Wednesday, July 27, 2016

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Senate Finance Committee Holds Hearing on Stark Law

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Department of Justice Moves to Block Insurance Mergers

On Thursday July 21, The Department of Justice announced it is suing to block two pending insurance mergers due to the risk of reduced competition in the marketplace. **Read below.**

GOP Releases 2016 Platform

The Republican Party has released its official 2016 platform, which includes both cancer research and Medicare funding. **Read below.**

Virginia Cancer Specialists First in the World to Enroll Patient in Cutting-Edge Lung Cancer Clinical Trial

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CMS Acting Administrator Suggests Possible MACRA Delay at Senate Hearing

On July 13, the Senate Finance Committee hosted a hearing during which the Centers for Medicare & Medicaid Services' (CMS) Acting Administrator Andy Slavitt suggested a possible delay in implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) currently slated to go into effect in January 2017.

In his opening statement, Chairman Orrin Hatch (R-UT) warned physicians and healthcare providers are concerned about MACRA's timeline, questioning if a final release of the rule on November 1 would give them enough time to prepare.

The MACRA rule gives CMS the flexibility to move the start date of the reporting period back. Slavitt indicated a delay in the start date could set physicians and healthcare providers, especially those in small practices, up for success by providing them with enough time to prepare for the changes.

Senator Hatch also stated that there could be an interim rule placed in the Fall which would allow for more feedback from stakeholders. This would also require a delay in the start date, but according to Slavitt, keeping the feedback process open will give CMS the option to close the divide between healthcare delivery and policy implementation.

To read Slavitt's testimony, CLICK HERE.

To watch the entire Senate Finance Committee hearing, CLICK HERE.

Senate Finance Committee Holds Hearing on Stark Law

On July 12, the Senate Finance Committee held a hearing examining the Stark Law and impacts of the law on care delivery and the healthcare marketplace. The Stark law is a health care fraud law that prohibits physician referrals under certain circumstances. The law includes an important exception for clinics that provide integrated care which allows physicians to self-refer for "ancillary services," such as radiation therapy and advanced imaging.

Chairman Orrin Hatch (R-UT) began the hearing by saying that the Stark Law is an "embodiment of good intentions muddled with complex execution." He emphasized that the law has had an important effect on the health care delivery system. Hatch questioned whether the Stark Law, with its current structure, retains its relevance as

federal health programs transition toward more value-based payment systems and away from fee-for-service models.

Witnesses at the hearing encouraged changes to the law to ensure hospitals, healthcare systems a physicians are able to work together to implement the reforms mandated by the Affordable Care Act as well as the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

Senate lawmakers indicated at the hearing that changes to the Stark Law could be introduced before the end of this year, but no details were provided.

Witnesses at the hearing included:

- Troy A. Barsky, Crowell & Moring LLP
- Dr. Ronald A. Paulus, Mission Health
- Peter Mancino, The Johns Hopkins Health System Corporation

To watch the entire hearing, CLICK HERE.

Department of Justice Moves to Block Insurance Mergers

On Thursday July 21, the Department of Justice (DOJ) announced it is suing to block two pending insurance mergers due to the risk of reduced competition in the exchanges. Aetna and Anthem, both of which have been working on acquisitions of Humana and Cigna respectively, will reportedly be taking action against the block.

The DOJ stated that the Aetna-Humana merger would diminish the number of choices available to senior citizens and that the Anthem-Cigna merger would prove no benefit to consumers by reducing the competition in the large group market. The DOJ also stressed that both mergers would diminish the number of options in health insurance exchanges.

In the announcement, Attorney General Loretta E. Lynch stated, “If allowed to proceed, these mergers would fundamentally reshape the health insurance industry. They would leave much of the multi-trillion dollar health insurance industry in the hands of three mammoth insurance companies, drastically constricting competition in a number of key markets that tens of millions of Americans rely on to receive health care. Among other consequences, the number of health insurance options available to nationwide employers would shrink from four to three.”

To view the DOJ remarks announcing the blocked acquisitions, CLICK HERE.

GOP 2016 Platform Calls for Cancer Funding, Medicare Reforms

The Republican Party released its official 2016 platform last week, which includes both cancer research and Medicare funding. In regards to breast cancer, prostate cancer and diabetes research, the party calls for expanded support for stem cell research through adult stem cell and umbilical cord blood research.

In regard to Medicare, the platform states the program must be brought under control before it consumes most of the federal budget, including national defense.

The GOP platform proposes the following Medicare reforms:

- Impose no changes for persons 55 or older;
- Give others the option of traditional Medicare or transition to a premium-support model designed to strengthen patient choice;
- Promote cost-saving competition among providers; and
- Better guard against the fraud and abuse.

To read the entire GOP platform, CLICK HERE.

Virginia Cancer Specialists First in the World to Enroll Patient in Cutting-Edge Lung Cancer Clinical Trial

Virginia Cancer Specialists (VCS) is the first in the world to enroll a patient in a new advanced lung cancer clinical trial that may hold promise for patients with ALK-positive locally advanced or metastatic non-small cell lung cancer (ALK+ NSCLC). The randomized Phase III clinical trial focuses on brigatinib, an investigational anaplastic lymphoma kinase (ALK) inhibitor from ARIAD Pharmaceuticals, Inc. The trial is designed to assess the efficacy of the drug candidate in a head-to-head comparison with the current recommended therapy, crizotinib, evaluating progression free survival.

Virginia Cancer Specialists conducts clinical trials through US Oncology Research, one of the largest community-based cancer research programs in the country. US Oncology Research has played a role in approximately 60 FDA approved cancer therapies, nearly one-third of all approved cancer therapies to date. Other practices affiliated with US Oncology Research are also participating in the trial. The trial is expected to be conducted at approximately 150 investigational sites in North America, Europe and the Asia Pacific region.

The Phase III clinical trial of brigatinib was launched in April, and the VCS Research Institute immediately began screening patients for eligibility, eventually identifying the

patient who would become the very first in the world to enroll in this advanced clinical study.

Brigatinib has received breakthrough designation from the US Food and Drug Administration (FDA), and ARIAD recently commenced submission of a New Drug Application for initial approval in patients who have experienced crizotinib failure.

To download the VCS press statement, CLICK HERE.