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

Food and Drug Administration (FDA) Investigations at O&P Facilities Were the "Early Warning System" that AOPA Members Needed Help in Understanding Their FDA Compliance Obligations

The Core of the Issue

If an FDA Inspector Knocks at Your Door Today...What Would You Do? One year ago, few, if any, patient care facilities or suppliers would know how to react. Most didn't know they were possibly subject to FDA regulations or that violations could trigger fines, product recalls or even facility closings. Who knew these were the perils if an investigator determined your facility was not in compliance with FDA requirements? As AOPA received more reports of investigators visiting O&P facilities, especially those with central fabrication activities, it became clear that FDA was seeking to expand their regulatory role in the O&P community. Not surprisingly, because this is another example of how this administration has upped the ante by expanding the regulatory role of many government agencies.

Here's what's going on. When an FDA inspector walks into a central fabrication facility, they think it looks more like a manufacturing operation than it looks like a patient care facility. They are asking—why isn't this company registered as a manufacturer under the registration requirements stated in FDA regulations. They also have taken an interest in complaint records.

FDA would assert that manufacturers of medical devices are subject to a broad range of specific FDA rules, which are independent of Medicare compliance. Key compliance issues an FDA Inspector would likely raise would include:

- *Are you required to register as a medical device manufacturer, under regulations stated in volume 21 of the Code of Federal Regulations?*
- *As a central fabrication facility, are you required to comply with FDA's Good Manufacturing Practice (GMP) regulations under those same FDA rules stated in 21 CFR Section 820?*
- *Are you maintaining the specific complaint files that are required under both the medical device experience reporting rules under Section 519 of the law, and under the GMPs as stated in 21 CFR Section 820.198?*

AOPA believes that: (1) FDA is incorrect in claiming central fabrication is a manufacturing process subject to FDA rules. There is some indication that FDA may view central fabrication facilities as being eligible for "custom device" exemption provisions of the FDA laws for medical devices, and that therefore these firms would not be subject to most aspects of device GMPs. AOPA would certainly agree with that. On (2) you argue strongly that you are an orthotic and prosthetic retail/patient care facility under 807.65(i) and that the FDA rules say you don't have to register. Members will probably need to comply with item (3).

Members are definitely going to want to be familiar with the provision in 21 CFR Section 807.65(i). O&P patient care facilities **acting only as retail facilities and/or appliance assemblers** need not register their establishments with FDA nor list their devices. Specifically, FDA's regulations exempt from the registration and listing requirements "[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, and 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) (emphasis added).

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Why Is It Important To You?

FDA Rules are important to everyone in O&P—manufacturers, central fabrication and traditional patient care facilities—because if you break the rules, FDA has the right to fine you, close your business or in extreme cases, put you in jail.

As to the three questions (highlighted on page 1), here is AOPA's best sense of where FDA seems to stand at this moment. AOPA members must understand that this is not solid—it is a best guesstimate, read or conclusion arrived at by AOPA staff and is VERY subject to change as FDA inspects more facilities.

- For custom orthotics FDA likely considers a central fabrication facility to be a manufacturer—they MAY recognize an exemption for custom devices that could be interpreted to exempt custom prosthetics, prefabricated orthotics and custom orthotics from most aspects of GMPs.
- FDA would almost certainly assert that central fabrication facilities are **required to register as a manufacturer** and also comply with some GMPs including—corrective and preventive action plans as well as document control. AOPA would argue strongly that you are an orthotic and prosthetic retail/patient care facility under 807.65(i) and that the FDA rules say you don't have to register.
- FDA would also expect that manufacturers, and quite possibly central fabrication facilities and patient care facilities as well, need to comply with medical devices patient experience reporting, including the processing and handling of complaint records. Our assessment is they can probably require O&P companies to do this.

What Is AOPA Doing About This?

In the middle of 2011, in recognition of this emerging problem, AOPA published the "*AOPA FDA Compliance Manual*" and a copy of this manual was mailed to every AOPA member patient care facility and every AOPA supplier company. The FDA Compliance Manual is also accessible for download from AOPA's web site: *www.AOPAnet.org* from the Legislative and Regulatory pull down menu on AOPA's home page.

While the *FDA Compliance Manual* is a good starting point on becoming familiar with FDA requirements, and especially the section on "What to Do When the Investigator Calls," much more is needed.

Part of the "more" is being met through AOPA's February 24, **2012 FDA Compliance Seminar** at the Inner Harbor Sheraton Hotel in Baltimore, MD, which will offer an opportunity for members to hear from and ask questions of the three very different, very knowledgeable FDA attorneys appearing on the one day program.

But going forward, the Manual and the Seminar may not address your particular question so please call AOPA and let us know your situation or questions. We'll do our very best to get you an answer.

Very truly yours,

Thomas F. Fise, JD
AOPA Executive Director

2012 FDA Compliance Workshop

Join AOPA on February 24 at the Sheraton Inner Harbor in Baltimore for an exclusive one-day seminar examining the compliance policies required of the O&P industry by the U.S. Food and Drug Administration (FDA).

Regulatory compliance awareness is important because regulatory agencies are legally entitled to conduct unannounced inspections if they believe there are suitable grounds for doing so. Regulatory compliance training is needed, so your organization can comply with FDA regulations that apply to manufacturing and distributing practices; medical devices and device classification; and forms, fees, and contacts. Penalties—ranging from fines to product recall—are severe if your company is in noncompliance.

AOPA is offering this compliance training in the wake of reports from members of increased FDA security. A major interest is whether FDA good manufacturing practices applies to O&P patient-care facilities, especially those with central fabrication companies.

Register online at *https://aopa.wufoo.com/forms/2012-fda-compliance-workshop-baltimore/* or contact Steve Custer at *scuster@AOPAnet.org* with questions.

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