

## McDermott Plus Check-Up: December 7, 2018

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### This Week's Diagnosis

Memorial services for President George H.W. Bush were held this week in Washington, DC and Texas. No agreement has been reached on border wall funding, which means Members may be here through at least December 21.

### Congress

- **Continuing Resolution is the Short-term Solution.** Congressional leaders decided to limit votes this week to attend the memorial services for President George H. W. Bush, delaying consideration of an omnibus appropriations bill to fund the remainder of the federal agencies beyond December 7. The extension to December 21, 2018, provides additional time to reach an agreement, but also sets the stage for a pre-holiday government shutdown negotiation.
- **Future of the Finance Committee.** Chuck Grassley (R-IA) and Ron Wyden (D-OR), the incoming Chairman and current Ranking Democrat of the Senate Finance Committee, respectively, introduced a bill this week that attempts to close a loophole in the Medicaid drug rebate program. The [Right Rebate Act](#) would give Medicaid more tools to conduct oversight and impose financial penalties on drug companies that knowingly misclassify drugs as generic (as opposed to brand name) in order to receive rebates on the drug. This legislation is significant for two reasons. First, it is a bipartisan bill addressing a piece of the prescription drug cost puzzle. Second, those Senators will be the new leaders of the Senate Finance Committee, and this bill signals not only their first collaborative endeavor since the election (indicating this is a priority for both men), but also their willingness and ability to work together in the new Congress.

### Administration

- **More Work Requirements for Medicaid Approved.** The Centers for Medicare and Medicaid Services (CMS) approved New Hampshire's work requirements waiver request this week. New Hampshire expanded Medicaid in 2014, but Republicans in the state legislature have been pushing for work requirements ever since. New Hampshire is the fourth state to secure approval from CMS to impose work requirements for certain Medicaid recipients.

- **White House Releases Report on Healthcare Competition.** The US Departments of Health and Human Services, Treasury and Labor released a joint report this week, "[Reforming America's Healthcare System Through Choice and Competition](#)," highlighting the role of state and federal laws and regulations on choice and competition in health care markets. The report identifies actions that states and the federal government could take to address some identified roadblocks, restating a number of already advanced Administration priorities, including improving transparency and loosening restrictive regulations. The report's recommendations provide a roadmap for other policy changes likely to be championed by the the Administration in 2019.
- **FDA Makes Changes to De Novo Pathway for Devices.** The Food and Drug Administration (FDA) released a [proposed rule](#) that would change the review process (known as "de novo" pathway) for new, lower-risk medical devices for which there are no similar devices on the market. This proposal would attempt to bring more transparency and efficiency to the application and review process – something the device industry has sought. As a result of these changes, the FDA anticipates more developers will use the de novo pathway. This comes on the heels of FDA changes to the 510(k) pathway (the alternative to the de novo). The proposed rule is currently open for public comment.
- **CMS Finalizes Risk Adjustment Rule for Exchange Plans.** CMS issued a [final rule](#) adopting the HHS-operated risk adjustment methodology for the 2018 benefit year. Last February, a federal judge in New Mexico ruled that the government had failed to justify its methodology for calculating risk adjustment payments for the 2014 to 2018 benefit years. The administration used that ruling as the basis for freezing payments for a short time in July. CMS then announced a final rule to resume the payments for the 2017 benefit year, readopting the existing methodology and adding an explanation of the program's budget neutrality and use of statewide average premiums. A similar fix for 2018 was proposed shortly thereafter. The final rule is intended to provide some stability for issuers. However, with multiple ACA-related lawsuits winding their way through the courts, predictability remains elusive. The final rule comes out during the open enrollment period, and amidst what appears to be a downturn in ACA enrollment across the federal exchange states.

## Other

- **GAO Report on Review of Orphan Drug Program.** The Government Accountability Office (GAO) issued a [report](#) on the FDA's orphan drug program. The report specifically examined the growth of the program, the use of consistent criteria in evaluating applications and steps taken to address rare disease drug development challenges. The report notes a number of stakeholder concerns, including the strength of the incentives and the high price of these drugs once they hit the market. This report may trigger hearings and further inquiries from Congress.
- **MedPAC Examines Adequacy of Medicare Payment.** The Medicare Payment Advisory Commission (MedPAC) held its [December meeting](#). Commissioners heard reports on payment adequacy for services across Medicare, including physicians and other health professionals, ambulatory surgical centers, and hospital inpatient and outpatient. MedPAC also examined hospital quality incentive programs and provided a status report on Medicare Advantage. The presentations highlighted focus areas for potential policy recommendations in the future, including discussion about eliminating incident to billing; examining coding intensity

in Medicare Advantage; and eliminating an update in 2020 and requiring costs reports for ambulatory surgery centers.

## **Next Week's Dose**

"Normal" order returns to the Hill next week, with both chambers back in session feverishly working toward wrapping up any outstanding legislation and the ever-elusive deal on border wall funding. Smell jet fumes anyone?

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