

21ST CENTURY CURES ACT PASSES CONGRESS

The 21st Century Cures Act passed the U.S. House of Representatives on November 30, 2016 with a 392 to 26 margin and passed the U.S. Senate on December 7, 2016 with an 85 to 13 margin. The \$6.3 billion health care bill is expected to be signed by President Obama on December 13, 2016. Above all else, the bill's primary purpose is to expedite Federal Drug Administration ("FDA") approval for new medicines and devices and to increase medical research funding.

The bill is mammoth in scope and size and incorporates nineteen core pieces of legislation. At 996 pages - 90 pages longer than the Affordable Care Act - the 21st Century Cures Act addresses funding on a wide scale basis, mental health reform and the FDA's drug approval process.

This article is the second Hall Render article in a series examining the 21st Century Cures Act, including how the Act impacts the field of behavioral health. On December 9, 2016, we issued an [article](#) that focused on one key aspect of the 21st Century Cures Act - a new exception for off-campus provider-based departments that were mid-build or under development before November 2, 2015.

Below is a grand overview of other significant features of the bill.

FUNDING

There are three key funding provisions in the bill:

- The National Institutes of Health ("NIH") would receive \$4.8 billion - \$1.4 billion to go for the Precision Medicine Initiative, \$1.8 billion for Cancer Moonshot and \$1.5 billion for the Brain Research through Advancing Innovative Neurotechnologies ("BRAIN") initiative.
- The FDA would receive \$430 million over ten years for streamlining clinical trials and for hiring for 600 open positions (including scientists).
- States would be eligible for \$1 billion in grants over two years to improve access to mental health programs and to combat opioid drug abuse (largely heroin and painkillers).

New funding for NIH's three programs all involve research. The Precision Medicine Initiative is intended to uncover how such factors as affluence, environment, genetics and lifestyle impact health and disease. The BRAIN initiative would map the human brain and boost neuroscience research dollars going to treat, prevent and cure brain disorders, including Alzheimer's and epilepsy and problems stemming from traumatic brain injuries. Cancer Moonshot dedicates research toward the causes and cures for cancer with the hope of cancer prevention and of increasing early detection. (The last initiative got its name from the president, who declared in his 2016 State of the Union address that finding a cure for cancer would be as bold a feat as launching someone to the moon.)

Young researchers would also get NIH support. Another NIH initiative called EUREKA ("Exceptional Unconventional Research Enabling Knowledge Acceleration") would create a competition for new treatments of diseases.

FDA MEASURES

The bill encourages the FDA to speed up the research, development and approval of new prescription drugs and devices (including adult stem cell treatments). Under the legislation, the FDA would develop clearer guidelines in designing clinical trials for fewer patients and enlist public-private conglomerates to confirm molecular or imaging biomarkers so that medications could be tailored for patient sub-groups. In the case of rare diseases, the FDA would be able to approve drugs that it had approved for a specific objective to counter a related disorder, based on genetic data without requiring the applicant to go through the whole approval process. "Real-world evidence" in some cases could replace clinical trials for drug approval. "Breakthrough" medical devices, even if risky, would be eligible for priority review. Manufacturers would be required to disclose publicly how they could provide experimental treatments to patients with severe or life-threatening disorders who do not meet the criteria for clinical trials.

MENTAL HEALTH REFORMS

Mental health reforms in the bill include:

- Creating an Assistant Secretary of the Department of Health and Human Services to oversee mental health and substance abuse;
- Creating a Chief Medical Officer ("CMO") to be appointed by the Assistant Secretary whose duties will include, among others, promoting evidence-based and promising best practices and assessing the use of performance metrics to evaluate activities related to mental and substance use disorder;
- Improving the coordination of behavioral health and primary care;
- Training additional mental health specialists;
- Diligently enforcing mental health and substance abuse parity (which requires insurers to cover mental illnesses as they cover other diseases);
- Reducing jail time for nonviolent criminals who are mentally ill;
- Making grants available for local treatment groups and outpatient care for uncooperative patients; and
- Financing temporary inpatient stays with Medicaid managed care plans.

Most notably, the Mental Health and Substance Use sections of the bill include enacting mechanisms aimed at strengthening quality improvement measures in relation to behavioral health services. The first step towards this goal was to put a vehicle in place aimed at data collection and evaluation. The Center for Behavioral Health Statistics and Quality ("CBHSQ"), an already existing governmental agency focused on behavioral health statistics and epidemiology, is codified in this bill. The bill provides that CBHSQ will be maintained under the new Assistant Secretary within the Substance Abuse and Mental Health Services Administration ("Administration"). Aimed at improving the quality of behavioral health services, CBHSQ will coordinate the Administration's integrated data strategy, provide statistical analytical support, recommend a core set of performance metrics and coordinate with the Assistant Secretary and the CMO to improve the quality of services provided by the Administration.

Armed with CBHSQ's ability to collect and evaluate the data, the bill provides that the Assistant Secretary develop and carry out a strategic plan no later than September 30, 2018 and every four years thereafter. The strategic plan aimed at mapping out the plans and operations of activities carried out by the Administration shall include:

- Identifying strategic priorities, goals and measurable objectives for mental and substance abuse disorders activities and programs;
- Identifying ways to improve the quality of services of individuals with mental and substance use disorders;
- Ensuring programs are providing access to effective and evidence-based prevention, diagnosis, intervention, treatment and recovery services;
- Developing or improving initiatives to increase the workforce trained to treat individuals with mental or substance use disorders;
- Identifying opportunities to improve collaboration with state and local governments; and
- Specifying a strategy to disseminate evidence-based and promising best practices related to the entire continuum of mental illness services (i.e., from prevention to recovery).

In addition to the above federal level initiatives, the bill also includes state specific funding for mental health reform. Key areas include Title VIII, which is designed to support state prevention activities including mental health and substance abuse prevention by providing block grant funding. Specifically, Section 8001 of Title VIII gives states additional flexibility to use community health services block grant funding to provide community mental health services for adults and children. Section 8002 also provides block grant funding and provides, among other things, that states are responsible for ensuring ongoing training for substance use disorder prevention and treatment professionals in a myriad of areas. Section 8002 also requires states to identify a single state agency to administer grant funding and establish goals and objectives, including describing how states will integrate substance use disorder services with primary health care and mental health care.

Title IX Subtitle A is designed to promote access to mental health and substance use disorder care by providing grants for treatment and recovery for homeless individuals, offering jail diversion programs, promoting integration of primary and behavioral health care, maintaining a "National Suicide Prevention Line" program and providing other types of programs that focus on acting as access points for psychiatric services.

Subtitle B of Title IX is focused on "Strengthening the Health Care Workforce," which includes grants to institutions of higher education or accredited professional training programs to support the recruitment and education of mental health care providers. Subtitle B also provides for liability protections for "health professional volunteers" at deemed entities through the Federal Tort Claims Act to remove barriers for volunteering. This coverage sunsets after five years.

Subtitle C of Title IX targets mental health on college campuses. Notably, Section 9031 of Subtitle C reauthorizes the Mental Health and Substance Use Disorder Services on Campuses grant program as well as allows for the education of students, families, faculty and staff to increase awareness and training to respond effectively to students with mental health and substance use disorders.

Lastly, the omnibus bill also addresses reducing hospital regulations, increasing participation in value-based care programs for rural hospitals and retaining health insurance options. Another part of the legislation deals with mHealth (mobile health) devices, including handheld PCs and tablet computers.

CRITICISM

The bill has its detractors. Some are concerned that the FDA may approve risky devices that may result in injury or death. Others are concerned that funding is being taken away from Medicare and Medicaid dollars in the Prevention and Public Health Fund that were meant to finance purchases of medical equipment and from \$1 billion in oil sales out of the Strategic Petroleum Reserve. Moreover, the FDA and NIH funding is not guaranteed but would require annual congressional appropriations. Still others see the medical device and pharmaceutical industries as the chief beneficiaries.

Despite these drawbacks, most people studying this bill see this as a step in the right direction for health care reform.

PRACTICAL TAKEAWAYS

- This new law will help providers improve the quality of care through new drugs, devices and technology.
- Providers should evaluate how the changes in law will impact their current policies and procedures related to medication management, medical device utilization, staffing mental health professionals and treatment teams.
- This new law will help ensure greater mental health treatment parity and assist states with addressing the substance abuse crisis. Behavioral health providers should start evaluating how this new law can help improve their services.

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