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President Obama Signs 21st Century Cures Act Into Law

On December 13, 2016, President Barack Obama signed H.R. 34, the 21st Century Cures Act (the Act), into law. This sweeping healthcare law addresses the discovery, development and delivery of new drugs and medical treatments; it also includes substantial mental health reforms and assorted Medicare- and Medicaid-related provisions.

The law is a product of the bipartisan 21st Century Cures Initiative, spearheaded by US House of Representatives Committee on Energy and Commerce Chairman Fred Upton (R-MI) and Representative Diana DeGette (D-CO). The Initiative held various events and authored policy papers on topics such as innovating public health agencies, incorporating patient perspectives into the regulatory process, and improving medicine and medical product regulation. The House passed a first version of the bill in July 2015.

On the other side of the Capitol, US Senate Committee on Health, Education, Labor and Pensions (HELP) Chairman Lamar Alexander (R-TN) and Ranking Member Patty Murray (D-WA) worked diligently on medical innovation legislation this past year, holding hearings and favorably reporting several pieces of legislation. The majority of these bills, however, did not reach the Senate floor.

Prior to the November elections, Senate Majority Leader Mitch McConnell (R-KY) and House Speaker Paul Ryan (R-WI) signaled their commitment to passing this legislation during the lame duck session, and the Act is a product of post-election bipartisan and bicameral negotiations.

The Act, which totals over 300 pages, includes many provisions of interest to healthcare providers. Highlights regarding care delivery and Medicare reimbursement include:

- **EHR Interoperability**: The Act addresses interoperability of electronic health records (EHRs) by creating a model framework to securely exchange health information between networks. The Act seeks to promote the exchange of information between patient registries and EHR systems and allows the US Department of Health and Human Services (HHS) Office of the Inspector General (OIG) to investigate information blocking claims and penalize practices interfering with the lawful sharing of medical information. (Secs. 4003-4005)
- **Telehealth**: The Centers for Medicare & Medicaid Services (CMS) and the Medicare Payment Advisory Commission (MedPAC) are required to inform Congress on the current use and limitations of telehealth services in the US. The provision underscores the need for a long-term solution for coverage of telehealth services and stresses the importance of covering telehealth services for Medicare beneficiaries as if the services were received in an in-person office setting. (Sec. 4012)
- **Hospital Readmissions**: CMS is required to implement a transitional risk adjustment methodology, based on a hospital's proportion of dual-eligible beneficiary patients, when assessing hospital readmission penalties. (Sec. 15002)
- **Payment Updates**: The annual reimbursement update of the Inpatient Prospective Payment System is reduced from an increase of 0.5% to 0.4588% in FY 2018. (Sec. 15005)
- **Long-Term Care Hospitals**: Under rules that went into effect in July 2016, Long-Term Care Hospitals (LTCHs) receive a lower reimbursement rate if more than 25% of their total annual Medicare patient population came from a single inpatient acute care hospital. This legislation reinstates the previous 50% threshold through October 2017. (Sec. 15006)

  Certain nonprofit LTCHs specializing in the treatment of spinal cord and acquired brain injuries are exempted from the lower site-neutral reimbursement rate for FY 2018 and FY 2019. LTCHs treating specific types of severe wounds are also exempted from the lower site-neutral rate in FY 2018. (Secs. 15009-15010)
- **Hospital Outpatient Departments**: Section 603 of the Bipartisan Budget Act of 2015 (BBA) effectively reduced Medicare compensation paid to new off-campus hospital outpatient departments (HOPDs) beginning January 1, 2017, by eliminating HOPD eligibility for compensation under Medicare's Hospital Outpatient Prospective Payment System (OPPS). Notably, the BBA contained no exception for HOPDs under development at the time of its passage. The Act corrects this by providing that HOPDs that (i) are the subject of a binding written agreement for construction, with an outside related party effective prior to November 2, 2015; and (ii) submit a provider-based attestation within 60 days of the Act's enactment, will be considered "Grandfathered" HOPDs, and will be eligible for compensation under the OPPS. The Act also contains certain exceptions for cancer hospitals. (Sec. 16001-16002)
- **Critical Access Hospitals**: The Act exempts Medicare providers for calendar year 2016 from enforcing the supervision requirements, originally finalized by CMS in 2008, for services and supplies provided in critical access hospitals. It also directs MedPAC to report to Congress within one year on whether the supervision exemption has impacted access to care for Medicare beneficiaries. (Sec. 16004)

The Act includes cost offsets, determined after months of negotiations. The offsets include: a drawdown of the strategic petroleum reserve; reductions in funding available from the Affordable Care Act, including the Prevention and Public Health Fund and funding available to territories; limitations of federal Medicaid reimbursement to states for durable medical equipment, prosthetics, orthotics and supplies to Medicare reimbursement rates; elimination of federal Medicaid matching funds for prescription drugs used for cosmetic purposes or hair growth, unless medically necessary; increased oversight of termination of Medicaid providers; and measures to reduce Medicare spending, including provisions focusing on payments for infusion drugs and home infusion drug services, and contracting and fraud penalties. (Secs. 5001-5012)

If you would like to discuss the implications of the Act for your business, or would like more information on expected legislation in the 115th Congress, please speak to one of the individuals listed in this publication or your firm contact.

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