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Food, Drug And Device Law Alert - FDA Issues Draft Guidance On Disseminating Patient-Specific Information From Medical Devices

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The Food and Drug Administration (FDA) recently issued a brief draft guidance titled “Dissemination of Patient-Specific Information from Devices by Device Manufacturers” in order “to clarify that manufacturers may share patient-specific information recorded, stored, processed, retrieved, and/or derived from a medical device with the patient who is either treated or diagnosed with that specific device.” The FDA also seeks, however, to ensure the content is clear and non-misleading and the context is appropriate.

The draft guidance defines patient-specific information as “any information unique to an individual patient or unique to that patient’s treatment or diagnosis that, consistent with the intended use of a medical device, may be recorded, stored, processed, retrieved, and/or derived from that medical device.” For purposes of the draft guidance, patient-specific information does not include any interpretations of data aside from those interpretations of data normally reported by the device to the patient or the patient’s healthcare provider.

The draft guidance places two limitations on providing patient-specific information to patients: (1) the patient must request the information; and, (2) “any labeling, as that term is defined in section 201(m) of the FD&C Act, that is provided to the patient by the manufacturer is subject to applicable requirements in the FD&C Act and FDA regulations.”

The draft guidance further recommends that device manufacturers take certain considerations into account when sharing patient-specific information to help ensure it is useable by patients and it is not confusing or unclear. With respect to the content of the patient-specific information, the draft guidance states “the manufacturer should take into consideration the characteristics of the intended audience that may affect interpretability. Depending on the type and scope of information being shared, the manufacturer may choose to provide supplementary instructions, materials or references to aid patient understanding.” This is the specific point at which the FDA reminds readers that labeling regulations will still apply. Further, “patient-specific information provided to patients should be comprehensive and contemporary.”

As to context, the draft guidance states generally the manufacturer should include relevant context to ensure the information is not misinterpreted and does not lead to invalid conclusions. As an example, the draft

RELATED PEOPLE

Lynn C. Tyler, M.S.
Partner
Indianapolis

P 317-231-7392
F 317-231-7433
lynn.tyler@btlaw.com

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guidance states “when providing data regarding a measured physiological parameter over time, it may be useful to a patient to include information regarding how that parameter was measured and recorded by the medical device.” FDA specifically recommends “at a minimum, that … manufacturers advise patients to contact their healthcare providers should they have any questions about their patient-specific information” and states manufacturers may provide their own contact information to answer questions from patients about the device at issue.

A copy of the draft guidance can be found here.

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or one of the following attorneys in the firm’s Food, Drug & Device Group: Lynn Tyler at (317) 231-7392 or lynn.tyler@btlaw.com; or Alicia Raines Barrs at (317) 231-7398 or alicia.rainesbarrs@btlaw.com.

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