

Small dispenser exemption and Waiver, Exception, or Exemption (WEE)

On June 12, 2024 the FDA announced exemptions from certain requirements of section 582 of the FD&C Act to small dispensers (pharmacies), and where applicable their trading partners, until November 27, 2026. This provides small dispensers additional time to stabilize their operations to fully implement the enhanced drug distribution security requirements of the Drug Supply Chain Security Act (DSCSA).

A dispenser is considered a small dispenser, for the purposes of these exemptions, if, as of November 27, 2024, the company that owns the dispenser has 25 or fewer full-time employees licensed as pharmacists or qualified as pharmacy technicians.

To learn more about the small dispenser exemption [click here](#)

What this means for small dispensers

- Small dispensers have additional time to have SOPs and processes for DSCSA in place.
- The new returns process will still apply this November.
- Who could be considered a small dispenser:
 - Independent pharmacies
 - Physician and community practices

If you do not meet small dispenser exemption

- The FDA is not extending the stabilization period beyond November 27, 2024 for the industry.
- If you are not a small dispenser and have a concerns about readiness or patient access, you can request a waiver, exception, or exemption (WEE).
 - To submit a WEE, visit the FDA [NextGen portal here](#)

Waivers, Exceptions, & Exemptions (WEE)

If trading partners, distributors, or dispensers are unable to meet the enhanced drug distribution security requirements of section 582 of the FD&C Act by November 27, 2024, they may request a waiver or exemption from those requirements.

- **Waiver:** Request if requirements result in undue economic hardship or for emergency medical reasons, including public health emergencies.
- **Exception:** Request if a product is packaged in a container too small to accommodate necessary labeling.
- **Exemption:** Request for other products or transactions to maintain public health or for other appropriate reasons. **The obligation to comply with enhanced drug distribution security requirements by November 27, 2024, will not be paused or extended upon submission of a request or while FDA's response is pending. The agency expects efforts be continued to meet the requirements until FDA has approved or denied the request.** To learn more about waivers, exceptions, and exemptions beyond the stabilization period [click here](#)