

# 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:** President Trump clashed with House Democratic Leader Nancy Pelosi (D-CA) and Senate Minority Leader Chuck Schumer (D-NY) in a meeting this week about how to keep the government's lights on. The President threatened to shut down the government on December 21, when the current short-term funding agreement expires, if his request for \$5 billion for border wall funding is not included in the appropriations agreement. The two week continuing resolution preventing a shut down on December 7 has given legislators extra time to pass some health bills.

## CONGRESS

- + **HOUSE PASSES MEDICAID PACKAGE.** The House passed several Medicaid bills including legislation improving care coordination for children with complex medical needs and a three month extension of Money Follows the Person demonstration ([H.R. 7217](#)), reauthorization of the traumatic brain injury program ([H.R. 6615](#)), and programs to support states in addressing maternal mortality ([H.R. 1318](#)). The Right Rebate Act ([S. 3702](#)) was also included in the package, which would allow the Department of Health and Human Services (HHS) to fine drug manufacturers who knowingly misclassify their products as generic as opposed to branded. This bill provided the funding necessary to offset the rest of the Medicaid provisions. The package now heads to the Senate where it is expected to pass as a standalone or be incorporated into spending bills.
- + **BILLS HEADED TO THE PRESIDENT.** The House also passed two bills that the Senate had previously approved: [S. 2465](#) reauthorizes the sickle cell disease prevention and treatment demonstration program; [S. 3029](#) continues research and education programs aimed at preventing preterm births to reduce infant deaths and improve infant health.
- + **Energy and Commerce Subcommittee Holds Hearing on Health IT Progress.** The US Department of Health and Human Services (HHS) Office of the National Coordinator for Health IT (ONC) testified on implementation of the 21st Century Cures Act. Members pressed the National Coordinator for details on the timing and content of the information blocking proposed rule sitting with the Office of Management and Budget for review. The long-awaited proposed rule that is required under Cures is expected to cover important topics such as information blocking and certification requirements. Legislators did not get the information they sought though, in part because the Coordinator cannot speak to the contents of rules before they are public. In response to several questions from lawmakers, the National Coordinator did note he does not believe the agency needs any additional authority or support from Congress to meet the requirements set forth under Cures.

- + **HOUSE AND SENATE LEADS RELEASED UPDATED DIAGNOSTIC DRAFT BILL.** After years of back-and-forth with the US Food and Drug Administration (FDA) and stakeholders, the leads of a bill that would reform how FDA regulates certain laboratory diagnostic tests released an updated [draft](#) late last week. Representatives Diana DeGette (D-CO) and Larry Bucshon (R-IN), along with Senators Michael Bennet (D-CO) and Orrin Hatch (R-UT), have been working for nearly a year to update a discussion draft. The Verifying Accurate, Leading-edge IVCT Development (VALID) Act incorporates much of the feedback provided to the office by the FDA. The authors are now seeking feedback on the updated draft, and hope to introduce a bill early in the new Congress in 2019 with hearings to follow.
- + **BRADY REVISES TAX PACKAGE.** Chairman of the House Ways and Means Committee Kevin Brady (R-TX) released an [updated version](#) of his tax package. Under this revised package, the “Cadillac tax” on high-end workplace health plans would be further delayed from 2022 until 2023, the medical device tax would be pushed back from 2020 to 2025 and the fee on health insurers would be pushed back from 2020 to 2022. Many other tax extenders were removed in this version. The timing for consideration of this package is unclear. While the House has at least another week of floor time, Chairman Brady has not yet secured enough Republican support for the updated proposal.
- + **ALEXANDER CALLS FOR IDEAS TO REDUCE HEALTH CARE COSTS.** Senate Health, Education, Labor & Pensions Committee Chair Lamar Alexander issued a letter to health care stakeholders requesting ideas on specific steps Congress can take to lower health care costs, incentivize care that improves patient health and increase patient access to information to make informed decisions. The request flows from a series of hearings the committee held on the topic. Expect price transparency and cost to continue to be hot topics in 2019, and one of a few areas with the potential for bipartisan action.
- + **MEMBERS CHALLENGE PUBLIC CHARGE PROPOSED RULE.** Ranking Member of Energy and Commerce Frank Pallone (D-NJ) and Ranking Member of Ways and Means Richard Neal (D-MA) sent a [letter](#) to Homeland Security Secretary Kirstjen Nielsen urging her to withdraw a proposal to change the public charge test. The proposed rule would place more negative weight on certain immigration applications if public services like food stamps or Medicaid were used.
- + **WAYS AND MEANS RED TAPE RELIEF PACKAGE.** The House Ways and Means Committee [announced](#) a series of health care bills flowing from the Committee’s Medicare Red Tape Relief Project. The bills include legislation that would give Medicare providers a vehicle to submit comments on reducing administrative burden; removing certain hospital and post-acute quality measures; incentivizing risk arrangements between Medicare Advantage plans and physicians; a bill requiring additional notice of prior authorization for Medicare beneficiaries; a bill requiring a feasibility study for reducing prior authorization burden in Medicare Advantage; and two bills related to reducing administrative burden on rural hospitals. Some of these proposals have bipartisan support, but most do not, and likely will not see action in the House given the tight legislative calendar. Outlook for re-introduction and action in the new Democratic-controlled House is murky at best.

## ADMINISTRATION

- + **HHS HIPAA RFI.** HHS released a [request for information \(RFI\)](#) about how Health Insurance Portability and Accountability Act (HIPAA) rules could be modified to further the Secretary's goal of promoting coordinated care. The RFI is the third in a series aimed at addressing regulations that impede the move to performance-based risk arrangements. It remains to be seen what further regulatory action will be taken resulting from these RFIs – the Stark Law and Anti-kickback Statute RFIs have not yet resulted in more formal proposed rules or recommendations.
- + **FDA RELEASES PLANS FOR BIOSIMILARS.** The FDA [announced](#) four new guidance documents to more effectively promote greater competition in the biosimilars marketplace. Two of these focus on providing more clarity on scientific and regulatory considerations for the development of biosimilars. The other two describe how the FDA plans to implement the requirement to transition certain biological products under the Food, Drug and Cosmetic Act to being licensed as biologics under the Public Health Service Act. By making this change, the biologics will be open to competition through the biosimilars pathway. The FDA Commissioner argues that this will improve innovation and competition for drugs that have been historically approved under the congenital drug pathway. This includes insulin, which has faced skyrocketing costs in recent years.

## OTHER

- + **CBO RELEASES OPTIONS TO SHRINK DEFICIT.** The Congressional Budget Office (CBO) released its annual [list of options](#) to reduce the \$779 billion deficit. The report includes over 100 possible policies across a wide range of programs. The CBO includes options that would cut Medicare Advantage payments, restrict Medigap coverage and require pharmaceutical companies to pay larger rebates for dual eligibles.

## NEXT WEEK'S DOSE

- + We are all watching as the window is shrinking for any compromise on funding the federal agencies whose money stops flowing on December 22, 2018. As these negotiations continue, Congress is filling the time with last-minute bills and judicial nominations.

For more information, contact [Mara McDermott](#) or [Rachel Stauffer](#).

[To subscribe to the McDermottPlus Check-Up, please contact Jennifer Randles.](#)



McDermott+Consulting LLC is an affiliate of the law firm of McDermott Will & Emery LLP. McDermott+Consulting LLC does not provide legal advice or services and communications between McDermott+Consulting LLC and our clients are not protected by the attorney-client relationship, including attorney-client privilege. The MCDERMOTT trademark and other trademarks containing the MCDERMOTT name are the property of McDermott Will & Emery LLP and are used under license.