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One Nation, Under DSCSA

What Manufacturers' 2017 Deadlines Mean to 2023 Compliance

The 2013 Drug Quality & Security Act, which aims to ameliorate compounding safety, brought with it the Drug Supply Chain Security Act (DSCSA), demanding traceability and verification of prescription drug products throughout the distribution supply chain by 2023. What does that mean to pharmaceutical manufacturers, re-packagers, distributors and dispensers? In one word: Serialization. That single word has sent a ripple effect through the industry, carrying with it questions over how to tackle such an effort, when to begin the implementation and testing of each of the regulatory milestones and what the risk of noncompliance might be. With manufacturers facing serialization deadlines in 2017, and the same for re-packagers in 2018, wholesalers in 2019 and dispensers in 2020, it's becoming clear the extent to which stakeholders are tethered to each other's accomplishments — which has some questioning the risk of doing the bare minimum.

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2017 mandates

With 2015/2016 deadlines met, which called for manufacturers, wholesalers and re-packagers to provide transaction information, transaction history and transaction statements (TI/TH/TS) and for dispensers to accept them, the industry is officially in the track-and-trace trenches. The next round of mandates, which become effective November 2017, involve the following directives:

- A unique product identifier must be adhered to each individual prescription drug package not exempt by DQSA.
- All TI/TH/TS must be submitted in electronic form.
- Systems and processes to verify product identifiers and re-saleable returns must be established.

While these seem like approachable mandates, and certainly worthwhile as they support patient safety, they merely represent the tip of the iceberg. It is in the details that manufacturers uncover the more extensive components to implementation, and perhaps the motivation to do more.

More than a number

Serialization is not simply putting a number on a bottle. There are a multitude of guidelines and implications to technology and operational infrastructure that must be understood and adhered to for successful serialization. To start, the product identifier must meet GS1® standards, and adhere to these specifications:

- Must be applied to each package and case
- Leverage a 2D DataMatrix on package, linear or 2D on case
- Feature the National Drug Code (NDC) and the Serial Number (SNI), lot number and expiration date
- Must be readable by machine and human

The relationship this soon-to-be-born number has to traceability and ultimately the mandates for 2018, 2019 and beyond is dramatic. After all, the barcode has to work when any number of the stakeholders scan it. And that means quite a bit of additional work needs to be done up front to ensure the data is funneled correctly and quickly.

Elevating pharma's IT IQ

The data generated by serialization, and the master data and transactional information linked to a uniquely serialized product that is packaged, shipped and verified across the supply chain presents a number of challenges to current technology infrastructure.

In addition to significantly increasing the amount of data that will be transmitted every time the 2D barcode is scanned, serialization events are more connected to real-time operations than lot-level events, including detecting, responding to and reporting potentially illegitimate drugs. This calls for manufacturers to establish complex bi-directional data exchange connections with a diverse set of supply and trade partners. It also means discussing and understanding standards for data exchange upfront, which are even at this stage still evolving, including Healthcare Distribution Alliance (HDA) Advanced Ship Notice (ASN) and GS1 Electronic Product Code Information Service (EPCIS).

Those manufacturers that do not approach serialization as the first step to traceability, ironing out a strategy and design for data exchange in tandem with serialization efforts, may see business grinding to a halt in 2019, when distributors can no longer transact drug products without electronic transaction documentation.

Aggregation creation

The demand to establish systems and processes to verify product in 2017, must also include the ability for manufacturers and distributors to verify returned re-saleable units. In order to do that, aggregated data is needed in addition to unit- and caselevel serialization data. Essentially, this means the unique barcodes need to be linked to associated bundles, cases and pallets to establish critical dyads for managing inventory and verifying returns for authenticity.

Without aggregation, distributors would have to manually verify each unit — a burden far too costly for most to bare, especially when one considers large distributors can average anywhere from 30,000 to 60,000 returned units a day.[1] And while the aggregation of data is not a requirement in 2017, its lack will greatly impact the very near future of distribution costs, which will undoubtedly be passed on to manufacturers in the form of fees.

The 2017 mandates conceal a multitude of reasons why stakeholders need to be educated in the current cause and future effect of simply complying with DSCSA versus engaging in a more holistic strategy. And while developing the network connections, infrastructure and processes needed to support successful serialization can seem daunting, it's important to keep in mind the potential business value it holds, from improved inventory management and returns reconciliation to optimized product launch planning. Most important, the industry will soon author a supply chain worthy of its mission to protect and care for patient health. And that's something all DSCSA stakeholders — manufacturers, re-packagers, 3PLs and dispensers — can get behind.

[1]Cao, Riya. "DSCSA Serialization Update: Where We Are Now and How to Prepare for What's Next." RxTrace. N.p., 15 Apr. 2016. Web. 20 Sept. 2016. <https://www.rxtrace.com/2016/04/dscsa-serialization-update-where-we-are-now-and-how-to-prepare-for-whats-next.html/>.

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About ICS

ICS, a business unit of AmerisourceBergen, partners with pharmaceutical manufacturers to deliver third-party logistics services that improve the quality and efficiency of their supply chains. As the pioneer in the specialty logistics market, ICS has helped bring hundreds of specialty pharmaceutical products to market and served as an integral component in their growth.

ICS was founded in 1997 and since then, has organically grown to become the industry leader in outsourced logistics and distribution services for pharmaceutical manufacturers. From strategic program design to enhanced 3PL and performance analytics, ICS goes the extra mile to ensure increased supply chain efficiency, maximum return on investment and enhanced patient care. ICS is the model of excellence in global healthcare logistics.


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