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What Is the Device Industry Getting for Its Money?

FDA user fee reauthorization legislation seeks to ease premarket regulatory burdens, but increases postmarket scrutiny.

On June 26, Congress passed the Food and Drug Administration Safety and Innovation Act, revising and extending the user fee program for medical devices and other products regulated by the U.S. Food and Drug Administration (FDA). Under the new law, the device industry will pay an estimated $595 million in user fees over the next four fiscal years (FYs 2013–2017). The law represents a congressional bipartisan compromise and thus includes provisions intended to ease regulatory burdens that have hindered device development, as well as provisions aimed at ensuring patient safety. Addressing concerns expressed by the device industry and other stakeholders, the new law includes changes relating to investigational device exemption (IDE) approval standards, criteria for device modifications requiring new 510(k) premarket notifications, an appeal process for regulatory decisions, and simplification of the de novo down-classification process. The new law also requires FDA to work with other agencies to develop recommendations and strategies for the regulation of health information technology.

To address patient safety, the new law includes provisions that increase the postmarket scrutiny of medical devices. New programs will more closely evaluate recall trends, increase requirements for recall audit checks, and enable FDA to order postmarket surveillance either at the time of approval or clearance or at any time thereafter. A potentially critical change is that the new law allows FDA to change the classification of a device from class II to class III (or from class III to class II) *by administrative order* rather than through the notice-and-comment rulemaking process. This provision will give FDA significant authority to act unencumbered by Administrative Procedure Act (APA) rulemaking requirements and, presumably, will enable FDA to act more quickly in the event of new information suggesting that a classified device presents a risk to patient safety.

Below is a summary of the more significant provisions in the new law for the device industry, which first addresses those provisions that are intended to ease regulatory burdens and facilitate device development and innovation, followed by those provisions intended to increase review of postmarket safety and identification of device risks.

Changes Intended to Reduce Regulatory Burdens

Investigational Device Exemptions (Section 601)

This provision seeks to address industry's concern that a recent draft FDA guidance on IDE decisions would allow FDA to disapprove an IDE based on a finding that the investigation may not support a device clearance or approval. Pursuant to Section 601, the new law clarifies that FDA may not disapprove an IDE on the following bases: (1) the investigation may not support a substantial equivalence or de novo classification determination, or approval of a device; (2) the investigation may not meet a data requirement, including a data requirement related to the approval or clearance of device; or (3) an additional or different investigation may be necessary to support clearance or approval of the device.

The provision also responds to concerns regarding the lengthened IDE process and the standards being applied by FDA reviewers to IDEs. Many manufacturers found that, because reviewers were applying standards more appropriate for premarket approval applications (PMAs) or 510(k) premarket notifications, the

IDE process often was extended by several rounds of responding to additional requests for information before FDA would approve the IDE. As a result, the ability of manufacturers and investigators to design protocols with a broader device development purpose was significantly limited. Consistent with the statute, this provision restores to scientific investigators the freedom to pursue discovery and development of new devices without being burdened with 510(k) clearance and PMA approval standards at the investigational stage.

Agency Documentation and Review of Significant Decisions (Section 603)

The law adds a new Section 517A to the Federal Food, Drug, and Cosmetic Act, which is intended to make FDA's decision-making on submissions more transparent and to expedite the appeal process for disputes relating to submissions. Section 517A requires that FDA prepare a substantive summary of the scientific and regulatory rationale for any significant decision relating to the submission or review of a 510(k), PMA, or IDE, *including documentation of significant controversies or differences of opinion and the resolution of such controversies or differences of opinion*. Upon request, FDA must furnish this summary to the person who has submitted an application or report. Within 30 days of a significant decision, a person can request a supervisory review of the decision at the next supervisory level or higher above the individual who made the significant decision. If requested, FDA must schedule an in-person or teleconference review within 30 days and must issue a decision not later than 45 days after the request was made, or 30 days after the meeting or teleconference. This time frame will not apply if consultation with experts outside FDA is necessary.

This new statutory provision provides important benefits to device companies making submissions to FDA. The summary required of FDA will reveal the scientific and regulatory reasons for FDA decisions on IDEs, 510(k)s, and PMAs, enabling industry to make better strategic decisions regarding how to proceed with those submissions. For example, summaries provided in response to PMA disapproval or "not substantially equivalent" determinations by FDA will better equip companies to make decisions regarding whether to conduct additional studies or to appeal the decisions. Further, the new statutory time frames for appeals will give device companies greater certainty regarding the time required for the appeal process.

Device Modifications Requiring Premarket Notification Prior to Marketing (Section 604)

This provision is a response to severe industry criticism of FDA's draft guidance on device modifications requiring a new 510(k) premarket notification, which, based on an AdvaMed survey, would increase the number of 510(k)s filed anywhere from 300% to 500%. To address industry's concerns, Congress has taken the unusual step of managing FDA's issuance of this guidance document. The new law requires FDA to withdraw the draft guidance on device modifications and to follow the 1997 guidance. Moreover, FDA is prohibited from issuing a new draft guidance until after FDA prepares a report to Congress on when modifications require a new 510(k). The report must specifically address how to define certain terms used in the regulation on device modifications, what processes manufacturers should follow in making these determinations, and how to leverage the quality system to reduce the premarket burden. Further, FDA is not permitted to issue a final guidance until one year after the date of receipt of the report by Congress.

Modification of the De Novo Application Process (Section 607)

Under current law, persons seeking down-classification of a low-risk device that has no predicate must first file a 510(k) premarket notification and obtain a "not substantially equivalent" (NSE) decision. This process has proved to be time-consuming and inefficient because the submitter is required to prepare and submit a 510(k) for the sole purpose of having it determined NSE. Under the new law, in lieu of submitting a 510(k), the person seeking down-classification can submit a request for classification, and FDA is required to respond to the request within 120 days. This process should ease some of the regulatory burden for developers of innovative, low-risk devices.

Health Information Technology (Section 618)

The new law requires FDA to work with other regulatory agencies to determine an appropriate regulatory approach for health information technology (health IT). Although FDA has in recent years attempted to tackle

certain areas of health IT regulation, such as in its regulation for medical device data systems and its draft guidance document on mobile medical applications, many in industry have complained of a lack of clear and consistent guidance on the applicability of FDA's device requirements to health IT products, particularly with respect to electronic health records (EHRs) and clinical decision support software. Industry also has expressed concern with potential duplicative or inconsistent regulation, as there is no clear line between FDA's authority for health IT products and the authority of other regulatory agencies, such as the Office of the National Coordinator for Health Information Technology (ONC) and the Federal Communications Commission (FCC).

To address these issues, the new law requires FDA to work with ONC and FCC to prepare a report on strategies and recommendations for the regulation of health IT. The report must be completed within 18 months of enactment. Significantly, the new law does not include a controversial requirement present in previous versions of the legislation that would have prevented FDA from finalizing its draft guidance on mobile medical applications until the interagency report on health IT was completed and submitted to Congress. In addition, the final law no longer requires that the report be submitted to Congress, but instead the report must be posted on the three agencies' websites. The revised law also states that the Department of Health and Human Services (HHS) has the option of convening a working group of stakeholders and experts to provide input for the report, but is not required to do so.

Provisions Intended to Increase Postmarket Safety

Reclassification (Section 608)

The law's new reclassification provision presents some concern for the device industry. The new law enables FDA to change the classification of a device by administrative order, instead of by notice-and-comment rulemaking under the APA. Instead of requiring FDA to publish a proposed rule soliciting comments, and then review and respond to those comments, the new legislation enables FDA to pursue reclassification of a device by issuing a proposed reclassification order in the *Federal Register*, with a summary of the valid scientific evidence concerning the proposed reclassification, including the public health benefit of the use of the device and the nature of the risk—and, if known, its incidence. While the law requires that FDA hold a device classification panel meeting, there is no requirement that the panel provide a recommendation or that its views be considered. Comments may be submitted to the public docket, but they are not required to be solicited or considered. The final order is to be issued in the *Federal Register*.

This change in the process for reclassification seems intended to make it easier for FDA to reclassify devices based on new information. While Congress's primary intent may have been to give FDA more flexibility in the event that a safety issue suggests a class II device should be reclassified as a class III device, the new law applies to both down-classification and "up-classification."

Recalls (Section 605)

As part of an overall FDA strategy to increase its postmarket scrutiny of device safety, the new law requires that FDA establish a program to "routinely and systematically" assess device recalls to facilitate identification of health risks presented by devices and development of strategies for mitigating those risks. Additionally, the law requires that FDA document the basis for termination of device recalls.

Clinical Holds on IDEs (Section 606)

Congress authorizes FDA to place a clinical hold on a device investigation at any time when the agency determines that the device being investigated presents an unreasonable risk to the study subjects. This provision gives FDA the same authority for device investigations that it currently possesses for drug investigations. The new law also provides that FDA may establish regulations for issuing a clinical hold for reasons other than an unreasonable risk to the safety of study subjects.

Unique Device Identifier (Section 614)

Because FDA has delayed issuance of regulations to implement the requirement for a unique device identifier (UDI) to be placed directly on a device, Congress is now requiring that FDA issue proposed regulations by December 31, 2012, and finalize the proposed regulations not later than six months after the close of the comment period. Additionally, the law requires that final regulations for implantable, life-saving, and life-sustaining devices be implemented not later than two years after the regulations are finalized. UDIs are intended to improve medical device reporting, facilitate recalls, help with identification of compatibility problems, and enhance FDA's postmarket surveillance capabilities.

Other Postmarket Review Programs: Sentinel and Postmarket Surveillance (Sections 615 and 616)

The sentinel provision of the new law requires FDA to include devices in its existing postmarket risk identification and analysis system. Under this program, FDA will obtain and review private sector health data, including medical device utilization data, health insurance claims data, and procedure and device registries, for use in the development of a system to identify postmarket risks.

Under the postmarket surveillance provision, FDA is authorized to order postmarket surveillance of a device either at the time of approval or clearance, *or* at any time thereafter. Manufacturers are required to commence surveillance not later than 15 months after the date of the order.

Implications

In response to the passing of this law, medical device companies should monitor FDA's execution of these new provisions. Although the new law may ease regulatory burdens and improve transparency in some areas, the new postmarket requirements will require medical device companies to keep abreast of FDA's implementation efforts and adjust their internal compliance systems accordingly. Device companies also will want to keep track of FDA's progress to ensure they can provide timely comments on any proposed regulations and new draft guidance documents issued by FDA. This significant legislation also signals continued discussion on FDA regulatory issues among Congress, FDA, and stakeholders.

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