

Checklist for Dispenser Compliance

This checklist provides dispensers with a baseline reference tool to help develop compliance methods to meet DSCSA requirements.¹



Ensure you are only purchasing from Authorized Trading Partners by determining if the entity from whom you are purchasing has the required state license for wholesale distribution. In the case of transactions involving purchases directly from the manufacturer, most companies can be found using their FDA registration(s) on the [Drug Establishment Current Registration Site database DECRS](#).



Have systems and processes in place that enable you to:

1. Ensure you can receive and store/use data related to each transaction.
2. Accept the drug product only after having received proper Transaction Information (TI), Transaction History (TH)² and Transaction Statement (TS) data.
3. Receive requests for transaction data and/or information and assist, when necessary, with suspect and illegitimate product investigations; further, electronically store all pertinent transaction data for six years in accordance with DSCSA.
4. Verify/submit verification requests when necessary.

Consider collaborating with a wholesale distributor or third-party service provider to assist with developing systems and/or maintaining the transaction data on your behalf. Remember, even if you use a third party, the dispenser is not absolved of the responsibility — accountability ultimately rests with your organization.



If engaging in certain transactions to an entity other than a consumer, ensure systems and processes are in place so that prior to or at the time of each transaction in which the dispenser transfers ownership of a product, the dispenser shall provide the subsequent owner with the appropriate transaction data.

The above does not include dispensing to a patient or returns OR sales from a dispenser to another dispenser to fulfill a specific patient need.



Obtain and maintain proper licensing, including as a wholesale distributor if engaged in the activity described above.

1—This checklist is not intended to provide legal advice. The reader is cautioned that it cannot cover all elements and we refer you to FDA, the DSCSA (and implementing guidance) and/or to their own legal counsel for more information.

2—Note: The requirement to send and/or receive TH sunsets as of Nov. 27, 2023. Dispensers must receive and store TH until sunset date.



Develop and FOLLOW current standard operating procedures to guide you and your staff through the process of identifying, quarantining and reporting suspect or illegitimate products:

1. See [NCPA's Pharmacy Checklist 2021](#)
2. See [PDSA's Q&A for Dispenser Requirements](#)
3. Under [Section 582\(d\)\(4\)\(A\)\(ii\)](#), when conducting a suspect product investigation dispensers must (1) verify whether the lot number of a suspect product corresponds with the lot number for such product, and (2) verify the product identifier, including the serial number, of at least 3 packages or 10 percent of such suspect product (whichever is greater).

Review recently released guidance [documents](#) from FDA.



Be able to identify proper machine scannable bar codes and human-readable product identifiers for all drug products:

- GTIN;
- Serial Number;
- Lot Number; and,
- Expiration Date.



After working with your wholesale distributor, if necessary, determine the need for consulting or hire a service provider to assist and confirm compliance with DSCSA.