U.S. FOOD & DRUG ADMINISTRATION

September 26, 2024

The Honorable Abigail Spanberger
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Spanberger:

Thank you for contacting the Food and Drug Administration (FDA or the Agency) regarding Emergency Medical Services (EMS) medication exchange kit programs in Virginia. FDA is responding below to your concerns regarding the Drug Supply Chain Security Act (DSCSA). We appreciate your interest in this topic.

FDA's actions related to the DSCSA do not warrant Virginia EMS agencies and area hospital pharmacies changing their current practice of replenishing/rotating out minimal quantities of product needed for EMS medical kits, based on our understanding of the practice.

The DSCSA outlines certain requirements, including requirements for electronic drug tracing at the package level, that apply when trading partners (e.g., manufacturers, wholesale distributors, dispensers, and repackagers) engage in transactions of products. FDA has announced a stabilization period of an additional year, until November 27, 2024, to allow trading partners throughout the supply chain time to implement the requirement that they exchange this information only electronically; currently they have the option to use paper.

Separately, FDA has provided guidance to industry that it generally does not intend to take action against a dispenser, such as a hospital pharmacy, who transfers ownership of product directly to a first responder where the dispenser does not provide the first responder with product tracing information, e.g., transaction information. [1] Additionally, FDA does not intend to take action against a first responder who accepts ownership of product without first receiving the product tracing information. This compliance policy will remain in place beyond November 27, 2024.

Additionally, apart from FDA's compliance policy, there are potentially other flexibilities in the statute that may apply; for example, in certain situations an exchange of medication kits between a pharmacy and first responder would not be considered a "transaction" under the DSCSA, and FDA also retains authority to grant waivers from DSCSA requirements in certain situations including for emergency medical reasons.

We hope that this helps alleviate any concerns, but we are happy to answer any additional questions as needed.

[1] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requirements-transactions-first-responders-under-section-582-federal-food-drug-and-cosmetic-act

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Sincerely,

Erin O'Quinn
Associate Commissioner for
Legislative Affairs