A TOPIC AOPA IS WORKING ON THAT IS IMPORTANT TO THE FUTURE OF YOUR BUSINESS

New Unique Device Identifier Regulations from the Food and Drug Administration (FDA) and How Does it Affect You and O&P?

The Core of the Issue

Retailing was transformed in many positive ways by the advent of the Uniform Product Code spearheaded by grocery and other major retailers more than forty years ago. Just in time manufacturing and inventory control systems became more sophisticated in the age of barcodes. FDA issued final regulations September 20, 2013 implementing the long awaited Unique Device Identifier System (UDI) which applies to medical devices including O&P devices. Many O&P devices fall under the Class I category and will benefit from the exemption from good manufacturing practices and exception from the UDI, but manufacturers and patient care facility providers must become familiar with compliance requirements that may apply to devices on the February 1, 2014 effective date or at later points. FDA has prioritized both the applicability of the UDI regulations as well as compliance dates based on the level of risk associated with devices.

Why Is It Important To You?

Consequences for violations are severe and may include seizure, injunction, civil and even criminal penalties. Some will see good news that product recalls and patient safety will both benefit by having UDI database resources available to track the movement of some O&P devices through the chain of distribution to the end patient. Others will see the good news that comments submitted by AOPA and other interested parties have persuaded FDA to provide two major exemptions that can apply to many Class I FDA devices, the FDA regulatory category into which most O&P devices have been relegated. UDI will also help identify counterfeit devices and help providers distinguish among similar devices that may have similar appearances but different functions. We can expect payers will require specific UDI numbers in billing to both pinpoint the specific device/component provided to the patient and to avoid any duplicate billing for a single device. Here are the relevant dates for compliance:

1. For a Class II medical device—* September 24, 2016
2. For a Class I medical device—* September 24, 2018
3. There is another subcategory of rules, applicable when the UDI is required to be displayed via 'direct marking' on the device itself **(we do not expect there will be very many, if any, O&P devices that will require 'direct marking').** The rule offers slightly more time, again providing it is not an implantable, life-supporting or life-sustaining device. The compliance date for these will be two (2) years after the compliance date that would have applied if there had not been 'direct marking' required, namely:
   - Class II device when FDA has specifically required 'direct marking' on the device itself—September 24, 2018
   - Class I device when FDA has specifically required 'direct marking' on the device itself—September 24, 2020
4. There is also a provision which allows that devices that were manufactured before the effective date be permitted to be offered for sale into commerce for three years without any penalty, even though they do not bear any UDI.

*that is not an implantable, life-supporting or life-sustaining device. Few if any O&P devices would fall into this group—which has an **earlier** compliance date.

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What Is AOPA Doing About This?

Congress authorized FDA to develop the UDI system in legislation which was signed into law September 27, 2007 and provided that only FDA had authority to implement medical device identifiers. Members may remember that the FDA exclusivity provision was overlooked by PDAC which published a proposal in September of 2011 to create an identifier system for O&P medical devices which would have been redundant with the then "in the works" FDA UDI program. PDAC's proposal would have required providers to submit samples. AOPA challenged PDAC and especially the PDAC requirement that samples of O&P medical devices be provided to PDAC without any reimbursement.

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Someone missed the fact that many O&P medical devices are custom—one of a kind and that requirement would have placed an unfair cost burden on the O&P community. AOPA retained former FDA general counsel, Richard Cooper, to join with the Foley Hoag law firm to submit formal protests which ultimately resulted in PDAC withdrawing the proposal. AOPA also submitted a statement to FDA In November of 2012 when the proposed UDI regulations were published expressing strong agreement with the Class I GMP exempt medical device exemption from UDI but also called for an exemption for Class II Cranial Remolding Orthoses. AOPA maintained that these are truly custom devices made to the unique mold of each patient and therefore each device is unique and should be considered for a categorical exemption to the UDI regulations.

The final regulations reflected AOPA's position on the Class I GMP exempt medical devices but, sadly, FDA did not accept APOA's argument that Class II Cranial Remolding Orthoses are truly custom devices and these Class I devices have not been exempted.

In addition to the FDA Compliance Manual which AOPA published in 2011 and the special FDA seminar held in February of 2012 plus special sessions at the 2013 World Congress and 2012 Boston National Assembly, AOPA's Board of Directors has urged an even more aggressive effort to help educate members on the impact and risks FDA regulations impose on the O&P community. The more detailed notice on the UDI topics shared with all AOPA members at *http://bit.ly/FDA_UDI_Regulations* is an early step in a plan AOPA will pursue, an education agenda, that will include articles in the *O&P Almanac*, updates in the *AOPA In Advance SmartBrief* and future National Assemblies and other venues.

The Bottom Line

FDA has an important place in the medical device field that perhaps has not been given as much attention as needed. There is bound to be increased enforcement as the UDI regulations are implemented and with any new regulation there will be some confusion as to what exactly manufacturers and patient care facilities must do to be in compliance. That's AOPA's continuing job—to make sure we're on top of any new regulations or activities affecting O&P so you can be prepared to do what's necessary to avoid problems and continue to run a successful business.

Very truly yours,

Thomas F. Fise, JD
AOPA Executive Director