

March 31, 2021

Dr. Janet Woodcock
Acting FDA Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20903

Re: Request for Meeting – White Bagging and DSCSA

Dear Commissioner Woodcock,

The American Society of Health-System Pharmacists (ASHP) and the American Hospital Association (AHA) are writing to express concern that the payer-mandated drug distribution model, known as “white bagging” is jeopardizing patient safety and exacerbating supply chain security challenges that the Drug Supply Chain Security Act (DSCSA) sought to address.

ASHP represents pharmacists who serve as patient care providers in hospitals, health systems, ambulatory clinics, and other healthcare settings spanning the full spectrum of medication use. The organization’s nearly 58,000 members include pharmacists, student pharmacists, and pharmacy technicians. For 79 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety. Like ASHP, the top priority of the AHA and its members is to provide high quality, safe health care to all patients, including the safe storage, preparation and administration of critical medications. Representing nearly 5,000 member hospitals, health systems and other health care organizations and clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders belonging to professional membership groups, the AHA is committed to curtailing payer efforts that threaten patient safety and safe medication acquisition processes.

Payers are using white bagging to circumvent hospital supply chain controls by requiring patient medications be distributed through a narrow network of specialty pharmacies that are often directly affiliated with the payer, thereby disregarding DSCSA’s requirements for wholesale distribution of drugs. Hospitals and providers are then forced to further manipulate and dispense these medications before they can be safely administered to patients.

White bagging has surged in frequency over the past decade, creating what amounts to a shadow inventory that hospitals and health systems do not legally own and which exists largely outside of the DSCSA’s track and trace requirements. A Drug Channels report found that in 2019, nearly a third of infusion drugs (both oncologic and non-oncologic) provided in hospital outpatient departments were distributed via white bagging.¹ Given the growing ubiquity of payer-mandated white bagging, we are concerned that this practice threatens DSCSA’s underlying goals. Further, because hospitals do not have legal title to white bagged medications and the drugs are delivered outside of hospital-established supply chains, white bagging can raise additional patient safety risks by enabling diversion and heightening the possibility of drug spoilage/wastage. In addition, as white bagged drugs bypass

¹ <https://www.drugchannels.net/2020/09/specialty-pharmacy-keeps-disrupting-buy.html>

established supply chain channels it also disrupts and significantly complicates the ability to respond to FDA drug recalls.

ASHP and AHA strongly encourage FDA to consider the patient safety and supply chain security risks of white bagging, and take appropriate enforcement action to protect patients. We would welcome the opportunity to meet with your team to discuss our hospital and health system compliance concerns in greater detail.

We are deeply appreciative of the work FDA staff has put into implementing DSCSA to date, and we recognize the challenge white bagging presents to the overall goals of DSCSA. We look forward to working collaboratively with the Agency to protect against the creation of payer-mandated distribution models that could undermine patient safety. Please do not hesitate to reach out to us, or Mark Howell, AHA Senior Associate Director of Policy at mhowell@aha.org or 202.626.2317, or Tom Kraus, ASHP Vice President of Government Relations at TKraus@ashp.org or 301.664.8605.

Thomas P. Nickels
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