

Reusable Medical Devices: Draft Guidance From FDA For Processing, Reprocessing.

We have the FDA's new draft guidance document on our website at <http://www.nursinglaw.com/FDAreprocessing.pdf>

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On May 2, 2011 the US Food and Drug Administration (FDA) announced the availability of a draft guidance document titled “Draft Guidance for Industry and FDA Staff: Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.”

The draft guidance is not in final form and is not mandatory at this time.

According to the FDA, in recent years there has been an evolution towards more complex reusable medical device designs that are more difficult to clean and disinfect or sterilize.

The new guidance document, a revision of a guidance document issued in 1996, reflects scientific advances in this area.

The guidance document is targeted by the FDA directly to medical device manufacturers, who are required by law to provide instructions to end-users in the healthcare community for proper sterilization and re-processing of the devices which they manufacture and distribute.

We believe, however, that the guidance document and the reference materials cited in it may contain information useful to end-users in the healthcare community.

The FDA's May 2, 2011 Federal Register announcement is available at <http://www.nursinglaw.com/FDA050211.pdf>

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