21st Century Cures

Key Provisions of Proposed Legislation
November 2016

On November 25, House lawmakers introduced a revamped 21st Century Cures bill, reconciling the House and Senate versions of the bill. This legislation overhauls drug and device regulations to accelerate access to new drugs and treatments; incorporates House-passed legislation — the Helping Hospitals Improve Patient Care Act of 2016 (H.R. 5273) — that addressed payments to hospital outpatient departments and adjusted the readmissions reduction penalty for hospitals that care for a significant portion of dually eligible beneficiaries; and includes provisions relating to health information technology and behavioral health programs.

Most notably, this bill addresses:

**National Institutes of Health funding.** Provides $4.796 billion for fiscal years (FYs) 2017-26, including $1.4 billion for the Precision Medicine Initiative, $1.564 billion for the BRAIN Initiative, $1.802 billion for cancer research and $30 million for clinical research to further the field of regenerative medicine using adult stem cells. (Various sections.)

**Opioid abuse prevention.** Provides $1 billion for the Secretary to distribute among states in FYs 2017 and 2018 for opioid abuse prevention and response efforts. (Section 10003; page 27.)

**Medical rehabilitation research.** Sets new requirements. (Section 2040; page 93.)

**Antimicrobial resistance monitoring.** Among other provisions, requires new reporting requirements for hospitals and long-term care hospitals (LTCHs) related to antimicrobial stewardship activities; outcomes of those activities will be made publicly available in the future. Does not conflict with California state law. (Section 3041; page 204.)

**Information blocking.** Requires, as a condition of certification, that health information technology (HIT) developers do not take any action that constitutes information blocking, do not publish application programming interfaces and real-world test the use of such technology for interoperability purposes. Establishes penalties for practices found to be interfering with the lawful sharing of electronic health records (EHRs). (Sections 4002 and 4004; pages 335 and 382.)

**Meaningful use exemptions.** Provides for a statutory hardship exemption, subject to annual renewal, from meaningful use requirements for eligible hospitals, critical access hospitals (CAHs) and professionals, if the certified EHR technology they use has been decertified by the Office of the National Coordinator for Health Information Technology. (Section 4002; page 339.)
Setting goals to reduce burden. Requires the U.S. Department of Health and Human Services (HHS) to establish goals and develop a strategy to reduce regulatory and administrative burdens relating to the use of EHR, subject to broad comment and consultation with health care providers, HIT developers and other stakeholders. (Section 4001; page 328.)

Local coverage determinations. Places procedural requirements on contractors related to transparency of local coverage determinations. (Section 4010; page 408.)

Coding review. Creates a “Pharmaceutical and Technology” Ombudsman within the Centers for Medicare & Medicaid Services (CMS) with respect to coverage, coding and payment. (Section 4011; page 409.)

Transparency. Gives CMS $6 million to create a price transparency website to allow comparison between outpatient prospective payment system and ambulatory surgical center (ASC) Medicare payment amounts and associated beneficiary liability. (Section 4012; page 410.)

Telehealth. Requires MedPAC and CMS to report to Congress on telehealth services, including a “sense of the Congress” that eligible originating sites for Medicare payment under the telehealth benefit should be expanded. (Section 4013; page 412.)

DME infusion drugs. Requires durable medical equipment (DME) infusion drugs to be paid at 106 percent of average sales price, rather than 95 percent of the 2003 average wholesale price, and excludes DME infusion drugs from the Competitive Acquisition program. (Section 5004; page 422.)

Home infusion therapy. Creates a new Medicare benefit that will allow Medicare to pay for professional services including nursing services, training and education for home infusion therapy suppliers with a payment limit at the Medicare physician fee schedule amount for a five-hour infusion. (Section 5012; page 443.)

HCPCS MS-DRGs. Requires CMS to create a HCPCS MS-DRGs for at least 10 surgical MS-DRGs by January 1, 2018, along with a free, publicly available MS-DRG definition manual and software. (Section 15001, page 758.)

Readmissions. Tiers hospitals, based on the proportions of dually eligible individuals treated, for purposes of applying the readmissions reduction penalties. Authorizes factors the Secretary may consider for risk adjusting the readmissions program and allows the Secretary to consider removing transplants, end-stage renal disease, burns, trauma, psychosis or substance abuse from the readmissions program. This provision is budget-neutral. (Section 15002; page 760.)

Rural Community Hospital Demonstration program. Extends the program for five years. (Section 15003; page 765.)
**IPPS update.** Reduces the adjustment for restoring the inpatient prospective payment system documentation and coding recoupment adjustment from 0.5 percentage points to 0.4588 percentage points for FY 2018 and 0.5 for FY 2019-23. This adjustment is the cost of the implementing section 16001, noted below, related the hospital outpatient department (HOPD) mid-build provision. *(Section 15005; page 771.)*

**LTCHs.** Makes changes to the LTCH outlier threshold that are not budget neutral. *(Section 15004; page 768.)*

**LTCHs.** Extends moratorium on 25 percent rule for one year, to October 1, 2017. *(Section 15006; page 771.)*

**LTCHs.** Allows all LTCHs to exclude Medicare Advantage and site-neutral discharges from the 25-day average length of stay requirement, not just those that took advantage of the exception prior to December 26, 2013. *(Section 1507, page 773.)*

**HOPDs.** Grandfathers off-campus HOPDs that were “mid-build” as of the November 2, 2015, enactment of Section 603 of the Bipartisan Budget Act of 2015, if a number of provisions are met — including attestation to the provider-based regulations. Provides the Secretary with $10 million to audit compliance with the mid-build exception and remove the exception if the requirements are not met. **The provision does not include the more expansive exception for relocation of existing HOPD advocated by CHA.** Additional details of the mid-build provisions are detailed in [CHA’s legislative summary](#). *(Section 16001; page 783.)*

**HOPD cancer hospital exemption.** Exempts cancer HOPDs from Section 603, but requires them to attest to meeting the provider-based rules and gives the Secretary funds to audit the accuracy of those attestations. *(Section 16002: page 787.)*

**EHR and MIPS exclusions for physicians in ASCs.** Excludes physicians who furnish substantially all of their Medicare services at ASCs from penalties under the Electronic Health Records (EHR) Incentive program and the Merit-Based Incentive Payment System (MIPS), until three years after HHS determines that EHRs are available at the ASC setting. *(Section 16003; page 791.)*

**Outpatient department supervision rules.** Places a moratorium on direct supervision in CAHs and small rural hospitals, extended through the end of 2016, and requires MedPAC to report on the effect of the moratorium since its beginning. *(Section 16004; page 793.)*

**Behavioral health policy.** Seeks to restructure and reprioritize federal health care programs, oversight and funding, placing a significant focus on serious mental illness. *(Sections 6000-14029; page 455.) Specific policy areas include:

- enhancing state requirements under mental health and substance abuse block grants.
- authorizing a variety of grants, including funding dedicated to addressing workforce shortages and integrating primary and behavioral health care.
• improving access to pediatric, early childhood and maternal mental health services.
• clarifications on information sharing under the Health Information Portability and Accountability Act.
• addressing mental health coverage under Medicaid.
• directing a study and reporting on states — including California — that participated in the Medicaid Emergency Psychiatric Demonstration Project, which permitted payment for services provided to Medicaid enrollees aged 21 to 64 receiving treatment for a mental health disorder in an institution for mental diseases.
• enhancing compliance with mental health parity.
• improving the mental health response by law enforcement and within the criminal justice system.