RESOURCES

Saleable Returns Verification: What You Need to Know About Enforcement Discretion



There is growing speculation across the industry that the FDA will announce a delay in enforcement action for the November 2019 DSCSA Saleable Returns Verification requirement at the request of the Healthcare Distribution Alliance (HDA).

Reasons for the HDA's request include:

- A lack of industry awareness around requirements.
- Concerns that the industry is not ready with their solutions, which could cause wholesalers to quarantine or destroy returned product rather than returning it to saleable inventory, leading to drug shortages.
- Sensitivity around manufacturers sharing product identifier information with partners with whom they do not have trusted, pre-existing relationships.

These perceptions have prompted discussions around the granting of enforcement discretion similar to actions taken for the earlier lot level and serialization requirements of DSCSA. However, TraceLink believes these concerns are largely unwarranted among most businesses that are preparing to comply with the saleable returns verification requirement.

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Awareness

The saleable returns verification requirement has been known since DSCSA was passed in November of 2013. Since that time, there has been a significant amount of guidance and education directed at pharmaceutical manufacturers and wholesale distributors by the FDA, industry stakeholders, and solution providers alike. Additionally, each of the Big Three wholesalers distributed letters to their suppliers in 2018 outlining their expectations and requirements for saleable returns verification.

Solution Readiness

Solution providers, along with many in the industry, have been working to define the standards by which verification solutions are implemented. A set of standards for verification router services (VRS) that will enable compliance with the law have been ratified by GS1, and solution providers are completing interoperability testing that will ensure these systems can communicate with each other with sub-second response times. In fact, TraceLink has been performing stress testing for its VRS solution and has simulated receiving up to 700 simultaneous requests per second with an average response time of 370ms.

Many of the complexities of building a verification system have been addressed through the standards setting process, and the remaining work largely lies in businesses choosing a vendor and getting started with implementation, developing standard operating procedures, and training staff.

Sharing Sensitive Information

Product identifier information is sensitive, and unauthorized access to that data can create supply chain vulnerabilities. The VRS standard accommodates the inclusion of a Global Location Number (GLN) which can be used by companies to control which partners they respond to. TraceLink combines the GLN with other unique business identifiers for trade partner authentication and to provide an added layer of security to its customers.

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Reasons to Act Now

Some Marketing Authorization Holders (MAHs) have stated that their wholesalers will not be ready by the deadline, so they are questioning why they should act now. This is a position that puts your business and your patients at significant risk:

- The DSCSA saleable returns verification requirement is designed to address a known supply chain vulnerability and ensure a safe drug supply.
- Even with an enforcement discretion action, the saleable returns verification requirement will still go into effect on November 27, meaning that companies are still required—by law—to verify returns before they can be resold.
- During the period before full enforcement begins, the FDA will be looking for evidence that the industry is making a good faith effort to meet the deadline and will want to know what each manufacturer is doing to ensure that they can respond within 24 hours to any request for verification after November 27, 2019.

The best way to demonstrate compliance is to partner with a solution provider and start working to develop integrations, standard operating procedures (SOPs), and training plans. This shows that the MAH is doing what they can to meet their obligation to the saleable returns verification requirement. The implementation of a VRS solution may take as long as six months and therefore, even if there is an enforcement discretion period, waiting to comply is far too risky.

The Big Three have 300 to 600 suppliers each. The earlier an MAH starts, the less time they will waste trying to get the attention of their wholesaler customers. This was a significant challenge when the industry went live with lot-level traceability and wholesalers simply did not have the bandwidth to onboard each MAH on their own timelines.

For smaller to mid-size companies that are holding off on preparing for the saleable returns verification requirements and planning to do everything manually, the lack of preparation presents a business risk, as wholesalers will simply return

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product for credit rather than waiting for manual verification, given the time it will take.

TraceLink's Status

With less than four months to go, TraceLink is fully prepared for the November 2019 deadline with its purpose-built saleable returns solution that combines sub-second VRS performance with integrated master data sharing and EPCIS data exchange, providing customers with a fast, secure, and compliant approach. With a secure network of 275,000 pre-validated members, manufacturers on the TraceLink network can be assured that the saleable returns requests are from companies that are authenticated and legitimate.

Once you partner with TraceLink, you can start responding to verification requests from direct and indirect authorized trading partners, without creating point-to-point connections or vetting inquiries from inbound trade partners while the distributor is waiting for a response. Additionally, to ensure network security and authorized access, TraceLink has dedicated substantial time and resources to network governance, with over 20 full-time in-house professionals responsible for authenticating companies.

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