

McDermottPlus Check-Up

McDermott+Consulting is pleased to introduce the McDermottPlus Check-Up, your regular update on health care policy from Washington, DC.



This Week's Diagnosis: Welcome back! Members are back in town for a sprint to the finish. Controversy over the House Democratic leadership elections fizzled, with the same faces in the top three positions.

CONGRESS

- + **HOUSE DEMOCRATIC LEADERSHIP ELECTIONS.** There were no changes as Democrats voted to fill the top three leadership positions: Representative Nancy Pelosi (D-CA) is the nominee for Speaker (an official vote will occur on the floor on January 3, 2019); Representative Steny Hoyer (D-MD) will be Majority Leader; and Jim Clyburn (D-SC) will be Majority Whip. Pelosi's victory was the most significant; she faced growing intraparty defections but ultimately won the nomination 203-32). As part of a deal to win some of these defectors back, Pelosi agreed to some rule changes that shift some power away from party and committee leadership and toward the will of the party majority. For example, a majority of the members on a committee can request and schedule a markup of the committee on which they serve. It remains to be seen if this is enough for Pelosi to get the 218 votes she needs in January.
- + **APPROPRIATIONS BATTLE CONTINUES.** Lawmakers are feverishly working on an omnibus package to fund certain federal agencies for which money runs out on December 7. Funding for a border wall remains a significant threat to an agreement. The President indicated he is willing to veto any spending package that does not include at least \$5 billion in border wall funding. Democrats are dug in at \$1.6 billion, a number that was previously negotiated with the Republicans. One path forward could be moving an omnibus without the US Department of Homeland Security (DHS) funding before December 7 and providing for another short-term continuing resolution for DHS. This strategy would buy time for additional negotiations.
- + **SENATE HELP HEARING ON HEALTH CARE COSTS.** The Senate Health Education Labor and Pensions (HELP) Committee held a [hearing](#) on Reducing Health Care Costs: Improving Affordability through Innovation. Witnesses testified about innovative strategies to control costs, including direct primary care, direct contracting between employers and providers, and state innovation models. The hearing was one in a series the Committee has held focusing on health care costs. We expect to hear more about how the federal government could reduce costs in the next Congress.
- + **SENATE HELP MARKS-UP SEVERAL HEALTH BILLS.** On Thursday, the HELP Committee passed a series of health bills out of Committee, including:

- The Building Our Largest Dementia Infrastructure for Alzheimer's Act ([S. 2076](#)) provides more resources for state and local public health officials to increase early detection and diagnosis of Alzheimer's, as well as provide supports for caregivers and people living with the disease. There is a similar bill in the House that has not been considered.
 - The Traumatic Brain Injury Program Reauthorization Act of 2018 (S. 3657) would simply reauthorize the program, which provides support for research and treatment for traumatic brain injuries. There is a similar bill in the House that has not yet been considered.
 - The Improving Access to Maternity Care Act ([H.R. 315](#)) seeks to address maternity health care provider shortages and passed the House in January 2017. The full Senate can now consider the bill. And with now changes, it can go to the President for his signature.
 - The Emergency Medical Services for Children Program Reauthorization Act of 2018 ([S. 3482](#)) would reauthorize the program, which provides support to medical professionals to meet the unique needs of pediatric patients and provides state of the art emergency medical care for ill and injured children and adolescents. There is a similar bill in the House that has not been considered.
- + **SENATE HELPS TO-DOS.** Reauthorization of the Pandemic and All-Hazards Preparedness and Advancing (PAHPA) Innovation Act of 2018 (S. 2852) and the President's Emergency Plan for AIDS Relief (PEPFAR) remain on the Committee's to-do list. Senator Johnny Isakson (R-GA) is holding up PAHPA in response to Senator Richard Burr (R-NC) holding up an unrelated over the counter drug reform bill.

Administration

- + **FDA IS CHANGING THE 510(K) PROCESS.** A series of news investigations highlighting the regulation of medical devices, spurred a [detailed response](#) from the Food and Drug Administration (FDA) Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health. The 510(k) clearance pathway for medical devices allows the manufacturer to submit information to the FDA that shows the device is at least as safe and effective, and substantially equivalent to, a device that is already on the market (often called a predicate device). This pathway was originally intended to be used in more limited cases. However, the vast majority of medical devices are now approved this way. Critics allege, too little post-market surveillance makes it difficult to track adverse health outcomes. FDA is planning to propose changes including making public a list of cleared devices tied to predicate devices more than 10 years old and sunseting older predicate devices. The FDA acknowledged it may need legislative changes, but has not specified what those might be. The device industry is rightfully anxious about any legislative or administrative changes that may add time and expense to the approval process.
- + **WORK REQUIREMENTS IN THE SPOTLIGHT, AGAIN.** The Centers for Medicare and Medicaid Services (CMS) took a number of actions on work requirements for Medicaid recipients:
- CMS approved a new version of Kentucky's Medicaid waiver requiring enrollee work this week. CMS previously granted the state approval to move forward, but

after a lawsuit was brought, a judge required CMS to reconsider the waiver. In that process, CMS re-opened the waiver to public comment (of which the agency received more than 8,500). CMS re-approved the waiver with no substantive changes. Advocacy groups who are part of the on-going lawsuit have already indicated their intention to update their filing against Kentucky.

- Arkansas is the only state that has been able to move forward with implementation of work requirements so far. It has become especially newsworthy since 12,000 residents reportedly have been removed from Medicaid. The Medicaid and CHIP Payment and Access Commission recommended that CMS cease allowing states to impose work requirements pending further study. CMS Administrator Seema Verma has so far refused to do so and reaffirmed the agency's interest in approving Medicaid work requirements waivers.
 - Virginia also got in on work requirement action by submitting a waiver to CMS this week. These requirements were part of the compromise to expand Medicaid in the commonwealth.
- + **HARGAN ANNOUNCES INNOVATION SUMMIT CORE GROUP.** Health and Human Services Deputy Secretary Eric Hargan [announced](#) the creation of the Deputy Secretary's Innovation and Investment Summit (DSIIS). The Summit will be a yearlong collaboration intended to improve and evolve healthcare in America. Selected leaders in digital health, life sciences, medical devices, payers, providers, and health technology investing and innovation will serve as core participants. The first meeting is December 18, 2018. The group is expected to develop new approaches and strategies to tackle problems facing the healthcare system.
- + **PART D PROPOSED RULE.** CMS released [a proposed rule](#) that gives Medicare Advantage (MA) and Part D plans new tools for negotiating lower drug prices and reducing out of pocket costs for consumers. The changes include: additional flexibility regarding the six protected classes of drugs; expanding MA plans' ability to use step therapy for Part B drugs; and changing the definition of negotiated prices for pharmacy payments. The proposed rule is the latest in a series of changes aimed at reducing drug costs consistent with the Administration's [American Patients First Blueprint](#) to lower drug prices.
- + **ONC REPORT ON BURDEN.** The Office of the National Coordinator for Health IT (ONC) and CMS were required to collaborate on [a strategy](#) to reduce the regulatory and administrative burden of using health IT and electronic health records (EHRs). The law required a 60-day public comment period for the report. The report includes three goals: (1) reduce the effort and time required to record information in EHRs for health care providers during care delivery; (2) reduce the effort and time required to meet regulatory reporting requirements for clinicians, hospitals and health care organizations; and (3) improve the functionality and intuitiveness (ease of use) of EHRs. The report also proposes multiple strategies around clinical documentation, usability and user experience, EHR reporting requirements and public health reporting requirements.
- + **340B CEILING PRICE RULE DROPPED.** On Thursday, the Health Resources and Services Administration (HRSA) released a long-delayed [final rule](#) that lays out how 340B ceiling prices are calculated and a penalty structure for drug manufacturers who fail to comply.

Hospital groups sued in September after HRSA delayed the effective date (again) to July 1, 2019. The new effective date is January 1, 2019.

- + **CMS LOOKS TO CHANGE USE OF ACA SUBSIDIES.** CMS [announced](#) new Affordable Care Act (ACA) “waiver concepts” that significantly increase flexibility for states in the individual insurance exchange marketplace. Under the current 1332 waivers, states can apply to create new programs, like reinsurance, to support high-cost costumers. The new waiver concepts allow states to change the way federal subsidies are used. The subsidies are for those buying health insurance through the individual marketplace and for those with incomes up to 400 percent of the federal poverty level. The guidance allows states to use the subsidies to purchase coverage outside of the marketplaces (including employer-sponsored health plans and short-term health plans) and to move the qualifying income limit. It is unclear which states, if any, will attempt this approach. Bets are the House Democrats will add this to their growing list of oversight items.

Next Week's Dose

Congress has until next Friday to avoid a partial shutdown. Members are working hard to address the issues mentioned above related to remaining appropriations and still hope to wrap up business next week. The House is expected to adjourn as soon as the outstanding funding bills are addressed. The Senate, however, seems set to stay in session until December 21 to continue to work through judicial nominations.

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