



Date Issued: July 12, 2024

Subject: DSCSA Exemptions from Certain Requirements Under Section 582 of the FD&C Act for Small Business Dispensers (revised with clarifying edits to June 12, 2024, letter)

The Food and Drug Administration (FDA, Agency, or we) is using authority under section 582(a)(3) of the Food, Drug, and Cosmetic Act (FD&C Act) to grant exemptions for small business dispensers¹ - and, where noted, small business dispensers' trading partners² - as outlined in these exemptions, from certain requirements in section 582 of the FD&C Act³ until November 27, 2026.

In August 2023, FDA announced two compliance policy guidances⁴ that explained, among other things, FDA's enforcement policy with respect to: (a) the enhanced drug distribution security requirements⁵ in section 582(g)(1) of the FD&C Act; and (b) verification requirements for dispensers regarding suspect or illegitimate product in sections 582(d)(4)(A)(ii)(II) and (d)(4)(B)(iii) of the FD&C Act, that went into effect on November 27, 2023. Together, the compliance policy guidances establish a 1-year stabilization period, from November 27, 2023, through November 27, 2024, to accommodate additional time that trading partners in the pharmaceutical supply chain need to implement, troubleshoot, and mature systems and processes to fully implement the Drug Supply Chain Security Act (DSCSA) enhanced drug distribution security requirements.

Since publishing the 2023 Compliance Policy guidances, FDA has continued to receive comments and feedback from stakeholders and trading partners, particularly small business dispensers, expressing concern with readiness to implement requirements under section 582(g)(1) of the FD&C Act at the conclusion of the stabilization period on November 27, 2024. Specifically, small business dispensers have described challenges related to the time, costs, and resources needed to further develop the robust technologies and processes to enable data exchange, establish business relationships with their trading partners and operationalize business practices. FDA recognizes that small business dispensers may still need additional time beyond November 27, 2024, when the enforcement policy set forth in the 2023 Compliance Policies expires, to focus resources and efforts on refining systems and technological infrastructures. Accordingly, FDA is issuing these exemptions to accommodate the additional time beyond November 27, 2024, that may be needed by small business dispensers to fully transition to interoperable, electronic

¹ Section 582(g)(2)(B)(i) of the FD&C Act specifically refers to agency authority to create alternative timelines for compliance with section 582(g)(1) of the FD&C Act requirements for "small business dispensers with 25 or fewer full-time employees."

² *Trading partner* is defined in section 581(23)(A) of the FD&C Act. Although third-party logistics providers are also considered trading partners under section 581(23)(B) of the FD&C Act, they are not subject to the same product tracing requirements of section 582 of the FD&C Act.

³ Pursuant to section 582(a)(3) of the FD&C Act, FDA has issued guidance on waivers, exceptions, and exemptions from section 582 of the FD&C Act requirements, that includes descriptions of circumstances and processes by which FDA may establish exceptions or exemptions on its own initiative. As noted in that guidance, if FDA establishes an exception or exemption to address a particular issue, it "intends to communicate the information in writing using a method appropriate for the circumstances (e.g., a letter to the affected trading partners or - if an exception or exemption applied to a broad segment of industry - a posting on its website). An exception or exemption that is established by FDA may be limited in duration or valid until further notice from FDA." Consistent with that guidance, we are posting these exemptions on our website.

⁴ For more information, see the compliance policy guidances for industry, *Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act — Compliance Policies* (August 2023) and *Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product — Compliance Policies, Revision 1* (August 2023).

⁵ *Enhanced drug distribution security requirements* refer to the requirements for interoperable, electronic, package-level product tracing, including systems and processes, in section 582(g)(1) of the FD&C Act.



product tracing at the package level under the DSCSA. The FDA has determined these exemptions are appropriate to maintain public health and help ensure continued patient access to certain prescription drugs in the United States.

For the purpose of this exemption, a dispenser⁶ is considered a small business dispenser if the corporate entity that owns the dispenser has a total⁷ of 25 or fewer full-time employees⁸ licensed as pharmacists or qualified as pharmacy technicians according to the applicable state board of pharmacy requirements. We believe this definition best incorporates small business pharmacy operations and those who are most in need of additional time to comply with the requirements of section 582(g)(1) of the FD&C Act outlined below.

If a small business dispenser relies on the exemptions outlined here, we recommend communicating such reliance to its trading partners as needed to further facilitate distribution of product without difficulty or delay. The exemptions described herein do not apply to other requirements in section 582 of the FD&C Act.

FDA has determined that the following FD&C Act exemptions for small business dispensers - and, where noted, their trading partners - are appropriate for products they transact with each other from November 27, 2024, until November 27, 2026:

- The requirements under sections 582(d)(4)(A)(ii)(II) and (B)(iii) of the FD&C Act for dispensers to verify the product identifier of the statutorily designated proportion of suspect or illegitimate product in the dispenser's possession or control. Small business dispensers are still obligated to meet all other verification requirements of section 582(d)(4) of the FD&C Act.
- The requirement under section 582(g)(1)(A) of the FD&C Act that the transaction information and the transaction statements be exchanged in a secure, interoperable, electronic manner in accordance with the standards established under the guidance issued pursuant to paragraphs (3) and (4) of section 582(h) of the FD&C Act. Small business dispensers and their trading partners may continue to rely on current methods for providing, capturing, and maintaining transaction information and transaction statements⁹ for transactions of product .
- The requirement under section 582(g)(1)(B) of the FD&C Act that the transaction information required to be exchanged include the product identifier at the package level for each package included in the transaction. Small business dispensers and their trading partners may continue exchange transaction information that does not include the product identifier at the package level for each package included in the transaction.
- The requirement under section 582(g)(1)(C) of the FD&C Act that systems and processes for verification of product at the package level, including the standardized numerical identifier, be in accordance with the standards established under the guidance issued pursuant to section 582(a)(2) of the FD&C Act and the guidances issued pursuant to paragraphs (2), (3), and (4) of section 582(h) of the FD&C Act. Small business dispensers and their trading partners may continue to rely on current methods for verification activities
- The requirement under section 582(g)(1)(D) of the FD&C Act for systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary, or other appropriate Federal or State official, in the event of a recall or for the purposes of

⁶ See Section 581(3) of the FD&C Act for the definition of *dispenser*.

⁷ The total number of employees as of November 27, 2024.

⁸ The Internal Revenue Service defines a *full-time employee* as "for a calendar month, an employee employed on average at least 30 hours of service per week, or 130 hours of service per month." For additional information on identifying full-time employees, see <https://www.irs.gov/affordable-care-act/employers/identifying-full-time-employees>.

⁹ Beginning on November 27, 2023, section 582(k)(1) of the FD&C Act effectively ended the requirement for trading partners to provide and receive transaction history.



investigating a suspect product or an illegitimate product. Small business dispensers and their trading partners may continue to rely on current methods to respond to such requests for such information.

- The requirement under section 582(g)(1)(E) of the FD&C Act for systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable (i) in the event of a request by the Secretary, or other appropriate Federal or State official, on account of a recall or for the purposes of investigating a suspect product or an illegitimate product; or (ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary, or other appropriate Federal or State official, with a request described in clause (i). Small business dispensers and their trading partners may use current methods respond to such requests with their relevant transaction information if they directly transacted the product(s) subject to the request.
- The requirement under section 582(g)(1)(F) of the FD&C Act that each person accepting a saleable return have systems and processes in place to allow acceptance of such product and may accept saleable returns only if such person can associate the saleable return product with the transaction information and transaction statement for the product. Small business dispensers' trading partners may use current methods to accept saleable returns.

The exemptions described in this notification are not intended to provide, and should not be viewed as providing, a justification for delaying efforts by small dispensers to implement the enhanced drug distribution security requirements under section 582(g)(1) of the FD&C Act. FDA strongly urges small dispensers to continue their efforts to implement necessary measures to satisfy these enhanced drug distribution security requirements. Small dispensers and their trading partners who utilize these exemptions do not need to submit anything to FDA.

Sincerely,

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