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CLIENT ALERT

FDA Solicits Input on Regulatory Approach to 3D Printing of Medical Devices at the Point of Care

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On Friday, the U.S. Food and Drug Administration ("FDA") issued a discussion paper intended to facilitate public feedback on its approach to regulating 3D printing of medical devices at the point of care ("POC"). In the paper, FDA identifies benefits and challenges of medical devices 3D printed at the POC,outlines a potential regulatory approach, and poses scenarios and questions to facilitate discussion. FDA anticipates issuing draft guidance on this topic following the public comment period, which is open for 60 days.

FDA recognizes that 3D printing at the POC can have significant benefits, such as quick and adaptable production of devices, production of personalized devices, promoting innovations in patient care, and lessening dependence on traditional supply chain models. It thus seeks flexibility in its oversight of 3D printing while still maintaining reasonable assurances of safety and effectiveness as it sorts out where to assign compliance obligations – to printing system manufacturers, healthcare facilities, or some combination of both.

Regulatory and Compliance Challenges

Developing a regulatory approach, however, poses many challenges including assuring appropriate controls for POC printing,clarifying the entity responsible for regulatory compliance, andensuring entities 3D printing at POC have appropriate training and capabilities. FDA particularly seeks input on challenges stemming from the non-traditional allocation of activities defined as "manufacturing" under the Federal Food, Drug, and Cosmetic Act ("FDCA") that may occur when medical devices are 3D printed at the POC. Of note, the Agency's determination of where to assign regulatory burdens will not likely answer all potential compliance obligations, as duties of care and potential product liability will still likely stretch from design, to implementation, to POC 3D printing, to actual use of the finished product, even when these activities are undertaken by non-traditional entities.

Entities that manufacture medical devices – including entities that make 3D printing systems intended to print devices – are required to meet FDCA regulatory requirements applicable to "manufacturers" of medical devices. These include requirements such as premarket clearance or approval for the device/system, quality system regulations, and post-market surveillance. Typically, the entities producing 3D printing systems are traditional manufacturers, and the users of their legally marketed printing system, in accordance with labeling, are not themselves considered manufacturers.

In the context of POC 3D printing, the users are often healthcare facilities such as hospitals, physicians' offices, or even dental centers, whose primary focus is patient services and who do not generally engage in activities that are considered device manufacturing. In certain circumstances, however, activities performed by the healthcare facility may be considered device manufacturing that may subject the user to applicable regulations. Examples might include where a healthcare facility undertakes post-processing activities such as machining, precision drilling, heat treatment, or sterilization, or where the healthcare facility takes on the role of a traditional manufacturer by designing its own devices.

Scenarios and Regulatory Approaches

FDA outlines three potential scenarios for 3D printing of medical devices at POC to illustrate potential role allocation (but recognizes these are not exclusive of other scenarios): (1) a healthcare facility uses an approved or cleared 3D printing system, manufactured by a traditional manufacturer, to print devices in accordance with the intended use; (2) a traditional manufacturer located at or near a healthcare facility's POC 3D prints devices for the healthcare facility; and (3) a healthcare facility assumes the role of a traditional manufacturer by, for example, 3D printing according to its own specifications, designs, etc. Each of these potential scenarios raises its own challenges and considerations on which FDA seeks input. Questions FDA poses include how to handle post-processing activities undertaken by a healthcare facility, how the use of 3D printing systems at POC fits into FDA's existing regulatory framework, what unique issues arise in the POC 3D printing setting, and what about FDA's existing regulatory framework would be difficult or easy to implement in the POC 3D printing setting.

To further inform discussion, FDA outlines the concepts it is considering in developing its regulatory approach, on which it also invites general comments and suggestions. Concepts include:

- A risk-based approach, in which the extent of oversight corresponds with degree of risk;
- The requirement for devices to meet specifications should not change based on location of manufacture (*i.e.* whether a device is manufactured by a traditional manufacturer versus a healthcare facility);
- Existing capabilities and controls of a healthcare facility (such as existing expertise with 3D printing and existing quality management systems, quality standards, or complaint handling processes) can be used to manage 3D printing risks and leveraged to make regulatory compliance the least burdensome;
- Entities should understand which requirements of the FDCA apply to them;
- The potential for regulatory flexibility when it comes to devices that are very low risk.

Business Implications

In addition to those raised in FDA's paper, there are many practical and business implications of 3D POC device printing to consider. Are there non-regulatory legal implications of engaging in manufacturing activities associated with 3D printing – for example, will healthcare facilities engaging in 3D device printing be the targets of product liability litigation? What practical steps should healthcare facilities not traditionally in the business of manufacturing take to ensure they understand and comply with relevant FDCA regulations? Entities interested in the medical device manufacturing and 3D printing space should think through how their 3D printing at POC may implicate regulatory obligations and other legal risk, consider submitting comments to FDA, and watch for FDA's forthcoming draft guidance.

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