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21st Century Cures Act

OVERVIEW

On December 13th, President Barack Obama signed the 21st Century Cures Act into law. The legislation was introduced by Representative Fred Upton (R-MI) in July 2015 and was heavily revised before ultimately securing bipartisan support in both the U.S. House of Representatives (392-26) and the Senate (94-5). The law is intended to advance biomedical research, streamline the approval process for drugs and medical devices, enhance mental health and substance abuse services, and promote the secure exchange of health information.

The legislation includes significant funding, including:

- $4.8 billion for the National Institutes of Health (NIH) to support the Precision Medicine Initiative and Cancer Moonshot Initiative;
- $1 billion to address the opioid epidemic; and
- $500 million for the Food and Drug Administration (FDA) to expedite the approval and repurposing process for drugs and medical devices.

The funding is scheduled to be allocated on an annual basis, but the release of funds will have to be approved by Congress each year as part of the appropriations process. On December 9th, Congress passed a continuing resolution that will fund Cures Act initiatives for FY 2017, including: $500 million for states implement opioid treatment and prevention programs, $352 million to the NIH, and $20 million to the FDA.

This document summarizes key provisions of the law. The text of the final legislation is available here.

NIH PROVISIONS

The law provides $4.8 billion over 10 years to support NIH Innovation Projects. Of that funding, nearly $3 billion will support biomedical research projects championed by President Obama: the Precision Medicine Initiative and the Brian Research through Advancing Innovative Neurotechnologies Initiative. Approximately $1.8 billion has been allotted to support Vice President Joe Biden's Cancer Moonshot Initiative and $30 million will be provided to enhance regenerative medicine research.

OPIOID ABUSE PROVISIONS

The legislation provides $1 billion over two years to implement an opioid-focused grant program that is intended to support states in efforts to:

- Enhance training for providers;
- Expand access to prevention and treatment services;
- Improve prescription drug monitoring programs; and
- Implement other public health activities deemed appropriate by the state.

The Department of Health and Human Services (HHS) is instructed to allocate funding among states based on the relative prevalence of opioid abuse.

FDA PROVISIONS

The law provides $500 million over 10 years to the FDA. The FDA is intended to use the funding to expedite the approval processes for prescription drugs and medical devices. The legislation directs the FDA to:

- Consider "real-world evidence" (including observational studies and registries) to approve new indications for existing drugs, in lieu of randomized clinical trials;
- Recruit new scientific, technical, and professional staff to bolster development, FDA review, and regulation of certain medical products;
- Expedite the approval pathway for antibiotics that address unmet treatment needs for serious or life-threatening infections among limited patient populations;
- Grant priority review to certain "breakthrough" medical devices that could improve diagnosis or treatment of individuals with life-threatening or irreversibly debilitating conditions; and
- Implement a streamlined process for reviewing combination drug-device products.

While the legislation's proponents maintain that the changes to the FDA's approval process will provide patients more timely access to life-saving drugs and medical devices, some have argued that an expedited approval process will undermine certain patient safety requirements.

MENTAL HEALTH PROVISIONS

The law contains many mental health provisions that are intended to expand children's mental health services, strengthen enforcement of existing mental health parity coverage requirements, enhance suicide prevention efforts, and improve patient and provider understanding of federal and state privacy laws, including the Health Insurance Portability and Accountability Act (HIPAA).

Children's Services

The law requires that children covered under state Medicaid programs have access to comprehensive mental health screenings and treatment services. It also eliminates what is known as the "same day" exclusion from coverage, allowing payment to be made for both physical and mental health treatments provided to a Medicaid beneficiary on the same day.

The law allocates funding for a series of grant programs to improve children's mental health, including: approximately $20 million to support early intervention and treatment for infants and children who are at risk of developing a behavioral health condition, and $9 million to expand access to pediatric mental health care through telehealth services. The law provides the following annual funding allotments for FYs 2018 through 2022:

- $119 million to programs for children with serious emotional disturbances;
- $50 million to support trauma recovery among children;
- $30 million to improve substance use disorder treatment and early intervention services for children and adolescents; and
- $5 million to expand screening and treatment of maternal depression.

Suicide Prevention

The law establishes or reauthorizes grants to support suicide prevention and interventions strategies. Funding includes, but is not limited to the following annual allotments for FYs 2018 through 2022:

- $30 million to support state Youth Suicide Early Intervention and Prevention Strategies grants; and
- Over $7 million to support the existing National Suicide Prevention Lifeline.

Integrated Care

The law provides integration incentive grants and cooperative agreements for states to work with community health centers to enhance the integration of mental and substance use disorder treatment services with physical health treatment services. Participating entities may receive a target amount of $2 million per year for five years. Entities that receive a grant or cooperative agreement will also be eligible for information, training, and technical assistance from HHS.

Community Mental Health Services Block Grant

The law allocates over $530 million for each FY from 2018 through 2022 for states to offer comprehensive community-based care for children and adults with mental health conditions.

Training Demonstration Programs

The law allocates $10 million for each FY 2018 through 2022 for HHS to establish a mental health and substance use disorder training demonstration program for psychiatry residents and fellows, nurse practitioners, physician assistants, psychologists, and social workers. The law also provides funding to help teachers and first responders identify the signs and symptoms of mental health conditions.

HHS Leadership

The law calls for the creation of two new roles at HHS: Assistant Secretary for Mental Health and Substance Use and the Chief Medical Officer. The new Assistant Secretary for Mental Health will oversee grants and promote innovative models of patient care. The Chief Medical Officer will be involved with new initiatives supporting evidence-based clinical practices in medical and mental health care.

Mental Health Parity

The law will require federal agencies to report on the actions taken to date to ensure compliance with mental health parity provisions in the Affordable Care Act and Mental Health Parity and Addiction Equality Act. These laws apply mental health parity to the individual market, Medicaid expansion group, and to employer sponsored insurance coverage. Health plans found to have violated mental health parity protections five times will be subject to audit. The law directs HHS to provide health plans and plan sponsors with additional guidance on how to comply with parity requirements.

Privacy Protections

HHS will be required to produce educational materials that help patients, providers, and care takers to better understand privacy protections. The legislation includes guidance on the permitted disclosures of health care information to the patient's designated care takers. The law notes that providers should communicate with designated caregivers if the patient poses a serious and imminent threat of harm to themselves or others.

HEALTH INFORMATION TECHNOLOGY (HIT) PROVISIONS

The legislation includes a number of provisions that promote HIT interoperability and the exchange of medical information.

HIT Advisory Committee

The legislation will create a HIT Advisory Committee to advise the National Coordinator for Health Information Technology (ONC) on various items related to certification criteria, exchange of information, and national and local infrastructure. The committee will include 25 members who will serve in three-year terms. Members will include representatives from HHS, the public health community, the advocate community, two appointments each by the majority and minority leaders of the House and Senate, and the remaining appointments will be made by the head of the Government Accountability Office.

Electronic Health Records (EHR) Voluntary Certification

The law directs the ONC to provide an EHR voluntary certification process for HIT to be used in practices and settings where similar technology is not yet available or further "technological advancement or integration" could be beneficial. The law also requires HHS to develop voluntary pediatric EHR certification standards.

Medicaid and Medicare Meaningful Use (MU) Incentives

The law requires that the HIT Advisory Committee review EHR standards and their adoption, with a focus on providers' ease of complying with EHR and MU standards under Medicare and Medicaid.

Providers and hospitals adopting HIT and EHRs that are later decertified under the new ONC certification program may be exempt for up to one year from Medicare and Medicaid penalties for not meeting those programs' MU standards. Payment adjustments under MIPS will still apply.

Medical Research

HHS is to provide "confidentiality certificates" to privately-funded medical researchers to facilitate broad sharing of research and patient information. The legislation retroactively applies these information sharing provisions to all ongoing research under Section 301(d) of the Public Health Service Act, beginning six months after the law is enacted.

Within a year from the law's enactment, HHS must issue guidance clarifying under what conditions researchers may remotely access (or remove) health information from systems. HHS will also be required to revise patient notices that govern consent for the release of patient data for medical research. Finally, the law establishes a working group to prepare and report on HIPAA-protected information being released for medical research purposes.

Trusted Exchange Network

The ONC Director will work with other agencies within HHS to ensure network-to-network free exchange of health information. HHS will convene public-private and public-public partnerships in order to establish a trusted exchange framework. This network will operate based on a "common agreement" to be used among health information exchange networks and providers across the U.S.

ONC and other HHS offices will provide technical assistance to vendors and committees charged with implementing the trusted exchange framework and common agreement. Pilot testing of the framework and related programs may be delegated to vendors and other entities under contract.

Information Blocking

The legislation requires HHS to issue regulations that limit information blocking and promote sharing information through open Application Programming Interfaces. Continued HIT and electronic medical record certification under the MU Incentive Program certification will be conditioned, not just on limiting information blocking and typical interoperability measures, but also on measures that require vendors to share information about product usability and data security.

Developers and vendors of certified HIT and health information exchanges identified as information blockers could face vendor penalties up to $1 million per instance. Penalties would be levied after a review process and take into account various factors associated with the violation. Health care providers could also be penalized for information blocking.

Concerns over ONC Resources to Implementation Law

The law requires ONC to develop, pilot, and roll out the trusted exchange framework, new interoperability requirements, and the HIT certification program, but does not provide ONC with new funding for any of these activities. With the ONC's existing budget constraints, the federal government may face challenges implementing the IT-related provisions of the law within the time frames prescribed by Congress.