The 21st Century Cures Act Will Have a Wide Impact

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IN JUNE I HAD THE GOOD FORTUNE to be with colleagues at the American Society for Automation in Pharmacy (ASAP) midyear conference in Palm Beach, Fla., where I provided a snapshot of the 21st Century Cures Act. The act garnered widespread bipartisan support, passing the House of Representatives (H.R.34) on Nov. 30, 2016, by a 392-26 vote, and then the Senate on Dec. 7, 2016, by a 94-5 vote. The president signed the act into law on Dec. 13, 2016 (becoming Public Law No.114-255). The act is composed of a number of provisions that are designed to improve and modernize different aspects of the healthcare system. The primary areas address acceleration of medical product discovery, development, and delivery. The act's goal is to improve the health of Americans across a wide array of initiatives.

The act's first title, Innovation Projects and State Responses to Opioid Abuse, adds upon the enacted Comprehensive Addiction and Recovery Act (CARA), granting states $1 billion over the next two years for drug abuse prevention and treatment programs. The first round of grants to states for $485 million was awarded by the Substance Abuse and Mental Health Services Administration in April 2017.

The act's other three titles are Discovery, Development, and Delivery. A brief summary of major provisions follows by title.

The Discovery title impacts primarily the National Institutes of Health (NIH). NIH will establish an Innovation Prizes Program to fund areas of biomedical research "that could realize significant advancements or improve health outcomes." NIH will also be able to offer support in later phases of clinical trials, and will be more collaborative with the FDA so that clinical trial data might be accessed for further research. It also creates a nonprofit organization, the Council for 21st Century Cures, to focus on accelerating medicine discovery, development, and delivery.

> Many stakeholders will be impacted by the 21st Century Cures Act, including patients, researchers, pharmaceutical companies, device manufacturers, payers, and healthcare providers. The act holds great promise to help drive innovation but much implementation needs to occur.

Four major projects within NIH will receive up to $4.8 billion over the next decade:

- ❑ $1.802 billion to fund the Cancer Moonshot, aimed at making more therapies available to more patients and improving cancer detection and prevention.
- ❑ $1.5 billion will go to the Brain Research through Advancing Innovative Neurotechnologies Initiative (BRAIN), an effort to map and understand the functioning of the human brain. Funding should lead to new cures and treatments, in part for Alzheimer's and epilepsy.
- ❑ $1.564 million for the Precision Medicine Initiative, which focuses on tailoring medicine to address individual differences and response potential in patients.
- ❑ $30 million to support work in the field of regenerative medicine using adult stem cells.

The Development title amends the federal Food, Drug, and Cosmetic Act (FD&C) to require the FDA to create processes that will bring patient experience data to be considered during the risk-benefit assessment of a new drug. The act requires the FDA to issue guidance regarding how to collect patient experience data. It also requires the FDA to evaluate real-world evidence submitted in support of a new indication for a previously approved drug. Precision drugs to treat serious or rare diseases will be identified, and their development expedited for priority review.

This title of the act also:

- ❑ Protects data and patient information in biomedical research.
- ❑ Enhances the rigor and reproducibility of scientific research.
- ❑ Addresses healthcare economic information (in Section 3037), broadening an existing safe harbor for sharing healthcare economic information with formulary committees, expanding eligible recipients to additional types of payer entities to support value-based healthcare models.
- ❑ Advances combination product innovation by requiring that the FDA work ahead with sponsors to smooth development and studies.
- ❑ Through the limited population pathway, gives the FDA flexibility to approve antimicrobial drugs based on a limited population if the drug treats a life-threatening infection.

The Delivery title helps deliver newly tested and approved drugs to patients. It also contains provisions to enhance interoperability of electronic health records systems that can help improve a seamless patient experience.

With regard to interoperability, the act strengthens efforts to improve and enforce health information interoperability. Interoperability is defined in the act as "Enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user." Beginning in January 2018, vendors' relative interoperability will be evaluated, and by 2019, vendors not in compliance will lose certification. It authorizes penalties for interfering with lawful sharing of electronic health records of up to $1 million per violation. The act's health information technology (HIT) provisions also create a new ONC-coordinated HIT Advisory Committee that replaces the HIT Policy Committee. The new committee will focus on infrastructure, privacy, patient access to health information, and security/demographic information. The HIT Advisory Committee will also identify priority uses of HIT focusing on meaningful use, the Merit-based Incentive Program (MIPS) implementation and other quality and value models. The committee will have 25 members appointed by the Department of Health and Human Services, Congress, and the comptroller general, and will include a wide variety of stakeholders.

The Delivery title also has numerous Medicare- and Medicaid-related provisions, many of which have implications for coverage and payment for medical devices and diagnostics. There is increased transparency for Medicare local coverage determinations (LCDs). The act 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. Section 5004 addresses payment for infusion drugs based on findings from the HHS Office of Inspector General. The payment amount for Part B infusion drugs furnished through durable medical equipment will be set to average sales price (ASP) plus 6% beginning on Jan. 1, 2017. The OIG concluded that applying the ASP+6% methodology to infused drugs would result in payment amounts that reflect actual transaction prices. The act establishes a new Medicare benefit and payment system for home infusion therapy.

The act also encourages the expansion of telehealth services under the Medicare program. CMS must report to Congress in this area, including in any reports 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.

In summary, many stakeholders will be impacted by the 21st Century Cures Act, including patients, researchers, pharmaceutical companies, device manufacturers, payers, and healthcare providers. The act holds great promise to help drive innovation, but much implementation needs to occur. To review all the act's provisions, visit https://www.congress.gov/bill/114th-congress/house-bill/34. **CT**

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FOR MORE ON THE 21ST CENTURY CURES ACT

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