
Drug Supply Chain Security Act (DSCSA) FAQ 3: Dispenser Support of First Responders

Q: Is the provision of medications to ambulance services and other first responders exempt from the transaction information, transaction history, and transaction statement requirements for dispensers?

A: Yes. The provision of medications to ambulance services and other first responders staffed by licensed Emergency Medical Technicians (EMT) and paramedics is exempt from the transaction information, transaction history, and transaction statement requirements for dispensers under the DSCSA. The DSCSA defines a “transaction” to mean “the transfer of product between persons in which a change of ownership occurs.” Among the exemptions in this definition is “the distribution of a product for emergency medical reasons.”^{1, 2}

Based on this interpretation, providing medications to EMTs, paramedics, or other first responders would be within the scope of an emergency medical reason.

Q: Is the provision of medications to first responders who are law enforcement personnel exempt from the transaction information, transaction history, and transaction statement requirements for dispensers? Many hospitals and dispensers are required to provide naloxone to law enforcement personnel as part of new local, regional, and state protocols.

A: This issue is less clear and ASHP will work with the FDA for clarification. Typically, law enforcement and other first responders work under protocols that are approved at the state level with the supervision of a medical director. Law enforcement’s role and scope of practice should be verified at the state level.

With respect to Title II of the Drug Quality and Security Act, providing naloxone to law enforcement personnel would be within the purview of an emergency medical reason and therefore exempt from the definition of a transaction. As a result, dispensers would not be required to provide transaction information, transaction history, and transaction statements.

NOTE: As of June 30, 2015, the Food and Drug Administration has provided enforcement discretion for certain aspects of the DSCSA until November 1, 2015. Dispensers should continue to implement steps to mitigate risk and identify illegitimate products in order to meet the requirements. ASHP recognizes that certain aspects of the DSCSA require clarification and will continue to work toward obtaining FDA guidance on these matters.

References:

1. [Drug Quality and Security Act](#). Title II: Section 581(24)(A)(B).
2. U.S. Food and Drug Administration. [DSCSA Updates and Readiness Check: Requirements for Dispensers and other Trading Partners](#).

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