
Drug Supply Chain Security Act (DSCSA) FAQ 4: Specific Patient Need and Emergency Medical Reason

Q: Under the Drug Supply Chain Security Act (DSCSA) who is classified as a dispenser?

A: A dispenser under the DSCSA is – “(A) a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and (B) does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5).”

Q: Under the DSCSA can a hospital or health-system pharmacy obtain drug from another pharmacy without providing transaction history, transaction statement, and transaction information?

A: Yes. Tracing requirements are exempt for drug product that is transferred between dispensers under common control, for specific patient needs, or emergency medical reasons. (See Appendix for DSCSA definitions)

Q: How is “specific patient need” defined in the DSCSA?

A: The term “specific patient need” refers to the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. However, this definition of specific patient need does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.

Product tracing details are also not required in instances when dispensers might sell medication to another dispenser to fulfill a specific patient need.

Subsection titled “Dispenser Requirements” for product tracing in the DSCSA defines tracing requirements for dispensers and indicates that “requirements of this clause shall not apply to sales by a dispenser to another dispenser to fulfill a specific patient need.”

Q: If a drug is transferred for an emergency medical reason, are the transaction requirements exempt in that situation?

A: Yes. The DSCSA states that transaction exemptions include “the distribution of a product for emergency medical reasons including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason.”

Q: Does any immediate need for an admitted hospital patient constitute an emergency medical reason?

A: Yes. Since delay of medication therapy or missed dose(s) of medication for an admitted hospital patient can compromise the health status of a hospitalized patient, drugs obtained to provide care for this emergency medical reason are exempt from the DSCSA. Additionally, obtaining medications in this scenario would also be exempt from transaction requirements under the specific patient need definition.

Q: If a drug is needed for an emergency medical reason that happens to also be in drug shortage status, is obtaining the drug exempt from the DSCSA requirements?

A: Yes, for the same reasons as listed above, delaying medication therapy or missed dose(s) of medication for an admitted hospital patient can compromise the health status of a hospitalized patient. In this scenario, transferring medications would be exempt from transaction requirements under the specific patient need definition.

It should be noted that exemptions do NOT include “the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.”

Q: If a public health emergency is declared causing a drug shortage scenario and drug is obtained to provide medication therapy to admitted hospital patients and/or non-hospitalized patients, is obtaining the drug exempt from the DSCSA requirements?

A: Yes. The distribution of a product for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, is exempt from transaction requirements.

Q. If a drug meets the definition of specific patient need or emergency medical reason, can a dispenser charge/sell the receiving dispenser for the drug transferred to the receiving dispenser?

A: Yes. In order to fulfill this important function a dispenser needs to have the ability to charge the receiving dispenser for providing patient specific medications in order to accommodate for the cost of the drug. It is advisable that the documentation accompanying this sales transaction include name and address of sending location (DEA # if controlled substance), name and address of receiving location (DEA # if controlled substance), drug name, strength, and dosage form, NDC #, lot number, manufacturer, expiration date, order date, ship date, and quantities transferred.

Additionally, since a specific patient need or emergency medical reason is an exempt transaction between dispensers, it is not necessary to follow the drug sales requirements for wholesalers outlined in the DSCA (assuming the volume of transactions do not exceed any state regulatory volume restrictions which may redefine the dispenser as a wholesaler).

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Appendix

Drug Supply Chain Security Act, Title II of the Drug Quality and Security Act

- 1) **SEC. 581. Definitions, Subsection (24) Transaction.**
 - (B) **EXEMPTIONS.** – The term ‘transaction’ does not include—
 - (ii) the distribution of a product among hospitals or other health care entities that are under common control;
 - (iii) the distribution of a product for emergency medical reasons including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

- 2) **Section 581. Definitions, Subsection (19) Specific Patient Need.** – The term ‘specific patient need’ refers to the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. Such term does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.

- 3) **Section 582 Requirements**
 - (d) **Dispenser Requirements** —
 - (1) **Product tracing**
 - (A) **In general.**--Beginning July 1, 2015, a dispenser –
 - (i) shall not accept ownership of a product, unless the previous owner prior to, or at the time of, the transaction, provides transaction history, transaction information, and a transaction statement;
 - (ii) prior to, or at the time of, each transaction in which the dispenser transfers ownership of a product (but not including dispensing to a patient or returns) shall provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product, except that the requirements of this clause shall not apply to sales by a dispenser to another dispenser to fulfill a specific patient need; and
 - (iii) shall capture transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintain such information, history, and statements for not less than 6 years after the transaction.