FDA issues final rule for device identification system

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(HealthDay)—The U.S. Food and Drug Administration has released a final rule for the unique device identification system (UDI) that, when implemented, will improve patient safety by providing a consistent way to identify approved medical devices.

The FDA has worked with industry, the clinical community, and patient and consumer groups to develop this rule, which builds upon current device industry standards and is a key component of the National Medical Device Post-Market Surveillance System proposed last year.

The UDI system is intended to enhance efficient identification of recalled marketed devices, improve the accuracy and specificity of adverse event reports, and provide a foundation for a global, secure distribution chain. UDI will also offer a clear way of documenting device use in clinical information systems. Class III medical devices will be required to carry the unique identifiers on their label and packaging within one year, and this number and corresponding device information must be submitted to the new database. For most Class II devices, manufacturers will have three years to comply; Class I device manufacturers not exempt from UDI requirements will have five years.

"UDI represents a landmark step in improving patient safety, modernizing our post-market surveillance system for medical devices, and facilitating medical device innovation," Jeffrey Shuren, M.D., director of the FDA's Center for Devices and Radiological Health, said in a statement.

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