

Health Policy Update – March 29, 2018

President Trump Signs \$1.3 Trillion Omnibus Spending Bill

On March 23, President Trump signed the \$1.3 trillion omnibus spending bill into law to avoid a government shutdown. The House of Representatives passed an omnibus spending bill to extend government funding through September 30 by a 256-167 vote on March 22. The Senate passed the same measure by a vote of 65-32 on March 23.

In terms of healthcare priorities, the bill did not include funding for cost-sharing reduction payments or a federal reinsurance program, as many lawmakers and insurance companies had hoped. Despite bipartisan support, the provisions were dropped from the final spending bill after legislators could not agree on other healthcare policies, including the auto-renewal of short-term plans and applying anti-abortion language to the cost-sharing payments.

The spending measure included the following funding for healthcare programs:

- \$3.6 billion for opioid addiction and mental-health services
- \$78 billion for HHS, \$10 billion more than in 2017
- \$37 billion for NIH
- \$4 billion for CMS

To view the full bill (H.R. 1625), [CLICK HERE](#).

CMS Finalizes Medicare Coverage for Gene Sequencing for Patients with Advanced Cancer

On March 16, the Centers for Medicare & Medicaid Services (CMS) finalized a National Coverage Determination (NCD) that covers diagnostic laboratory tests using Next Generation Sequencing (NGS) for patients with advanced cancers. The NCD permits such tests as a companion diagnostic to help identify patients with certain genetic mutations that may benefit from U.S. Food and Drug Administration (FDA)-approved treatments. The tests will also determine if a patient would be an appropriate match for clinical trials if he or she cannot be matched to a treatment.

Tests that gain FDA approval or clearance as an in vitro companion diagnostic will automatically receive full coverage under this final NCD, provided other coverage criteria are also met. The NCD also expands coverage to patients with relapsed, refractory, or stage III cancers, while also extending coverage to repeat testing.

To view the CMS press release, [CLICK HERE](#).

Alliance for Site Neutral Payment Reform Issues Letter to Transparency Working Group

On March 22, the Alliance for Site Neutral Payment Reform sent a letter to a bipartisan group of Senators requesting stakeholder input on price and information transparency in the healthcare sector. The Alliance urged the Senators to remove all exemptions from the site neutral payment law so that payment parity in the market could be ensured across all outpatient settings.

The letter also highlighted the negative impact that hospitals' consolidation with independent physician offices has on patient costs and access. In order to empower patients, the Alliance believes that Congress should equalize payments between independent practices and hospital outpatient departments (HOPDs).

The working group is comprised of Senators Bill Cassidy, MD (R-LA), Michael Bennet (D-CO), Tom Carper (D-DE), Chuck Grassley (R-IA), Claire McCaskill (D-MO), and Todd Young (R-IN).

To view the Alliance letter, [CLICK HERE](#).

ASP Coalition Sends Letter to HHS Secretary Azar

On March 19, the Part B Access for Seniors and Physicians (ASP) Coalition sent a letter to HHS Secretary Alex Azar and CMS Administrator Seema Verma to congratulate Azar on his confirmation and share their optimism for working harmoniously on ensuring Medicare beneficiaries continue to have access and physician practices continue to offer vital Part B therapies.

The letter outlines the ASP Coalition's efforts over the last two years to oppose harmful changes to the Part B program and then concludes stating their appreciation for the initial guiding principles created in the request for information (RFI) by CMMI released in 2017. However, the ASP Coalition is still concerned that proper safeguards are necessary to ensure future payment and delivery models protect patient choice and access to preferred providers and treatments through Medicare Part B.

To view the letter, [CLICK HERE](#).

House Passes Right to Try Legislation, Senate Action Remains Unclear

On March 21, House lawmakers passed The Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2018 (H.R. 5247) by a vote 267-149. The legislation is designed to improve access to experimental treatments for patients with terminal diseases or conditions. Specifically, the bill will:

- Create a new alternative pathway for patients who do not qualify for a clinical trial
- Establish a robust informed consent to access unapproved drugs
- Specify that any unapproved drug used in the new alternative pathway must have an active application and is not the subject of a clinical hold
- Include a sponsor and manufacturer notification to the FDA after they make an unapproved drug available to an eligible patient
- Guard patients from manufacturers purposefully misbranding or mislabeling drugs
- Provide liability protections for manufacturers, sponsors, physicians, clinical investigators, and hospitals that participate in the existing expanded access program and the new alternative pathway; unless there is reckless or willful misconduct, gross negligence, or an intentional tort

- Obligate sponsors and manufacturers to report adverse events to the FDA
- Provide certainty to manufacturers regarding how the FDA will use patient outcomes when evaluating new drug applications
- It is unclear if the bill will pass in the Senate as the Senate has already passed their own version and neither the House or the Senate bill was included in the omnibus spending legislation.

To read the Energy & Commerce Committee statement on H.R. 5247, [CLICK HERE](#).

More Bills Introduced to Combat Opioid Abuse

On March 26, Senator Lamar Alexander (R-TN), Chairman of the Senate Health, Education, Labor, and Pensions Committee, unveiled discussion drafts for two new bills designed to limit the over-prescription of opioids and prevent fentanyl from being illegally brought into the U.S.

If enacted, the legislation would make it easier for doctors to prescribe lower doses by requiring drug manufacturers to package certain opioids in blister packs. It would also authorize the FDA to spend nearly \$100 million to improve drug testing and seizure at the border.

Congress has held a series of hearings on different aspects of the opioid crisis, most recently on March 21 when the House Energy & Commerce held a hearing titled, [Combatting the Opioid Crisis: Prevention and Public Health Solutions](#). House leaders hope to pass opioid legislation by Memorial Day.

To view a statement on Sen. Alexander's draft opioid legislation, [CLICK HERE](#).