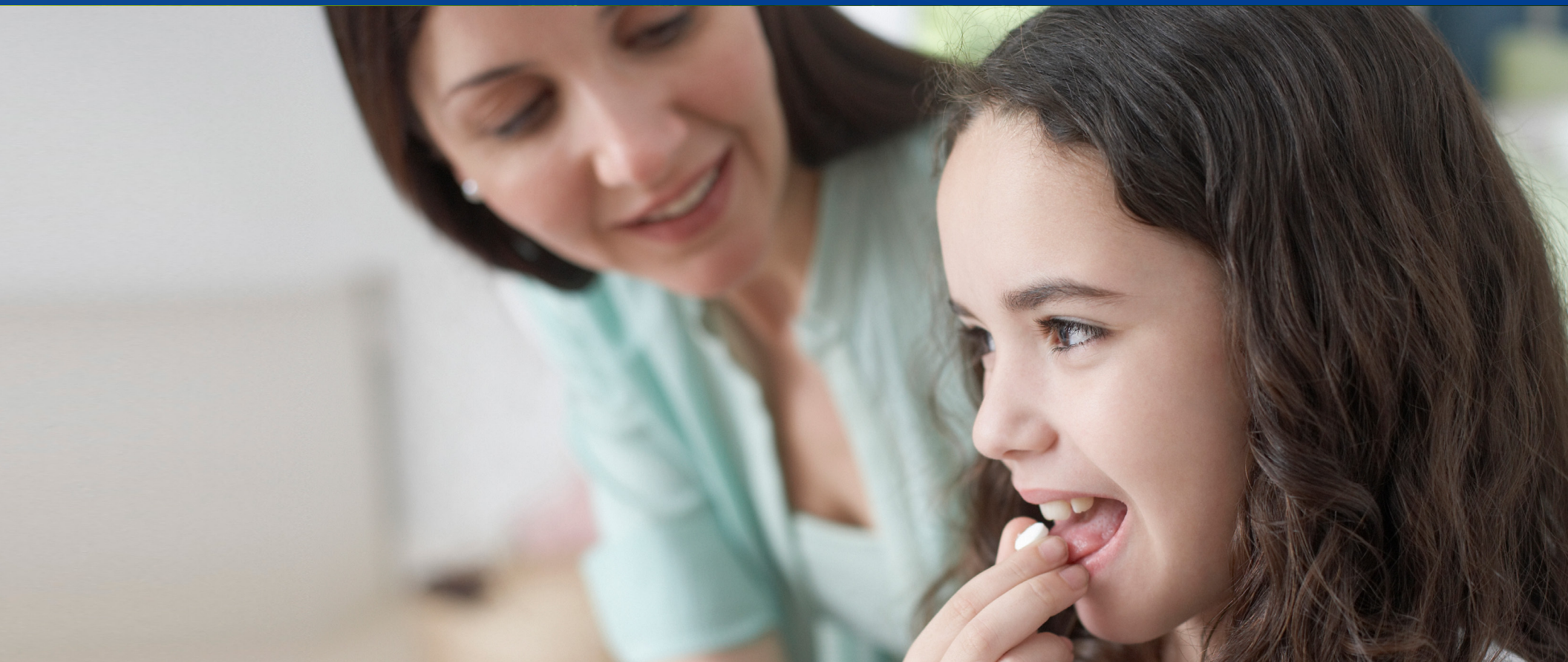
tracelink
Life Sciences Cloud

Keeping Patients Safe with Drug Serialization:

Top 8 Questions from Hospitals and Pharmacies about the Next Phase of DSCSA



Introduction

In July 2015, U.S. hospitals and pharmacies began taking steps to enhance patient safety through the elimination of counterfeit drugs, per the Drug Supply Chain Security Act (DSCSA). Dispensers are currently required to participate in drug traceability at the lot level, a responsibility that has raised questions about how to do so without jeopardizing operational efficiency.

Now, the serialization phase of the law is about to begin, presenting even greater operational challenges and risks. Although dispensers must comply with this phase by 2020, hospitals and pharmacies will be directly affected just months from now, when manufacturers begin shipping serialized product to meet their November 2017 serialization deadline. As processes evolve to meet these new requirements, so do questions being asked across the industry.

The following 8 DSCSA-related questions and answers have surfaced from dispensers as they seek the intersection of legal compliance and process efficiency, while ensuring patient safety.



Beyond the Barcode: What to Expect with Serialization

1 What do serialization barcodes look like? And what kind of scanner technology is needed to read them?

To understand the pharma supply chain's use of a barcode for serialization, it's useful to know how the industry got there. Let's begin with the law: To uniquely identify each drug package, DSCSA calls for data to be in both human-readable and machine-readable form, with a graphic that conforms to standards of a recognized international standards organization.

For the machine-readable part of the requirement, the industry and FDA have aligned with a 2D DataMatrix barcode defined by GS1. This was set as the standard to uniquely identify each drug package at the smallest saleable unit.

2D DataMatrix barcode

By the November 2020 serialization deadline, dispensers must only transact with serialized product, per the law, and must be able to identify it in the event of an official inquiry into suspect product.

If your business plans to scan serialized product to comply with these requirements, you'll need:

1. Scanner technology that can read the GS1 2D DataMatrix barcode.

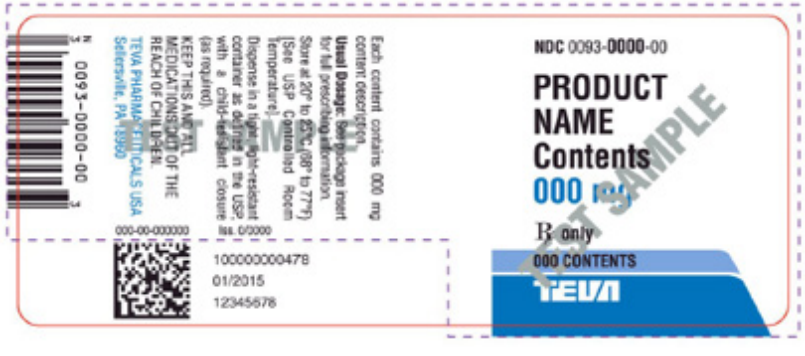
2. Software associated with your scanner that can interpret the four core data elements encoded into every 2D DataMatrix for this use: the National Drug Code (NDC), serial number, lot number, and expiry date.

Even before the 2020 deadline, scanning serialized product can yield particular benefits for dispensers, based on their operating procedures and what they choose to accomplish at their business. For example:

- Greater insight into expiration dates, which is useful for inventory shelf-life management.
- Knowledge of specific units of product subject to a recall or quarantine.
- Last-minute safe drug checks in the moment of care, just before medications are administered.

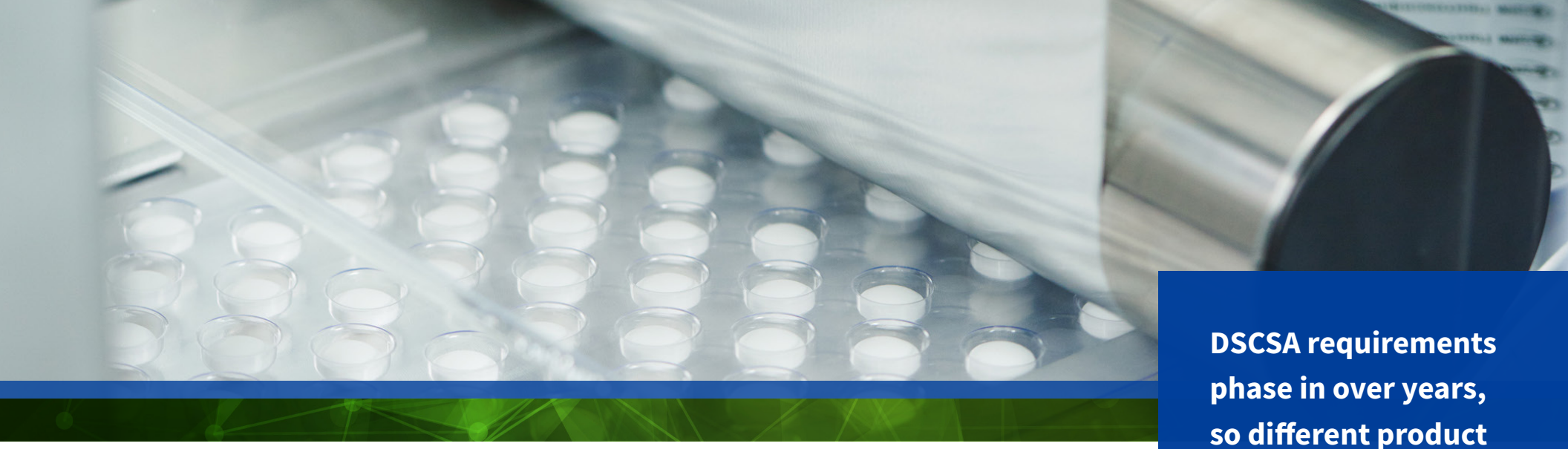
2 Does serialization affect the use of linear barcodes on packages?

No. The 2D DataMatrix used for serialization is not intended to replace any existing data carrier on a drug package. It serves the purpose of uniquely identifying drug product, per DSCSA.



Companies use linear barcodes for a variety of business and operational reasons, and the Healthcare Distribution Alliance (HDA), an organization representing pharma distributors, **specifically recommends against the removal of linear barcodes because of their multiple uses.** This sample label provided by the HDA shows how a linear barcode and 2D DataMatrix would co-exist.

If a company determines that the data encoded in the 2D DataMatrix eliminates the need for a linear barcode, that's their business decision to make. However, considering the diverse use of linear barcodes, it's likely your pharmacy will see packaging with both the 2D DataMatrix and a linear barcode (or other data carrier) when manufacturers begin shipping serialized product by their DSCSA serialization deadline of November 2017.



DSCSA requirements phase in over years, so different product data is introduced into the process at different times.

3 Why is the expiry date required in serialization barcodes, but not T3 documentation?

When regulators were putting together DSCSA requirements, they determined the best ways to reach the drug safety goal set for 2023: electronic-only, interoperable, unit-level traceability of drug product.

As part of that process, they identified information that would be required as part of the first stage of DSCSA—lot-level traceability—and other information to appear later during serialization.

Although the expiry date is not required as part of T3—Transaction History, Information, and Statement—at the lot level, it must be included in product identifier information by the 2023 deadline, at which point all companies in the supply chain must have the unique product identifier present in every buy / sell transaction.

There are no specific requirements stating what dispensers must do with serialized product when they receive it.

4 When pharmacies receive serialized drug product, what are they required to do with it?

The DSCSA has no documented policies or procedures dictating what dispensers must do with serialized product when they receive it. In terms of serialization, the law only states that companies may "engage in transactions involving a product only if such product is encoded with a product identifier." For dispensers, the deadline for this requirement is November 2020.

But you will start receiving serialized product by November 2017, manufacturers' serialization deadline. Although you're not legally required to take any particular action, you may want to begin a process that ensures your pharmacy is receiving compliant product, meaning it's encoded with a proper product identifier. That way, the process will be an efficient part of your operation by the 2020 serialization deadline.

The process you implement, if any, is up to your individual business. You might choose to simply look at each package to confirm there's a barcode and human-readable product ID information – both required for serialization. Or, you may want to validate that the barcode actually contains encoded product information. You might verify that the information on the package matches the data in its T3 documentation.

Although the choice of processes is up to each dispenser, we anticipate the FDA will provide general best-practice guidance for identifying and verifying serialized product. This would apply not just to dispensers, but to any business receiving serialized drug product, such as wholesale distributors.

We received similar questions leading up to the first phase of DSCSA requirements in 2015, and the situation is comparable: The law stated a requirement—T3 documentation must be received with all prescription products—but the FDA didn't provide clear guidance on how, and didn't require companies to check the information received. In general, the FDA tends not to deliver a prescriptive playbook.

The law requires manufacturers to deliver T3 electronically by November 2017 – but is unclear in the case of drop shipments.

5 Will a pharmacy receive T3 electronically in the case of a drop shipment?

Not necessarily. Let's first review what the regulation says about T3: By the November 2017 serialization deadline, manufacturers must send T3 electronically along with each prescription product shipped. This starts moving the industry toward that 2023 requirement of a fully electronic, interoperable, per-unit traceability system.

But does this requirement apply to drop shipments, in which the typical product flow of manufacturer to wholesaler to dispenser is bypassed? In the case of a drop shipment, the wholesaler takes the order for the product but is unable to fulfill it, so the manufacturer delivers the product directly to the dispenser.

Because the product changes ownership, the manufacturer must send T3 with the product shipment, per the first phase of DSCSA requirements. (The T3 must also be annotated with the wholesale distributor's name and contact information.)

Although the law states that manufacturers must send T3 electronically by November 2017, in the separate portion of the law that discusses drop shipments, **there is nothing that dictates how T3 should be delivered in that case**, only that it be delivered directly to the dispenser.

Until the FDA or another regulatory body issues a more specific ruling, the required method for delivering T3 in the case of a drop shipment is unclear.

When DSCSA Rules Do – and Don't – Apply

6 When a pharmacy acquires the business and inventory of another pharmacy, are they obligated to obtain that pharmacy's T3 information?

DSCSA does not explicitly address T3 documentation in the case of mergers or acquisitions, and the FDA has not issued any guidance on the topic, with one notable exception.

Acquiring a drug product through a merger or acquisition is listed as exempt from the definition of a "transaction." Therefore, when one pharmacy acquires another, they are not required to receive T3 for the current stock of newly acquired product. As for existing T3 records, there is nothing specific in the DSCSA regulation.

However, it's important to consider the following:

1. **How will you handle other regulatory documentation, such as financial and tax records?** Because T3 is legal documentation, you may want to think of it similarly, and treat it just as you would those other records.

2. **It's in your best interest to have information about the drug stock and inventory you're acquiring**—especially if an investigation concerns that inventory—even for product that has been previously dispensed by the pharmacy you're acquiring.

3. **There is an obligation for dispensers to store compliance documentation for at least six years.** So, even without specific requirements concerning acquisitions, it's safe to say that you've acquired T3 documentation as part of the acquisition – just as you've acquired other assets and liabilities in the deal.

7 Do DSCSA regulations apply to physicians' offices?

Because DSCSA covers pharmacy dispensers, the best way to answer this question is to ask another: Is the physician's office performing as a pharmacy dispenser? If not, then that office is not subject to DSCSA requirements.

DSCSA defines a dispenser as "a retail pharmacy, hospital pharmacy, a group of chain pharmacies under a common control or ownership… or any other person authorized by law to dispense or administer prescription drugs."

More specifically, the law states that tracing and verification requirements "shall not apply to licensed health care practitioners authorized to prescribe or administer medication under State law…"

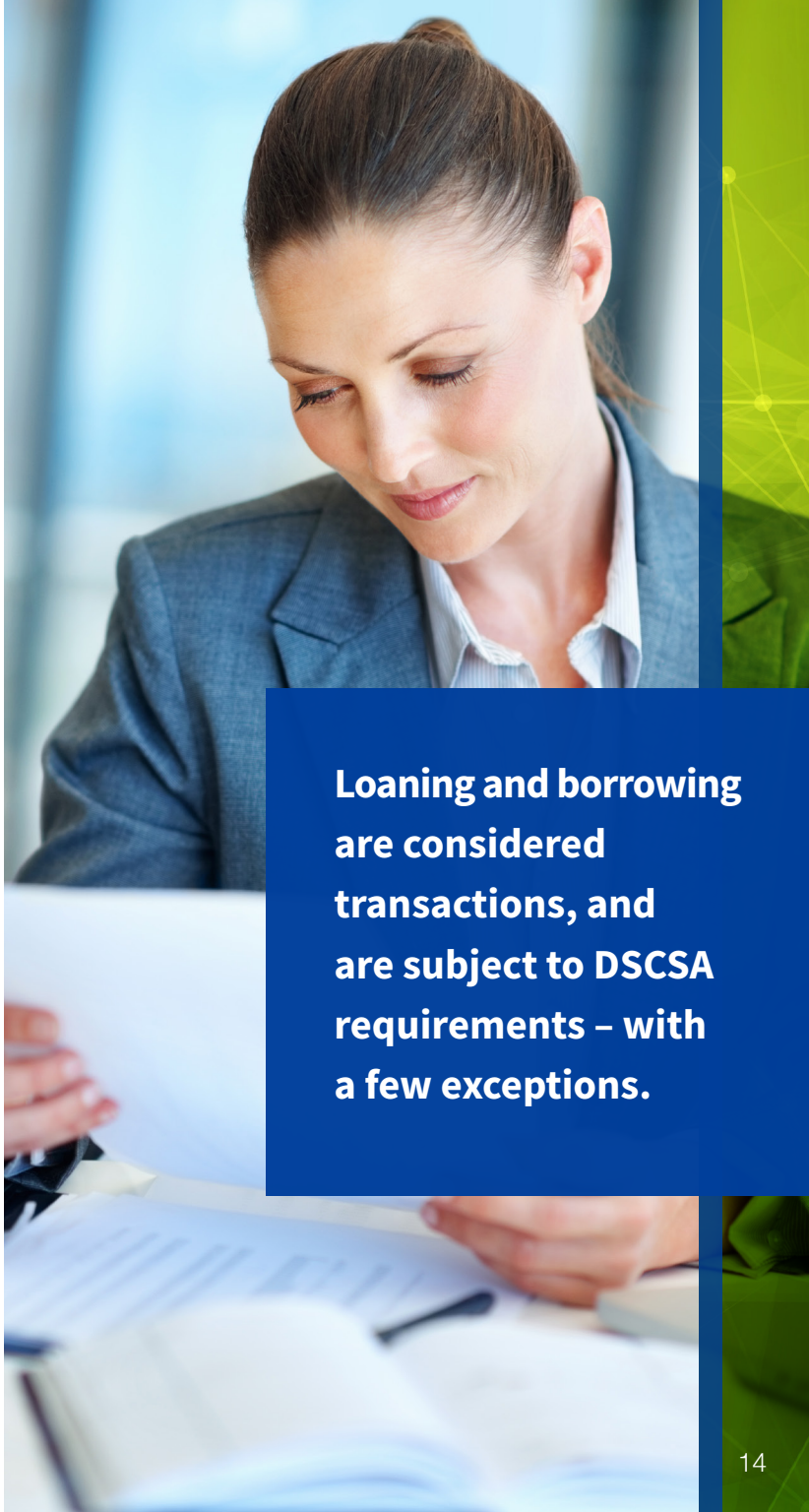
8 Is a hospital or pharmacy required to comply with DSCSA when loaning or borrowing drug product with other hospitals and pharmacies?

In short, yes. The FDA has clarified that loaning and/or borrowing is considered a transaction between two parties – with the organization delivering the product acting as a wholesale distributor.

Any company in the drug supply chain that engages in wholesaler activity must follow wholesaler regulations, such as providing T3 documentation with any product distributed, and transacting only with serialized product by the wholesaler deadline of 2019.

However, there are potential exemptions to this requirement worth noting:

- Selling what the law calls "minimal quantities" of a drug product to a licensed health care practitioner for office use.
- Selling product to another dispenser to fulfill "a specific patient need".
- Distributing product for "emergency medical reasons," such as a public health crisis.



Loaning and borrowing are considered transactions, and are subject to DSCSA requirements – with a few exceptions.

tracelink
Life Sciences Cloud

Want to gain operational efficiency while ensuring patient safety?

Have additional questions about serialization and other DSCSA requirements?

Contact a TraceLink expert today.