

Wide-Ranging 21st Century Cures Act Signed into Law

On December 13, 2016, 38 days before leaving office, President Obama signed into law the *21st Century Cures Act*.¹ The law, considered by legal experts to be the “most comprehensive healthcare legislation to be enacted since the Patient Protection and Affordable Care Act [ACA] of 2010,”² covers a wide variety of topics related to healthcare delivery, administration, and research, including:

- (1) Mental Health Treatment;
- (2) Biomedical Research;
- (3) Opioid Addiction Treatment;
- (4) Billing for Off-Campus *Hospital Outpatient Departments* (HOPDs);
- (5) ACA Health Insurance Exchanges; and,
- (6) The *Hospital Readmissions Reduction Program* (HRRP).³

The law is expected to impact providers in a multitude of ways, including the delivery of mental health services and modifications to certain quality programs and site-of-service requirements. However, the ultimate effect of the law on healthcare delivery is still unclear, as Congress delegated implementation of numerous aspects of the law to various federal agencies. This *Health Capital Topics* article will summarize the important provisions of the *21st Century Cures Act* as it relates to healthcare providers and discuss the potential benefits, as well as stated criticisms, of the legislation.

The *21st Century Cures Act* contains numerous provisions related to the treatment of mental health and substance abuse problems (in particular, opioid addiction), including:

- (1) Section 14003, which requires the U.S. Department of Justice to establish a pilot program to test the effectiveness of mental health and drug courts to divert persons with mental illness and substance abuse disorders from prison;⁴
- (2) Section 6001, which creates the office of the “Assistant Secretary for Mental Health and Substance Use,” which reports to the Secretary of the U.S. Department of Health and Human Services (HHS), to oversee mental health and substance abuse response efforts in HHS;⁵
- (3) Sections 13001 and 13002, which seek to strengthen mental health parity laws by mandating the creation of guidance to develop compliance programs detecting violations of

federal law relating to mental health, as well as requiring the development of an “action plan” among federal agencies tasked with enforcing mental health parity laws;⁶

- (4) Section 9003, which creates a grant program to provide funding that promotes the development of integrated care models between primary care providers and behavioral health providers;⁷ and,
- (5) Sections 8001-8004, which create block grant programs targeted at providers of mental health and substance abuse treatment.⁸

Additionally, the law earmarks \$1 billion to be distributed to states over a two-year period to combat opioid abuse.⁹ The law contains a non-exhaustive list of acceptable uses of grant money for opioid addiction treatment, including prescription drug monitoring, development of addiction prevention programs, and training for healthcare providers to identify opioid abuse and safely prescribe opioids to patients.¹⁰

In addition to provisions targeting the treatment of mental health and substance abuse disorders, the *21st Century Cures Act* includes provisions related to the funding of biomedical research, as well as the approval of drugs, devices, and therapies stemming from such research. The law earmarks approximately \$4.8 billion of research funding for the National Institutes of Health,¹¹ which funding is subdivided into a variety of projects, e.g.:

- (1) Cancer Research – \$1.8 billion.¹²
- (2) Neurological Disease Research – approximately \$1.5 billion; and,¹³
- (3) Precision Medicine – approximately \$1.4 billion.¹⁴

Additionally, the law provides new avenues for medical device approval by the U.S. Food and Drug Administration (FDA). In particular, Section 3501 of the law provides for the creation of an expedited approval process by the FDA for “breakthrough devices.”¹⁵ Under the law, a “breakthrough device” is a medical device submitted for FDA approval:

- (1) “[T]hat provide[s] for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; **and**,
- (2) “[T]hat represent[s] breakthrough technologies:
 - (a) “[F]or which no approved or cleared alternatives exist;”

- (b) “[T]hat offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients’ ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; **or**,”
- (c) “[T]he availability of which is in the best interest of patients.”¹⁶ [Emphasis Added]

The law delegates to the FDA the responsibility of developing the exact timing and requirements of this streamlined approval process through the release of proposed and final regulations, with initial guidance to be released by December 2017.¹⁷

While the *21st Century Cures Act* primarily targets biomedical research and the treatment of mental health and substance abuse disorders, the law also addresses areas within the healthcare delivery system that have been the subject of controversy in recent years. First, the law broadens the original exceptions to the prohibition against off-campus HOPDs billing under Medicare’s *hospital outpatient prospective payment system* (HOPPS) promulgated under the *Bipartisan Budget Act of 2015*. Originally, Section 603 of the *Bipartisan Budget Act of 2015* prevented off-campus HOPDs that expected to begin billing Medicare after November 2, 2015, from utilizing the HOPPS as the primary form of facility reimbursement after December 31, 2016.¹⁸ However, this law provided for two exceptions to the HOPPS billing prohibition:

- (1) HOPDs that qualified as a “*Designated Emergency Department*,”¹⁹ or,
- (2) *Grandfathered facilities*, i.e., off-campus HOPDs receiving Medicare reimbursement under the HOPPS prior November 2, 2015.²⁰ (For a further discussion regarding these exceptions, please reference the December 2015 *Health Capital Topics* article, entitled, “*Congress Changes Reimbursement Rules for Off-Campus Facilities*.”²¹)

The *21st Century Cures Act* expands the exception related to *grandfathered facilities* under the *Bipartisan Budget Act of 2015* in two forms. First, for calendar 2017, an off-campus HOPD fits within the *grandfathering* exception if HHS had received an attestation from the provider that the facility would operate as an off-campus HOPD – and therefore bill under the HOPPS – by December 2, 2015.²² Second, for calendar years 2018 and beyond, an off-campus HOPD fits within the *grandfathering* exception if:

- (1) The provider submits an attestation to HHS within sixty (60) days after the passage of the *21st Century Cures Act* (i.e., by mid-February 2017) that the HOPD meets the requirements to be considered an HOPD under the Medicare program;

- (2) The provider includes the HOPD on its Medicare enrollment form with HHS; and,
- (3) The subject HOPD was “*mid-build*” (i.e., the provider “*had a binding written agreement with an outside unrelated party for the actual construction of [the HOPD]*”) as of November 2, 2015.²³

Additionally, the *21st Century Cures Act* provides for a small but potentially significant modification to the tax treatment of health insurance coverage that may influence participation in the health insurance exchanges created under the ACA. Section 18001 of the *21st Century Cures Act* makes it permissible for small businesses to subsidize the cost of out-of-pocket medical expenses and premiums that are incurred by their employees without incurring a tax burden with the Internal Revenue Service, starting in 2017.²⁴ The provision, which was originally included in the *Small Business Health Care Relief Act of 2016*, but was ultimately consolidated into the final *21st Century Cures Act*, is designed to encourage small businesses to provide financial support to their employees to obtain health insurance coverage through the use of health reimbursement accounts.²⁵ However, the provision may secondarily encourage participation in the ACA-established individual health insurance marketplaces. First, the law may provide a financial incentive that indirectly prompts consumers to enter the ACA-established marketplaces for individual health insurance products, as consumers may become less price-sensitive to the costs of health insurance in light of their employer’s contributions.²⁶ Second, if the provision does increase the number of persons in the individual health insurance market, the risk pool within this sector may diversify, likely with healthier, less costly beneficiaries enrolling in this market, in comparison to many current participants who are less healthy, and therefore more expensive to insure.²⁷

In another noteworthy provision, the *21st Century Cures Act* modifies Medicare’s HRRP program to account for *dual eligibles*, i.e., patients that possess coverage under both the Medicare and Medicaid programs. HRRP, established under the ACA, is intended to reduce the number of unintended hospital readmissions for conditions such as acute myocardial infarction, heart failure, and pneumonia.²⁸ To accomplish this goal, the program reduces a hospital’s Medicare Severity Diagnosis Related Group payment rates based on a hospital’s ratio of *expected readmissions* to *actual readmissions*, with reductions of three (3) percent in fiscal year 2015 and beyond.²⁹ Critics of HRRP, including the American Hospital Association, noted that the program, as originally established, did not account for socioeconomic factors in the calculation of its penalties, which negatively impacted hospitals serving vulnerable populations such as *dual eligibles*.³⁰ The *21st Century Cures Act* attempts to address this issue by creating an “*adjustment factor*” to account for *dual eligibles* when determining penalties under HRRP.³¹ However, the overall impact of this change is yet uncertain, as the law delegates to HHS the responsibility to determine the

exact nature of the “*adjustment factor*,” which must be implemented by fiscal year 2019.³²

The ultimate impact of the *21st Century Cures Act* remains unknown. The law has been praised by pharmaceutical companies for increasing research funding and streamlining the approval process for certain drugs and medical devices.³³ Further, hospital groups have applauded Congress for decreasing HRRP penalties for safety-net hospitals treating a disproportionate share of *dual eligibles*.³⁴ However, patient safety groups have criticized the law’s provisions related to the streamlined drug and device approval process, arguing that loosening

approval requirements for drugs and medical devices may negatively impact patient safety.³⁵ Further, critics to the law, including members of Congress, have argued that the bill does not fund enough research into innovative medical treatments for rare and chronic diseases.³⁶ Synthesizing these competing perspectives may be difficult currently, as the law assigns the task of implementing many of its provisions to various regulatory bodies. Providers should follow regulatory changes implementing the *21st Century Cures Act*, as well as prepare to meet applicable deadlines set forth in the law, including those related to off-campus HOPDs.

- 1 “Actions: H.R.34 – 21st Century Cures Act” Congress.gov, 2017, <https://www.congress.gov/bill/114th-congress/house-bill/34/actions> (Accessed 1/5/17).
- 2 “The 21st Century Cures Act” By Matthew Horton, American Health Lawyers Association, AHLA Practice Groups E-mail Alert, December 19, 2016.
- 3 “21st Century Cures Act” H.R. 34, 114th Cong. (December 13, 2016).
- 4 *Ibid.* § 14003(b).
- 5 *Ibid.* § 6001(a).
- 6 *Ibid.* § 13001(a), 13002(a)(1).
- 7 *Ibid.* § 9003(a).
- 8 *Ibid.* § 8001-8004.
- 9 *Ibid.* §1003(b)(2)(A).
- 10 *Ibid.* §1003(c)(2).
- 11 *Ibid.* §1001(b)(2)(A).
- 12 *Ibid.*
- 13 *Ibid.*
- 14 *Ibid.*
- 15 *Ibid.* §3051(a).
- 16 *Ibid.*
- 17 *Ibid.*
- 18 “Bipartisan Budget Act of 2015” H.R. 1314, 114th Cong., § 603, (October 30, 2015).
- 19 *Ibid.*
- 20 *Ibid.*
- 21 “Congress Changes Reimbursement Rules for Off-Campus Facilities” Health Capital Topics, Vol. 8, No. 12 (December 2015).
- 22 “21st Century Cures Act” H.R. 34, 114th Cong., §16001(a)(1)(B), (December 13, 2016).
- 23 *Ibid.*
- 24 *Ibid.* §18001.
- 25 “Small Business Health Care Relief Act of 2016 – Report” U.S. House of Representatives, Committee on Ways and Means, June 21, 2016, <https://www.congress.gov/114/crpt/hrpt634/CRPT-114hrpt634-pt1.pdf> (Accessed 1/4/17) p. 9. The Small Business Health Care Relief Act of 2016 was included in the version of the 21st Century Cures Act signed into law. “Related Bills – H.R.34 – 114th Congress (2015-2016): 21st Century Cures Act” Congress.gov, 2017, <https://www.congress.gov/bill/114th-congress/house-bill/34/related-bills> (Accessed 1/5/17).
- 26 “Could a Provision in the Cures Act Help Stabilize the ACA Exchanges?” By Shelby Livingston, Modern Healthcare, December 16, 2016, <http://www.modernhealthcare.com/article/20161216/NEWS/161219918/could-a-provision-in-the-cures-act-help-stabilize-the-aca-exchanges> (Accessed 1/4/17).
- 27 “New Law Eases Small Business Health Care Burden (But May Make Repealing ObamaCare Harder)” By Robb Mandelbaum, Forbes, December 14, 2016, <http://www.forbes.com/sites/robbmandelbaum/2016/12/14/repealing-obamacare-just-got-harder-thanks-to-small-business-relief-in-21st-century-cures-act/print/> (Accessed 1/4/17).
- 28 “Readmissions Reduction Program” Centers for Medicare and Medicaid Services, August 4, 2014, <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program.html> (Accessed 2/4/2015).
- 29 “Hospital readmissions reduction program” 42 U.S.C. § 1395ww(q) (2013).
- 30 “Rethinking the Hospital Readmissions Reduction Program” American Hospital Association, March 2015, <http://www.aha.org/research/reports/tw/15mar-tw-readmissions.pdf> (Accessed 1/4/17) p. 1; “The Medicare Hospital Readmissions Reduction Program: Potential Unintended Consequences for Hospitals Serving Vulnerable Populations” By Qian Gu, et al., Health Services Research, Vol. 49, No. 3 (June 2014) p. 830.
- 31 “21st Century Cures Act” H.R. 34, 114th Cong., §15002(a)(2), (December 13, 2016).
- 32 *Ibid.*
- 33 “Sweeping Health Measure, Backed by Obama, Passes Senate” By Jennifer Steinhauer and Robert Pear, The New York Times, December 7, 2016, http://www.nytimes.com/2016/12/07/us/politics/21st-century-cures-act-senate.html?_r=0 (Accessed 1/4/17).
- 34 “Will the 21st Century Cures Act Level the Playing Field on Hospital Readmissions?” By Elizabeth Whitman and Steven Ross Johnson, Modern Healthcare, December 13, 2016, <http://www.modernhealthcare.com/article/20161213/NEWS/161209902/will-the-21st-century-cures-act-level-the-playing-field-on-hospital> (Accessed 1/4/17).
- 35 “Congress Passes 21st Century Cures Act, Boosting Research and Easing Drug Approvals” By Mike DeBonis, The Washington Post, December 7, 2016, https://www.washingtonpost.com/news/powerpost/wp/2016/12/07/congress-passes-21st-century-cures-act-boosting-research-and-easing-drug-approvals/?utm_term=.dcc00e1d1c51 (Accessed 1/4/17).
- 36 Steinhauer and Pear, December 7, 2016; “Editorial: The 21st Century Christmas Tree Act” By Merrill Goozner, Modern Healthcare, December 3, 2016, <http://www.modernhealthcare.com/article/20161203/MAGAZINE/312039985/editorial-the-21st-century-christmas-tree-act> (Accessed 1/4/17).



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