The Ohio Society of Health-System Pharmacy

To: The Ohio House of Representatives: Insurance Committee
HB156: Proponent Testimony
12 / 6 / 23

To: The Ohio House of Representatives Insurance Committee

Dear Chairman Lampton, Vice Chairman Barhorst, Ranking Member Miranda, and esteemed members of the House Insurance Committee, on behalf of the Ohio Society of Health-System Pharmacy (OSHP) we would like to thank you for the opportunity to provide proponent testimony on House Bill 156, a bill with the goal of limiting payer-mandated distribution models which compromise pharmacist and other providers' ability to provide optimal patient care.

The Ohio Society of Health-System Pharmacy represents hundreds of Ohio's pharmacists, students, technicians, and other healthcare associates with a specific focus on health-system pharmacy practice. OSHP strongly supports HB156 and the advancement of legislation addressing payer-mandated white-bagging models that jeopardize patient safety.

To fully express the rationale for our positions, we feel that we should first start by defining some of the key terminology related to this legislation that we will be using throughout our testimony.

White-Bagging: The practice of disallowing a provider from procuring and managing the handling of a drug used in patient care. Instead, a third-party specialty pharmacy dispenses the drug and sends it to a hospital or physician office for administration to a patient on a one-off basis.

Brown-Bagging: Like white-bagging, the provider is not permitted to procure and manage the handling of the drug being used in patient care. However, in this instance, the third-party specialty pharmacy dispenses the drug directly to a patient who then brings the drug with them to the hospital or a physician's office for administration.

Historically, payment for drugs administered within a hospital setting has utilized the "buy and bill" model, in which providers purchase, store and administer drugs to patients. Afterwards, payers will reimburse the providers for the cost and the administration of the drug. In an effort to improve profit margins in recent years, insurance companies and pharmacy benefit managers (PBM's) have begun restricting providers' ability to acquire, store and dispense the drugs that their patients need, instead requiring patients to have these

medications dispensed from a third-party specialty pharmacy that will ship the drug to either the hospital or physician's office (white-bagging) or to the patient so that they can bring the drug with them to their appointment for administration (brown-bagging). As a result of this practice, reimbursement for the acquisition and dispensing of a drug goes to the third-party specialty pharmacy rather than the provider. Thus, payer-mandated white-bagging and brown-bagging of medications shifts the revenue associated with drug procurement and storage away from providers and instead funnels that revenue to third-party specialty pharmacies which are often owned or affiliated with the insurance company or PBM itself.

This process negatively impacts the provider's ability to receive revenue for the patient care that they are providing, and in many cases where a hospital refuses to accept a white-bagged or brown-bagged drug for safety reasons, they will receive no reimbursement from the insurer, resulting in a net loss for providing optimal patient care. However, the payer will still retain the significant profit margin at the expense of the patient's interest.

The issues associated with payer-mandated white-bagging, while manufactured by insurance companies to maximize revenue, goes far beyond financials. This process requires additional steps, which overly complicate the process of drug procurement, storage, and administration, and introduce additional opportunities for errors that can result in significant consequences for patients. Many of whom are cancer patients simply trying to receive their life-sustaining chemotherapy.

By requiring health-systems to acquire the drug via a third-party specialty pharmacy, it bypasses the comprehensive safety systems within the providers electronic health record and fragments their records of patient prescriptions. Since the provider now must receive the acquired drug from a third-party pharmacy, providers are unable to properly oversee the supply chain, which can lead to inappropriate shipping and storage conditions for temperature-controlled medications, as well as delays in patient care due to unexpected delivery delays and misdirected mail. This also requires the provider to maintain a separate inventory for drugs procured via white-bagging, introducing a host of new potential errors. Ultimately, this prevents providers from properly ensuring that the product meets minimal safety standards before being administered to the patient, as they cannot validate the quality or integrity of the drug product that was delivered.

Many of the medications subjected to payer-mandated white-bagging practices are chemotherapy agents. In oncology, it is very common for cancer patients to see their provider on the same day as their scheduled infusion. This allows for the treatment plan to be modified as needed depending on the patient's presentation and lab values on the day of infusion. Dosing regimens for these medications are often modified the day of administration based upon new imaging results, new lab values, changes in weight or various other patient specific factors. The ability to adjust these regimens is negated when the hospital is not able to have the infusion regimen immediately available, this ultimately leads to additional medication waste and

therapy delays for patients, which can not only be frustrating for patients but can adversely impact their recovery.

Payer-mandated white-bagging and brown-bagging policies place profits over patients. These policies negatively impact both patients and their providers, yet they remain in place because there is one clear winner from these policies, the payers themselves. By shifting the reimbursement for drug acquisition and storage to pharmacies that are often owned or affiliated with the insurance company themselves, providers lose revenue which the payer can funnel back into their own organization via their affiliated pharmacy. As a result, patients are more likely to have a delay in their therapy and/or receive a drug product that cannot have it's quality and integrity verified by their trusted providers.

For these reasons, the OSHP supports legislation aimed at limiting the practice of payer-mandated white-bagging and brown-bagging. The national affiliate of OSHP, The American Society of Health System Pharmacists (ASHP) has developed 5 key elements that should be included within any legislation aimed at limiting white-bagging, these key elements are as follows.

1. Define clinician-administered drugs.
2. Require health plans to permit enrollees to obtain clinician-administered drugs directly from the administering facility on equal financial terms.
3. Permit any qualified specialty pharmacy to dispense clinician administered drugs.
4. Prohibit plans from requiring brown-bagging for any clinician-administered drug.
5. Prohibit plans from requiring home infusion and/or alternative sites of care for any clinician administered drug.

We would next like to provide an analysis of how these elements should be included in legislation aimed at limiting payer-mandated white-bagging and assess how House Bill 156 would address each element.

1. **Define clinician-administered drugs.**

    a. Policy must establish which medications are subject to payer-mandated white-bagging, an overly broad definition could result in unintended barriers for self-administered medications while an overly narrow definition may leave regulatory gaps that can be exploited by bad actors.

        i. In House Bill 156 "Physician-administered drug or medication" means an outpatient drug, other than a vaccine, that cannot reasonably be self-administered by the patient to whom the drug is prescribed, or by an individual assisting the patient with the self-administration, and that is typically administered by a healthcare provider in a physician's office, hospital outpatient infusion center, or other outpatient clinical setting.

ii. We applaud the sponsors for the inclusion of this definition. We however would encourage a slight modification to the definition to read as follows:

1. *"Clinician-administered drug" means an outpatient prescription drug other than a vaccine that:(A) cannot reasonably be self-administered by the patient to whom the drug is prescribed or by an individual assisting the patient with the self-administration; and*
(B) is typically administered: (i) by a health care provider <u>authorized under the laws of this state to administer the drug, including when acting under a physician 's delegation and supervision; and</u>
(ii) in a physician 's office, hospital outpatient infusion center, or other clinical setting.

2. Require health plans to permit enrollees to obtain clinician-administered drugs directly from the administering facility on equal financial terms.

a. Plans should be required to make clinician-administered drugs available directly from the administering provider on equal financial terms. Prohibited monetary advantage or penalty includes higher copayment, a reduction in reimbursement for services, or promotion of one participating pharmacy over another.

i. In House Bill 156: A health benefit plan issued, amended, or renewed on or after the effective date of this section may offer, but shall not require or incentivize, physician-administered drugs or medications to be dispensed by a specific pharmacy or affiliated pharmacy if any of the following are true: (1) The choice of drug, strength, or dose depends on the covered person's clinical presentation, including weight changes, lab results, or adverse event grading. (2) The drug requires compounding. (3) The covered person, or the covered person's legal representative, has not consented in writing to the offered dispensing arrangement for a specified course of treatment.

ii. (C) A health benefit plan issued, amended, or renewed on or after the effective date of this section shall not do any of the following: (1) Limit or exclude coverage for a physician-administered drug or medication when it is not dispensed by a pharmacy or affiliated pharmacy if the drug is otherwise covered under the health benefit plan; (2) Cover the drug or medication at a different benefits tier or with cost-sharing requirements that impose greater expense for a covered person if it is dispensed or administered at the physician's office, hospital outpatient infusion center, or other outpatient clinical setting rather than a pharmacy.

iii. We applaud the sponsors for preventing payers from requiring or incentivizing medications to be dispensed by a specific pharmacy. We however would encourage a slight modification to the verbiage to define more specifically what constitutes incentivizing, such as:

1. *A health benefit issuer shall not: (1) refuse to authorize, approve, or pay a participating provider for providing covered clinician-administered drugs and related services to covered persons; (2) impose coverage or benefits limitations, or require an enrollee to pay an additional fee, higher copay, higher coinsurance, second copay, second coinsurance, or other penalty when obtaining clinician-administered drugs from a health care provider authorized under the laws of this state to administer clinician-administered drugs, or a pharmacy; (3) interfere with the patient's right to choose to obtain a clinician-administered drug from their provider or pharmacy of choice, including inducement, steering, or offering financial or other incentives.*

3. Permit any qualified specialty pharmacy to dispense clinician administered drugs.

a. In cases where administering providers choose to obtain clinician-administered drugs via a specialty pharmacy, providers should also be given freedom to obtain such drugs from any qualified specialty pharmacy on equal financial terms.

i. While House Bill 156 limits payers' ability to require patients to use an affiliated specialty pharmacy instead of the provider themselves. Additional language could be added to ensure that providers who require a medication be acquired via white-bagging will not suffer negative repercussions for using an unaffiliated, qualified specialty pharmacy.

ii. With this in mind, we would propose the following verbiage.

1. *A health benefit issuer shall not:(1) require clinician-administered drugs to be dispensed by a pharmacy selected by the health plan; (2) limit or exclude coverage for a clinician-administered drug when not dispensed by a pharmacy selected by the health plan, if such drug would otherwise be covered; (3) reimburse at a lesser amount clinician-administered drugs dispensed by a pharmacy not selected by the health plan; (4) condition, deny, restrict, refuse to authorize or approve, or reduce payment to a participating provider for a clinician-*

administered drug when all criteria for medical necessity are met, because the participating provider obtains clinician-administered drugs from a pharmacy that is not a participating provider in the health benefit issuer's network; (5) require that an enrollee pay an additional fee, higher copay, higher coinsurance, second copay, second coinsurance, or any other form of price increase for clinician-administered drugs when not dispensed by a pharmacy selected by the health plan.

4. **Prohibit plans from requiring brown-bagging for any clinician-administered drug.**

    a. Payers should not require any clinician-administered drug to be dispensed directly to a patient. There is strong clinical consensus that requiring patients to properly store and transport a drug to their clinician for administration jeopardizes patient safety.

        i. We propose the addition of the following verbiage.

            1. *A health benefit issuer shall not require a specialty pharmacy to dispense a clinician-administered medication directly to a patient with the intention that the patient will transport the medication to a healthcare provider for administration.*

5. **Prohibit plans from requiring home infusion and/or alternative sites of care for any clinician administered drug.**

    a. The decision whether to use home infusion should be made by providers and patients in cases where a provider and patient determine that drugs can be safely shipped, stored, and administered in the patient's home.

        i. House Bill 156 could potentially be circumvented by bad actors who may begin requiring more patients to utilize home-infusion, leading to increased usage of their affiliated pharmacies.

            1. We propose the addition of the following verbiage.

                a. *A health benefit issuer may offer but shall not require:(1) the use of a home infusion pharmacy to dispense clinician-administered drugs to patients in their homes or; (2) the use of an infusion site external to a patient's provider office or clinic.*

Conclusion:

In closing, The Ohio Society of Health-System Pharmacy urges the House Insurance Committee to consider the impact of payer-mandated white-bagging on patients and providers here in Ohio. We look forward to continuing to collaborate with this committee, the sponsors, payers, and other organizations to help ensure that Ohioan get the care that they deserve. We appreciate your thoughtful consideration of this important legislation and stand ready to address any questions or concerns you may have.

Thank you for your commitment to the well-being of your constituents, our patients, and the advancement of public health.

Sincerely,

Daniel Arendt Pharm.D., BCPS

Legislative Affairs Director: The Ohio Society of Health-System Pharmacy

PAYER-MANDATED WHITE BAGGING MODEL

American Hospital Association™
Advancing Health in America

HOSPITAL

1

Health system treats patients and develops medication treatment plan.

Delays in Treatment: Changes in clinical status result in the need to re-order the medication from the external pharmacy, which delays patient care and can also result in drug waste.

2

Insurer mandates that the hospital send the prescription to a third-party mail-order specialty pharmacy instead of providing the medication using its own on-site or affiliated pharmacy.

Bypassing Safety Systems: Pharmacy ordering through a third-party specialty pharmacy bypasses comprehensive EHR safety systems and fragments medical records for patient prescriptions.

3

Third-party specialty pharmacy receives the order, prepares the medication for an individual patient and ships it with a delivery company.

THIRD-PARTY SPECIALTY PHARMACY

Insurer-selected specialty pharmacies are often owned by or affiliated with the insurance company.

4

The product is shipped to the health system, which is responsible for receiving, storing and managing the inventory whenever it arrives in the mail from a delivery service, often without notice.

Supply Chain Logistics: A variety of supply chain issues may compromise the integrity of the product or delay delivery and treatment, such as misdirected mail or inappropriate shipping and storage conditions for temperature controlled medication.

Separate Inventories Create Opportunities for Error: The third-party pharmacy sends medication dispensed for an individual patient to a health system — which typically maintains medication inventory in bulk supply — bypassing safety systems and creating opportunities for error with separate inventory systems.

Benefits to Insurer: White bagging allows insurers to steer business to their own pharmacies at the expense of hospitals and patients.

In cases where hospitals refuse to accept white bagged drugs and provide drugs to patients in-clinic for safety reasons, hospitals will often receive no payment from the insurer, resulting in hospitals taking a loss while insurers profit from not having to pay for drugs administered to their members.

HEALTH INSURANCE PLAN

5

If/when the medication arrives, the patient must return for medication administration.

PATIENT

6

If updates to the medication treatment plan are required based on changes in clinical status, the process begins again and treatment is delayed until the adjusted medication is ordered and received from the third party specialty pharmacy.

Inability to Ensure Product Safety Standards: The health system often does not have a contract or affiliation with the third-party specialty pharmacy and cannot validate the quality or integrity of the product being delivered, including chain of custody or shipping and storage conditions.

HOSPITAL AND HEALTH-SYSTEM MODEL

Adheres to Safety Protocols: Medications flow through standard safety channels, including medication ordering and management systems with built-in safeguards. This model avoids requiring the involvement of outside, third-party vendors, which may circumvent hospital safety systems.

Streamlined Logistics: Patient medications are provided from on-site inventory, avoiding potential delays in shipping or delivery, misdirected mail, or other disruptions in medication delivery.

HEALTH SYSTEM PHARMACY

HOSPITAL

PHARMACY

Avoids Delays in Treatment: Medications are provided to patients from on-site inventory and can be adjusted day-of based on the patient's most up-to-date clinical status.

1

Health system treats patients and develops medication treatment plan.

2

Health system enters medication order into EHR, which provides comprehensive safety checks and a complete record of medication orders and administration.

Enhanced Care Coordination: The patient's care and medication management is centralized with their healthcare provider, ensuring care coordination and avoiding medication record fragmentation.

3

The health system pharmacy prepares medication on the day of clinic infusion from its own inventory. Updates to the medication treatment plan resulting from changes in clinical status can be adjusted day-of, on-site to prevent delays in care.

American Hospital Association™

Advancing Health in America