

Medical Malpractice Update

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New FDA Draft Guidance on Medical Devices Would Notify Public of Risk Before Analysis or Confirmation

On December 31, 2015, the FDA released a draft policy which would alter how and, more significantly, when the public is notified of a potential risk associated with a medical device that has already been approved for the market.

Historically, upon receipt of a complaint or information regarding an issue with a medical device, the FDA has undertaken a rigorous analysis of the issue before releasing any information to the public. Because of the time inherent in the collection, analysis and verification of evidence related to a potential safety issue, the FDA has been criticized for failing to timely alert the public to such issues. In an effort to provide more timely notice, the FDA proposes to notify the public upon receipt of information that raises a safety issue with a medical device (an "Emerging Signal") without waiting until that risk can be fully analyzed or verified.

The draft guidance titled, Public Notification of Emerging Postmarket Medical Device Signals,^[1] defines an "Emerging Signal" as new information about a medical device the Agency is monitoring that has the potential to impact patient management decisions or to alter the known risk benefit profile of the device. The FDA proposes to release such information even though it has not been validated or confirmed, and even though the Agency does not have specific

recommendations as to how to address the issue.^[2]

This proposal will authorize the FDA to alert the public to any issue that has the potential to impact a patient's decision on use. Recognizing that the information, described as "evolving in nature," would be disseminated "prior to confirmation and full evaluation of the data,"^[3] the Agency states that "access to the most current information concerning the potential benefits and risks of marketed medical devices" is sufficiently important to warrant early notification^[4] The FDA acknowledges the implicit risk of information that is provided "without context,"^[5] specifically where patients may become unnecessarily alarmed or choose to discontinue therapy with a beneficial device that in actuality has no causal relationship to any adverse clinical outcome.^[6] To mitigate these concerns, the FDA states it "will include specific information on the known benefits and risks of the device and its use, as well as information on the emerging signal."^[7]

Although it is unclear how public notification of "Emerging Signals" would impact medical device manufacturers, healthcare providers should prepare to address an influx of information that could alter the landscape for patient care generally. Perhaps more significantly, there will be a greater impact on patient communications

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in informed consent discussions. With an increase in notification letters that lack FDA verification or recommendations, the onus will shift to providers to attempt to determine whether evidence of a potential problem with a device is sufficiently serious to outweigh its potential benefits. Given the nature of “Emerging Signals,” providers will need to be increasingly vigilant to notify patients of issues and to document the consideration of, and patient discussions about, the information contained in the notification letters. Moreover, while the draft guidance states that the Agency “may provide updates” on Emerging Signals over time,[8] it does not say whether providers will receive a communication notifying them of such an update, or whether the provider would be expected to monitor a website to learn whether the Agency has received additional information. Thus, providers should be mindful that updated information on a medical device may not be “actively” communicated.

With regard to informed consent, this proposed guidance should serve as a reminder of the importance of thorough note-keeping. Discussions with the patient about a particular device should be ongoing and noted in the patient’s records. As more and more early notifications pour in, having a clear record of the information discussed with the patient could be critical in defending a claim. Because of the high interest in this proposal, the FDA has recently extended the deadline to submit comments to March 29, 2016.

[1] United States Food and Drug Administration, “Public Notification of Emerging Postmarket Medical Device Signals (“Emerging Signals”), Draft Guidance for Industry and Food and Drug Administration Staff,” dated December 31, 2015, available by clicking [here](#).

[2] Draft Guidance, pg. 3

[3] Draft Guidance, pg. 4

[4] Draft Guidance, pg. 5

[5] Draft Guidance, pg. 7

[6] Draft Guidance, pg. 7

[7] Draft Guidance, pg. 7

[8] Draft Guidance, pg. 7

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