



Thursday, March 29, 2018

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

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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. [Read below.](#)

Dr. Randolph Broun: The Biggest Threat to Local Cancer Care

On March 15, Dr. Randolph Broun, president and chairman of The Network's OHC Inc. and board member at Community Oncology Alliance published an article in the *Cincinnati Business Courier*, detailing how the 340B program is abused by some hospitals as a strategy to maximize profits at the expense of low income and uninsured patients. [Read below.](#)

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 Administrator Seema Verma to congratulate Azar on his confirmation and share their optimism for working harmoniously on ensuring that Medicare beneficiaries continue to have access and physician practices continue to offer vital Part B therapies. [Read below.](#)

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. [Read below.](#)

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' consolidations 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.](#)

Dr. Randolph Broun: The Biggest Threat to Local Cancer Care

On March 15, Dr. Randolph Broun, president and chairman of The Network's [OHC Inc.](#) and board member at Community Oncology Alliance published an article in the *Cincinnati Business Courier*. The article details how the 340B program is abused by some hospitals as a strategy to maximize profits at the expense of low income and uninsured patients. As a result, local cancer care and independent cancer doctors in Ohio are at risk of closing. Similarly, Dr. Broun argues that patients with cancer have limited choices for care and incur higher costs.

In order to help reverse this trend and prevent abuse, Dr. Broun urged Ohioans to tell their members of Congress to support the HELP and 340B PAUSE Acts, which would increase the transparency and accountability of hospitals.

To view the article, [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 Administrator Seema Verma to congratulate Azar on his confirmation and share their optimism for working harmoniously on ensuring that 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 states 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 ASP Coalition 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 Senate bill was included in the omnibus spending legislation.

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