FDA Issues Facing O&P

Overview: and what AOPA is doing about them

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FDA Regulatory Authority and O&P

- Every patient care facility should have a plaque on its wall with the excerpt from the FDA Regulations:

> Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), with certain exceptions, manufacturers of medical devices are required to register with FDA. 21 U.S.C. § 360.
>
> FDA's regulations exempt from the registration requirement "[p]ersons who dispense devices to the ultimate consumer or whose major responsibility is to render a service necessary to provide the consumer (i.e., patient, physician, layman, etc.) with a device or the benefits to be derived from the use of a device; for example, a hearing aid dispenser, optician, clinical laboratory, assembler of diagnostic x-ray systems, a personnel from a hospital clinic, dental laboratory, orthotic or prosthetic retail facility, whose primary responsibility to the ultimate consumer is to dispense or provide a service through the use of a previously manufactured device." 21 C.F.R. § 807.65(i)(2009). This exemption is authorized by 21 U.S.C. § 360(g)(5).

FDA Regulatory Authority and O&P

- Are Pure O&P Patient Care Facilities Required to Register?
- Ramped Up FDA Activity Relating to Central Fabrication Facilities
- What to Do When the FDA Investigator Calls
- FDA Obligations of Companies: (a) Involved in ***Any Private Labeling/Relabeling*** of Devices; and (b) Which Serve as ***Initial U.S. Distributors of Imported Medical Devices***
- New Unique Device Identifier Regulations—How They Will Impact O&P
- AOPA FDA GMP and Compliance Manual

FDA Unique Device Identifier Final Regulations

- Applicability to O&P Devices
  - FDA is granting an exception from UDI as to medical devices classified in Class I, and as to which FDA has also granted exemptions from good manufacturing practices/QSR
  - FDA also has established an exception as to devices which qualify as "custom devices" within the meaning of 21 CFR Section 812.3(b).—Does NOT Appear Productive for O&P
  - Class I's but not exempted from GMPs/QSR regulations--section 801.40(d) provides: "that a Class I device that bears a UPC (universal product code) on its label and device packages and is deemed to meet all UDI labeling requirements and that the UPC will serve as the UDI required by section 801.20."
- Compliance Date
  - Class I – September 24, 2018
  - Class II – September 24, 2016
- **Medicare and other payers will require inclusion of UDIs (to the extent applicable in O&P) in billing statements, to ascertain specific device delivered.**

Take Aways

- O&P Is NOT Exempt from FDA
- Manufacturers have responsibilities to register, product listing and complaint reports, and quite possibly GMP compliance

Take Aways

- Where do you find out about how an O&P device is classified (I,II, or III), and what exemptions?
  - http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=890

Take Aways

- Get and Use "AOPA FDA Compliance Manual"
  - Free at www.AOPAnet.org for members

When you are thinking about new products…

DON'T FORGET ABOUT THE FDA!

When CMS, PDAC or anyone else talks about what should be in your labeling…

DON'T FORGET ABOUT THE FDA!

When you think about whether CMS should consider your product as an OTS orthotic device…

DON'T FORGET ABOUT THE FDA!

When you think about 3-D printing…

DON'T FORGET ABOUT THE FDA!