

Repackaging is defined as buying pharmaceutical drugs in bulk and repackaging the drugs with a pharmacy or hospital brand package. In some cases, the customized package has a specific number of doses or a specific use (i.e., the ICU, recovery room, etc.). The big three, such as McKesson and its McKesson RxPak program, leverage their buying power and offer these custom services with competitive pricing.²⁷

With the new law, wholesale distributors will not only have to make sure they receive and pass on the prior ownership information, recall information, and quarantine information, but also be required to affix or imprint a product identifier on each package sold to pharmacies and hospitals. The only exception will be if the pharmaceutical drug has a standardized numerical identifier and the packaging with the identifier is not disturbed in the repackaging process. The specifics are still being worked out, and I am sure the wholesale distributors are working closely with the FDA to map out their repackaging processes with the new regulations to assess their new responsibilities. However, what I do know is that their repackaging operations will be impacted by the new law.²⁸

TRANSACTION STATEMENT

There exist several areas that expose the pharmaceutical drug supply chain to product substitution, theft, and product diversion. One of the ways that the FDA is attempting to address these areas of exposure is through the transaction statement. The FDA is requiring a transaction statement to accompany the pharmaceutical drugs when transferring ownership in the supply chain. It is my understanding that this transaction statement will also be new for the wholesale distributors, although several of the items should not be new to them.

The FDA is requiring a statement, in paper or electronic form, that the entity transferring ownership in a transaction:

- Is authorized as required under Title II: Drug Supply Chain Security Act (DSCSA)
- Received the product from a person that is authorized as required under DSCSA
- Received transaction information and a transaction statement from the prior owner of the product, as required under the law
- Did not knowingly ship a suspect or illegitimate product