



June 17, 2024

Dear ODEMSA emergency medical service partners:

Central Virginia Hospitals take great pride in the collaborative relationship we have with area emergency medical service (EMS) providers in partnering to deliver care in our communities. In the Commonwealth of Virginia, many EMS agencies have historically relied upon hospitals to support their operations by providing routine medication and supply replenishment through a kit exchange system. Hospitals have always been supportive and willing to provide these resources even though most states have moved away from this practice to an EMS agency-owned process. As you know, forthcoming regulations require us to change this practice in Virginia and we have been collectively assessing our aligned approach.

There are multiple recent and upcoming federal actions responsible for this shift. A new Act passed by Congress, **Protecting Patient Access to Emergency Medications Act (PPAEMA)**, modifies specific requirements under the existing Controlled Substances Act (CSA) that govern how EMS professionals can administer controlled substances to individuals receiving emergency medical services. Specifically, the bill directs the **Drug Enforcement Agency (DEA)** to register EMS agencies to administer controlled substances to be fully responsible for the maintenance and administration of their own controlled substances (CII-V).

In addition to meeting forthcoming DEA requirements, the practice of hospital supported EMS kit exchanges will need to be overhauled to comply with the **Food and Drug Administration's (FDA) Drug Supply Chain Security Act (DSCSA)**. DSCSA regulation is currently active, but the FDA has delayed enforcement until November 27, 2024 as a grace period to allow all parties to ease into the requirements. This law ensures the integrity of the drugs in the pharmaceutical supply chain by requiring tracking of the product through each step in the chain to an ultimate end user, or patient. EMS agencies are exempted from meeting the DSCSA regulations as dispensers; however, hospitals are still beholden to the requirements if supplying a drug to the agency. Hospital systems are not optimized to track the transfer of ownership to parties other than a patient in their direct care. Additionally, the information capture, record keeping requirements, and audit requirements make compliance exceptionally challenging.

The forthcoming federal regulations conflict with the current process for EMS kit exchanges. Hospitals need to meet these federal requirements and cannot put their sites at risk of federal investigation, fines and/or loss of their pharmacy licenses. Consistent with our understanding of the Virginia Board of Pharmacy's approach for transitioning the EMS kit exchange program, Hospitals will continue to support the current process until a mutually agreed upon date no later than November 27, 2024, when the FDA's DSCSA is fully enforceable. At the agreed time in November (currently anticipated to be November 4, 2024), EMS agencies will need to take full ownership of their medication and supply kits; please accept

this as formal notice that we, the undersigned hospitals/health systems, will discontinue drug and supply kit exchanges no later than November 27, 2024.

Respectfully,



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HCA VA Health System – Capital Division President



Chris Accashian, MHA, FACHE
Bon Secours Richmond – Chief Operating Officer



Michael Elliott, PharmD, MSHA, FACHE
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