

Addressing uncertainty in DSCSA implementation — Best practices to meet regulatory deadlines

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The concept of creating a “track and trace” system within the U.S. pharmaceutical supply chain has been much debated for decades. Early, state-led efforts to implement drug “pedigree” or “e-pedigree” legislation experienced multiple iterations in states including Florida and California.

At long last, in 2013, the United States Congress passed the Drug Supply Chain Security Act (DSCSA), to create a national framework for governing the identification, management, and traceability of drug products, at the unit level, within the United States. The overarching purpose of the law is to more efficiently ensure patient safety by preventing illegitimate, counterfeit or recalled drug products from reaching patients.

The law preempts a 50-state patchwork of pedigree requirements with a single, federal solution to trace prescription medications throughout the supply chain. The federal government created a phased timeline to provide pharmaceutical supply chain partners with time to comply with the law — and all trading partners are expected to fully comply with all the law’s provisions by 2023.

However, for drug manufacturers that must update their operations to comply with the law, implementing serialization technology and processes may pose a significant challenge. Indeed, while many companies think they’re prepared to be compliant by the 2023 deadline, they may not be as on-track as they believe.

In a recent study conducted by the Healthcare Distribution Alliance (HDA) of 57 pharmaceutical manufacturers, approximately half reported that they would fall short of having 100 percent of their product supply serialized by November 2018. Significant concerns were expressed with compliance to the 2019 saleable returns requirements, and specifically the Verification Router Service (VRS). In response to concerns regarding verification of saleable returns, FDA announced a one-year delay in the enforcement of this phase until November 2020.

As one of the leading 3PL service companies in the industry, Cardinal Health has been partnering with manufacturers on serialization planning and DSCSA compliance for the past several years.

In this paper, we will share insights into where drug manufacturers should be in the compliance process; discuss the major challenges they are likely to face when working to comply with the first serial-number-specific phase of the law; and explore some of the best practices we’ve identified as we’ve partnered to help pharmaceutical companies reach full DSCSA compliance by 2023.



Goals of the DSCSA

At the highest level, the Drug Supply Chain Security Act (DSCSA) aims to:

- Create a consistent, efficient process for verifying — and protecting — the legitimacy of drug products, at the unit level, as they move throughout the U.S. pharmaceutical supply chain;
- Make it easier to detect and quarantine illegitimate medications, and enhance the process for all pharmaceutical supply chain partners to notify FDA of illegitimate medications, so they can be removed from the supply chain before reaching patients;
- Confirm authorized trading partners and strengthen distributor licensure standards across the United States; and
- Improve the efficiency of the drug recall process.

The ultimate goal of all of these measures is to protect patient safety by significantly decreasing the number of illegitimate or unsafe products on the market.

Key milestones towards DSCSA implementation

Between 2013, when DSCSA was originally passed, and 2023, when all pharmaceutical supply chain partners are expected to be in full compliance, FDA has intentionally created a phased approach to implementation.

Here's an overview of the key steps that need to be taken to comply with DSCSA, and when each step needs to be implemented.



Developing an effective approach to serialization

For manufacturers that are behind in the process, there is still time to catch up before 2023. However, as FDA enforcement deadlines are fast approaching, it's important to move quickly to develop an effective serialization strategy. Here are some key issues to consider if you are still developing your approach to serialization, or exploring possible partnerships with a third-party supplier.

- **Consider what you'll use for your system of record:** Key to a successful serialization strategy is the ability to track and store unit-level data. For dozens of manufacturers, Cardinal Health manages key product flow information, and makes it available to customers via existing, customer-facing web portals, for maximum convenience and ease-of-use.
- **Ensure your CMO is prepared to share data with your partners, in an effective and cost-efficient manner.** If you're working with a contract manufacturing organization (CMO), one key to your successful and cost-efficient serialization strategy will be ensuring, early on, that they can create and send EPCIS data downstream to trading partners. It's also important to ensure that they follow GS1 Electronic Product Code Information Services (EPCIS) standards. Following these standards can help ensure readability among partners. Whether you leverage a 3PL to help implement your serialization strategy or use a third-party technology vendor, this should ideally be done without the need to purchase additional user-managed software — to make the process as cost efficient as possible. Before you "go live," it's also prudent to conduct testing with all partners, including your CMO, 3PL and any other third parties that you've engaged. This advance testing can identify obstacles and provide time to work out any kinks in the system.
- **Determine what process you'll use to commission and apply serial numbers to products.** Whether you use a company like Cardinal Health to perform this service, or work with a CMO to complete this task, ensure that your vendor has processes in place to ensure the accuracy of the data included in the serial numbers.
- **If you are evaluating outsourced partners, ensure they have systems in place to support current regulatory requirements and can evolve along with FDA guidance and regulations.** As key DSCSA milestones approach, it is likely that FDA will make modifications to the requirements. Having flexibility in your systems will make it easier to adapt if changes occur down the road.
- **Be prepared for enforcement of Verification Systems related to the identification and handling of suspect and illegitimate products.** Have detailed, written processes and procedures so FDA can inspect and evaluate them. Make sure those processes are carefully followed by employees, and that appropriate documentation is maintained.
- **Learn from the experiences of fellow manufacturers.** When it comes to complying with DSCSA, there's no substitute for first-hand insight from other manufacturers who are well on their way to implementing a serialization strategy. Talk to your peers in other companies about their best practices and about what they have learned. They can also serve as references for potential partners.



Real world DSCSA implementation: top eight lessons learned

Cardinal Health has partnered with numerous pharmaceutical developers in successfully complying with DSCSA — and as part of that work, we've also supported nearly 100 manufacturers in the implementation of serialization requirements. In fact, 14.8 million inbound, serialized units and nearly 2,000 serialized lots of product had been processed by Cardinal Health as of early 2019. In the process, we've identified some common pitfalls in execution — hidden or unforeseen challenges that can get in the way of serialization compliance. As your company embarks on serialization, follow these tips to avoid costly and inefficient delays in implementation.

- 1. Collaborate closely with CMOs to ensure they understand the law, and evolving industry standards.** A recent HDA survey found that 65 percent of manufacturers cited “CMO knowledge of DSCSA” as their top concern related to the serialization process. Indeed, many of the issues Cardinal Health has encountered when processing serialized product have been created by CMO failure to follow accepted industry standards related to compliance. That's why it's critical for manufacturers to work closely with CMOs to ensure they understand, and are supporting compliance with, the law.
- 2. Ensure SSCC barcode labels are securely affixed to each pallet:** One of the most common challenges we've encountered is missing – or unreadable – SSCC barcode labels at the pallet level. Sometimes it is because CMOs or other supply chain partners fail to apply the SSCC label to the pallet altogether. In other cases, the labels are not adhered well and fall off during transit. In still other cases, pallets are rewrapped after the SSCC labels had been affixed, rendering them unreadable. The solution? Affix SSCC labels to at least two sides of each pallet (per HDA guidelines) or to all four sides of the pallet for extra assurance they won't be displaced. Also, only affix labels to the outermost layer of wrapping and reinforce to your trading partners not to remove the outermost layer of wrapping. This obviously causes labels to be lost, which makes tracking the pallet impossible.
- 3. Properly associate partial cases with a pallet, through aggregation:** Because this best practice is not required by law, many supply chain partners don't follow it. However, HDA guidelines encourage partial cases to be labeled with an SSCC label/identifier, and then associated with a pallet through aggregation. A GTIN identifier is not valid on a partial case. When this guideline isn't followed, it makes it impossible to effectively trace product included in partial cases.
- 4. Don't re-stack product or add products to a pallet after the SSCC barcode label has been applied.** This often happens when there's a “middle man” between the CMO and the distributor or 3PL. Often times, product gets re-stacked or added to a pallet that has already been affixed with an SSCC barcode. This usually occurs because handlers are trying to transport as many products as possible in a single container or pallet. This is a practice that needs to be avoided because in doing so, the added products are no longer aggregated appropriately.
- 5. Use updated versions of EPCIS data.** It's critical that all manufacturers use the correct version of EPCIS when serializing product. Most trading partners cannot support EPCIS 1.0, because it does not include all federally required data fields.
- 6. Include aggregation data on each pallet.** The DSCSA does not explicitly require aggregation data to be shared for each pallet. And again, because aggregation is not expressly required by law, some supply chain partners are skipping this important step. However, it's critical that manufacturers follow this HDA recommendation. Including aggregate data in each pallet label enables distributors to confirm, with a single scan, that each pallet does, indeed, include the specific items that it's supposed to house. Failure to include this aggregate information would mean that distributors would need to individually scan each unit or case to confirm receipt. That process is not efficient, affordable, or sustainable. Further, pallet level aggregation also helps distributors identify packaging and data issues, to be shared with the manufacturer for remedy.
- 7. Verify labeling accuracy in advance.** FDA has provided time for manufacturers to perform the necessary quality assurance to make sure their labeling processes work. If you have questions about your labels, Cardinal Health can test barcodes to confirm their validity. Contact barcodes@cardinalhealth.com to get help testing your sample labels and barcodes.
- 8. Communicate in advance of serialized product moving through the supply chain.** In most cases, it's the first few shipments of serialized product that tend to experience the most issues — like failure to serialize the first and last pallets on the line, missing data on pallets, or partially serialized lots. Providing advance notice will enable your trading partners to pay special attention to those first few serialized shipments, so they can immediately alert you to issues or concerns.



The road to 2023: action items to stay on track

- **Get involved, and stay up-to-date:** No pharmaceutical manufacturer will be fully successful with DSCSA implementation without collaborating closely with others. Stay up-to-date on evolving challenges – and best practices – for each step in the implementation journey, by regularly participating in industry calls and updates hosted by other trading partners, HDA, FDA and information standards organization GS1.
- **Adhere to HDA guidelines:** While the DSCSA does include specific, phased implementation deadlines, legislators intentionally provided latitude for the industry to work together to determine the most cost- and time-efficient processes for implementation. HDA is working diligently to foster collaboration among all stakeholders in the supply chain, and to create consistent, agreed-upon standards for sharing serialization information. Failure to follow these industry-accepted specifications and guidelines for sharing data can render barcodes unreadable and data unusable. It can also create inefficient and costly delays in your ability to comply with the law.
- **Stay ahead of the requirements.** As illustrated earlier, each requirement will come with a learning curve. That's why procrastination isn't an option. Each phase of implementation will have its unique challenges. Staying ahead of the game will allow you the opportunity to identify and remove the roadblocks so they don't get in the way of compliance.
- **... but not too far ahead.** While it's important not to procrastinate, it's equally as important not to work too far ahead. As mentioned earlier, further modifications to the DSCSA requirements may occur before 2023. Serialization is an expensive process to implement. Building non-regulatory functionality into your systems can be beneficial — but be sure to conduct a thorough cost-benefit analysis prior to making any investments in technology that go beyond regulatory requirements.
- **Connect with the right partner.** Look for a partner with proven experience in managing serialization. Consider the advantages of partnering with a supplier that can both manage the data and handle the product in one location. This can lead to a more streamlined workflow and help you avoid costly and time-consuming delays.

FDA September 2018 guidance

In September 2018, FDA issued additional guidance regarding the implementation of DSCSA. In summary, that guidance confirmed that:

- A package or case of homogeneous product is considered grandfathered, or exempt from being serialized, if there is documentation that it was packaged by the manufacturer or repackaged by a repackager before November 27, 2018.
- Trading partners may engage in transactions involving grandfathered product until the product's expiration date.
- The transaction statement may be used to indicate that non-serialized product is grandfathered.
- As of November 2019, wholesale distributors will only be able to trade in serialized product, unless grandfathered.
- It's important to **advise downstream partners if a product is covered by a waiver, exception or exemption** to ensure product is not held up due to perceived lack of compliance.

2023, the final deadline for full DSCSA implementation, may seem a long way off. But the deadlines for each phase will arrive quickly. Cardinal Health 3PL Services can help manufacturers fulfill DSCSA requirements by expertly facilitating key facets of your serialization strategy, including:

- Inbound scanning;
- 2-D barcode testing;
- Electronic TI/TH/TS transmission via EDI or web-based portal;
- Data storage;
- Identification and verification of serialized product returns intended for resale;
- Reporting for your serialization data;
- Verification of serialized product throughout the supply chain, within 24 hours; and
- Verification Router Service (VRS) support.

Regardless of whether you are already on track with the preliminary requirements, or need assistance putting a serialization program in place, we can help you, step-by-step, to ensure you are ready for 2023.

Contact us

To learn more about how we can help you comply with DSCSA, visit us at cardinalhealth.com/dscsa or call us at 888.438.2673.

