

Health Industry Alert

December 9, 2016

Key Points

- The 21st Century Cures Act (“Cures” or the “Act”) significantly impacts FDA’s review and approval of medical devices, and how medical devices are covered and paid for.
- These new authorities give FDA greater flexibility in regulating medical devices, but their ultimate impact will depend on how they are implemented by the agency under a new administration.
- Because the Cures device provisions are more heavily focused on premarket review, expect additional consideration of postmarket device surveillance in next year’s FDA reauthorization process.



Key Implications of the 21st Century Cures Act for Medical Devices

This week, the U.S. Senate passed the comprehensive legislative package referred to as the 21st Century Cures Act. The Senate’s passage follows an overwhelming passage by the House of Representatives last week, and the President is expected to sign the legislation into law on December 13th.

The legislation, which follows more than two years of discussion, contains a vast array of changes for the health care system and authorizes, over 10 years, \$4.8 billion in funding for research and \$1 billion to fight the opioid crisis; it provides an additional \$500 million to FDA, although Congress has appropriated only the first year of funding so far. In addition to making significant changes to FDA regulation of medical products, the legislation addresses National Institutes of Health (NIH) research, opioids, mental health, hospitals and medical countermeasures. This client alert focuses on the key Cures provisions affecting medical devices and diagnostics.

FDA Regulatory Reforms Related to Devices

Breakthrough Devices

Cures creates a priority review program for “breakthrough” devices that is modeled on the breakthrough pathway for drugs.¹ The provision as enacted is available to qualifying devices that will go through the premarket approval (PMA), *de novo*, or 510(k) pathways. The breakthrough pathway criteria are somewhat broader than the criteria for FDA’s existing Expedited Access Pathway. To qualify, a device must demonstrate that it provides for more effective treatment or diagnosis of a life-threatening or

¹ H.R. 34, 114th Cong. § 3051 (2016).

irreversibly debilitating human disease or condition, and meets one of the following criteria: (1) it represents a breakthrough technology; (2) it has no approved or cleared alternative; (3) it offers 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 . . . , or establish long-term clinical efficiencies”; or (4) its availability is in the best interest of patients.

FDA will have 60 days to accept or deny a sponsor’s request for designation as a breakthrough device. FDA’s denial of an application constitutes a “significant decision,” which a sponsor may appeal. To facilitate expedient review, FDA must assign a team of staff, adopt an efficient dispute resolution process, provide for interactive and timely communication with the sponsor, collaborate with the sponsor on clinical trial design, and expedite review of manufacturing and quality systems compliance. FDA must publish guidance on implementation of this section within one year of enactment of the Act.

Medical Device Software

Cures clarifies which types of digital health applications constitute medical devices.² Although the Cures medical software provisions mirror FDA’s current approach in many respects, they appear to depart from FDA policy in several ways. **Akin Gump plans to issue a separate alert specifically addressing the Medical Device Software provision.**

Under Cures, the following five functions or uses, subject to certain conditions, will not be considered medical devices:

- **Administrative Support:** administrative support of a health care facility, including the processing and maintenance of financial records, claims, billing information, information about patient populations, business analytics, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, and population health management
- **Healthy Lifestyle/Wellness:** maintaining or encouraging a healthy lifestyle, provided the function is unrelated to the diagnosis, cure, mitigation, prevention or treatment of a disease or condition
- **Electronic Patient Records:** use as electronic patient records, including patient-provided information, to the extent that the records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart so long as the records were created, stored, transferred or reviewed by health care professionals or individuals working under their supervision; are part of health information technology certified by the Office of the National Coordinator; and are not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition
- **Transfer/Storage of Medical Device Data:** transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with

² H.R. 34, 114th Cong. § 3060 (2016).

respect to such data and results, general information about the findings, and general background information about the test or other device, unless the function is intended to interpret or analyze clinical laboratory tests or other device data, results, and findings (note that this provision is not perfectly aligned with FDA's definition of Medical Device Data Systems)

- **Clinical Support:** (1) displaying, analyzing or printing medical information; (2) supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and (3) enabling such health care professional to independently review the basis for such recommendations, so long as the function is not intended to acquire, process, or analyze a medical image or signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system.

For certain of the exempted functions, however, FDA may apply device requirements if the agency determines through notice and comment rulemaking that it is reasonably likely to have serious adverse health consequences.

FDA must publish a report within two years of enactment, and then every two years thereafter, that examines information about risks and benefits to health associated with these software functions, taking into account input from industry stakeholders.

Regulation of Accessories

The Cures software provisions also address medical device accessories. Under the Act, accessories are to be classified by FDA based on their own intended use and not on the intended use of any devices with which they are intended to be used (which often results in a higher risk classification for the accessory).³ This has relatively recently been FDA's position (and has been proposed in draft guidance), but it is now codified in law.

Cleaning Instructions and Validation Requirements for Reusable Devices

Cures requires FDA to publish a list of reusable device types for which 510(k) clearance will require validated instructions for use and validation data regarding cleaning, disinfection, and sterilization.⁴ Any 510(k) submissions for such device types made after the date that FDA publishes its list must include these validated instructions for use and validation data. FDA must revise the list as it deems appropriate by issuing a notice in the Federal Register.

This provision stems, in large part, from recent reports of infections spreading among patients from the use of reusable duodenoscopes.

Humanitarian Device Exemption

This section expands the humanitarian device exemption (HDE) to devices that treat or diagnose a disease or condition that affects no more than 8,000 individuals in the United States per year, an increase

³ H.R. 34, 114th Cong. § 3060(c) (2016).

⁴ H.R. 34, 114th Cong. § 3059 (2016).

from the current limit of 4,000 individuals. FDA is also required to issue guidance on the “probable benefit” criterion for granting an HDE.⁵

Least Burdensome Device Review

FDA must provide training to reviewers regarding the meaning and implementation of the “least burdensome” principles of the Food, Drug, and Cosmetic Act (FDCA), which require FDA to consider the least burdensome means of evaluating device effectiveness or substantial equivalence for purposes of premarket review.⁶ Within 18 months of enactment, the ombudsman must audit the implementation of these requirements. FDA must consider the least burdensome means necessary to demonstrate a reasonable assurance of safety and effectiveness when it requests additional information regarding a PMA application, including evaluation of postmarket information.

IRB Flexibility

This section removes the statutory reference to a sponsor of a medical device trial using a local institutional review board (IRB).⁷ This change allows for the use of centralized IRB models for multicenter trials.

Recognition of Standards

This section establishes a process for submission, review and recognition of standards established by nationally or internationally recognized standard organizations for purposes of facilitating medical device review.⁸

Certain Class I and Class II Devices

Within 120 days of enactment, and then at least once every five years, FDA must publish a list of the types of Class I devices that are newly exempted from 510(k) in the Federal Register.⁹ FDA must do the same for Class II devices within 90 days of enactment, and then at least once every five years.

Classification Panels

This provision aims to improve medical device classification panels by ensuring adequate expertise among panel members, allowing a sponsor to offer recommendations on the required expertise and permitting a sponsor representative to address the panel.¹⁰

CLIA Waiver Improvements

FDA must update its 2008 guidance on determining when a test is eligible for a Clinical Laboratory Improvement Amendments of 1988 (CLIA) waiver by allowing for demonstration of accuracy through comparable performance between a waived and a moderately-complex user.

⁵ H.R. 34, 114th Cong. § 3052 (2016).

⁶ H.R. 34, 114th Cong. § 3058 (2016).

⁷ H.R. 34, 114th Cong. § 3056 (2016).

⁸ H.R. 34, 114th Cong. § 3053 (2016).

⁹ H.R. 34, 114th Cong. § 3054 (2016).

¹⁰ H.R. 34, 114th Cong. § 3055 (2016).

Other FDA-Related Provisions Affecting the Device Industry

Other FDA-related Cures provisions are not solely directed at medical devices, but hold implications for device makers.

Combination Products

The Act reforms the process for reviews of combination products, requiring FDA to issue guidance on a structured review process.¹¹ The provision seeks to address the concern that FDA treats the presence of any chemical action as rendering the “primary” mode of action (PMOA) to that of a drug or biologic.¹² In determining a product’s PMOA, FDA categorizes combination products based on the statutory definition that a product is not a device if it “achieve[s] its primary intended purposes through chemical action within or on the body of man.” Sponsors can request a substantive rationale that references scientific evidence for the agency’s determination of the PMOA. Although this provision clarifies that FDA cannot classify combination products with merely “any” chemical action as having the PMOA of a drug or biologic, the degree of chemical action that may be present for a product to have a device PMOA may still be difficult to discern.

In addition:

- Sponsors may meet with the review team and receive FDA’s feedback on proposed studies to establish the relevance of any chemical action.
- When reviewing a combination product that contains a component that has already been approved or cleared, FDA must take into account the prior determination of safety and effectiveness and may request only data or information that is necessary to make a premarket review decision on the product as a whole, such as data on the incremental risks and benefits posed by the combination product.
- Under the Act, certain device-led combination products shall be considered, for purposes of determining eligibility for drug marketing exclusivity, to have been submitted as a “505(b)(2)” application (in reference to the FDCA provision)—a drug application that relies, in part, on studies not conducted by the applicant. This provision may make it easier for combination products to qualify for marketing exclusivity, but it also may allow a sponsor of a drug under exclusivity to “block” device-led combination products that use that drug.
- FDA is required to publish a list of proposed combination product types that could employ less burdensome Good Manufacturing Practices (GMP) requirements than would apply under FDA’s current streamlined GMP regulations.

¹¹ H.R. 34, 114th Cong. § 3038 (2016).

¹² *Prevor v. FDA*, 895 F. Supp. 2d 90, 95 (D.D.C. 2012); *Prevor v. FDA*, 67 F. Supp. 3d 125, 135 (D.D.C. 2014).

Off-Label Communication of Economic Information

The Act amends the FDCA's prohibition on misbranding to expand the scope of off-label information that manufacturers can share with payors.¹³ Specifically, the provision broadens an existing safe harbor for sharing "health care economic information" with additional types of payor entities in addition to formulary committees. Although the expanded language refers to off-label information about drugs and biologics, the same principles might provide a road map in the event that FDA—or Congress in next year's FDA user fee reauthorization—clarifies the parameters for the sharing of health care economic information about off-label uses of devices.

Real World Evidence

Cures requires FDA to evaluate the use of "real world evidence" to help support approval of a new indication for a previously approved drug and help support or satisfy post-approval study requirements.¹⁴ This provision does not apply to medical devices, although the draft commitment letter for the Medical Device User Fee Agreement reauthorization package contemplates a similar initiative for devices. Under the commitment letter, FDA will apply user fee funding to support a National Evaluation System for health Technology (NEST), which will establish programs to assess the feasibility of applying real world evidence for expanded indications for use, new clearances and approvals, and improved malfunction reporting.

Precision Medicine Initiative and Cancer Moonshot Efforts

The Act codifies congressional support for the Obama administration's goal to cure cancer by providing funding and encouraging the Secretary HHS to support its efforts. The Act allocates \$1.4 billion over the next decade to fund NIH to support the Precision Medicine Initiative, which is President Obama's effort to advance development of individualized patient care through research, technology, and policy-making. It also provides \$1.8 billion in funding to the NIH for fiscal years 2017 to 2021 to support the Cancer Moonshot, the Administration's mission to end cancer led by Vice President Biden. This funding is intended to support cancer research through development of combination therapies, cancer vaccines, more sensitive diagnostic tests, immunotherapies, and research that has the potential to transform the scientific field, that has inherently higher risk, and seeks to address major challenges related to cancer.

In addition, the Act empowers the HHS Secretary to carry out the Precision Medicine Initiative, which may include developing a network of scientists, developing new approaches to address regulatory and scientific issues, applying genomic technologies, and gathering information to better understand health and disease.

Regenerative Medicine Provisions

A relatively late addition to the Cures legislation was a set of provisions on regenerative medicine.¹⁵ These provisions direct FDA to consider certain regenerative medicine therapies (including combination products) under existing expedited approval pathways/processes. FDA must also issue guidance within

¹³ [Footnote missing]

¹⁴ H.R. 34, 114th Cong. § 3022 (2016).

¹⁵ H.R. 34, 114th Cong. §§ 3033–3036 (2016).

one year of enactment to clarify how it will evaluate devices used in the recovery, isolation or delivery of regenerative advanced therapies. The guidance must address:

- how FDA will streamline regulatory requirements for combination device and cell or tissue products
- which intended uses or attributes would make a device used with a regenerative therapy a Class III device
- when the FDA requires an intended use to be specific to only one particular type of cell
- application of the least burdensome approach to demonstrate how a device may be used with more than one cell type.

Coverage and Payment Provisions

Cures also includes a number of Medicare and Medicaid-related provisions, many of which have implications for coverage and payment for medical devices and diagnostics.

Increased Transparency for Medicare Local Coverage Determinations (LCDs)

LCDs are decisions made by Medicare Administrative Contractors (MACs) to cover (or limit coverage for) a particular item or service, such as a device, within the MAC's assigned geographic region.¹⁶ Beginning six months after enactment, MACs must post certain information on their websites at least 45 days prior to the effective date of a final LCD, including a summary of the evidence considered and an explanation of the rationale supporting the LCD. Although current Centers for Medicare & Medicaid Services (CMS) policy requires MACs to provide notice and opportunity for stakeholder comment on draft LCDs, the Cures provision enhances these existing procedural protections.

Medicare Pharmaceutical and Technology Ombudsman

Cures establishes a "pharmaceutical and technology ombudsman" within CMS to handle complaints, grievances, and other requests from pharmaceutical and medical device manufacturers seeking Medicare coverage for their products.¹⁷ The ombudsman would specifically be charged with addressing coverage, coding and payment, providing manufacturers with a potential new avenue to work with the agency to resolve access barriers arising from these issues.

Medicare Part B Payment for Home Infusion Therapy and Durable Medical Equipment (DME) Infusion Drugs

Cures establishes a new Medicare benefit and payment system for "home infusion therapy," which encompasses the nursing, training and education, and remote monitoring services associated with administering certain infusion drugs in a patient's home.¹⁸ Pharmacies and other providers furnishing these services would receive a single payment for each day of infusion administration. The Medicare reimbursement formula for DME infusion drugs (i.e., drugs that are infused through DME-covered infusion

¹⁶ H.R. 34, 114th Cong. § 4009 (2016).

¹⁷ H.R. 34, 114th Cong. § 4010 (2016).

¹⁸ H.R. 34, 114th Cong. §§ 5004; 5012 (2016).

pumps) is reduced from 95 percent of Average Wholesale Price to 106 percent of Average Sales Price, bringing payment for such drugs in line with other types of Part B-covered drugs.

Expansion of Telehealth Services under Medicare

The Act includes a “sense of the Congress” that telehealth services be expanded under the Medicare program.¹⁹ Toward this end, CMS must report certain relevant information to Congress, including the Medicare patient populations that may benefit from increased access to telehealth and any barriers that might prevent its expansion. It also calls for a Medicare Payment Advisory Commission report to Congress on telehealth.

Delay in Implementation of Payment Cuts to the Medicare DME Fee Schedule

Cures delays by six months the expansion of DME competitive bidding to rural geographic areas that were not originally subject to competitive bidding.²⁰ Full implementation of these cuts, which have already been delayed by Congress this year, will take place on January 1, 2017, instead of July 1, 2016. The extension of the current transition period for these rate reductions comes in response to industry concerns about the impact on patient access, particularly in rural areas. HHS is also directed to study the impact of the cuts on the number of suppliers and patient access.

Medicaid Reimbursement for DME

Current law limits federal payments to state Medicaid programs based on Medicare payment rates for DME beginning in 2019.²¹ Cures applies Medicare rates to Medicaid one year earlier, in 2018.

Sunshine Act Changes Omitted

The draft version of the Cures legislation released after Thanksgiving, as well as the 2015 House-passed bill, contained a provision to exempt certain transfers of value to physicians and other covered recipients from disclosure under the Sunshine Act, including textbooks, medical journal reprints, and honoraria and other costs associated with presenting and attending Continuing Medical Education (CME) that does not promote a specific product. This provision was removed from the final Cures legislation. As a result, such payments from device and drug manufacturers must continue to be disclosed to CMS’ Open Payments system, except for industry-sponsored CME, which remains excluded at CMS’ discretion.

¹⁹ H.R. 34, 114th Cong. § 4012 (2016).

²⁰ H.R. 34, 114th Cong. § 16007 (2016).

²¹ H.R. 34, 114th Cong. § 5002 (2016).

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