AHRMM
Association for Healthcare Resource & Materials Management
Advancing the Healthcare Supply Chain
A personal membership group of the American Hospital Association

1/6/2015

AHRMM Issues & Legislative Committee Advisory: UDI and Adverse Event Reporting

The Food and Drug Administration (FDA) UDI system is being phased in over several years. The first sunrise date (certain Class III devices) occurred 09/24/14. Recognizing UDI implementation will take time, healthcare supply chain and risk management professionals should be aware of already-implemented changes in the FDA's adverse event reporting methodology. One of the changes required immediately is the use of the UDI in adverse event reporting.

In September 2014, the FDA implemented a change to the Medical Device Reporting (MDR) regulation (Code of Federal Regulations, Title 21, Part 803) that requires the collection and use of UDI for adverse event reporting purposes.

Per the MDR regulation, a "device user facility" is a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility, which is not a physician's office. User facilities must report suspected medical device-related deaths to both the FDA and the manufacturer. User facilities are also obligated to report medical device-related serious injuries to the device manufacturer and/or to the FDA (if the medical device manufacturer is unknown). Refer to 21 CFR 803.32.

When a user facility experiences and reports at least one suspected medical device-related death or serious injury (if the medical device manufacturer is unknown) during a calendar year, there is an obligation to submit an annual report (FDA form 3419 or electronic equivalent) to the FDA by January 1 of the new year. For each reportable event that occurred during the annual reporting period, the involved medical device's UDI must be collected and reported. Refer to 21 CFR 803.33.

It is presumed that, in most user facilities, FDA adverse event reporting is a collaborative effort between risk management and supply chain professionals. The American Society for Healthcare Risk Management (ASHRM) and the Association for Healthcare Resource and Materials Management (AHRMM) will explore collaboration efforts to inform and educate membership on the recent inclusion of UDI as a reportable data element in individual and/or annual MDR adverse event reports.

FDA Medical Device Reporting Resources:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=803

Other resources:
http://www.modernhealthcare.com/article/20141018/MAGAZINE/310189960/%7B%7BbuttonURL%7D%7D
http://www.meddeviceonline.com/doc/understanding-the-udi-rule-a-guide-for-medical-device-manufacturers-0001
http://himssvirtual.org/VB/20141119_VB_quality.asp

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