Senate passes 21st Century Cures Act funding research and medicine

December 9, 2016 By Danielle Kirsh Leave a Comment

The Senate passed the 21st Century Cures Act on Dec. 7, in a 94 to 5 vote, leaving the $6.3 billion legislation for President Barack Obama to sign.

"[We are] pleased that the president is intending to sign the bill," said AdvaMed president and CEO Scott Whitaker. "Our view is it's a great victory for patients, for this industry, the medical technology and innovative industry that we represent and also for the FDA, who we work with so closely on so many issues."

The 21st Century Cures Act will help fund the fight against opioid abuse, mental health treatment, help the FDA speed up drug approvals and push for better use of technology in medicine.

The NIH will be given $4.8B in funding over the next ten years that will further the Precision Medicine Initiative and fund research into the genetic, lifestyle and environmental variations of disease; reinforce VP Biden's "Cancer Moonshot" to speed up cancer research; and invest in the BRAIN initiative to improve understanding of diseases like Alzheimer's.

$1B in grants will be provided to states over a two-year period to supplement opioid abuse prevention and treatment activities. The grants will help with improving prescription drug monitoring programs, implementing prevention activities, training for healthcare providers and expanding access to opioid treatment programs.

The 21st Century Cures Act strengthens laws mandating uniformity for physical and mental healthcare. Grants will also go toward increasing the number of psychologists and psychiatrists in the country.

The bill will also advance new therapies for patients by modernizing clinical trials, providing the FDA with $500M for regulatory modernization and grant the agency the ability to recruit the best scientists, doctors and engineers.

"There's improvements in the process for hiring very highly qualified staff at the FDA, something we've worked with the FDA on for a number of years. It provides, in the medical device and technology area, another $500M in discretionary appropriations for the FDA to implement a number of these provisions and other activities," said Whitaker.

Medical software regulation will be clarified with this bill, identifying five specific categories of medical software that will not be regulated as medical devices by the FDA based on their low-level risk to patients. However, it will provide the FDA with the authority to regulate software in these categories if there are safety concerns.

Janet Trunzo, Senior Advisor to AdvaMed President and Senior Executive VP of Technology and Regulatory Affairs, said, "I would say that it tracks FDA's guidance on this topic such that certain devices that would have software in it would fall into the various categories where the FDA had originally tried to identify when a software, as a medical device, would be regulated as such and when it would not. That's the clarification."

"We were brought apart of a very broad coalition of a number of stakeholders who were engaged in working on this bill, from the patient community to the research community to provider and life science communities as well," said Whitaker.

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