

## **FDA: New Regs For Adverse Event Reporting In Electronic Format.**

On August 21, 2009 the US Food and Drug Administration published proposed new regulations, not yet mandatory at this time, which, if formally adopted, will require user facilities and others to report adverse events associated with FDA-regulated medical devices by using the FDA's specified electronic format.

We have placed the FDA's Federal Register announcement on our website at [www.nursinglaw.com/FDA082109.pdf](http://www.nursinglaw.com/FDA082109.pdf).

The regulations pertaining to user facilities begin on page 13 of the PDF document, Federal Register page 42215.

FEDERAL REGISTER August 21, 2009  
Pages 42203—42217.