
By Anthony H. Nguyen, J.D.

The House passed the 21st Century Cures Act (Cures Act) on a 392-26 vote nearly three years after it was first introduced. The bipartisan legislation would primarily expedite FDA approval of new drugs via $500 million in funds to hire more staff to review drug applications, but includes a slew of provisions intended to benefit various sectors of health care industry. In addition to the boon to healthcare industry, the Cures Act includes provisions to address mental health treatment in the U.S., including administrative positions at the Substance Abuse and Mental Health Services Administration and state funding to combat opioid addiction. The version of the Cures Act the House passed remained essentially intact, with various technical changes, from the version sent to the House earlier in the week for vote. One notable deletion was the deletion of an exemption from reporting requirements used for tracking financial relationships between companies and physicians. Overall, the Cures Act bill would spend $6.3 billion over the next decade (see $6.3B 21st Century Cures bill headed for House vote, November 28, 2016).

Hospitals and patient advocacy. Patient advocacy groups have been generally supportive of the Cures Act, although some have cautioned that the changes for expedited FDA approval of certain drugs and devices could be dangerous. For instance, in a study published in The BMJ last year, researchers concluded that increasing reliance on expedited development and review procedures by the FDA are being driven less by drugs that provide "noticeable clinical advances," and more by drugs that are not first in class and are less innovative (see Is FDA expedited review encouraging less-innovative drugs?, September 25, 2016).

Although in favor of the Cures Act's goals, members of The Alliance for Site Neutral Payment Reform, a coalition of patient advocates, providers, payers, and employers who support payment parity, expressed reservations that the Cures Act includes provisions that would exempt cancer hospitals and certain hospital outpatient departments (HOPDs) from site neutral payment policies signed in to law as part of the Bipartisan Budget Act of 2015 (BBA) (P.L. 114-74).

The coalition noted that when Congress passed the BBA, stemming consolidation in the health care marketplace was a key driver in the creation of the site neutral payment provision. The coalition pointed out that data continues to demonstrate the negative effects that hospital acquisition of independent physician practices has on health care costs and access to community-based care. For instance, studies found in the six months from July 2014 to January 2015, 13,000 physician practices were acquired. Community-based cancer clinics have been hit particularly hard with a 172 percent increase in consolidation into hospitals since 2008.

Hospital alliances were pleased the Cures Act also includes a change to take into account patient socioeconomic status in the Medicare Hospital Readmissions Reduction Program. The American Hospital Association (AHA) offered its support for the Cures Act, commending the legislation's improvement of hospitals' ability to treat vulnerable patients.

The AHA highlighted the following aspects of the Cures Act that was of import to its members: (1) addressing the consequences of the BBA on Medicare outpatient payment to hospital-based clinics that were under development at the time of the legislation's passage; (2) establishing a socioeconomic adjustment in the readmissions program; (3) extending the Rural Community Hospital Demonstration Program; (4) addressing the "25 percent Rule" relief for LTCHs, as well as other LTCH concerns (H.R. 2580, 5713, 5688, 5723, 5614, and 5559); (5) providing flexibility in physician supervision for critical access hospitals; (6) providing significant advances in behavioral health treatment and funding; and (7) making meaningful investment to combat the opioid abuse crisis and help patients in recovery.

FDA. The Cures Act would also 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).

Although there is new funding for the FDA to expedite review, the Cures Act retains some controversial provisions affecting how regulators evaluate certain types of medical products. Despite lawmaker assurances and the insertion of language that would keep the FDA’s approval standards intact, these provisions could be interpreted to afford the HHS considerable discretion in applying those standards.

For instance, “real-world evidence” could be used in support of new indications for existing drugs. This is defined as information on drug outcomes derived from non-clinical trial sources. As such, this type of data is problematic and less reliable because it would likely not have been uniformly collected. Another problematic area for the FDA is provisions intended to speed up medical device approvals. One provision formalizes an ongoing pilot program that allows high-risk medical devices priority review, if considered a "breakthrough." Under the Cures Act, it would be possible to classify a medical device as a breakthrough even if the advantages to the device are not “clinically meaningful.” In turn, this could lead to post-market safety problems.

Controversial provision removed. The Cures Act (as issued on November 28, 2016) initially included a rollback of requirements for companies to report certain payments to doctors, including reporting payments made to doctors for receiving continuing medical education sessions, medical journals, or textbooks. The exemption was perceived as an attempt to remove requirements for reporting such payments to a federal database that tracked financial relationships between companies and physicians. That provision was deleted Tuesday before it was sent to the House floor for vote, after a protest by Sen. Charles Grassley (R-Iowa) threatened to hold up the bill.

Other notable additions. Incorporated into the Cures Act are a number of other legislative provisions that address various industry wide concerns. Local employers would be allowed to provide health benefits to their employees via health reimbursement accounts (HRAs), which would be used by individuals to purchase an insurance plan or pay for out-of-pocket health care costs. Qualified substitute therapists would be allowed to continue patient care if a patient’s physical therapist was unavailable. Finally, anticipated CMS payment rate reductions to suppliers of durable medical equipment provided to rural residing seniors would be delayed for 15 months.

History. The Cures Act first passed the House in July 2015 (see House welcomes 21st century medicine and hopes Senate is forward looking too, July 15, 2015). Funding disagreements in the Senate stalled its progress, as it was divided into multiple bills that passed committee but was never sent to the floor for a full vote. Earlier this year, the Senate Committee on Health, Education, Labor and Pensions (HELP) advanced the final five of 19 bipartisan pieces of legislation that would be incorporated as the Senate companion to the 21st Century Cures Act passed by the House (see Bills advance, aiming to improve the “health of virtually every American”, April 7, 2016).

Budgetary impact. Beyond the $6.3 billion price tag for the entire package, the Congressional Budget Office (CBO) estimated that the Cures Act as sent to the House and in an amended version (H.R. 34, a separate bill to which the amended version of the Cures Act was appended), would have savings of $873 million offset with expenditures of $872 million for a net gain of $1 million to federal coffers. The expenditures are funds allocated to the National Institutes of Health (NIH) and FDA innovation programs, as well as additional state funding to address the opioid epidemic. In subsequent years, any savings generated would be offset by similar amounts of expenditures. The CBO also projected that the Cures Act would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2027.

Senate opposition. Although the Cures Act is expected to pass the Senate, some senators oppose the health care package. Senators Elizabeth Warren (D-Mass) and Bernie Sanders (I-Vt) have said the Cures Act includes too many concessions to the pharmaceutical industry.

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Sen. Warren remarked in a strongly worded Senate floor speech that the Cures Act did not address the medical innovation as originally intended, but instead "extorted" special favors in the form of campaign donations and protections for the pharmaceutical industry. According to Warren, adjusted for inflation, federal spending on medical research over the last 12 years has been cut by 20 percent. As such, the Cures Act did not significantly invest in medical research.

Instead, Sen. Warren noted that the Cures Act would allow drug makers more leeway in making off-label marketing claims and pushing treatments without scientific evidence. She also highlighted the dangers of drug and device companies profiting from bringing unproven treatments to market.

Sen. Sanders issued a brief statement decrying the Cures Act for its "corporate giveaways" and cutting Medicare and Medicaid by $1 billion, while not even guaranteeing funding for medical research or substance abuse treatment.

The Senate will take up the Cures Act on a vote early next week and President Obama has indicated that he would sign it into law if it clears that chamber.