
Drug Supply Chain Security Act (DSCSA) FAQ 2: Third Party Management of Transaction Information, Transaction History, and Transaction Statements (3Ts)

Q: Is there a requirement for dispensers to have a written agreement if a third party is used to maintain required transaction information, transaction history, and transaction statements?

A: The Drug Supply Chain Security Act states a “dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party confidentially maintains the transaction information, transaction history, and transaction statements required to be maintained under this subsection on behalf of the dispenser. If a dispenser enters into such an agreement, the dispenser shall maintain a copy of the written agreement and shall not be relieved of the obligations of the dispenser under this subsection.”

Any such agreement should be reviewed by the dispenser’s compliance and contract staff to ensure that it meets all of the DSCSA requirements and that the identified third party can effectively maintain and ensure the security, retrievability, and integrity of the dispenser’s transaction data. Additionally, such agreements should clearly outline the terms to transfer the data in the event the third party relationship is dissolved.

Q: Does a dispenser need to verify if the transaction information, transaction history, and transaction statements have been “received” into the third party’s repository or software platform at the time of receipt of product?

A: Yes. Beginning July 1, 2015, a dispenser — “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.”

Q: What should a dispenser do in the event a wholesaler or trading partner does not provide the transaction history, transaction information, and transaction statement with the product?

A: Beginning July 1, 2015, a dispenser — “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.”

Dispensers should establish a process and procedure with their key wholesalers and trading partners to quickly rectify a situation in which the 3Ts are not received, especially since hospitals and health systems may be receiving products to manage an urgent patient care need. If the situation cannot be rectified, dispensers should follow DSCSA rules for dealing with “Suspect Product” as follows: *“(I) quarantine such product within the possession or control of the dispenser from product intended for distribution until such product is cleared or dispositioned; and “(II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product.”*

Q: If an organization chooses to use a non-wholesaler third party to manage their transaction history, transaction information, and transaction statements from trading partners (including primary wholesalers), does a dispenser need to verify if the transaction information, transaction history, and transaction statements have been “received” into the third party’s repository or software platform at the time of receipt of product?

A: Yes. Beginning July 1, 2015, a dispenser— “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.”

It is incumbent upon the dispenser to negotiate the terms of data security, retrievability, and integrity with any non-wholesaler third party. Standard operating procedures should be developed and should include terms outlining transfer of all transaction data in the event the third party relationship is dissolved.

Q: If a trading partner (i.e., wholesaler or manufacturer) chooses to outsource the function of receiving, storing, and accessing the transaction history, transaction information, and transaction statements for dispensers, with whom should the dispenser have the required written agreement to ensure it has due access and ownership of the transaction history, transaction information, and transaction statements?

A: The DSCSA does not seem to anticipate this scenario. The only reference to the use of third parties for maintaining transaction history, transaction information, and transaction statements is outlined within dispenser responsibilities.

It is advisable that dispensers obtain assurances in writing from the relevant trading partner that the trading partner's third party storage company:

- Ensures the dispenser's ability to request and receive data at any time;
- Demonstrates access that fulfills the dispenser's responsibilities under DSCSA, and;
- Outlines contingency plans for data access in the event that the third party agreement is changed or the third party business ceases to exist.

Dispensers should also consider whether or not they intend to use a different third party to store these documents on their behalf. If doing so, dispensers should ensure that any third party company used by their trading partner will make information available to the dispenser's designated third party company.

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