FDA’s Final UDI Rule: A Few Tricks But Mostly Treats

by Cathi Crist and Scott Gibbard

On September 24, 2013, the FDA published its final rule for a system of Unique Device Identification (UDI). The rule has been a few years coming, so industry insiders that had time to get intimate with earlier drafts of the rule likely let out a sigh of relief when they saw the final version.

The core framework for the final UDI rule is mostly unchanged from the proposed rule published earlier this year. However, beyond the core rule, the FDA listened to feedback from industry and incorporated a number of meaningful changes to its original proposal. The final rule strikes a good balance of common sense and public safety without overly burdening the industry.

Taken as a whole, the changes made to the final UDI rule were mostly favorable to industry. But, some provisions will be trickier than others to implement.

Read the entire article HERE on the MD+DI website.

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