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The 21st Century Cures Act (H.R. 34)

Vizient Office of Public Policy and Government Relations – Legislative Summary

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The 21st Century Cures Act: Overview

On Wednesday, Dec. 7, the Senate passed the 21st Century Cures Act (H.R. 34) by a vote of 94-5. The legislation overwhelmingly passed the House with bipartisan support on Dec. 1. And President Obama signed the bill into law on Tuesday, Dec. 13. The legislation was designed to spur biomedical innovations, improve processes and provide new funding for the National Institutes of Health (NIH) and the Food and Drug Administration (FDA). While much of the focus of the legislation was centered on the changes to processes in place within the NIH and FDA, the legislation also includes a number of provisions that are important to hospitals and health systems. Vizient has [voiced its support](#) for passage of the revised [21st Century Cures Act](#).

In total, the act authorizes approximately \$6.3 billion in new spending. These investments have the potential to markedly enhance health care delivery, and improve the lives of patients across the country. Specifically, the bill authorizes \$4.8 billion for the NIH to support new initiatives around precision medicine, cancer, neuroscience, and regenerative medicine. It provides \$500 million over 10 years to the FDA to facilitate the development of new drugs and devices, drug therapies, antimicrobials, and medical countermeasures. In addition, the funding also includes provisions related to modernizing clinical trials, the development of evidence, and improving patient access to therapies and information. And finally, the bill includes more than \$1 billion over two years for grants to states to help address the opioid epidemic, as authorized under the [Comprehensive Addiction and Recovery Act](#) that was signed into law earlier this year.

Key Takeaways:

- The bipartisan legislation incorporates a number of hospital priorities sought throughout the year. Specifically, provisions to allow new under-construction off-campus hospital outpatient departments to be grandfathered in under the outpatient payment system and major changes to hospital readmission reduction program have been key advocacy goals for many hospitals.
- The bill also includes positive changes promoting interoperability, aiming to prevent information blocking and other improvements to electronic health records (EHR) incentive programs as well as a meaningful bipartisan effort to improve the delivery of mental and behavioral health.
- While the bipartisan bill includes a number of provisions supported by hospitals and other health care advocates, the legislation has also faced criticism for eliminating \$3.5 billion in funding for the Prevention and Public Health Trust Fund established by the Affordable Care Act. In addition, some have raised concerns that the bill's changes within the FDA could lead to less stringent safety reviews for certain drugs and devices.

Key Hospital Provisions:

Services Furnished by Mid-build Off-campus Outpatient Departments: Section 603 of the Bipartisan Budget Act of 2015 made a change to prohibit new, off-campus outpatient departments from being reimbursed under the Outpatient Prospective Payment System (OPPS) rate. Under that law, and subsequent regulations, new facilities would be paid at a lower rate under another Part B payment system. The Cures bill revises that law and extends grandfather protection to allow some HOPDs that narrowly missed the Nov. 2, 2015 deadline, but already have opened or will soon open, to qualify for the higher OPPS rate. Specifically, for purposes of items and services furnished in 2017, if CMS received an attestation from a hospital prior to Dec. 2, 2015 indicating that their department was a provider-based department of the hospital, the HOPD would be fully grandfathered, even if they were not providing services and billing Medicare under the OPPS before Nov. 2, 2015.

While this new exception benefits only hospitals with complete projects that fell just short of the furnishing services deadline, another exception in the bill may apply to more facilities. For services furnished on or after Jan. 1, 2018, the new legislation would exclude from the site-neutral policy, off-campus outpatient department locations that had a "binding written agreement with an outside unrelated party for the actual construction" of the new off-campus outpatient

department before Nov. 2, 2015. **To be eligible under this alternative exception, the hospital must also:** (1) file a provider-based attestation for the new off-campus outpatient department not later than December 31, 2016 (or, if later, within 60 days of the date of the enactment of the legislation), (2) submit a certification to CMS within 60 days of the date of the enactment that the hospital had the required binding written construction agreement, and (3) add the off-campus outpatient department to the host hospital's Medicare enrollment form.

While the more narrow relief for off-campus outpatient departments with provider-based attestations filed before Dec. 2, 2015, would be applicable only for 2017, the broader relief for off-campus outpatient departments with construction agreements in place as of Nov. 2, 2015, (which would include hospitals eligible for the 2017 exception) would not be available until Jan. 1, 2018. Hospitals able to take advantage of only the broader relief would not be eligible for OPPI payments during 2017 and instead would be subject to lower modified payments until Jan. 1, 2018. **However, the alternative exception would impact payments for items and services furnished in 2018 and beyond.** CMS will audit each of the HOPDs that were grandfathered under the alternative exception for compliance with these provisions by Dec. 31, 2018.

Establishing Beneficiary Equity in the Medicare Hospital Readmission Program: The 21st Century Cures Act also calls for CMS, in consultation with the Medicare Payment Advisory Commission (MedPAC), to modify the Hospital Readmissions Reduction Program (HRRP) to account for the socioeconomic status of patients in a hospital's community. This consideration is something that Vizient, along with other hospital groups, has lobbied for in recent years. Beginning in FY 2019, CMS will be required to make a "transitional adjustment" in which it assigns each hospital to groups based on the proportion of patients dually eligible for Medicare and Medicaid, and compares each hospital's performance to others within its dual-eligible grouping. The bill would allow for additional changes, and requires MedPAC to report to Congress to assess whether changes in readmission performance are related to changes in the utilization of outpatient and emergency department services. It also would require CMS to assess whether it could use V codes and other ICD codes to exclude non-compliant patients from the calculation of readmissions performance; and assess whether it should exclude burns, trauma, psychosis, end-stage renal disease and substance abuse patients from the calculation of hospital readmission performance.

Development of Medicare Study for HCPCS Versions of MS-DRG Codes for Similar Hospital Services: The bill requires, no later than Jan. 1, 2018, the creation of a crosswalk between HCPCS codes (outpatient) and ICD-10-PCS codes (inpatient) for no fewer than 10 surgical Medicare-Severity diagnosis-related groups (MS-DRGs). CMS is required to develop a HCPCS MS-DRG definitions manual and software for ICD-10-PCS codes for these 10 DRGs. It will be posted on the CMS website and available for public use/redistribution without charge. In doing this, CMS will consult with MedPAC and consider the MedPAC analysis related to short inpatient stays.

Other Hospital Provisions:

The legislation provides for a five-year extension of the **Rural Community Hospital Demonstration Program**. It also extends relief from the **25% rule** for long-term care hospitals until Sept. 30, 2017. The bill requires that the Secretary of HHS make available a searchable database that provides **Medicare Site-of-Service Transparency**. That database should include information related to items and services furnished in hospital outpatient departments and ambulatory surgical centers – including the estimated payment amount and estimated beneficiary liability for the item or service. Under the bill, CMS will also be prohibited from enforcing the "**direct supervision**" regulations for outpatient **therapeutic services** provided in critical access hospitals and certain small, rural hospitals for CY 2016. As an offset for other costs in the bill, the legislation also includes a small reimbursement reduction of 0.041% in FY2018 relating to restoration of previous coding cuts.

Mental Health Reforms

The 21st Century Cures Act prioritizes behavioral health within HHS by creating an Assistant Secretary for Mental Health and Substance Use, makes broad grant reforms, and includes numerous provisions including strengthening the behavioral health workforce and improving mental health care parity and integration with physical health services. It also establishes a new grant program to promote behavioral health integration in pediatric primary care by supporting statewide or regional pediatric mental health care telehealth access programs.

Medicaid Mental Health Coverage: This section clarifies that Medicaid allows separate payment for the provision of primary care and mental health services at a facility on the same day. It also requires a study and report to Congress about coverage of services provided through Medicaid managed care organizations or prepaid inpatient health plans with respect to individuals over the age of 21 and under the age of 65 for the treatment of mental health disorders in institutions for mental disease. Further, CMS will be required to issue guidance to state Medicaid programs about opportunities to design innovative service delivery systems for adults with a serious mental illness or children with a serious emotional disturbance. The guidance must include opportunities for section 1115 demonstration projects, which could provide much greater flexibility for states to cover patients in other settings such as Institutions for Mental Disease.

Promoting Access to Mental Health and Substance Use Disorder Care: This section of the legislation primarily establishes, reauthorizes, and/or updates various behavioral health-related grant programs, such as those aimed at integrating primary and behavioral health care; preventing suicide; providing mental health and substance use disorder treatment services for homeless individuals; and supporting education and training of the behavioral health workforce. It also changes a program that helps designate hospitals as Emergency Mental Health Centers; it will now enhance community-based crisis response systems and help states develop and maintain databases of beds at treatment facilities.

Health Information Technology (IT)

Interoperability: The 21st Century Cures Act includes a provision that defines interoperability and sets forward steps for the creation of a trusted exchange framework and common agreement for sharing health information. It also creates a new Health IT Advisory Committee to combine and replace the existing Health IT Policy and Standards Committees.

Electronic Health Records (EHRs): The Secretary of HHS must establish a goal, strategy and recommendations to reduce the regulatory or administrative burdens related to the use of EHRs. The Secretary is required to encourage, keep or recognize the voluntary certification of health IT for use in medical specialties and sites of service for which no such technology is available. The Secretary must make recommendations for the voluntary certification of health IT for use by pediatric health providers. Eligible professionals and hospitals in the Medicare EHR Incentive Program and eligible professionals in the Medicare Merit-Based Incentive Payment System (MIPS) will be exempt from payment adjustments if compliance with program requirements is not possible due to the decertification of EHR technology.

Treatment of Eligible Professionals in Ambulatory Surgical Centers (ASCs) for Meaningful Use and MIPS: This section protects eligible professionals that deliver substantially all of their care in ambulatory surgical centers from cuts under the Medicare EHR Incentive Program in 2017 and 2018. Protections continue under MIPS until three years after the Secretary of HHS determines, through rulemaking, that certified EHRs are available for the ASC setting.

Telehealth in Medicare: CMS and MedPAC are required to provide information regarding the potential expansion of telehealth to Congress, including the types of Medicare beneficiaries who could benefit from expanded telehealth services, testing of expanded telehealth, high-volume services that might be appropriately provided via telehealth, and barriers to telehealth expansion, as well as how Medicare could provide telehealth coverage.