

McKesson Response to recent FDA Announcement of DSCSA Compliance Policy on the Nov. 27, 2023, Requirements:

On Friday, Aug. 25, the U.S. Food and Drug Administration (FDA) announced through a compliance policy that it would not take action to enforce the Enhanced Drug Distribution Security requirements of the Drug Supply Chain Security Act (DSCSA), section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act, until Nov. 27, 2024. The FDA is providing a one-year stabilization period (“Stabilization Period”), beyond the legal deadline of Nov. 27, 2023. This period will allow all key players within the supply chain (manufacturers, distributors, dispensers and trading partners) to mature processes and refine operations that are required to comply with these specific package-level tracing requirements. **The FDA will continue to enforce the other DSCSA requirements during this Stabilization Period.**

The FDA expects all parties to continue progressing toward stabilization and maturing the implemented systems during this Stabilization Period. McKesson will continue to roll out enhanced DSCSA capabilities including:

- Sending enhanced DSCSA transaction information using customer portals and EPCIS (Electronic Product Code Information Services) data files
- Providing additional educational tools to further prepare dispensers for the full DSCSA implementation

During this Stabilization Period, McKesson will continue to provide the lot level DSCSA Transaction Information, Transaction History and Transaction Statements using the existing portals and DSCSA enabled EDI files.

McKesson will continue to monitor the FDA’s policy and requirements for DSCSA implementation and will adapt its processes as needed.