

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: Hearings are beginning and priorities are emerging. The shutdown drags on. And updates are trickling out of the Administration.

CONGRESS

- + **SHUTDOWN ENTERS UNCHARTED WATERS.** We have entered day 35 of the partial government shutdown. Some furloughed employees will be missing their second paycheck this week. The House continues to vote on various funding measures, with passage largely landing on party-lines. The Senate failed to pass two different measures: (1) \$5.7 billion for a border wall and some temporary protections for some immigrants (mirroring the President's offer), and (2) a bill that passed the House which would fund the closed agencies at 2018 levels through February 8, with no money for the border wall. The fact that the Senate voted at all is somewhat of a breakthrough, as Majority Leader Mitch McConnell (R-KY) had previously refused a vote on any measure the President would not support. Look for continued political jockeying, with the Democrats using their majority power in the House to draw attention to the negative impacts of the shutdown in hearings (see: Energy and Commerce Committee [hearing](#) on January 31).
- + **HEARINGS GALORE.** The Senate and House scheduled their first health hearings for the 116th – all on January 29. Can you be in four places at once? The hearings set the tone for what are expected to be high priority issues this year – drug pricing, coverage for pre-existing conditions and tackling health care costs.
 - Senate Finance Committee will focus on drug pricing: *Drug Pricing in America: A Prescription for Change, Part I*.
 - Chairman Chuck Grassley (R-IA) has introduced and supported legislation that allows limited importation of prescription drugs. He also promised oversight and a thoughtful approach in working with colleagues and the Administration on viable policy solutions.
 - Senate Health, Education, Labor and Pensions Committee will focus on accessibility to care: *Access to Care: Health Centers and Providers in Underserved Communities*.
 - This is part of Chairman Lamar Alexander's (R-TN) initiative on tackling health care costs more broadly.

- House Ways and Means Committee will follow through on the top Democratic campaign issue – preexisting conditions: *Protecting Americans with Pre-existing Conditions*.
 - Chairman Richard Neal (D-MA) was quick out of the gate to promise a hearing on this issue back in November. More hearings of this type are expected across relevant committees (i.e., Energy and Commerce, Oversight and Reform).
- House Oversight and Reform Committee will also focus on prescription drug pricing. Although the formal title for the hearing has not been made, it is reportedly going to focus on the patient perspective.
 - Chairman Elijah Cummings (D-MD) has already initiated an investigation on prescription drug costs with letters requesting information and document related to drug pricing for [12 drug companies](#).
- + **DELBENE LEADS LETTER TO CMS TO DELAY MSSP APPLICATION TIMELINE.** Representative Suzan DelBene (D-WA) [sent a letter](#) asking the Administration to extend the application timeline for the new Pathways to Success, Medicare Shared Savings Program Accountable Care Organizations. Representatives Mike Kelly (R-PA), Markwayne Mullin (R-OK) and Peter Welch (D-VT) also signed the letter. The new model is set to begin July 1, 2019, with applications due on [February 19, 2019](#). Because the final rule was released at the end of December, some ACO stakeholders have indicated that the window is too short to allow meaningful evaluation of program changes in advance of filing the application.

ADMINISTRATION

- + **WHITE HOUSE GETS IN ON SURPRISE BILLING.** On Wednesday, the White House held a roundtable discussion with patients on the impact of surprise billing. Attendees included President Donald Trump, White House counselor Kellyanne Conway, National Economic Council Director Larry Kudlow, Deputy Director of the Domestic Policy Council Lance Leggett, US Department of Health and Human Services Secretary Alex Azar and Labor Secretary Alex Acosta. Joe Grogan, who leads health policy at the Office of Management and Budget and will soon head the Domestic Policy Council, also attended. Patients from across the country in Colorado, Florida, Ohio, Maryland, Massachusetts and North Carolina shared their stories. Notably, four of the 10 patients came from Colorado, where Senator Cory Gardner (R-CO) is up for reelection in 2020 and is considered a vulnerable Republican. Surprise billing has been in the news more frequently with patients using social media to share their stories. Several bills were introduced in the late in the 115th Congress that included various legislative approaches to prohibit or restrict this practice. There is expectation that some of these bills will be reintroduced early this year.
- + **FDA ISSUES FINAL GUIDANCE ON MEDICAL DEVICE APPROVALS.** The US Food and Drug Administration (FDA) released the [final guidance](#) that updates the 510(k) approval pathway. 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. The draft guidance released in November sought to address this issue. The new Safety and Performance Base Pathway will give some manufacturers the ability to compare their devices to a more updated set of metric as opposed to older, similar products.

NEXT WEEK'S DOSE

Some regular congressional activity resumes with a slew of health hearings. There will be no State of the Union. The focus on re-opening the government continues.

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