

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: The Senate was working in full force this week. The House is back next week for what is rumored to be the last session week until the election.

CONGRESS

- + **SENATE PASSES OPIOIDS BILL.** The [Senate opioid package](#) passed almost unanimously on Monday (99–1, with Senator Mike Lee (R-UT) being the lone dissenter). This was a heavy lift for the Senate, which incorporated new policy from three Senate committees into the House-passed opioid bill ([HR 6](#)), and stripped a few controversial and costly provisions (see below) from the underlying House bill. Because the Senate removed some of the House-passed provisions, the Senate bill has no new spending. Now comes the extra heavy lift: working out the differences between the House and Senate, and on a short timeline. Two of the trickier outstanding policy issues include:
 - o *Medicaid Institutions for Mental Diseases exclusion:* The House-passed version of HR 6 temporarily lifts the ban on Medicaid funding for opioid and cocaine addiction treatment at mental health treatment facilities with more than 16 beds for up to 30 days. The Senate did not include a similar provision, mostly because of the cost. However, this week, a group of bipartisan senators introduced [a bill](#) that would go further than the House version—the ban would be lifted for 90 days under the proposed bill. The policy itself is not necessarily in question; rather, the controversy is over how to pay for it.
 - o *Personal health records:* There has been a push to more closely align 42 CFR Part 2 with the Health Insurance Portability and Accountability Act to effectively allow doctors and insurance companies to more easily and seamlessly share a patient's mental health records. The House passed a bill addressing this issue ([HR 6082](#)) as part of its opioid-related work, but the Senate has not taken up a similar measure yet, and there is no comparable provision included in the Senate-approved version of HR 6. This is a controversial and highly sensitive policy dilemma—one on which it is not easy to come to an agreement in short order.

Chairman of the Senate Health Education Labor and Pensions (HELP) Committee, Senator Lamar Alexander (R-TN), has publicly expressed his desire to wrap up negotiations with the House today in order to give the House time to pass the bill when it returns next week. (Rumors are that, barring a shutdown, the House is looking to leave DC and head back to the campaign trail as soon as possible.) This is a tall order, but that does not mean that it can't be done.

- + **SENATE PASSES BILL ON “GAG CLAUSE” AND BIOSIMILARS PAY-FOR-DELAY.** The Senate also passed the Patient Right to Know Drug Prices Act ([S 2554](#)) with a vote of 98–2.
 - o The bill would prohibit health insurance issuers and group health plans from limiting the information shared by pharmacy providers to enrollees (also known as removing the “gag clause”) so that pharmacy providers can inform enrollees if there are cheaper options.
 - o The bill also includes a provision requiring manufacturers of biosimilars and biologics to file patent settlements with the Federal Trade Commission.

As we mentioned last week, a similar measure passed out of the House Energy and Commerce Committee ([HR 6733](#) includes the gag clause, but not the biosimilars provisions). Expect a reconciled bill to move through both chambers soon.

- + **DISCUSSION DRAFT ON SURPRISE MEDICAL BILLS.** A bipartisan group of senators released a [discussion draft](#) of legislative language intended to prevent surprise medical bills. The legislation would limit patient cost-sharing for emergency services to the amount required by their health plan; require notification for patients receiving follow-up from an out-of-network provider after receiving emergency services; and ensure that plans and providers cannot bill a patient in excess of in-network cost sharing for a non-emergency service provided by an out-of-network provider in an in-network facility. The draft flows from a March 2018 request for information soliciting feedback on ways to address price transparency. Lawmakers are now working to refine this discussion draft before formally introducing a bill. The earliest we expect action on this bill would be in the new Congress in 2019.
- + **SENATE HELP HEARINGS ON HEALTH CARE COSTS.** The HELP committee held a [hearing](#) on “Reducing Health Care Costs: Examining How Transparency Can Lower Spending and Empower Patients.” The hearing examined the role of the government in encouraging patients to shop and compare prices for health care services. Witnesses agreed that better access to pricing and quality information is needed, but it remains challenging to determine the federal government’s role in the process. The next hearing in the series will examine “[Improving Affordability through Innovation](#),” and will occur September 27, 2018, at 10 am EDT. While the legislative next steps for improving transparency remain unclear, the topic has been identified as a Trump Administration priority and congressional area of interest. We expect to see continued activity on health care costs and efforts to empower consumers in medical purchasing decision-making in the lead up to the mid-term elections and their aftermath.
- + **HHS APPROPRIATIONS – NO LONGER THE ONE LEFT BEHIND.** The Senate passed a “minibus” appropriations package on Tuesday by a vote of 92–7, that included fiscal year 2019 funding for the US Department of Health and Human Services (HHS). A few things to note about this:
 - o Combining the largest domestic spending package (Labor-HHS-Education) with Defense has been a fruitful strategy for the appropriators. This is the first time in many years that the HHS appropriations appear to be headed for passage before the end of the fiscal year (September 30, 2018). The House is expected to consider and pass the bill next week.

- This year the bill includes nearly \$178.1 billion in discretionary funding, which is close to \$1 billion more than fiscal year 2018, and more than the administration's request.
- Call it clever (or not), but the appropriators also included a continuing resolution for the federal agencies that will not see annual appropriations completed before September 30. With veto threats continuing to emanate from the White House, this tactic sends a clear message to the president that Congress does not support a government shutdown in the weeks leading up to the elections. The continuing resolution for those agencies would run through December 7, 2018.
- + **CREATES ACT IS A MONEY SAVER.** The Senate Judiciary Committee approved the [Creating and Restoring Equal Access to Equivalent Access Act](#) (S 974) on June 21, 2018, but the Congressional Budget Office (CBO) just this week released [the score](#), showing that the legislation saves *a lot of money*: \$3.3 billion over the next 10 years. The bill would allow developers of generic drugs or biosimilar products to bring civil lawsuits against manufacturers of brand-name drugs if samples of the brand-name product are not made available to the generic developers for premarket testing. While the similar bill awaiting consideration in the House Energy and Commerce Committee ([HR 2212](#)) has not seen action, the release of the official score from CBO might prompt faster consideration. (Also, we hear that some must-pass bills need some pay-fors . . . ahem, opioids.)

Administration

- + **CMS RELEASES REGULATORY RELIEF PROPOSED RULE.** The Centers for Medicare & Medicaid Services released a [proposed rule](#) intended to reform select Medicare regulations that the administration has identified as unnecessary or overly burdensome on health care providers and suppliers. The proposed rule is one in a series of responses to suggestions from stakeholders made through the administration's repeated requests for information. The proposed rule includes changes to the conditions of participation and conditions for coverage, and seeks additional information on regulatory reforms that reduce burden on providers for future rulemaking. Comments are due November 15, 2018.
- + **ONC MEGA-RULE HITS OMB.** The Office of the National Coordinator for Health Information Technology's (ONC's) long awaited rule to implement many of the health IT-related provisions of the 21st Century Cures Act was sent to the Office of Management and Budget (OMB) on Tuesday. This proposed regulation will tackle policies related to interoperability, the Certification Program and information blocking. While the statutory deadline for many of these regulations has long since passed, ONC has maintained that this process required a very thoughtful approach. What happens now? We wait for OMB to complete its review.

Next Week's Dose

- + The Senate HELP Committee will hold the next hearing in its series on cost, [Improving Affordability Through Innovation](#), on September 27, 2018.

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

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



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