

# Update on the DSCSA Product Serialization November 2017 Mandate

Q & A with Terrence Jones, Director of Strategic  
Manufacturer Services for ICS



To help drive illegitimate products out of the pharmaceutical supply chain, tighter controls were established by DSCSA in 2013. Serialization is the mechanism DSCSA mandates to yield better product traceability by lot, expiration date and a unique product identifier. The goal is to use real-time data capture to detect, respond to and report potentially illegitimate drugs faster and more effectively, before they can become a safety hazard to patients.

For the past four years, ICS has been working with our manufacturers to help them prepare for product serialization and ultimately traceability—ironing out a strategy and design for data exchange in tandem with serialization efforts—to ensure they are in full compliance in 2019, when DSCSA mandates that distributors can no longer transact drug products without electronic transaction documentation.

We asked Terrence Jones to give us an update on how ICS is helping manufacturers achieve DSCSA readiness.

**Q. Is the November 27, 2017 DSCSA deadline for product serialization still in place?**

**A.** DSCSA is a 10-year journey that started back in November of 2013. Now four years after the law was signed into effect, November 27, 2017, manufacturers are required to comply with the guidelines concerning serializing their product. Nothing has really changed from that perspective. The only difference is that on June 30 of this year, the FDA released a draft guidance that delayed enforcement. As a result, manufacturers that were not able to serialize their product by November 27, 2017 will not be penalized. But technically, as you look at the law, it has not changed.

ICS is conveying to our manufacturers that if they are not ready by the deadline, for whatever reason, technically by law they are supposed to be. We are urging them to keep their foot on the gas and keep moving. On our side, we are actively making sure everything at ICS is ready to meet those demands.

**Q. Are most manufacturers complying with the deadline?**

**A.** The majority of the manufacturer partners we work with had the November deadline top of mind for several years and were pushing to be compliant by having their product serialized as quickly as possible. Typically, manufacturers that leverage several CMOs (contract manufacturing organization) or packagers, have some packagers that are ready to serialize, but there may be a handful that just aren't ready yet. For those manufacturers that are not ready, it's not necessarily every product that's in their portfolio, but it might be a small subset that their CMOs are lagging on.

**Q. How has ICS helped manufacturers meet the November 27, 2017 deadline?**

**A.** When DSCSA was new, manufacturers were looking to ICS, the model of excellence in global healthcare logistics, to be consultative in this space. They were leaning on us to help them understand DSCSA and the overall impact to both manufacturers and downstream trading partners. Additionally, there are other services that ICS was able to offer manufacturers, such as reviewing their bar codes, and working closely with our AmerisourceBergen partners to ensure that their labeling was complaint and met industry best practice. Our manufacturers look to ICS to be consultative in the commercialization of their products, and this was just one more example of how we get in front of the market and understand changing needs.

**Q. What impact has ICS's pilot programs had on DSCSA readiness?**

**A.** Much of what ICS is implementing for product serialization is a direct result of working with our manufacturers during our Phase One pilot. We discovered five distinct best practices for scanning and capturing serialized data for inbound shipments to the distribution center, as well several new challenges affecting labelling, data exchange, and operations.

Our Phase Two pilot is in progress and is focused on operational efficiency—making sure ICS is able to handle the serialized product that's in our facility, including managing both outbound activity and the exceptions situations we know will arise when dealing with serialized data and product exchange. From an ICS perspective, the Phase Two pilot is focused on maintaining service levels by leveraging our people, process, and technology.

**Q. Are any of the results of the pilot programs being implemented now?**

**A.** We have modified all of our SOPs to reflect the results of the Phase One pilot, and all applicable procedures have been published out to our manufacturers. We are actively modifying many of our operational and outbound picking procedures. We will be able to share more specifics as we get closer to 2018.

**Q. ICS is taking a best-in-class approach to product serialization benefit manufacturers?**

**A.** ICS implemented a best-in-class approach to serialization because we knew that would result in added value for our manufacturers. A key aspect of unique approach is our focus on both inbound and outbound serialization services.

Some 3PL companies have chosen not to scan and retain data on inbound product, and selected to scan only on the outbound. We recognized early on that inbound scanning would provide added information and value to the manufacturer by minimizing the number of issues and exceptions on the backend. From our perspective of maintaining service levels, delivering that added value was important to us.

It also gives the manufacturer a better story of where their product is going and where it has been in the supply chain. We capture the data on incoming product and send it back to the manufacturer on the outbound shipments, so they will have a visual timeline of their products. That's best-in-class product traceability, and that's the ICS way.



**Q. When will ICS be offering enhanced serialization services?**

**A.** We're pleased to announce our equipment is set up in our distribution center and we are actively building out and validating our enhanced serialization services. We should be making our announcement in early 2018 in conjunction with the results of the Phase Two pilot.

**Q. What advice do you have for manufacturers right now?**

**A.** We're still working closely with all of our manufacturers, encouraging them to keep their foot on the gas, to get ahead of the game, and to be ready for full DSCSA implementation in 2023. The longer a company waits, the more challenges they will face down the line.

When you look the full 10-year DSCSA journey, 2019 is the next major milestone. While this aspect of the mandate primarily impacts wholesalers, manufacturers need to be aware of wholesaler requirements because those requirements will impact the manufacturer's business. Aggregation, for example, isn't a regulatory requirement, but wholesalers are requesting that manufacturers aggregate their product in advance of the November 2019 requirement. It might seem like a long way off, but 2019 is right around the corner.

That's why ICS is intensely focused on continuing our DSCSA readiness initiatives and educating our manufacturers on what they need to do 2019. Additionally, we are actively involved with our supply chain partners to ultimately meet the 2023 requirements.

**For more information about complying with DSCSA serialization requirements, contact Terrence Jones: [Terrence.Jones@absq.com](mailto:Terrence.Jones@absq.com).**

Terrence Jones is the Director of Strategic Manufacturer Services for ICS. Mr. Jones is the business lead for serialization efforts and also manages the team responsible for supporting enhanced 3PL and analytics offerings from ICS. He has more than 13 years of experience in the 3PL space—working closely with manufacturers, wholesalers, specialty distributors and specialty pharmacies to develop technology solutions that support commercialization of specialty products. Prior to joining ICS, Terrence led a number of strategic initiatives for AmerisourceBergen focused on delivering innovative technologies that support business transformation objectives

## 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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