DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs
Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document, contact (CDER) 301-796-3130, or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)

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Revision 1

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Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance identifies the standards necessary to facilitate adoption of secure, interoperable, electronic data exchange among the pharmaceutical distribution supply chain, and clarifies the trading partners,[2] products,[3] and transactions[4] subject to such standards. This guidance is issued subject to sections 582(h)(4)-(5) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1(h)(4)), as added by the Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54), and is a revision of the draft guidance for industry *DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information,*[5] issued in November 2014 as required by section 582(a)(2)(A) of the FD&C Act. The revisions described in this guidance update the policy articulated in the November 2014 draft guidance to reflect the enhanced drug distribution security requirements that will go into effect on November 27, 2023, including that paper-based methods of product tracing will no longer be permitted and verification of product at the package level will be required, unless a waiver, exception, or exemption applies.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

The DSCSA outlines requirements for enhanced drug distribution security, which include the steps to achieve interoperable, electronic tracing of products at the package level[6]. These requirements for enhanced drug distribution security go into effect on November 27, 2023. Section 582(g)(1) of the FD&C Act sets forth enhanced drug

[1] This guidance has been prepared by the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) and the Office of Regulatory Affairs (ORA) at the Food and Drug Administration.

[2] *Trading partner* is defined in section 581(23) of the FD&C Act. Although third-party logistics providers are also considered trading partners under section 581(23)(B), the provisions of section 582(b)-(e) do not impose requirements on them.

[3] *Product* is defined in section 581(13) of the FD&C Act.

[4] *Transaction* is defined in section 581(24) of the FD&C Act.

[5] When final, this guidance will represent FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[6] *Package* is defined in section 581(11) of the FD&C Act.

distribution security requirements for trading partners, including adherence to standards established by FDA for the exchange of transaction information and transaction statements[7] in a secure, interoperable, electronic manner and the verification[8] of product at the package level. Additionally, section 582(h)(4)(A) of the FD&C Act specifies that FDA issue a draft guidance, and revise the draft guidance as appropriate, to identify and make recommendations with respect to the standards necessary for adoption to support the secure, interoperable, electronic data exchange among the pharmaceutical distribution supply chain that comply with a form and format developed by a widely recognized international standards development organization.

In this revised guidance, FDA considered the standards established under sections 505D of the FD&C Act (21 U.S.C. 355e) and 582(a)(2) of the FD&C Act in the November 2014 draft guidance *DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information*. The pilot projects conducted per section 582(j) of the FD&C Act also informed revisions made to this guidance.[9] This revised guidance is intended to facilitate the creation of a uniform methodology for product tracing while ensuring the protection of confidential commercial information and trade secrets. FDA also published other guidances addressing the enhanced drug distribution security requirements, including the attributes necessary for enhanced product tracing and verification, which should be read in conjunction with this guidance.[10]

III. TO WHOM DOES THIS GUIDANCE APPLY?

This guidance applies to manufacturers, wholesale distributors, dispensers, and repackagers[11] who engage in transactions of "products" as defined in section 581(13) of the FD&C Act. Whether an entity meets the DSCSA definition of a particular type of trading partner depends on the activities engaged in by such entity. If an entity meets the definition of more than one type of trading partner, the entity must comply with all applicable requirements under section 582(a)(1) of the FD&C Act. However, trading partners are not required to duplicate requirements.[12] The DSCSA requires that manufacturers, wholesale distributors, dispensers, and repackagers who engage in transactions of products meet the applicable requirements for being authorized[13] trading partners.[14]

IV. WHAT PRODUCTS DOES THIS GUIDANCE ADDRESS?

This guidance applies to transactions involving products as defined in section 581(13) of the FD&C Act. In general, a *product* is a prescription drug in a finished dosage form for administration to a patient without requiring substantial further manufacturing, such as capsules, tablets, and lyophilized products before reconstitution. See section 581(13) of the FD&C Act for specific exclusions from the definition of *product*. Stakeholders should review these exclusions to determine whether a specific prescription drug is excluded from the DSCSA definition of *product* and is thus excluded from the product tracing requirements of section 582 of the FD&C Act.

V. WHAT TRANSACTIONS DOES THIS GUIDANCE ADDRESS?

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[7] *Transaction information* and *transaction statement* are defined in sections 581(26) and (27) of the FD&C Act, respectively.

[8] *Verification* is defined in section 581(28) of the FD&C Act.

[9] See FDA's Drug Supply Chain Security Act Pilot Program web page at https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/dscsa-pilot-project-program.

[10] See FDA's Drug Supply Chain Security Act Law and Policies web page at https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-law-and-policies for DSCSA-related guidance documents.

[11] *Manufacturer*, *wholesale distributor*, *dispenser,* and *repackager* are defined in section 581(10), (29), (3), and (16) of the FD&C Act, respectively.

[12] See section 582(a)(1) of the FD&C Act.

[13] *Authorized* is defined in section 581(2) of the FD&C Act.

[14] See sections 582(b)(3), (c)(3), (d)(3), and (e)(3) of the FD&C Act.

This guidance applies to transactions as defined in section 581(24) of the FD&C Act. In general, a *transaction* is defined as a transfer of product between persons in which a change of ownership occurs. The definition exempts certain types of transfers. See section 581(24)(B) of the FD&C Act for specific exemptions from the definition of *transaction*. Stakeholders should review these exemptions to determine whether a specific transfer is exempt from the DSCSA definition of *transaction* and is thus exempt from the product tracing requirements of section 582 of the FD&C Act.

VI. WHAT DOES INTEROPERABILITY ENCOMPASS FOR PURPOSES OF THE INITIAL STANDARDS FOR THE EXCHANGE OF TRACING INFORMATION UNDER SECTION 582(A)(2)(A)?

As stated in the previous draft of this guidance, FDA believes that "interoperability," for purposes of the initial standards for the exchange of tracing information under section 582(a)(2)(A), encompasses the ability (1) to exchange transaction history,[15] transaction information, and transaction statements accurately, efficiently, and consistently among trading partners; and (2) for a subsequent purchaser's system, process, or practice to successfully capture and maintain the transaction history, transaction information, and transaction statements, regardless of whether they are provided in a paper or electronic format. Until November 27, 2023, wholesale distributors, dispensers, and repackagers can use either paper-based or electronic-based methods to provide transaction history, transaction information, and transaction statements to subsequent purchasing trading partners as long as the selected method allows the information to be exchanged in a manner that complies with the requirements of section 582(c)(1), (d)(1), and (e)(1) of the FD&C Act, respectively.

Section 582(b)(1)(C) of the FD&C Act currently requires manufacturers, unlike other trading partners, to use electronic-based methods to provide transaction history, transaction information, and transaction statements to subsequent purchasing trading partners.[16] However, a manufacturer may provide transaction history, transaction information, and transaction statements in a paper format if the subsequent purchaser is either a: (1) State licensed health care practitioner authorized to prescribe medication; or (2) licensed individual who dispenses product in the usual course of professional practice and is under the supervision or direction of a licensed prescribing health care practitioner.[17]

VII. WHAT DOES INTEROPERABILITY ENCOMPASS FOR THE PURPOSE OF ENHANCED DRUG DISTRIBUTION SECURITY UNDER SECTION 582(G)(1) BEGINNING ON NOVEMBER 27, 2023?

Beginning November 27, 2023, electronic-based approaches are generally required to be used among all trading partners to meet the enhanced drug distribution security requirements outlined in section 582(g) of the FD&C Act.[18] On that date, trading partners are required to use secure, interoperable, electronic approaches to: (1) exchange transaction information that includes package level product identifiers for each package included in transactions and transaction statements; [19] (2) verify products at the package level; (3) promptly respond with the transaction information and transaction statement for a product in the event of a recall or for investigations; (4) facilitate the gathering of transaction information for a product going back to the manufacturer in the event of a recall or for investigations; and (5) accept saleable returns under appropriate conditions.[20]

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[15] *Transaction history* is defined in section 581(25) of the FD&C Act.

[16] See section 582(b)(1)(C)(i) of the FD&C Act.

[17] See section 582(b)(1)(C)(ii) of the FD&C Act.

[18] See section 582(g)(1) of the FD&C Act.

[19] Beginning November 27, 2023, section 582(k)(1) of the FD&C Act effectively ends the requirements for trading partners to provide and receive transaction history.

[20] See section 582(g)-(m) of the FD&C Act for more information on enhanced drug distribution security requirements.

Considering trading partners' transition to exclusively utilize electronic-based approaches to satisfy the enhanced drug distribution security requirements by November 27, 2023, FDA believes that interoperability for purposes of the enhanced drug distribution security requirements differs from the processes and capabilities that allow a system, process, or practice to be interoperable under the initial standards for exchange of tracing information in section 582(a)(2)(A) of the FD&C Act. Based on trading partner and other stakeholder progress and/or piloting activities, we believe that: (1) the processes and capabilities that promote more standardization of how product tracing information is exchanged and documented have become available; and (2) electronic approaches have evolved and become more affordable and accessible to a wider range of trading partners with various business operation structures. As such, for the purpose of the enhanced drug distribution security requirements under section 582(g)(1), FDA interprets interoperability for enhanced drug distribution security to encompass the ability to securely exchange, capture, and maintain electronic transaction information and transaction statements accurately, efficiently, and consistently among trading partners, in a manner that enables compliance with all enhanced drug distribution security requirements.

VIII. WHAT STANDARDS SHOULD TRADING PARTNERS ADOPT FOR THE ENHANCED DRUG DISTRIBUTION SECURITY REQUIREMENTS?

FDA recommends that trading partners use the Electronic Product Code Information Services (EPCIS) standard[21] to provide and maintain the data associated with transaction information and transaction statements. EPCIS is a global GS1 standard that allows trading partners to capture and share information about products as they are transacted through the supply chain. Use of EPCIS can support and enable electronic and interoperable interfaces used by trading partners to help ensure compliance with the DSCSA requirements and is compatible with a range of different technological approaches. FDA believes that EPCIS is an appropriate globally recognized standard, and FDA understands there is considerable agreement among stakeholders that EPCIS is a suitable standard to adopt for the enhanced drug distribution security requirements.

It is essential for trading partners to adopt standards for how the data associated with transaction information and transaction statements are electronically exchanged to achieve enhanced drug distribution security interoperability. To help ensure successful, efficient enhanced drug distribution security interoperability, FDA recommends that trading partners make a collaborative effort to follow the same standards for how the data associated with transaction information and transaction statements are electronically exchanged.

IX. BUILDING TECHNOLOGICAL APPROACHES TO COMPLY WITH ENHANCED DRUG DISTRIBUTION SECURITY REQUIREMENTS

FDA recognizes there are a variety of technological approaches available to trading partners to comply with enhanced drug distribution security requirements outlined in section 582(g)(1) of the FD&C Act, and FDA does not expect all trading partners to rely upon a single technological approach. However, the Agency recommends that a trading partner use a technological approach utilizing the EPCIS standard. In addition, any technological approach a trading partner uses should utilize data standards that facilitate a uniform process or methodology for product tracing and ensure the protection of confidential commercial information and trade secrets.[22] We note that trading partners' efforts to protect such information should not be limited to adhering to EPCIS, but should also include using individual system(s) and procedure(s), and business practices that ensure the confidentiality of such information. For data capture and exchange specifically, a trading partner should use a globally recognized standard as described in this guidance. FDA believes the recommendations in this guidance can serve as foundational steps toward establishing enhanced drug distribution security. As FDA continues to make recommendations for the DSCSA enhanced drug distribution security requirements, supply chain stakeholders should consider these recommendations for successful implementation.

[21] EPCIS (Electronic Product Code Information Services) is a standard developed by GS1. For more information see https://www.gs1.org/standards/epcis.

[22] Id.