
By Anthony H. Nguyen, J.D.

House and Senate health committees issued the final version of the "21st Century Cures" bill, which would accelerate discovery, development, and delivery of new cures and treatments under the auspices of medical innovation. The landmark legislation, which also includes new funding for the National Institutes of Health and FDA, will head to the House of Representatives for a vote mid-week. The House will also vote to include in the Cures bill legislation that updates major mental health programs for the first time in a decade with new funding of $1 billion in state grants to fight opioid abuse.

The 21st Century Cures legislation would help bring drugs and devices to market more quickly and at less cost by reforming the FDA, including: expedited review for breakthrough devices, increased patient involvement in the drug approval process, a streamlined review process for combination products that are both a drug and device, and freedom from red tape for software (see Faster, please: expedited drug approval pathways increasingly popular, July 2, 2015).

In terms of funding, $4.8 billion will go to the NIH, including $1.4 billion for President Obama’s Precision Medicine Initiative to drive research into the genetic, lifestyle and environmental variations of disease; $1.8 billion for Vice President Biden's "Cancer Moonshot" to speed research; and $1.6 billion for the BRAIN initiative to improve understanding of diseases like Alzheimer's and speed diagnosis and treatment. In addition, the FDA would receive over $500 million in new funding.

House legislation addressed. The 21st Century Cures Act captured a number of House measures to improve quality care and reduce health care costs. A provision eliminated by the Patient Protection and Affordable Care Act (ACA) (P.L. 111-148) would be restored for Medicare beneficiaries, namely the flexibility to switch plans to meet health needs with a second open enrollment and disenrollment period (H.R. 2488).

Three additional House bills, H.R. 5273, H.R. 2580, and H.R. 887, would remove regulations affecting hospitals, outpatient facilities, and ambulatory surgical centers to expedite quality care access. H.R. 5713 would postpone regulations that that would make it difficult for long-term care hospitals (LTCH), which treat patients suffering from the most severe illnesses and injuries, to deliver quality care.

In addition, patients with kidney failure could enroll in Medicare Advantage (H.R. 5659) and current Medicare Advantage beneficiaries would have protections against sudden coverage loss with a slew of bills (H.R. 5273, H.R. 2506, H.R. 2505, H.R. 5268, and H.R. 3291).