

ALERTS

Food, Drug And Device Law Alert - Major FDA Reform Bill Becomes Law: Medical Device Overview

December 13, 2016 | [Atlanta](#) | [Chicago](#) | [Columbus](#) | [Dallas](#) | [Delaware](#) | [Elkhart](#) | [Fort Wayne](#) | [Grand Rapids](#) | [Indianapolis](#) | [Los Angeles](#) | [Minneapolis](#) | [South Bend](#)

President Obama recently signed the 996-page [21st Century Cures Act](#) to implement a variety of reforms to the Food and Drug Administration's (FDA) regulation of the medical device and pharmaceutical industries. This alert summarizes the major provisions of the act related to medical device regulation found in Subtitle F.

Section 3051 – Breakthrough Devices

Section 3051 of the act is titled “Breakthrough Devices” and authorizes the FDA to expedite the development of, and provide priority review for, breakthrough devices, which are defined as devices:

1. that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and
2. (A) that represent breakthrough technologies;
(B) for which no approved or cleared alternatives exist;
(C) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or
(D) the availability of which is in the best interest of patients.

Device firms may request designation under this section and the FDA must respond within 60 days of the request.

Section 3052 – Humanitarian Device Exemption (HDE)

The Humanitarian Device Exemption (HDE) is the subject of Section 3052. The existing HDE program is limited to diseases or conditions affecting up to 4,000 patients annually and this section increases that number to 8,000. It also directs the FDA to publish a guidance defining “probable benefit” in 21 U.S.C. 360j(m)(2)(C), which states that the criteria for an HDE include: “the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.”

Section 3053 – Recognition of Standards

Section 3053 addresses the recognition of standards and authorizes a device firm to request recognition of a standard established by a

RELATED PEOPLE



Lynn C. Tyler, M.S.

Partner
Indianapolis

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

RELATED PRACTICE AREAS

Food, Drug and Device Law

nationally or internationally recognized standard-setting organization. Within 60 days of receiving the request, the FDA is required to respond by recognizing all, part, or none of the standard and providing its rationale. FDA is also required to provide relevant employees with periodic training on the recognition of standards, and review and update, if necessary, existing guidance documents related to the recognition of standards.

Section 3054 – Certain Class 1 and Class II Devices

Under Section 3054, the FDA is required to publish a notice in the Federal Register – within 120 days from enactment of the act for Class I devices and within 90 days for Class II devices – that identifies devices that no longer require clearance under section 510(k). For Class II devices, the FDA must provide a 60-day notice and comment period and finalize the list within 210 days. The FDA is to update these lists every five years.

Section 3055 – Classification Panels

For devices subject to review by a classification panel, Section 3055 requires the FDA to ensure that the classification panel includes “adequate expertise ... to assess [1] the disease or condition which the device is intended to cure, treat, mitigate, prevent, or diagnose; and [2] the technology of the device.” Moreover, device firms must be given an opportunity to make recommendations on the necessary expertise. The section defines “adequate expertise” as “(i) two or more voting members with a specialty or other expertise clinically relevant to the device under review; and (ii) at least one voting member who is knowledgeable about the technology of the device.”

Section 3056 – Institutional Review Board Flexibility

Section 3056 strikes the requirement for Institutional Review Boards (IRB) to be local, effectively allowing a single IRB to supervise a multi-center device trial.

Section 3057 – CLIA Waiver Improvements

Section 3057 gives the FDA one year from enactment to revise a specific section of a 2008 guidance document on Clinical Laboratory Improvement Amendments (CLIA) Waiver Applications for In Vitro Diagnostic (IVD) manufacturers to allow “the appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy.” Previously, accuracy had to be demonstrated based on comparison to a gold standard. As a result to the change, it should be easier for some IVD tests to be exempt from routine inspections and most CLIA requirements.

Section 3058 – Least Burdensome Device Review

The FDA must provide training and supervision to relevant employees involved in device review on the meaning and implementation of the least burdensome review requirements, according to Section 3058 of the act. Within 18 months of enactment, the FDA must conduct an audit of the training and other aspects of the program and later make a written report of the audit available to Congress and to the public via the FDA’s website. For 510(k) applications, when the FDA requests additional information it must consider the least burdensome means necessary to establish

reasonable assurance of safety and efficacy, “necessary” meaning “the minimum required information.” The FDA must consider post-market information in making this determination.

Section 3059 – Cleaning Instructions and Validation Data Requirement

Under Section 3059, within 180 days of enactment the FDA must identify and publish a list of reusable device types subject to section 510(k), which are required to include “(A) instructions for use, which have been validated in a manner specified by the [FDA]; and (B) validation data, the types of which shall be specified by the [FDA]; regarding cleaning, disinfection, and sterilization, and for which a substantial equivalence determination may be based.”

Section 3060 – Clarifying Medical Software Regulation

Finally, section 3060 seeks to clarify medical software regulations. This section modifies the definition of “device” in the Food, Drug & Cosmetic Act to exclude the following categories of software:

- For the administrative support of a healthcare facility
- For maintaining or encouraging a healthy lifestyle and unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition
- For use as electronic health records, subject to other conditions
- For transferring, storing, converting formats or displaying (but not interpreting) clinical laboratory tests or other device data and results, findings by a healthcare professional with respect to such data and results, general information about such findings, and general background information about such laboratory tests or other devices
- For displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines); supporting or providing recommendations to a healthcare professional about prevention, diagnosis, or treatment of a disease or condition; and enabling healthcare professionals to independently review the basis for recommendations that software presents so it is not the intent that healthcare professionals rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient; unless the software is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system. The exception applies to all three subparts of this category.

A copy of the act 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; Beth Davis at (404) 264-4025 or beth.davis@btlaw.com; or Alicia Raines Barr at (317) 231-7398 or

alicia.rainesbarr@btlaw.com.

Visit us online at www.btlaw.com/food-drug-and-device-law-practices.

© 2016 Barnes & Thornburg LLP. All Rights Reserved. This page, and all information on it, is proprietary and the property of Barnes & Thornburg LLP. It may not be reproduced, in any form, without the express written consent of Barnes & Thornburg LLP.

This Barnes & Thornburg LLP publication should not be construed as legal advice or legal opinion on any specific facts or circumstances. The contents are intended for general informational purposes only, and you are urged to consult your own lawyer on any specific legal questions you may have concerning your situation.

Visit us online at www.btlaw.com and follow us on Twitter [@BTLawNews](https://twitter.com/BTLawNews).