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American Pharmacists Association

FDA Drug Compounding Annual Listening Session –
Hospital and Health System Organizations
Nicholas Capote, PharmD, MS, BCSCP, System Director, Pharmacy Infusion Services, Tufts Medicine
American Pharmacists Association (APhA) Vice Chair and Incoming Chair, Health System Strategy Council (HSSC)
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- **Thank you for the opportunity to represent our nation's pharmacists at today's compounding listening session on hospital and health system organizations.**

First, I would like to address: The Controls and Capabilities of Hospital and Health System Compounding Pharmacies:

- In reference to the October 2021 Draft Guidance: Hospital and Health System Compounding Under Section 503A of the Food Drug and Cosmetic Act, I wanted to acknowledge some of the positive elements that recognize both the capability and value brought to the general public by leveraging sterile compounding pharmacies embedded within hospitals and health systems.

- We appreciate the FDA's acknowledgement that certain patients cared for by a hospital or health system require compounded drugs prior to the placement of a patient-specific order to meet an emergent need. The institution's pharmacy, under the appropriate controls and monitoring, is well-equipped to compound, dispense, transport, store, and safely dispose of compounded sterile products.

- Second, we appreciate the acknowledgment that the typical distribution scope of CSPs by hospital and health system pharmacies is often quite limited. CSPs are distributed to locations under common ownership with corresponding recordkeeping systems; both of which are chain of custody and quality control advantages. In addition, this level of control provides potential for reliable processes that can regularly be improved upon, if needed.

- Finally, we appreciate the acknowledgement from the FDA that while 503B outsourcing facilities produce tremendous value, these entities cannot meet patient needs 100% of the time. Supply or drug shortage situations, products that do not have a strong return on investment for the 503B, quality issues requiring recalls, or simply a short stability patient-specific preparation are all situations in which hospital and health system compounding pharmacies must be leveraged.

2215 Constitution Ave. NW
Washington, DC 20037
800 237 2742
pharmacist.com

Now: About Providing CSPs Beyond the Brick and Mortar of a Hospital or Health System:

- As the FDA continues to contemporize guidance related to sterile compounding within hospitals and health systems, **we urge the FDA to consider all sites of care, and how valuable compounding services can and should play a role.**

- For example, the CMS Hospital Without Walls – also known as Hospital at Home - program is considered an extension of an inpatient acute care hospital unit. To provide the intended level of care in the home, the same approach to safety and compliance will occur from hospital and health system pharmacy departments, yet the proposed 24-hour rule included in the October 2021 draft guidance could impose unintended difficulties on patients and the hospitals that serve them. This same logic can apply to the home infusion environment, as hospitals and health systems are more widely adopting this additional site of care as an internal service. Requiring 24 hours of use time for the CSP, while incorporating courier pick up, transit and delivery times could result in less availability of CSPs due to this restrictive dating by unnecessarily increasing waste and potentially exacerbating the already difficult drug shortage situation plaguing our health care system. Oftentimes, at least a couple of days of medications are delivered at a time. In the proposed model, less than one day's worth would be available.

- Hospitals and health systems have the capability to account for the drug chain of custody prior to and after compounding, and through dispensing and delivery. **Given these capabilities, hospitals and health systems should be able to utilize the most updated and evidence-based beyond use dates from United States Pharmacopeia Chapter 797.**

"White Bagging" and Lack of Product Integrity Guarantees:

- The last topic I wish to highlight has to do with a process adopted by certain health care organizations, often vertically aligned (health plan, pharmacy benefit manager or PBM, and specialty pharmacy). In order for the patient's drug to be covered, these organizations require patients to use a medication from a health plan's preferred pharmacy. This drug is distributed to a local hospital pharmacy, but not in ready to use form. The hospital becomes obligated to utilize ingredients often not supported by the hospital formulary, and not integrated into its systems for safety and quality control. As you know hospitals make interdisciplinary decisions about medications placed on formulary that would be most appropriate for the patient situation, including but not limited to decisions around clinical benefit, opportunity to leverage biosimilars, more accessible routes of administration, and other factors.

- This process has been dubbed “white bagging” and results in steerage of prescriptions to a particular pharmacy under the pretext of lowering the total cost of care.

- The issue I wish to address has to do with the compounding process and the downstream care provided to the patient.

- When this practice is utilized by a plan, the origins and transit conditions of the sterile ingredients yet to be compounded are unknown. The product could arrive to the compounding pharmacy, or patient’s home if self-injected, without exact delivery time known. The product could be exposed to temperatures during summer or winter months for periods of time beyond what the FDA has approved. The pharmacy is then expected to take these ingredients and combine them as if they came from their own inventory. The problem is not only that the origins and integrity of the product upon arriving to the pharmacy are unknown, but also that the amount of drug could be inadequate.

- As an example, the standard for oncology is often to take laboratory measurements at the point of care, which could change the dose. If the dose increases beyond what the plan’s preferred pharmacy sent in the mail, not enough drug could be available – forcing the pharmacy to make decisions on how to best take care of the patient despite not having enough drug.

- While the practice of a medication coming from the plan’s preferred pharmacy might be useful in certain situations, such as rural areas where another pharmacy is not as accessible, these decisions should still be made between patient and provider, and with known conditions related to the drug’s integrity throughout transport.

- Additionally, it is unclear how compounding pharmacies will comply with the upcoming enforcement of the Drug Supply Chain and Security Act (DSCSA) when the origin and integrity of these products is not provided by the distributing pharmacy.

- While I do not have enough time today to further elaborate on this practice, I urge the FDA to consider the quality, compliance, and safety risks this has on patient care and pharmacies alike. I will end with a real-life situation: a fellow pharmacist had life-saving therapy delayed after diagnosis with HER-2 positive breast cancer.

- She qualified to receive a novel **subcutaneous** injection of trastuzumab to treat her cancer, yet her plan required she receive the **intravenous** form after it was shipped (i.e., white bagged) from the plan’s preferred pharmacy. Additionally, any peripheral venous access is quite difficult for her because of her size. As a result of her plan requiring the

use of a white-bagged IV product, she needed a more invasive line placement, which not only imposed additional infection risk, but it required her to obtain the medication in an infusion center through a more risky route of administration – not to mention, her therapy was delayed.

- While the practice of prescription steerage or white bagging is unfortunately not a new tactic utilized by these organizations, as this has been a pervasive practice with mail order pharmacies in the community arena for oral solids, the additional risk imposed by these practices on IV and other parenteral route of administration products is cause for even more concern. States are now having to address this practice with legislation against white bagging; they include Tennessee, Vermont, and Florida – just a few examples of many in recent months.

- **In summary, we strongly urge the FDA to consider what approaches it might take to curb the unregulated distribution of pharmaceuticals from preferred network pharmacies so that drug components maintain their integrity, chain of custody is known, and the best possible treatment option is available to the patient.**