

## 21<sup>st</sup> Century Cures Act (H.R. 34) Summary of Key Provisions

### Hospital-Related Provisions

- Revises the 2015 Bipartisan Budget Act to provide relief from site-neutral Medicare payments for hospital outpatient departments (HOPDs) considered to be “under development” at the time of enactment. H.R. 34 would move the grandfather date for these HOPDs from Nov. 2, 2015, to Dec. 31, 2016, or 60 days after enactment, whichever is later. Current law reimburses grandfathered facilities at the outpatient prospective payment system (OPPS) rate, while new facilities are paid at a lower rate.
- Adjusts the Hospital Readmissions Reduction Program to account for socioeconomic status.
- Prohibits the Department of Health and Human Services (HHS) from enforcing the “direct supervision” regulations in calendar year 2016 for outpatient therapeutic services provided in Critical Access Hospitals and certain small, rural hospitals.
- Extends the Rural Community Hospital Demonstration Program for five years.
- Provides one full year of relief from the long-term care hospital 25 percent rule.
- Requires HHS to translate inpatient hospital codes (International Classification of Disease) to outpatient hospital codes (Healthcare Common Procedure Classification System) for 10 surgical procedures. This “crosswalk” is required to be completed no later than Jan. 1, 2018.

### Authorized Funding

- \$4.8 billion over 10 years to the National Institutes of Health (NIH) for the Precision Medicine Initiative, the Brain Research Through Advancing Innovative Neurotechnologies Initiative, cancer research and regenerative medicine using adult stem cells. Authorizes funding for President Obama’s precision medicine initiative, the cancer “moonshot” effort and Alzheimer’s research.
- \$500 million to the Food and Drug Administration (FDA) over 10 years to implement provisions in Title III to move drugs and medical devices to patients more quickly.
- \$1 billion over two years to support programs included in the Comprehensive Addiction and Recovery Act, which was enacted earlier in 2016. Funding will support grants to states to supplement opioid abuse prevention and treatment activities, such as improving prescription drug monitoring programs, implementing prevention activities, training for health care providers and expanding access to opioid treatment programs.

It should be noted that the 21<sup>st</sup> Century Cures Act authorizes, but does not provide, funding. Instead, the funding will be provided through the appropriations process, which could reduce federal funding of other HHS programs.

### Mental Health Care Provisions

- Creates a new HHS Assistant Secretary for Mental Health and Substance Use.
- Reauthorizes suicide prevention programs and authorizes a minority fellowship program for mental health professionals.
- Authorizes grants for community treatment teams and assisted outpatient treatment for noncooperative patients.
- Clarifies that Medicaid can pay providers for the delivery of mental health and primary care services to a patient on the same day.
- Does not change 42 CFR Part 2, which requires patients to sign off on each provider who can view their substance abuse treatment records, but requires HHS to clarify the circumstances in which covered entities may disclose protected health information of a patient with a mental illness.

- Strengthens enforcement of parity rules for insurers to cover mental health care on the same level as physical health.
- Supports training of mental health professionals.
- Requires a costs and benefits study of Medicaid paying for inpatient mental health care treatment.

#### **Electronic Health Record and Telehealth Provisions**

- Establishes a grant program to create an unbiased reporting system to engage stakeholders and gather information about electronic health record (EHR) usability, interoperability and security to help providers better choose EHR products.
- Expedites interoperability among EHRs by developing or supporting a voluntary model framework and common agreement for the secure exchange of health information by:
  - Creating a digital health care provider directory to facilitate the exchange; and
  - Requiring HHS to defer to health information technology (HIT) standards developed in the private sector.
- Establishes authority for the HHS Office of the Inspector General to investigate claims of information blocking and assign penalties for practices found to be interfering with the lawful sharing of EHRs.
- Requires specific actions of government bodies identified as critical to developing a long-term solution to telehealth services under the Medicare program.

#### **Food and Drug Administration**

- Establishes an expedited pathway to approval for medical devices the FDA deems breakthrough devices.
- Directs the agency to evaluate data collected on the use of a drug in the real world to help support approval of a new use of an approved medicine.
- Allows the FDA to accept conditional approval of regenerative, or stem cell, therapies, to get them to patients more quickly and allows manufacturers to prove benefits while the products are on the market.

#### **Provisions Offsetting the Bill's Cost of \$6.3 Billion**

- Sets payment amounts for Part B drugs infused through durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) items using the methodology used for most physician-administered drugs: Average Sales Price (ASP) plus 6 percent.
- Rescinds \$3.5 billion over 10 years from the Prevention and Public Health Fund established under the Affordable Care Act (ACA).
- Rescinds \$464 million available to territories under the ACA.
- Directs the Department of Energy to sell a portion of the Strategic Petroleum Reserve, subject to certain conditions. Under the bill, the proceeds from such sales would be deposited in the general fund of the Treasury by the end of each fiscal year.

Additional information about the 21<sup>st</sup> Century Cures Act is available in a [section-by-section summary](#) prepared by the House Energy and Commerce Committee and House Ways and Means Committee.