HALL RENDER'S THIS WEEK IN WASHINGTON – MAY 18, 2018

SENATE HELP COMMITTEE TAKES ANOTHER LOOK AT 340B

The Senate Health, Education, Labor, and Pensions Committee held its second hearing on the 340B program. Representatives from two major government watchdogs, the Government Accountability Office and the HHS Office of the Inspector General, testified at the hearing. The testimony focused on oversight reports related to the program and shared recommendations for improving it. Members of the committee asked the witnesses why the Trump administration has delayed for the fifth time a rule that would set ceiling prices and why 340B hospitals don't know what they ought to be paying for the discounted drugs.

Throughout the hearing, the witnesses encouraged the idea that Congress take a new look at clarifying the intent of the program and its structure. Chairman Lamar Alexander (R-TN) cautioned, "It would be hard for us to do anything else until we clarify the intent of the program."

The GAO plans to look at the financial arrangements between contract pharmacies and 340B providers. Officials will also look at what portion of the 340B discounts are passed on to low income patients, HRSA's oversight work, and dive into the audits of 340B providers.

As part of President Trump's plan to lower drug prices, HHS asked providers and pharmaceutical companies to weigh in on potential changes to the 340B program in a new request for information. Stakeholders are to weigh in on measures that have been considered by Congress, such as including a "patient definition" that would specify who qualifies for the drug discount, and moving 340B regulatory authority to HHS. Additionally, HHS is looking for feedback on whether 340B's growth has raised list prices in the commercial market and ultimately affected payers, including Part D plans.

FDA REPORT TO CONGRESS BACKS THIRD-PARTY MEDICAL DEVICE SERVICE PROVIDERS

In a much anticipated report to Congress released this week, the Food and Drug Administration said there isn't sufficient objective evidence to support the allegations of poor quality servicing delivered by third-party servicers of medical devices that would justify the new burdensome regulatory requirements called for by original equipment manufacturers ("OEMs"). It also noted that many third-party service providers deliver "high quality, safe, and effective" service and that "continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system." The report was requested by Congress through the Food and Drug Reauthorization Act of 2017 after failed attempts by some OEMs to convince lawmakers to pass legislation that would place additional burdens on the third-party medical device service provider industry. Many hospitals and health systems across the country rely on third parties to service their medical equipment as a high-quality/low-cost alternative to purchasing a service contract from the OEM.

The FDA's conclusions came after an examination of the available evidence pertaining to medical device servicing. That evidence included a review of all complaints and allegations of misconduct related to servicing of medical devices and radiation-emitting products it has received since 2009. While the FDA acknowledged "there may be isolated instances of poor quality servicing by OEMs or third party entities," it found no evidence of a widespread public health concern that warrants the regulatory action called for by OEMs. In fact, of the 68 potentially relevant complaints identified, 29 alleged inadequate servicing by OEMs and only 10 alleged inadequate servicing by third party entities. Those complaints made against OEMs ranged from not providing service manuals and "critical replacement parts" to poor technician training.

Instead of passing new regulations on the third party service provider industry, the FDA told Congress it intends to promote the adoption of quality management principles, clarify the difference between servicing and remanufacturing, strengthen cybersecurity practices associated with servicing of medical devices and foster evidence development to assess the quality, safety and effectiveness of medical device servicing. These efforts will include "the creation of a public-private forum, such as a Collaborative Community, to address the challenges associated with delivering high quality, safe and effective servicing of medical devices. Members of the newly formed Alliance for Quality Medical Device Servicing, which includes third-party service providers TRIMEDX, Sodexo Clinical Technology Management, Aramark Healthcare Technologies, Crothall Healthcare and ABM Healthcare, met with FDA officials this week to express their support for creation of a Collaborative Community and will be working to further educate lawmakers and staff on Capitol Hill regarding the need to protect the third-

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party medical device servicing industry.

CONCENTRATION ON OPIOID CRISIS IN CONGRESS

Both the House Ways and Means Committee and the House Energy and Commerce Committee continued work on opioid legislation this week. House Republican leadership is aiming to have an opioid package to the floor by June. On May 16, the Ways and Means Committee passed seven opioid measures. Most of the legislation makes small changes to the Medicare program to prevent future prescription painkiller misuse among seniors and to make addiction treatment more readily available to beneficiaries of the program.

On May 17, the Energy and Commerce Committee marked up 34 opioid-related bills. Most of the legislation asked for studies or reports related to the crisis. Other legislation marked up by the committee included legislation to allow more providers to prescribe medication-assisted therapy, enable Medicaid to pay for up to a month of care in large mental health treatment facilities, and more prescription monitoring. Federal agencies are also acting to address the crisis. On May 16, the FDA approved the first non-opioid product to treat symptoms of opioid withdrawal.

CMS RELEASES DRUG DASHBOARDS WITH MEDICARE PARTS B AND D DRUG SPENDING DATA

CMS updated the Parts B and D drug spending dashboards with 2016 information. For the first time, CMS included year-over-year information on drug pricing and indicated which manufacturers have been increasing their prices. The updated dashboards detail average spending on drugs per dosage unit in 2015 and 2016, the change in average spending per dosage unit from those years, and the annual growth rate in average spending per dosage unit from 2012 to 2016. They also offer data on the total number of Medicare beneficiaries using the drugs in 2016 and the average speeding per beneficiary for Part B and Part D drugs. The 2016 data shows double-digit increases in price for 876 Part D drugs and 145 Part B drugs with 31 drugs increasing by more than 100 percent.

HEALTH-RELATED BILLS INTRODUCED THIS WEEK

Rep. Michael Burgess (R-TX) introduced H.R. 5806 to require the Secretary of Health and Human Services to issue guidance with respect to the expedited approval of certain drugs.

Rep. John Shimkus (R-IL) introduced H.R. 5804 to provide for modifications in payment for certain outpatient surgical services.

Sen. Robert P. Casey Jr. (D-PA) introduced S. 2851 to improve regional health care emergency preparedness and response systems

NEXT WEEK IN WASHINGTON

Congress is back for a full legislative work week. On May 22, the Senate HELP Committee is holding a hearing on "The Health Care Workforce: Addressing Shortages and Improving Care." Also, the House Energy and Commerce Health Subcommittee announced a hearing for Wednesday entitled “Reauthorization of the Children’s Hospital Graduate Medical Education Program.” The hearing will focus on reviewing H.R. 5385, the Children's Hospital GME Support Reauthorization Act of 2018. H.R. 5385 will reauthorize the Children’s Hospital Graduate Medical Education program for five years.

THIS WEEK IN WASHINGTON IN HISTORY

1800 – 218 years ago this week, President John Adams orders the federal government to pack up and leave Philadelphia and set up shop in the nation’s new capital in Washington, D.C. After Congress adjourned its last meeting in Philadelphia on May 15, Adams told his cabinet to make sure Congress and all federal offices were up and running smoothly in their new headquarters by June 15, 1800. Settling in to the White House was a challenge for the new first lady. In December, Abigail Adams wrote to a friend later she had to line dry their clothes in what eventually became the East Room.

1917 – 101 years ago this week, U.S. Congress passes Selective Service Act. Six weeks after the United States formally entered the First World War, the U.S Congress passes the Selective Service Act on May 18, 1917, giving the U.S. president the power to draft soldiers. When he went before Congress to deliver his war message, President Woodrow Wilson had pledged all of his nation’s considerable material resources to help the Allies—France, Britain, Russia and Italy—defeat the Central Powers.

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