

Henry Schein, Inc. Update Regarding DSCSA

On October 9, 2024, the FDA granted exemptions from specific requirements under the Drug Supply Chain Security Act (DSCSA) for certain trading partners. The purpose of these exemptions is to provide a phased approach and extend the timeline for the implementation of the DSCSA to allow further stabilization of the pharmaceutical supply chain. More information about this exemption and all exemptions issued can be found [here](#) on the FDA's Waivers, Exceptions, and Exemptions web-site.

Henry Schein has been actively preparing for the implementation of the DSCSA including establishing connections with all suppliers, receiving serialized data, activating inbound and outbound scanning operations in our distribution centers, and sending serialized data to our customers. Additionally, Henry Schein has systems and processes in place for the identification and investigation of suspect and illegitimate product as well as the verification of authorized trading partners.

Throughout the stabilization period, Henry Schein continued to work with upstream trading partners to receive serialized data for its products and saw great improvements in data quality and exchange. Those efforts continue as some of our trading partners require the additional time provided by the FDA to further stabilize the exchange of data with their downstream trading partners. To that end, Henry Schein will continue to send the portion of data that has been consistently and accurately received and will continue to notify customers as additional data is available, with the intent of being fully compliant with all enhanced DSCSA requirements by the dates outlined in the DSCSA exemption: May 27, 2025 for manufacturers and repackagers and August 27, 2025 for wholesale distributors. Additionally, our enhanced DSCSA portal will now be released in the second quarter of 2025.

For those customers that are required to receive EPCIS transaction data who have not already connected with Henry Schein, please contact serialization@henryschein.com to begin the onboarding process and receive an onboarding packet.

Henry Schein will continue to work with our suppliers and industry stakeholders to fully realize the goal of the DSCSA, a fully interoperable system of traceability for prescription drugs.

We appreciate your support while we continue our implementation efforts.