American Hospital Association™
Advancing Health in America

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Lina M. Khan
Chair
Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue, N.W., Room H-113 (Annex J)
Washington, DC 20580

RE: Request for Public Comment on the Impact of Pharmacy Benefit Managers' Practice

Dear Chairwoman Khan:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners — including more than 270,000 affiliated physicians, two million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to provide comments in response to the Federal Trade Commission's (FTC) February 24th solicitation for public comments on the business practices of pharmacy benefit managers (PBMs) and their impact on independent pharmacies and consumers. There are several pertinent issues around PBM and PBM-affiliated organizations that raise significant concern for hospitals and health systems. **Specifically, we urge the FTC to increase scrutiny on insurer-mandated white bagging policies, as well as the impact of PBM-negotiated rebates and other business practices on the 340B drug discount pricing program and overall drug prices and drug price increases.**

INSURER-MANDATED WHITE AND BROWN BAGGING

Increases in ownership, consolidation and alignment between commercial health plans and PBMs, especially those with their own specialty pharmacies, have resulted in a series of business practices designed to steer patients to insurer-affiliated pharmacies and away from patients' longstanding providers to the detriment of patient care. Three of the largest PBMs, which account for nearly 80% of PBM business across the country — CVS Caremark, Optum Rx, and Express Scripts — all are owned by or aligned with major health plans. This level of health plan and PBM consolidation allows plans to maximize their negotiating leverage; consolidate the use of pharmacies among a small,

plan-owned or affiliated network; and increase plan profits through their role as an intermediary in the pharmacy supply chain. In addition, these maneuvers, achieved by manipulating insurance rules and benefit design particularly with respect to specialty drug coverage, establish a clear motivation for steering patients in ways that may financially benefit the plan and PBM but are often not in the patients' best interest — clinically or financially. Indeed, while these plan-mandated specialty pharmacy policies are often justified as creating efficiencies in the health care system, the numbers tell another story. Between 2017 and 2019, PBM gross profit increased 12% to $28 billion — much of that driven by PBM-owned mail order and specialty pharmacy services.[1] During the same time period, health insurance premiums increased by nearly 11%.[2] These figures suggest that such arrangements are not increasing health system efficiencies but rather are contributing to *increased spending* across the health care system.

As previously shared in a letter to the FTC last year, we believe one of the most significant challenges patients and providers face as it relates to PBMs is the steering of patients to third-party specialty pharmacies to acquire medication necessary for clinician-administered treatments.[3] This practice is commonly referred to as "white bagging." White bagging is the practice of disallowing a provider from procuring and managing the handling of a drug used in patient care. These are typically infused or injected medications which require a clinician to administer in a hospital or clinic setting in order to provide medication management and safe patient monitoring. Instead, in cases of white bagging, the health plan requires a third-party pharmacy to dispense the drug and sends it to a hospital or physician office on a one-off basis for administration. In cases of another similar practice referred to as "brown bagging," a health plan requires a patient to obtain the medication from the health plan's designated specialty pharmacy and bring the drug in to the clinic for administration. These practices raise egregious safety concerns; for example, for temperature-controlled medications that require specific storage conditions, and cause patient care delays when shipments do not arrive on time or are insufficient for the patient's needed dose. They also reflect the broader trend of health plans shifting cost and burden to patients.

As large health plans engage in broad vertical integration efforts, including the acquisition of PBMs and specialty pharmacies, the practice of mandated white bagging has increased dramatically. PBMs, like Optum Rx, state that "[t]here are some things in life we depend on. Medication is often one of them. We promise to deliver simple ways to get the medication you need." Yet, white bagging practices are anything but simple, adding significant complexity to the system, posing a number of safety issues for patients and introducing a variety of added safety risks across the drug supply chain

[1] https://www.beckershospitalreview.com/pharmacy/pbms-profits-are-increasing-while-their-revenue-sources-remain-unclear-report-says.html
[2] https://content.naic.org/sites/default/files/inline-files/2020-Annual-Health-Insurance-Industry-Analysis-Report.pdf
[3] https://www.aha.org/system/files/media/file/2021/02/aha-urges-ftc-examine-anticompetitive-behavior-nurse-staffing-agencies-commercial-insurers-2-4-21.pdf

(*see Attachment A*). Not only do these practices create significant risks and challenges, their design deliberately shifts higher costs to patients by covering medications under the pharmaceutical benefit, not the medical benefit. Doing so often exposes patients to higher costs because that benefit is frequently subject to its own deductible and other differing cost-sharing rules.

As white bagging mandates become more prevalent, America's hospitals and health systems are forced to navigate substantial supply chain and logistical challenges in order to continue to provide safe and effective care to the patients they treat. Our specific concerns include the following:

Delays and Risks in Patient Care. As mentioned above, white bagging has implications for the safe care of patients requiring certain drug therapies. For example, cancer patients are a high acuity patient population who require a variety of supportive therapies and medications and are particularly vulnerable to harm by white bagging policies. Specifically, many cancer patients are seen the same day as their scheduled infusion. Depending on a patient's day-of lab results and clinical presentation, initial treatment plans or dosing may be adjusted or cancelled altogether. Similarly, if imaging is conducted during the patient's visit, infusion regimens may need same-day adjustments depending on the progression of the disease shown in the CT scan results. However, under white bagging policies, those drugs are not available on-site and require external processing and shipping, resulting in the inability for clinicians to adjust medications in accordance with clinical and patient needs without delaying treatment. Failing to allow a hospital to use their own pharmacy inventory to manage patient care can result in substantial delays in treatment, ultimately increasing risk for the patient and potentially adversely impacting patient clinical outcomes.

These types of safety issues and delays in care are well-documented and further supported by testimony from patients and health care providers in videos, blogs and legislative hearings across the country. For example, one AHA health system member shared the experience of a cancer patient whose health plan implemented a white bagging policy for the patient's specific treatment needs. In this instance, the mandated white bagging policy resulted in a care delay of more than a month due to shipping delays from the third-party specialty pharmacy. The first medication shipment had to be discarded upon arrival because it was improperly stored overnight on a freight truck, making it no longer safe to use for treatment given the inappropriate storage conditions for a medication requiring specific temperature controls. Since the initial shipment was unusable, the medication was re-ordered and the patient was rescheduled for the infusion a few weeks later. The day before the rescheduled appointment, the health system pharmacy was notified that the medication delivery would be delayed due to inclement weather across the country, requiring the patient's appointment to be rescheduled a second time. After a month-long delay directly attributable to white bagging processes the care team was concerned about potential clinical ramifications of the delayed care and sought a waiver of the white bagging policy for this patient. The health plan eventually agreed to provide a waiver for one dose only, allowing the health

system pharmacy to intervene before greater patient harm occurred. However, the health plan required the provider to revert back to the white bagging process for future doses. The health system had the necessary medication in stock throughout the duration of these delays and, without an insurer-mandated white bagging policy, could have provided it to the patient as intended from the outset. Instead, the white bagging requirement forced the patient to go without medically necessary care for over a month while the hospital tried to negotiate on their behalf to resolve the situation.

In another example, Landon Claeys, a child with cerebral palsy, requires Botox injections to help loosen his muscles; however, his treatment was delayed by more than a month due to white bagging requirements.[4] Or Jessica Gendron, a cancer patient in Indiana, whose health plan stopped covering a white blood cell boosting shot that needed to be provided through infusion at the hospital between chemotherapy treatments. Instead, the health plan required that a third-party pharmacy ship the medication to her home for self-administration, which her oncologist deemed extremely unsafe.[5] There are countless other patient stories, which appear alongside videos and explainers from nationally recognized hospitals and health care professionals demonstrating the patient safety issues associated with white bagging, such as this explainer video created by Moffitt Cancer Center.[6] In addition to potential risks associated with delays in treatment, there is also potential harm resulting from a white bagging process that circumvents established patient safety systems. Hospitals use sophisticated medication ordering and management systems, which are directly linked to the electronic health record and have built-in mechanisms to ensure safe ordering and dispensing of patient medications. These records include detailed information about the formulation of a medication that was dispensed, which can differ by pharmacy and product, and ensures providers have a complete medication record, which is especially critical for complex and high acuity patients who often take multiple medications. This critical information is missing when drugs are processed and dispensed by an external pharmacy that is not linked to the patient's medical record.

Planning and Preparedness. To ensure the highest quality of care and patient safety, providers must have a clear line of sight into the acquisition, storage and administration of medications. In fact, they are legally required to do so. White bagging and brown bagging remove providers from the drug storage and supply chain process, creating significant yet avoidable challenges that circumvent patient safety protections. For example, under the "buy and bill" model, hospitals are the purchasers and owners of medications necessary for patient care. This purchaser/ownership role allows providers to manage inventory; monitor dispensing, compounding, and dosing; and ensure proper preparation and storage of drugs from purchase through administration in a way that is integrated into the patient's medical record. White and brown bagging policies interrupt that process, and its built-in safety mechanisms, and require hospitals to receive and

[4] https://www.wha.org/Patients-First-Wisconsin/Stories/Stories/Patient-Story
[5] https://www.ihaconnect.org/member/newsroom/Pages/Whitebagging-Harmony.aspx
[6] https://www.youtube.com/watch?v=NZlkjf4SnPs

store product that is not their own, sometimes with little to no notice. As a result, these policies often violate individual hospital policies for medication supply acquisition and have the potential to overwhelm hospital storage capacity as medication is delivered for individual patients on an ad hoc basis — and providers have to determine whether they can treat the patient with their own inventory solely based on their insurance status. Further, because these drugs are ordered for specific patients, tracking and keeping record of each patient-specific product presents an unreasonable and resource-intensive challenge in a system that was designed to manage bulk product for all clinic-administered drugs.

Quality of Handling to Ensure Patient Safety. More complex medications require increased care and attention to ensure product quality control. When hospitals control and own medications dispensed through their own pharmacy, they can certify the point of origin of the drug and demonstrate a clear chain of custody needed to ensure that the product is safe for patient administration. White bagging and brown bagging, however, interrupt that process, disrupting a hospital's ability to guarantee the safety of such drugs firsthand. For example, when a health plan implements a white bagging policy for a specific drug, the hospital is unable to determine where the product is manufactured or validate if storage requirements, like refrigeration, were met prior to delivery to the facility. In the absence of a contract with the third-party pharmacy, the hospital cannot request that the specialty pharmacy provide this information for inspection or confirmation. In addition, certain drugs have very limited windows for use once mixed or compounded, further complicating matters and adding to concerns around excessive product waste.

Information on Drug Shortages. Prior to the advent of white and brown bagging practices, hospitals had more information to manage, address and navigate drug shortages because they had clear line of sight into the medications their patients required and could more accurately project future utilization. With the implementation of these new practices, hospitals are no longer responsible for the purchasing of pharmaceutical products, but still are left with the real consequences of drug shortages, such as needing to explore alternative medication options or experiencing delays in receiving drugs needed for patient care.

Inefficiency and Increased Costs. In addition to increasing risk and cost for patients, each of the work-around steps needed to comply with insurer-mandated white bagging policies results in a tremendous amount of administrative effort, inefficiency and duplication of tasks. To accept a white bagged drug, the hospital must:

- Create and manage two separate pharmacy inventory systems (one for individual patient medications shipped from external pharmacies and one for drugs used in the hospital's clinic from their own inventory);
- Manage an entirely new supply chain and vendor, including shipping and logistics with a company who is not contractually obligated to respond to hospital requests;

- Manually fill in gaps in the patient's medical record to link together the pharmacy order from an external entity and the records of the medication that was administered in the clinic;
- Engage in time-consuming plan processes to seek approval for patient-specific waivers or appeals to allow the hospital to dispense the medication through usual channels in cases where the clinical team indicates it is unsafe to delay treatment or to accept a white bagged drug either because of the profile of the medication or the clinical characteristics of the patient; and
- Educate patients about their insurance benefits and explain delays in treatment caused by health plan requirements to use an outside pharmacy.

Each of these steps creates additional resource-intensive burden on providers that adds further complexity and cost to the health care system. Specifically, the costs of all of these work-around processes accrue to hospitals, which must manage a myriad of issues to ensure they protect the safety of their patients and receive appropriate payment for administration of the drug. Increased costs as a result of these policies range from additional labor expenses to increased workload and supply chain coordination to health plan refusal to reimburse hospitals and health systems for care provided to patients.

For example, one member reports that in the span of two days, a financial coordinator spent three hours on the phone with a health plan (with over 20 transfers) and a clinic nurse spent eight hours on the phone trying to coordinate with the specialty pharmacy for a single patient case involving a white bagging requirement for the administration of Neulasta, which is a supportive oncology medication. It took a full month of resource-intensive phone calls between the health system pharmacy, clinical staff, health plan, and the third-party specialty pharmacy to resolve the specific issues associated with this case, which involved confusion around whether the white bagged medication would be billed under the medical benefit or the pharmacy benefit; the need to overturn an initial denial because of an error by the third-party specialty pharmacy; logistical issues related to coordinating the medication delivery; and efforts from the specialty pharmacy to insist the patient self-inject the medication at home because it is a more "economic avenue for medication delivery" despite the patient being adamantly opposed to self-injection.

The top priority for America's hospitals and health systems is to provide high-quality, safe and effective care to their patients. However, under the cloak of "increased efficiency," these examples show that health plans are directly jeopardizing the ability of providers to meet patient care needs, refusing to meet their financial obligations when the hospital acts in the best interest of its patients, and adding immense administrative burden and complexity to the health care system.

Many hospitals feel so strongly about the serious patient safety concerns associated with white bagging that they have refused to accept white bagged drugs at all. When

this occurs and the provider delivers the care using their own drug supply, the health plan typically denies the claim, and the hospital receives no payment as a result. In these cases, hospitals are penalized for prioritizing the safety of their patients — and health plans accrue a substantial savings as a result. We object to health plans' notion that efficiency is achieved by shifting non-reimbursable costs to providers who are unwilling to put their patients at risk.

IMPACT OF PBM PRACTICES ON 340B DRUG DISCOUNT PRICING PROGRAM

The 340B Drug Pricing Program established under Section 340B of the Public Health Service Act in 1992 allows providers that serve vulnerable communities to purchase certain outpatient drugs at a discounted price and use those savings to stretch scarce resources to provide more comprehensive services to their patients. Over 2,000 hospitals around the country participate in the 340B program and use the resulting savings to offer critical programs and services to their patients such as mobile treatment clinics, discounted or free medication, medication therapy management, and diabetic counseling. Rather than supporting 340B hospitals and their patients, PBMs have engaged in a number of harmful tactics to reduce the scope and benefits of the program.

Most importantly, PBMs have created terms and policies that discriminate against 340B hospitals by paying them less than non-340B hospitals for certain outpatient drugs in order to protect their rebate revenue from drug manufacturers. PBMs require 340B hospitals to accept unfair terms and policies in order to participate in their pharmacy networks, which are needed to give hospital patients greater access to those drugs.[7] This practice, widely referred to as "discriminatory 340B pricing," forces hospitals to accept lower and discriminatory reimbursement rates that threaten hospitals' ability to provide more comprehensive services to their patients as the law intends in order to ensure patient access to drugs through PBM pharmacy networks.

Some of the tactics of concern entail PBMs establishing barriers for pharmacies that 340B hospitals contract with to participate in their networks, disallowing PBM members from using 340B pharmacies, and even wholly excluding certain hospital-based pharmacies from their networks. While some states have explicitly prohibited 340B discriminatory pricing by PBMs[8], this practice as well as their other harmful policies remain prevalent in many parts of the country and continue to enrich PBMs at the expense of 340B hospitals.[9]

[7] https://340breport.com/16-states-have-passed-laws-since-2019-targeting-pbms-340b-payment-cuts/
[8] https://www.ncsl.org/research/health/state-policy-options-and-pharmacy-benefit-managers.aspx
https://340breport.com/16-states-have-passed-laws-since-2019-targeting-pbms-340b-payment-cuts/
[9] https://www.jdsupra.com/legalnews/new-supreme-court-ruling-affirms-state-2371638/

EFFECTS OF PBM FEES AND REBATES ON DRUG PRICES

In addition to the challenges presented by increased adoption of white bagging policies, the AHA remains concerned by the overall impact of high and rising drug prices. In the current drug acquisition system, PBMs play the role of an intermediary negotiator between drug manufacturers and payers. However, that negotiation process relies on a series of fees and rebates based on the proposition that these negotiations help to lower the overall cost of drugs. In turn, PBMs collect and retain fees and a percentage of the rebates achieved, which goes toward their bottom line. While PBMs argue that their role lowers the overall cost of drugs, the process actually results in significant incentives to maintain high drug prices and decrease competition.

Of most concern is whether **PBMs increase, rather than reduce, overall health care spending.** The rebate practice in particular poses two problems. **First, it is directly related to and incentivizes continued list price increases.** A USC Schaeffer study on the issue found that "[d]rug rebates and list prices are positively correlated: On average, a $1 increase in rebates is associated with a $1.17 increase in list price."[10] While lowering overall cost is important, failure to directly impact high list prices leads to increased health care spending, additional financial burden on patients and providers and significant financial impact on the uninsured and underinsured. **Second, the use of rebates to achieve preferred formulary placement directly inhibits competition.** Competition in the drug market is necessary to lower list prices. As the number of generic and biosimilar products become available on the market, the list price of the already marketed products declines in order to be competitive.[11] However, preferred formulary placement for brand-name drugs incentivizes continued use of high-priced products over lower-priced generics and biosimilars, effectively pushing those generic and biosimilar options out of a preferred cost structure and leaving little reason for brand-name drug manufacturers to lower the list price of their products.

Thank you for attention to these important policy and safety issues. Please contact me if you have questions at mhatton@aha.org or (202) 626-2336.

Sincerely,

/s/

Melinda Reid Hatton
General Counsel

[10] https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/
[11] https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices