medications. If an individual applies for temporary credentialing at a hospital, but the provider does not meet those privileging requirements, would the provider still be permitted to write the prescription, and would the hospital be required to dispense it? If so, we see this as a major patient safety risk.

Sub. H.B. 73 also poses concerns related to the use of unverified medication in the hospital. The bill contains several provisions specific to dispensing and administering an off-label drug in a hospital or inpatient facility, including when the drug is not in stock. The bill states that a pharmacist must make a good faith effort to obtain the drug and document such efforts. 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 medication into the hospital for use. The requirement to dispense a medication brought from home for use in the hospital poses significant patient safety risks because there is no satisfactory way to accurately identify the drug. Even if a drug can be identified in limited scenarios, it may be unable to determine all the necessary specifics for safe dispensing (e.g., is the medication expired, whether a medication requiring refrigeration has been properly stored, that oral dosage forms are not damp or soiled, that topical or liquid dosage forms are not separated or discolored, etc.) Additionally, this proposed legislation is in direct conflict with the requirements of the FDA's Drug Supply Chain Security Act (DSCSA). Health-system pharmacies are required to track drugs back to their origin of procurement directly. This proposed legislation is in direct conflict with the requirements of DSCSA. Requiring a hospital to dispense a drug without following DSCSA would result in a violation with penalties that include regulatory or legal action, including seizure and injunction.

Sub. H.B. 73 also does not consider drug shortages and other situations when a medication may be in very limited supply. In those cases, hospitals generally implement specific processes to prioritize certain patient populations who are most likely to benefit from taking the medication. The allocation and use of medications in limited supply are restricted based on a set of ethical principles called the "allocation of scarce medical resources" which attempts to prioritize which patients would benefit most from the use of a limited availably medication or treatment. If a provider with temporary credentials solely for the purpose of prescribing a medication were to prescribe one of these medications to a patient who did not meet the allocation criteria, requiring that hospital to dispense the medication to the lower priority patient would directly harm other patients who would have a higher probability of benefiting from that medication.

Sub. H.B.73 also has provisions that would allow a hospital to independently bill a patient directly for out of pockets costs for the off-label medication prescribed. In the case of commercial insurance plans, pre-existing contracts would not permit a hospital to bill a patient outside of the provisions of that contract. It is not clear that commercial insurance companies would permit this billing practice just because it is permitted in state law because pre-existing contracts would prohibit that practice. Similarly, for Medicare and Medicaid patients, this provision would be in direct conflict with current Federal and state regulations related to how patients may be billed for services.

We believe strongly in access to off-label medications that are safe and effective and work tirelessly to ensure that patients have access to medications that aid in their healing. However, multiple provisions in Sub. H.B. 73 will have a negative impact on the safe and effective use of medications both at home and in the inpatient hospital environment. We urge you to not move the bill out of committee. Thank you for your consideration of these comments.