April 27, 2023

The Honorable Chairman Bernie Sanders
Senate Committee on Health, Education, Labor and Pensions
United States Senate
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ranking Member Bill Cassidy, M.D.
Senate Committee on Health, Education, Labor and Pensions
United States Senate
428 Dirksen Senate Office
Washington, DC 20510

Re: Senate Health, Education, Labor and Pensions Committee Markup of the Ensuring Timely Access to Generics Act of 2023, Expanding Access to Low-Cost Generics Act of 2023, RARE Act, and Pharmacy Benefit Manager Reform Act.

Dear Chairman Sanders and Ranking Member Cassidy:

Thank you for holding the upcoming May 2nd markup on key legislation that will make pharmaceuticals more affordable and available as well as provide greater transparency and oversight over the pharmacy benefit manager (PBM) marketplace. ASHP is the largest association of pharmacy professionals in the United States, representing over 60,000 pharmacists, student pharmacists, and pharmacy technicians in all patient care settings, including hospitals, ambulatory clinics, and health system community pharmacies. Our members have seen firsthand how PBM practices and threats to generic competition can limit access to pharmaceuticals and put patient care at risk.

Specifically, we strongly support S. 1607, the Ensuring Timely Access to Generics Act of 2023, sponsored by Senators Jeanne Shaheen and Susan Collins, that would enable the Food and Drug Administration (FDA) to deny citizen petitions that are primarily used to delay generic competition. This legislation is necessary to ensure the citizen petition process is not misused and Americans have timely access to affordable and safe generic drugs.

We also strongly support S. 1114, the Expanding Access to Low-Cost Generics Act of 2023, sponsored by Senators Tina Smith and Mike Braun, which would remedy collusive activity between a brand and generic manufacturers, such as where a brand company agrees not to sue the first generic filer of a drug as long as the generic manufacturer agrees to delay bringing its product to market. This practice limits the efficient access to safe and affordable generic alternatives to costly branded medications.

We also strongly support S. 1214, the Retaining Access and Restoring Exclusivity (RARE) Act, sponsored by Senator Tammy Baldwin, which would clarify that orphan drug exclusivity only applies to the same approved use or indication within such rare disease or condition instead of the same disease or condition, thus giving the FDA authority to approve a drug from two different manufacturers if the manufactures are seeking to serve different patient populations.

We support the Pharmacy Benefit Manager Reform Act, sponsored by yourselves and Senators Patty Murray, and Roger Marshall, and its efforts to bring greater transparency and accountability to the PBM marketplace. In particular, we applaud the Act requiring PBMs to report critical information on rebates, fees, and other remuneration, and prohibiting PBMs from enriching themselves through spread pricing and rebates. We particularly support the requirement that all rebates and other remuneration be passed through and considered a plan asset. We agree the Act provides greater clarity of the role and practices of PBMs in the individual and group marketplaces.

However, we do have some suggested improvements that will prohibit PBM practices that are harmful to plans, issuers, providers, and participants and beneficiaries, as well as provide greater transparency necessary to enforce the requirements Act. Specifically, to increase transparency, we recommend the Act also require PBMs report on network adequacy and any restrictions on pharmacy participation. Specifically, PBMs have been discriminating against 340B eligible entities by excluding them from their networks. This behavior should be prohibited and greater transparency will assist the agencies in enforcing such a prohibition.

The Act also requires issuers or entities providing PBM services to report any benefit design parameters that encourage or require participants and beneficiaries in a plan to fill prescriptions at mail order, specialty, or retail pharmacies that are wholly or partially-owned by the issuer or entity providing pharmacy benefit management services. The trend of issuers and PBMs requiring participant and beneficiary medications be distributed through a narrow network of pharmacies, usually specialty, that are wholly or partially owned by the issuer or PBM is of concern. Often specialty medications are required to go through the wholly- or partially-owned pharmacy before it is then sent to a hospital where it will be administered, heightening the possibility of drug spoilage/wastage, or delays in administration of essential medications. In some cases, the wholly- or partially-owned pharmacy ships medications to a participant or beneficiary, who then must take the pharmaceutical to the provider for administration, further placing the patient at risk. See the attached illustration to understand the patient care risks associated with this practice.

We recommend issuers and PBMs be prohibited from referring participants and beneficiaries to wholly or partially-owned pharmacies, or that issuers and PBMs that require such arrangements indicate that under the Act's reporting requirements, as well as the clinical basis for such mandates.

The Act also requires reporting of PBM fees and prohibits issuers and PBMs from charging plans and participants and beneficiaries greater than the price paid by the pharmacy, while permitting penalties to be charged to pharmacies. While we agree fees should be reported by PBMs, the data should be granular and such fees should be prohibited when clinically inappropriate. Specifically, we have found that PBM fees, originally intended to spur quality, have been inappropriately and retroactively used as

a way to claw back reimbursement from pharmacies. Many times the basis for such fees is clinically inappropriate for the applicable drug for which they are applied. We recommend that no administrative, prescription, quality, performance, or other care-related fees be collected retroactively, but clearly outlined at the point of service. We also recommend PBMs be prohibited from enforcing pharmacy fees except when the quality measure on which a fee is based is directly related to the condition for which a patient is being treated and is appropriate for the setting the patient is being treated. Lastly, we recommend that any fee collected be clearly outlined in scope and magnitude within the contract with a pharmacy, allowing pharmacies to properly forecast budgeting and understand expectations. All such data should be reported pursuant to the Act's reporting requirements.

Relatedly, while we agree that penalties are reasonable to mitigate fraud, the broad scope of the penalties exception in the Act is susceptible to abuse. The penalty exception allows any fee under a pharmacy agreement to be defined as a penalty. The Act should require detailed reporting on the intent and enforcement of penalties, and prohibit their use except for plan integrity.

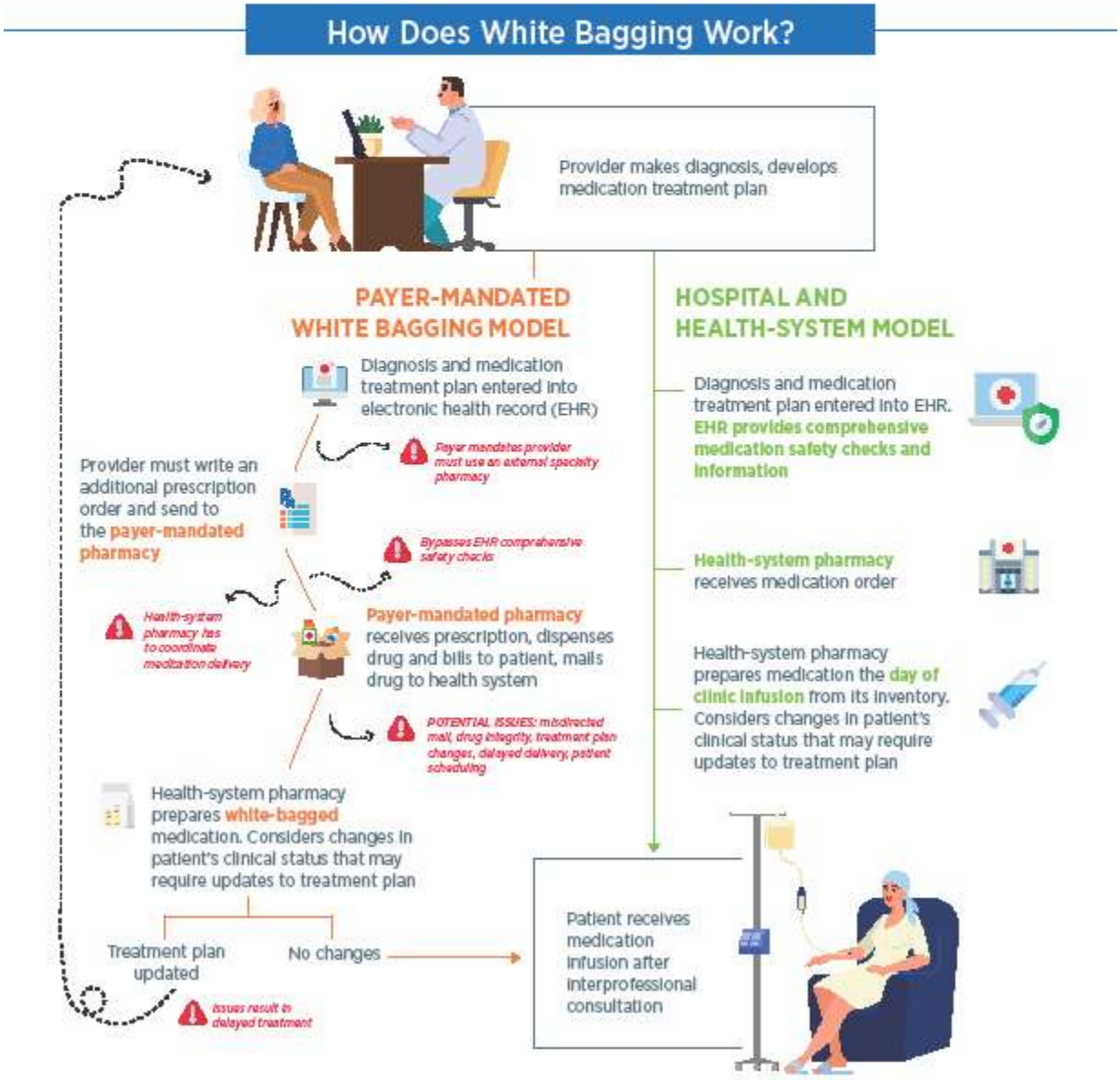
ASHP thanks you for your work on these issues. We look forward to continuing to work with you on these bills. If you have questions or if ASHP can assist in any way, please contact Frank Kolb at fkolb@ashp.org.

Sincerely,

Tom Kraus
American Society of Health-System Pharmacists
Vice President, Government Relations

Attachment: ASHP white bagging Informatic.


ashp
pharmacists advancing healthcare
WHITE BAGGING
Jeopardizes Patient Care
White bagging occurs when payers require a narrow network of plan-selected pharmacies to dispense clinician-administered drugs and bill a patient's prescription medication plan. White bagging is a risk prone process that should only be considered when determined by the provider to be necessary and appropriate to support patient care.


How Does White Bagging Work?
Provider makes diagnosis, develops medication treatment plan
PAYER-MANDATED WHITE BAGGING MODEL
Diagnosis and medication treatment plan entered into electronic health record (EHR)
Payer mandates provider must use an external specialty pharmacy
Provider must write an additional prescription order and send to the payer-mandated pharmacy
Bypasses EHR comprehensive safety checks
Health-system pharmacy has to coordinate medication delivery
Payer-mandated pharmacy receives prescription, dispenses drug and bills to patient, mails drug to health system
POTENTIAL ISSUES: misdirected mail, drug integrity, treatment plan changes, delayed delivery, patient scheduling
Health-system pharmacy prepares white-bagged medication. Considers changes in patient's clinical status that may require updates to treatment plan
Treatment plan updated
No changes
Issues result in delayed treatment
HOSPITAL AND HEALTH-SYSTEM MODEL
Diagnosis and medication treatment plan entered into EHR. EHR provides comprehensive medication safety checks and information
Health-system pharmacy receives medication order
Health-system pharmacy prepares medication the day of clinic infusion from its inventory. Considers changes in patient's clinical status that may require updates to treatment plan
Patient receives medication infusion after interprofessional consultation