



Opportunities for Drug Serialization to Make U.S. Drug Supply Chain Safer, More Secure

The Drug Supply Chain Security Act (DSCSA), signed into law in 2013, requires drug manufacturers and repackagers to identify each individual package of a prescription drug with a unique serial number.¹ This significant requirement provides a way for stakeholders in the pharmaceutical supply chain to verify the drug's authenticity and track its ownership as it moves from the manufacturer to the wholesale distributor to the pharmacy. The law establishes baseline obligations for checking serial numbers, but as repackagers, shippers, and businesses at every link in the supply chain work with regulators to implement the law, they have the opportunity to also use serial numbers to provide even stronger protections against counterfeit, tainted, or stolen drugs.

DSCSA minimum requirements for drug serialization and authentication

Drug serialization is the foundation for the fully electronic, interoperable drug tracing system that must be established by 2023. Most drug packages have a linear bar code^{*} with a 10-digit national drug code (NDC).[†] Starting in November 2017, manufacturers must add a two-dimensional bar code that includes the NDC, the lot number,[‡] the expiration date of the drug, and a serial number unique to each package. Repackagers will start serializing pharmaceutical products in November 2018.

By late 2020, companies in the supply chain must start using the serial numbers to check the authenticity of drugs they suspect to be illegitimate. Companies must also verify serial numbers when reselling returned products.

The law requires a fully electronic traceability system by late 2023 that includes exchanging information about the purchase and sale of each serialized package in an interoperable, electronic manner between supply chain trading partners. These baseline requirements will aid in preventing potentially dangerous or compromised products from reaching patients.

* Certain drugs, such as prescription drug samples and radiopharmaceuticals, are exempt from linear bar code labeling requirements.

† The national drug code is composed of a labeler code issued by the Food and Drug Administration and a product code assigned by the manufacturer. It is used to identify a pharmaceutical or biological product and package configuration in the United States.

‡ Lot number refers to any distinctive combination of letters, numbers, or symbols, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined.

Going beyond minimum requirements to create more powerful protections

As regulators, manufacturers, wholesalers, and pharmacists work together to develop a national traceability system and launch pilot projects mandated by Congress to test it,^{*} they can also pursue other opportunities to better protect patients by safeguarding the pharmaceutical supply. For example, establishing routine, proactive checks of serial numbers as a business practice could help identify counterfeit, illegally diverted, or compromised drugs that look authentic and might otherwise escape detection. Serial numbers could also help companies to improve tracking and inventory management, which could make drug recalls more efficient and effective and could assist in ensuring the quick and complete removal of these products from the market.

Building systems that make better use of drug serialization

While DSCSA describes the elements of a drug serialization and traceability system, the law leaves significant discretion to the Food and Drug Administration and supply chain stakeholders to determine how those elements will be implemented. This flexibility in the statute gives supply chain stakeholders the opportunity to develop robust systems that will more effectively track the events in a drug's distribution life cycle and allow stakeholders to proactively use serial numbers as screening tools to detect potential problems. These include:

- **Linking to additional information.** The life of a unique serial number begins when a manufacturer assigns it to a drug package and links it to the drug's NDC, lot number, and expiration date, as required by DSCSA. Manufacturers could build on this requirement by also linking the serial number to other useful information, such as the time, date, and location of packaging, or the packaging facility number and packaging line number.
- **Routine authenticity checks.** In addition to assigning serial numbers, manufacturers and repackagers must establish systems that allow wholesale distributors, dispensers, and other health care providers to verify the authenticity of a medicine using serial numbers. Manufacturers and repackagers must respond to verification requests within 24 hours, but stakeholders are only required to request verification when they already believe a product is suspect. Creating a more robust serial number management system that permits near-instantaneous electronic verification could allow trading partners to verify serials on a more routine basis, which would more thoroughly screen the supply chain for illegitimate products.
- **Container aggregation to support efficiency.** The practice of aggregation uses serial numbers to capture which drug packages are in specific cases, pallets, or other shipping containers. While this is not required by law, the practice increases efficiency by identifying the individual packages in a case or pallet without opening each one. Many stakeholders view aggregation as a critical component in successful distribution operations under the full, package-level traceability system scheduled for 2023.
- **Shipping and receiving to track physical location.** As required by law, serial numbers will be used to document a shipment's change in ownership, but they can also track a shipment's physical origin and intended destination. Documenting shipping and receiving locations could be an additional and valuable tool for stakeholders and regulators to detect and investigate any attempted introduction of illegitimate product into the system.

^{*} DSCSA requires that FDA establish one or more pilot projects, in coordination with manufacturers, repackagers, wholesale distributors, and dispensers, to explore and evaluate methods that enhance the safety and security of the pharmaceutical distribution supply chain.

- **Tracking transformations.** Companies can also use serial numbers to document irreversible or transformational changes to a product, as is the case with repackaging. Pharmaceutical repackagers must apply new serial numbers to repackaged products and maintain records linking them to the original from the manufacturer. While the law does not specify how companies should track these transformations, a robust, interoperable system will allow a drug to be traced through repackaging without losing information. Such systems will also allow for the quick identification of compromised repackaged products if anyone discovers a problem with the original drug.
- **Decommissioning serial numbers.** When an individual drug package has exited the market either by being dispensed to a patient or destroyed because of expiration or recall, the manufacturer can decommission the serial number, so that it is no longer valid in the supply chain. The law does not explicitly require serial number decommissioning, but this practice as part of a robust package-level traceability system can help prevent criminals from reselling or diverting dispensed or expired drugs back into the supply chain.

Supply chain stakeholders must work to determine how the new serialization and traceability system is built and operated, through regulatory collaboration with FDA and pilot programs mandated by Congress, in order to build robust safeguards from the very start and protect the public from the terrible consequences of tainted, counterfeit, or expired drugs.

Endnotes

- 1 Title II of the Drug Quality and Security Act of 2013, H.R. 3204, 113th Cong. (2013), <http://www.gpo.gov/fdsys/pkg/BILLS-113hr3204enr/pdf/BILLS-113hr3204enr.pdf>.

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