FDA Waives Some Track and Trace Requirements During the Pandemic

Today, the Food and Drug Administration (FDA) announced that it will delay enforcement of certain provisions of the Drug Supply Chain Security Act (DSCSA) until November 2023. Specifically, FDA will not enforce the requirement that dispensers (i.e., pharmacies) investigate product identifiers on suspect and illegitimate product. This requirement was previously slated to take effect next month. Similarly, FDA is delaying enforcement of the distributor verification requirement for saleable returned product, which was also scheduled to take effect next month.

FDA's announcement follows ASHP advocacy requesting enforcement delays in both comment letters to agency staff and in joint letters with other national pharmacy organizations to FDA leadership.

While ASHP is pleased that FDA has taken this step, we are concerned that FDA has not yet agreed to enforcement discretion for another rapidly approaching DSCSA deadline, which requires pharmacies to only accept products from an authorized trading partner if they are encoded with a product identifier.

This week, ASHP and other stakeholders requested that FDA Commissioner Stephen Hahn delay enforcement of the product identifier requirement until Nov. 27, 2021. We anticipate that the agency will provide more information shortly about whether it will allow any delay in the product identifier requirement. ASHP will keep members updated on any FDA actions regarding DSCSA implementation. ASHP will also publish a podcast in the coming days that will offer members a quick refresh on DSCSA implementation and upcoming dispenser requirements.