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UDI Final Rule Timing

In a letter to FDA Commissioner Hamburg, three members of Congress, Allyson Schwartz, Kurt Schrader, and Bill Owens, asked when FDA would issue the final rule on Unique Device Identification.

In their letter, the members assert that the deadline, set by law, is May 7, 2013. The Food and Drug Administration Safety and Innovation Act (FDASIA) requires FDA to issue the final rule within six months of the close of the comment period. FDA issued the first set of draft regulations and closed the comment period on November 7, 2012. However, FDASIA also changed the UDI law, so FDA revised the draft regulations and closed that comment period on December 19, 2012.

Using the first closing date, the deadline is May 7, 2013, as stated in the letter to Commissioner Hamburg. Using the second closing date the deadline is June 19, 2013.

In an update to its medical device postmarket surveillance plan, published in April 2013, the FDA provides a timeline for UDI implementation.

By June 30, 2013, FDA will issue the final rule, establish the global UDI database (GUDID), and complete a report on a successful UDI implementation roadmap.

By September 30, 2013, FDA will provide UDI technical requirements and use cases related to electronic health records.

By December 31, 2013, FDA will complete reports on UDI implementation in a multi-hospital information system.

The UDI final rule will change Part 820 as well as other parts of medical device regulations.