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United States Regulatory Updates

This is a compilation of the recent regulatory updates for the United States. Every week, we post an update of what's new, which you can **view here**.

2023

- **October 9:** PDG released new resources to aid trading partners in developing processes and policies in line with the final phase of the DSCSA. The topics include communications and corrective actions between trading partners as well as DSCSA and business continuity planning.
- **August 28:** The FDA finalized its guidance on EDDS (Enhanced Drug Distribution Security). In line with the enforcement discretion guidance issued by the FDA, the FDA updated its guidance for wholesale distributors on policies for product verification.

- **August 21:** The FDA published its DSCSA “enforcement discretion” guidance for the Enhanced Drug Distribution Security (EDDS) phase of requirements, which go into effect on Nov. 27, 2023.
- **July 31:** The FDA published final guidance on Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act (DSCSA). This document spells out procedures for requesting such waivers and finalizes guidance originally issued in 2018.
- **July 17:** The Partnership for DSCSA Governance (PDG) published a document that offers guidance on authoring SOPs for initiating and responding to DSCSA tracing requests.
- **June 19:** GS1 has published an Implementation Guide Addendum with XML examples.
- **May 29:** The FDA published its final report for the DSCSA Pilot Project Program.
- **April 17:** PDG published a position statement on Waivers, Exceptions, and Exemptions for industry consideration.
- **April 3:** The FDA published final guidance on definitions of suspect and illegitimate product for verification obligations and includes expanded definitions on “counterfeit”, “unfit for distribution”, “diverted”, and other terms not legally defined in DSCSA.

2022

- **October 10:** The Partnership for DSCSA Governance (PDG) finalized its Tabletop Simulation report for its workshop held in June 2022. The report contains takeaways from the simulations that evaluated collaboration effectiveness amongst regulators and trade partners. The insights will also be used to inform PDG's functional design.
- **October 10:** GS1 Healthcare US published Release 1.3 of its Implementation Guideline to apply the Lightweight Messaging Standard for DSCSA verification.
- **September 19:** The Healthcare Distribution Alliance held the third installment of its webinar series for dispensers. The series offers a practical understanding of the law and how to implement systems, solutions and processes to be compliant with DSCSA for 2023.
- **September 5:** The FDA has proposed a rule change for National Drug Codes; the consultation is in effect until 22 November 2022.
- **September 5:** The public consultation period for two draft guidance documents, "Interoperability Standards" and "Trade Partner Identification," ended on September 3, 2022.
- **September 5:** PDG published Blueprint v1.1, an update to the first chapter that was published one year ago. PDG expects to publish the next five chapters of the Blueprint this month.
- **July 3:** The Food and Drug Administration (FDA) published two new draft guidance documents that will inform requirements for the Drug Supply Chain Security Act

(DSCSA) 2023.

    - **DSCSA Standards for the Interoperable Exchange of Information:** The FDA effectively endorsed the usage of the EPCIS standard for transaction information and for transaction statements.
    - **Identifying Trading Partners under DSCSA:** The FDA issued guidance to assist industry and government organizations in categorizing the entities in the drug supply chain in accordance with the DSCSA.

- **June 20**: Healthcare Distribution Alliance, in collaboration with various professional associations, launched the DSCSA.pharmacy website to help dispensers navigate their way to DSCSA 2023 compliance.
- **June 13:** Stakeholders from across the supply chain and federal and state regulators gathered in Washington, D.C., this week for Partnership for DSCSA Governance (PDG) Tabletop Workshops. Attendees simulated various tracing scenarios.
- **May 29:** The FDA has extended the consultation period for 3PL and wholesaler licensure rules until September 6, 2022.
- **May 22:** The Partnership for DSCSA Governance (PDG) is holding a “DSCSA Pilot & Workshop” June 15 – 16 in Washington, DC.
- **May 22:** The consultation period on the most recent FDA draft guidance on Verification Systems ended on May 9, 2022. The Healthcare Distribution Alliance (HDA) requested that the comment period be extended until June 24, 2022.

- **May 15:** The Partnership for DSCSA Governance (PDG) is holding a “DSCSA Pilot & Workshop” June 15 – 16 in Washington, DC.
- **May 15:** PDG is working on the next five chapters of its Foundational Blueprint for 2023 Interoperability, which will describe functional specifications to meet DSCSA 2023 requirements. Publication is expected in September 2022:
    - Chapter 2: Interoperability
    - Chapter 3: TI/TS Exchange
    - Chapter 4: PI Verification Architecture
    - Chapter 5: Tracing Architecture
    - Chapter 6: Credentialing and User Authentication
- **May 8:** The consultation period on the most recent FDA draft guidance on Verification Systems ended on May 9, 2022. The FDA received 6 submissions of comments. HDA requested that the comment period be extended until June 24, 2022.
- **May 1:** The Partnership for DSCSA Governance (PDG) is holding a “DSCSA Pilot & Workshop” on June 15 and 16 in Washington, DC. The workshop is for the FDA, U.S. States, and industry stakeholders (including solution providers) to perform verification and tracing simulations and role-plays.
- **May 1:** The consultation period on the most recent FDA draft guidance on Verification Systems ends on May 9, 2022.

- **April 24:** The consultation period on the most recent FDA draft guidance on Verification Systems ends on May 9, 2022.
- **April 17:** The Healthcare Distribution Alliance (HDA) published its 2022 edition of "Guidelines for Bar Coding in the Pharmaceutical Supply Chain," which incorporates FDA guidance and other updates since the previous edition in 2017.
- **April 17:** The FDA published an on-demand webinar for the proposed rule on national standards for licensure of wholesale drug distributors and 3PLs. The consultation period ends June 6, 2022.
- **April 10:** The FDA published an on-demand webinar for the proposed rule on national standards for licensure of wholesale drug distributors and 3PLs.
- **April 10:** The consultation period on the most recent FDA draft guidance on Verification Systems ends on May 9, 2022.
- **March 27:** The Healthcare Distribution Alliance (HDA) published "Manufacturer Data Quality: Best Practice Considerations for DSCSA," compiled by the HDA's Exceptions Handling Work Group composed of manufacturers and wholesalers.
- **March 27:** The consultation period on the most recent FDA draft guidance on Verification Systems ends on May 9, 2022.
- **March 20:** The consultation period on the most recent FDA draft guidance on Verification Systems ends on May 9, 2022.
- **March 6:** The FDA has released a draft update to its guidance on Verification Systems. Industry, including PDG and TraceLink, is analyzing the document to

determine impact on current design approaches.

- **March 6:** The FDA has still not published its final guidance on EDDS (Enhanced Drug Distribution Security).
- **February 13:** The FDA is proposing nationwide standards for the licensure of wholesale distributors and 3PLs in order to standardize and streamline DSCSA implementation. The FDA will be outlining the proposed new rules in a webinar in the near future. The consultation ends in June 2022.
- **February 13:** The FDA has still not published its final guidance on EDDS (Enhanced Drug Distribution Security).
- **February 13:** The FDA still has not published their summary report of the FDA Pilot Project nor the collection of individual project reports, including from TraceLink.
- **January 30:** The FDA is proposing nationwide standards for the licensure of wholesale distributors and 3PLs in order to standardize and streamline DSCSA implementation. The FDA will be outlining the proposed new rules in a webinar in the near future.
- **January 30:** The Healthcare Distribution Alliance (HDA) circulated a strongly worded video regarding industry readiness for DSCSA 2023 and reiterated its call for the FDA to retract its previously-issued EDDS draft guidance. (The FDA has still not published its final guidance on EDDS).

2021

- **December 5:** The FDA has not yet published its final guidance on the Enhanced Drug Distribution Security (EDDS) document.
- **November 28:** On November 16, the FDA held an all-day public meeting on Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act . Attendance was approximately 500. The FDA communicated that a key objective of the meeting was to solicit further comments on the June 2021 EDDS guidance it had issued, with the aim of finalizing the guidance as soon as possible.
- **November 14:** The FDA held an all-day public meeting with an attendance of approximately 500. A key objective of the meeting was to solicit comments on the June 2021 Enhanced Drug Distribution System (EDDS) guidance, with the goal of finalizing the guidance as quickly as possible. The meeting offered greater clarification of the distributed nature of the “Enhanced System.”
- **November 7:** Registration has closed for the FDA’s all-day public meeting on November 16 due to capacity constraints.
- **October 31:** Final guidance on the FDA’s Enhanced Drug Distribution Security (EDDS) has not been issued. Additional input is expected from the November 16 public meeting.
- **October 24:** The FDA will hold an all-day public meeting on November 16 to cover various aspects of its Enhanced Drug Distribution Security (EDDS). Registration is required and the FDA has asked stakeholders to be comment-ready on certain

topics.

- **October 17:** The FDA has published the on-demand replay for the October 5 meeting on its EDDS (Enhanced Drug Distribution Security) Draft Guidance. The presentation from the meeting is also available.
- **October 10:** The FDA held a public meeting on October 5 to present its EDDS (Enhanced Drug Distribution Security) Draft Guidance. The meeting was aimed at all supply chain stakeholders and presented a comprehensive overview of 2023 requirements. Webinar slides are available on the Small Business and Industry Assistance (SBIA) Education Events website.
- **September 26:** The FDA reports that it has received 29 submissions to its EDDS (Enhanced Drug Distribution Security) Draft Guidance. The FDA has not communicated the date for issuing a final version.
- **September 26:** The FDA will hold a public meeting on October 5 to discuss EDDS. The meeting is open to all supply chain stakeholders and requires registration.
- **September 19:** The FDA EDDS (Enhanced Drug Distribution Security) draft guideline consultation period ended on September 2. The FDA has not communicated the date for issuing a final version.
- **September 5:** The FDA EDDS (Enhanced Drug Distribution Security) draft guideline consultation period ended on September 2. The FDA has not provided a further extension.

- **August 29:** The FDA EDDS (Enhanced Drug Distribution Security) draft guideline consultation period ended on September 2.
- **August 15:** The FDA's EDDS (Enhanced Drug Distribution Security) draft guideline consultation period is scheduled to end on September 2, 2021.
- **August 8:** The FDA extended its industry consultation period on the EDDS (Enhanced Drug Distribution Security) draft guideline to September 2, 2021 based on the complexity of the guidance and its impact on the industry developing systems and processes for meeting DSCSA 2023 requirements. Turnaround time for finalizing the EDDS guideline will depend on volume and complexity of comments received.
- **August 8:** The FDA still has not published their summary report of the FDA Pilot Project nor the collection of individual project reports, including from TraceLink.
- **August 1:** The FDA stated they will consider extending the August 3 deadline for providing feedback on the Enhanced Drug Distribution Security draft guideline and notes that the turnaround time for finalizing the Enhanced Drug Distribution Security guideline will depend on the volume and complexity of comments received.
- **August 1:** The FDA still has not published their summary report of the FDA Pilot Project nor the collection of individual project reports.
- **July 11:** The Partnership for DSCSA Governance (PDG) will be publishing its first version of its **Interoperability Blueprint** on July 14.

- **July 11:** The Partnership for DSCSA Governance (PDG) Identity and Credentialing workgroup holds its next meeting on July 13. Agenda to be published.
- **July 11:** The Partnership for DSCSA Governance (PDG) Serialized Transaction Information workgroup met on July 6:
    - Agreed that it is too early to have the June 21 FDA guidance impact the group's work immediately. Workgroup will monitor industry comments and FDA/Industry discussions.
    - Agreed to encourage additional work on master data management practices. The current GS1 U.S. guideline treatment of master data continues to be recognized as the near-term solution.
    - Discussed and diagrammed Drop Ship and 340b processes for further discussion.
- **July 11:** The next Partnership for DSCSA Governance (PDG) Tracing Architectures workgroup meeting is planned for July 14. Agenda to be published.
- **July 11:** The Partnership for DSCSA Governance (PDG) Verification Architectures workgroup held its meeting on July 7 to focus on pending issues before the group focuses on flow diagrams and technical incorporation of identity credentialing into potential verification architectures.
- **June 6:** The FDA released four long-awaited DSCSA guidance documents:

    - **Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act** (draft - comments and suggestions may be submitted within 60 days)
    - **Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification** (final version)
    - **Product Identifiers Under the Drug Supply Chain Security Act: Questions and Answers** (final version)
    - **Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act** (draft - comments and suggestions invited for submission within 30 days)

- **June 6:** AmerisourceBergen (ABC) released a new supplier letter in which they outlined their intentions with respect to DSCSA 2023 compliance.
- **June 6:** AmerisourceBergen (ABC) announced in a supplier letter their intention to start increasing their production scans in June for saleable returns, leading to anticipated rise in the overall VRS network scanning activity.
- **June 6:** The FDA still has not published their summary report of the FDA Pilot Project nor the collection of individual project reports.

2020

- **October 4:** The US Department of Health and Human Services (HHS) and the US Food and Drug Administration (FDA) released a "Safe Importation Action Plan,"

which provides baseline rules for the safe importation of certain drugs originally intended for foreign markets. The rules state that medicines imported from Canada, which were not originally targeted for the US, must be relabeled to meet US requirements. Manufacturers can also import versions of FDA-approved drug products sold in foreign countries that are the same as the US versions, provided they use a new National Drug Code (NDC) for those products.

- **August 23:** The Healthcare Distribution Alliance (HDA) Verification Router Service (VRS) Task Force is meeting this week to discuss policies for exception management. The Task Force will also present at the upcoming US Food and Drug Administration (FDA) industry listening session on August 31, 2020.
- **August 16:** The US Food and Drug Administration (FDA) is holding an industry listening session on August 31, 2020. Issues related to the upcoming deadlines for saleable returns and dispenser requirements under the US Drug Supply Chain Security Act (DSCSA) will be discussed.
- **May 10:** The US Food and Drug Administration (FDA) published new guidance for medical device manufacturers to follow during the COVID-19 public health emergency. Manufacturers are required to notify the FDA about interruptions in the manufacturing of certain devices that may lead to a shortage. The new guidance is designed to help manufacturers provide the FDA with timely notifications that include the correct information.

- **May 3:** The US Food and Drug Administration (FDA) published new guidance that seeks to clarify the scope of temporary exemptions and exclusions from DSCSA for the duration of the COVID-19 public health emergency. The guidance is focused on products used to diagnose, treat, or cure COVID-19.
- **March 29:** AA $2 trillion federal coronavirus relief bill has been signed into law in the United States. In addition to providing economic stimulus and helping those affected by the pandemic, the CARES Act contains several provisions related to drug and medical device shortages and healthcare industry risk management planning.
- **March 15:** The US Congress may consider multiple new bills aimed at improving the overall visibility and readiness reporting for the U.S drug supply. The bills are primarily focused on reporting of production sites and raw materials. While the bills have significant support, there is still uncertainty as to whether they will be formally taken up by lawmakers.

2019

- **November 24:** The US Office of Management and Budget is reviewing a proposed rule from the US Food and Drug Administration (FDA) that would allow certain medicines to be imported from Canada and other countries as a cost-saving measure. It’s still unclear whether new DSCSA requirements will arise if the rule is adopted.

- **November 3:** A new report from the US Food and Drug Administration (FDA) Drug Shortages Task Force outlines the major causes of drug shortages and recommends steps the FDA and the pharmaceutical industry can take to combat this growing problem. The root causes of shortages often involve economic factors driven by both private and public-sector policies, according to the report.
- **October 27:** The state of New York passed a new pharmaceutical recalls law that aims to increase patient safety. The law requires pharmacies to alert affected patients within three days of a Class 1 recall notification.
- **March 31:** The Pharmaceutical Distribution Security Alliance (PDSA) published a white paper that highlights their plan for US DSCSA governance, which includes both 2019 VRS and 2023 unit-level tracing. For further information, the PDSA will be holding a webinar the week of April 1 and an open meeting the week of May 1 in Washington, DC.
- **February 10:** The Food and Drug Administration (FDA) officially launched their **Pilot Program for DSCSA 2023**, which is intended to assist members of the pharmaceutical distribution supply chain in the development of an electronic, interoperable system that will identify and trace certain prescription drugs as they are distributed within the United States.

2018

- **November 25:** Major industry associations have published their comments on the FDA product identifier Q&A guidance.

- **October 28:** The FDA published new draft guidance for verification under DSCSA.
- **September 30:** The FDA published a **new decision tree** for determining if a product should have a product identifier under the Drug Supply Chain Security Act (DSCSA).
- **September 23:** The FDA finalized three DSCSA-related guidance documents: A compliance policy for serialized products; a grandfathering policy for non-serialized product; and a general question and answer document along with key questions related to serialized product.
- **August 26:** The FDA announced an initiative to revise the National Drug Code (NDC). The initial announcement was made for the program along with an invitation for a first public meeting at the FDA, which will be held on 11/5.
- **May 13:** The FDA published guidance on waivers, exceptions, and exemptions this week for DSCSA compliance.
- **April 1:** The FDA released the Office of Inspector General report on pharmacy dispenser status with DSCSA compliance.
- **March 4:** The FDA published two new draft guidance documents for DSCSA on 2/28/18. The internal summary for these documents was prepared and circulated on 3/3/18.
- **January 28:** The FDA published their 2018 planned guidances for DSCSA.
- **January 28:** Medical Device: The FDA has published a letter postponing the implementation of UDI requirements for Class 1 by 2 years. The implementation is now slated for 2020 for phase 1 and 2022 for phase 2, which is direct marking.

- **January 28:** The USAID organization published new standards (requirements, implementation guidelines, and technical guidelines) that support the use of GS1 standards and require the supply of master data via a GDSN provider by the end of 2019. USAID provides these standards as part of its work with developing countries and their governments in enhancing medicine supply chains.

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