

Health Policy Update – October 12, 2018

Senate Passes Historic Opioid Legislation Sending Final Bill to President Trump

On October 3, the Senate overwhelmingly passed the final package of legislation (the Opioid Crisis Response Act) to address the nation's opioid crisis by a 98-1 margin. The package, which was already approved by the House by a 393-8 vote, is expected to be signed by President Trump before the midterm elections.

The package ties together many proposals to help stem the tide of the nation's opioid epidemic. Once enacted, the legislation will help expand access to addiction treatment by creating a grant program for comprehensive recovery centers that include housing and job training, as well as mental and physical health care, increased access to medication-assisted treatment and Medicaid coverage for 30 days of residential treatment at an institution of mental health (IMD exclusion). A provision to allow healthcare providers greater leeway in sharing patients' substance use records was not included in the final package.

The passing of the bipartisan bill was welcomed, many public health advocates argue that more action is needed. Congress appropriated \$8.5 billion to implement the provisions within the bill, but that funding is seen as insufficient by many and is not guaranteed to reoccur in subsequent years.

To read a statement from Senate Majority Leader McConnell on the bill's passage, [CLICK HERE](#).

House Passes \$854B Spending Bill

On September 26, the House of Representatives passed an \$854 billion spending bill by a vote of 361-61. The vote came a week after the Senate passed an identical measure by a margin of 93-7. The spending package fully funds the Defense, Labor, Health and Human Services (HHS) and Education Departments for fiscal year 2019 which make up about two-thirds of the annual appropriations total for the year. The appropriations package is notable for being the first time in 10 years that the DoD appropriations bill has been passed on time and the first time in 22 years that Labor-HHS appropriations bill was passed on time. The package also included a continuing resolution (CR) extending current funding levels for any unfunded agencies through December 7, 2018.

Despite President Trump threatening to veto the bill for not including funding for his proposed border wall, he announced that he would sign it into law to avoid a government shutdown ahead of the midterm elections.

CMS Announces Participants in New Value-Based Bundled Payment Model

On October 9, the Centers for Medicare & Medicaid Services (CMS) announced that 1,299 entities—representing acute care hospitals and physician group practices – have signed agreements with the agency to participate in the Bundled Payments for Care Improvement – Advanced (BPCI Advanced) Model. The participating entities will receive bundled payments for 32 episodes of care (29 inpatient and 3 outpatient) as an alternative to fee-for-service payments.

Unlike the fee-for-service model which pays providers and suppliers for each service they perform, the new model will provide providers and suppliers with an additional payment if all expenditures for a beneficiary's episode of care are

less than a spending target, which factors in measures of quality. However, if the providers and suppliers spend more than the target price for an episode, they will be required to refund Medicare. The model will run from October 1, 2018 to December 31, 2023.

To read the full announcement from CMS, [CLICK HERE](#).

CMS to Strengthen Oversight of Medicare's Accreditation Organizations

On October 4, the Centers for Medicare & Medicaid Services (CMS) announced it is taking steps to enhance transparency, improve quality and safety of healthcare facilities, empower patients with key information to choose their own settings of care, and improve the oversight of Accrediting Organizations (AO).

CMS will begin posting performance data for Accrediting Organizations online, including complaint surveys, compliance information, and performance data. CMS also pledged to post the most recent annual report to Congress on AO performance online to further enhance transparency and accountability.

Finally, it will launch a pilot for testing direct observation for AO validation surveys to assess providers' and suppliers' compliance with health and safety standards. The direct observation will supplant the second-round of validation surveys that CMS has previously used to assess the reliability of accountability mechanisms in order to reduce duplication of work and undue burdens on healthcare facilities.

To read the full announcement from CMS, [CLICK HERE](#).

To read the most recent annual Report to Congress, the "Review of Medicare's Program for Oversight of Accrediting Organizations and the Clinical Laboratory Improvement Validation Program Fiscal Year 2017," [CLICK HERE](#).

Hospitals Urge Lawmakers to Protect 340B Drug Discount Program

In light of recent legislative proposals and regulations regarding the 340B drug discount program, over 700 hospitals and health systems are asking the House and Senate to reconsider actions which providers say will undermine the safety net and "undo more than two decades of bipartisan work."

The letter refers to the 2018 hospital outpatient pay rule which reduced hospitals' Medicare payments for 340B drugs percent to ASP -22.5 percent – something which has resulted in two lawsuits by the Association of American Medical Colleges and America's Essential Hospitals. Although hospital off-campus facilities continued to receive higher payments due to specific site neutrality provisions within the Bipartisan Budget Act of 2015 –CMS is now proposing to expand the reduced reimbursement rate to those facilities as well.

Other hospitals have expressed disappointment with the Health Resources and Services Administration's repeated delay for implementation of the 340B ceiling price and penalties rule. Even though some groups have sued HRSA to force implementation of the rule, a final outcome is still uncertain.

To read the full letter to Congress, [CLICK HERE](#).

CMMI Chief Adam Boehler Comments on ACO Participation

On October 4, Center for Medicare & Medicaid Innovation (CMMI) Chief Adam Boehler told accountable care organizations (ACOs) that, in return for providing transparent and predictable value-based care models, ACOs must be held accountable for their care. Those ACOs who failed to meet higher standards of accountability, according to Boehler, should be replaced by others who can.

Boehler argues that his agency only seeks to increase the simplicity and clarity of value-based health care models for patients, however many ACOs have expressed concern that finding replacement ACOs will be difficult.

To accommodate their most recent proposal to overhaul the Medicare Shared Savings ACO program, CMS has given ACOs only two years to begin providing the agency with savings and losses information. Reiterating his commitment to transparency, Boehler assured accountable care organizations that providing value-based care does not mean increasing financial risks to their bottom line.

The National Association of ACOs (NAACOS) has criticized the infeasibility of finding replacement ACOs, but also the unrealistic speed which CMS expects ACOs to take on risk.

CMS Updates Local Coverage Determination (LCD) Process

Pressured by stakeholders frustrated with ambiguities and inconsistencies within the local coverage determination (LCD) process, the Centers for Medicare & Medicaid Services (CMS) recently updated its Medicare Program Integrity Manual. The goal of the revamp, according to CMS, is to increase transparency and encourage stakeholder engagement in the LCD and Medicare administrative contractor (MAC) processes.

In the absence of national coverage rules, MACs assist in deciding the coverage of specified goods and services in local markets, known as LCDs. The recently proposed changes come as a result of CMS's Patients Over Paperwork Initiative, as well as requirements established under the 21st Century Cures Act which sought to increase accountability of the LCD process.

Some of the most important changes include allowing stakeholders to request meetings with MACs to discuss LCDs, establishing a clear-cut process that MACs must follow for LCDs and requiring MACs to publish evidence summaries explicating LCD decisions and the rationale behind such decisions, among other things.

The changes proposed by CMS come in conjunction with Congressional attempts to revitalize the LCD process through recent [legislation](#).

OIG Report: Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials

In a study published by the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS), officials sought to determine whether the capitated payment model utilized in Medicare Advantage provided a

possible incentive for Medicare Advantage Organizations (MAOs) to deny payments for important services in pursuit of higher profits.

The OIG found that MAOs had overturned 75 percent of their own decisions after hearing appeals from beneficiaries and providers originally denied payment. This high number of overturned denials, according to the OIG, “raises concerns that some Medicare Advantage beneficiaries and providers were initially denied services and payments that should have been provided.” This is particularly alarming – given that between 2014 and 2016, only 1 percent of beneficiaries and providers appealed denials – indicating that a far great number of decisions could have been potentially overturned if appealed.

Worse still, the OIG reported widespread and systemic problems related to the denial of care and payments by MAOs. Through a series of CMS audits, it was revealed that 45 percent of contracts for denial letters contained incomplete and/or incorrect information.

To address these problems, the OIG recommends CMS enhance oversight over MAO contracts, fix problems related to denials and incomplete denial letters in Medicare Advantage and provide beneficiaries with transparent and accessible information of violations by MAOs.

To read the full report from the OIG, [CLICK HERE](#).