

# DSCSA Compliance Checklist for Pharmacies

Step 1: find your deadline. Step 2: check what already applies to every pharmacy today.

## STEP 1 · WHICH DSCSA DEADLINE IS YOURS?

Full-time (30+ hrs/week, or 130 hrs/month) licensed pharmacists + qualified pharmacy technicians, across all stores your company owns, as of November 27, 2026: \_\_\_\_\_

- ☐ 25 or fewer → electronic deadline Nov 27, 2027 (FDA letter, Aug 6, 2026). Lessons 04–05, 13.
- ☐ 26 or more, but 25 or fewer in Nov 2024 → electronic deadline Nov 27, 2026 (FDA's 2024 letter ends that day). Lesson 12.
- ☐ 26 or more already in Nov 2024 → any extra time ended Nov 27, 2025: the electronic requirements apply now. Lesson 05.

## STEP 2 · REQUIRED TODAY, FOR EVERY PHARMACY

- ☐ **Tell your wholesaler and other trading partners which deadline applies to you (recommended by FDA).**  
FDA letter, Aug 6, 2026 · Lesson 05
- ☐ **Buy from and sell to authorized trading partners only, and check their licenses or registrations.**  
§582(d)(3); §581(2) · Lesson 06
- ☐ **Accept product only with its transaction information (TI) and transaction statement (TS).**  
§582(d)(1)(A)(i) · Lesson 06
- ☐ **Keep TI and TS for at least 6 years. If a third party stores them, keep a copy of the written agreement; you stay responsible.**  
§582(d)(1)(A)(iii), (B) · Lesson 07
- ☐ **Transact only product that carries a product identifier (2D code: NDC, serial number, lot, expiration).**  
§582(d)(2); §581(14) · Lessons 06, 10
- ☐ **When selling to another pharmacy, send TI and TS, unless the sale fills a specific patient's prescription.**  
§582(d)(1)(A)(ii); §581(19) · Lesson 09
- ☐ **Keep a written suspect-product procedure, and train everyone who receives deliveries on FDA's red flags.**  
§582(d)(4); FDA guidance, Jun 2021 · Lesson 08
- ☐ **Quarantine and investigate suspect product with your trading partners; keep records for 6 years.**  
§582(d)(4)(A) · Lesson 08
- ☐ **If a product is illegitimate, notify FDA (Form FDA 3911, via CDER NextGen) and the immediate trading partners who may have received it, within 24 hours.**  
§582(d)(4)(B)(ii) · Lesson 08
- ☐ **Answer FDA or state requests for TI and TS during a recall or investigation within 2 business days.**  
§582(d)(1)(D) · Lesson 09

# Before your electronic deadline

What must work by Nov 27, 2026 or Nov 27, 2027, and a plan for each path.

## STEP 3 · THE ELECTRONIC REQUIREMENTS (SECTION 582(g)(1))

- ☐ **Exchange transaction information and statements in a secure, interoperable, electronic way (FDA recommends the EPCIS standard).**  
§582(g)(1)(A); FDA standards guidance, Sep 2023 · Lessons 10, 12, 13
- ☐ **Receive transaction information that includes the product identifier of each package.**  
§582(g)(1)(B) · Lessons 10, 12, 13
- ☐ **Have systems and processes to verify product at the package level.**  
§582(g)(1)(C) · Lessons 10, 12, 13
- ☐ **Have systems to promptly answer FDA or state requests with TI and TS, and to help trace product.**  
§582(g)(1)(D)–(E) · Lessons 10, 12, 13
- ☐ **Verify the product identifier of a set share of suspect or illegitimate packages.**  
§582(d)(4)(A)(iii)(II), (B)(iii) · Lessons 10, 12, 13

### IF YOUR DEADLINE IS NOV 27, 2026

#### Your next five weeks

- Week 1: ask your primary wholesaler how it will send electronic DSCSA data.
- Week 2: choose how you'll receive it: portal, own system, or a connector such as Connect RX.
- Weeks 3–4: connect and test with real orders; fix missing or mismatched data.
- Week 5: update procedures and keep evidence of every step.
- Can't make it? Request a waiver through CDER NextGen early. Obligations don't pause.

### IF YOUR DEADLINE IS NOV 27, 2027

#### Use the extra year

- This quarter: ask your wholesaler how data will arrive.
- Next quarter: compare at least two solutions and negotiate price and setup time.
- Then: connect and test well before the deadline.
- Before the deadline: update procedures and train the team.
- FDA strongly urges small dispensers to keep implementing during the exemption.

### BEFORE YOU HIRE A DSCSA SOLUTION, ASK

- ☐ Does it connect to all my wholesalers and drop-ship partners, using EPCIS?
- ☐ Can I find any record from the last six years in minutes, and answer FDA within two business days?
- ☐ What's the total cost and setup time, who helps me test, and what happens when the rules change?

# Your DSCSA records sheet

Fill it in once, keep it with your DSCSA records, and update it when something changes.

Our full-time pharmacists + technicians on Nov 27, 2026, and how we counted:

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Our electronic deadline, and the FDA letter we follow:

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Date we told our wholesaler (and how):

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Wholesalers / suppliers and license or registration numbers (date checked):

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Where our TI and TS are stored (system, portal, written agreement):

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Who answers FDA or state requests, and their backup:

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Quarantine shelf location:

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How we will receive electronic data (portal, own system, connector) and test date:

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CDER NextGen account ready (for Form FDA 3911 and waiver requests)?

☐ Yes ☐ No

**maltexi**

**Start your electronic DSCSA connection early.**

Connect RX by Maltexi connects your pharmacy to your trading partners for electronic DSCSA data. [connectrx.maltexi.com](https://connectrx.maltexi.com)

## SOURCES (CHECK BEFORE YOU ACT)

FDA, DSCSA exemptions for small business dispensers until Nov 27, 2027 (Aug 6, 2026): [fda.gov/media/194424/download](https://www.fda.gov/media/194424/download)

FDA, Exemptions under the DSCSA (updated Aug 26, 2026): [fda.gov/drugs/drug-supply-chain-security-act-dscsa](https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa)

FD&C Act §581 and §582: [law.cornell.edu/uscode/text/21/360eee](https://www.law.cornell.edu/uscode/text/21/360eee) and [/360eee-1](https://www.law.cornell.edu/uscode/text/21/360eee-1)

FDA, Notify FDA of Illegitimate Products (Form FDA 3911) · FDA guidance, Waivers, Exceptions, and Exemptions (Aug 2023)