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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: House Democrats passed a sweeping drug pricing reform package and key House and Senate committees announced a surprise billing deal.

CONGRESS

+ **HOUSE PASSED DEMOCRATS' DRUG PRICING PACKAGE.** The Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3), named to honor the recently deceased long-serving and highly-respected Representative, passed the House by a 230-192 margin (all present Democrats and two Republicans voted for the bill). The bill would, among other things, authorize Medicare to negotiate prices for up to 250 drugs, use international reference pricing, cap out-of-pocket costs for Part D beneficiaries, require manufacturer rebates if Part B or Part D prices increase faster than inflation, and increase insurer and drug manufacturer responsibility for Part D costs. The bill would deploy the savings from these drug pricing control measures to add dental, vision and hearing benefits to Medicare. The Congressional Budget Office (CBO) estimates that the drug price negotiation measures would reduce the federal deficit by $456 billion, but that the additional benefits would consume $358 billion of that savings. Overall, the total savings of the bill is about $5 billion over a 10-year scoring window. CBO also predicts that the loss of revenue for drug companies could result in eight fewer drugs coming to market over the next 10 years. H.R. 3 was championed by House Speaker Nancy Pelosi (D-CA). Senate Majority Leader Mitch McConnell (R-KY) has said he will not bring H.R. 3 up for a vote in the Senate. Last week, House Republicans introduced the Lower Costs, More Cures Act (H.R. 19) as an alternative to H.R. 3, and offered the bill as a substitute amendment to H.R. 3 during the floor vote this week. The motion was defeated by a vote of 223-201, and it is unlikely that H.R. 19 will receive a stand-alone vote on the floor. Now that H.R. 3 has passed, we expect work to shift toward finding a bipartisan, bicameral agreement on drug pricing. As we have noted, there are areas of policy agreement like capping out-of-pocket costs for seniors, limiting price increases, and reforming catastrophic coverage, among other issues.

+ **NEW PROPOSALS ON SURPRISE BILLING.** Republican and Democratic leaders of the House Energy and Commerce Committee and Chairman Lamar Alexander (R-TN) of the Senate Health, Education, Labor and Pensions (HELP) Committee released a section-by-section summary of a bipartisan, bicameral agreement to address surprise billing (Notably, Senate HELP Committee Ranking Member Patty Murray (D-WA) has not endorsed the agreement). The plan would hold patients harmless from surprise medical bills and set a benchmark rate for out-of-network bills at the median in-network rate for a geographic area. The proposal also includes arbitration as a means to settle payment disputes between insurers and providers for claims over $750. The hybrid benchmark and arbitration approach is a concession for the HELP Committee, which used just a benchmark as resolution. The $750 threshold is a concession to the provider community, as it is a decrease from the $1,250 threshold approved by the House Energy & Commerce Committee. While legislative text and an official CBO score are not yet available, the bill is expected to save the federal government approximately $22 billion over 10 years, according to committee leaders, making it an attractive pay-for for other spending priorities. The White House has voiced support for the compromise plan, which also includes some drug pricing policies relating to Food and Drug Administration (FDA) policies, provider-payer transparency and contracting reforms, raises the tobacco purchasing age to 21, and funds community health centers. Also this week, the House Ways and Means Committee released an outline of an alternative surprise billing plan, which Committee leaders say would respect existing market dynamics between hospitals and insurers. However, the announcement included very few details, and details are not expected this year. An additional alternative, especially one that lacks disclosed details, and the controversial nature of addressing surprise billing payment disputes could be enough to slow negotiations and push final agreement on surprise billing into 2020.

+ **SENATE PASSED REFORM OF FDA'S OVER-THE-COUNTER DRUG REGULATIONS.** The Over-the-Counter Monograph Drug Safety, Innovation, and Reform Act (S. 2749) establishes a user fee for the over-the-counter (OTC) drug industry, in part to help streamline the FDA's process of responding to safety concerns. The bill also provides 18 months of patent exclusivity for innovative OTC drugs and amends certain provisions in the Sunscreen Innovation Act. A similar version of the bill passed the House as part of the Pandemic All-Hazards Preparedness and Advancing Innovation Act in January. The Senate version, which does not include the pandemic preparedness provisions, now returns to the House for consideration. If passed, S. 2749 would represent the first congressional overhaul of the FDA's OTC medication approval process regulations since the 1970s.

ADMINISTRATION

+ **CMS WILL REPAY HOSPITALS FOR 2019 SITE-NEUTRAL PAYMENT CUT.** The Centers for Medicare and Medicaid Services (CMS) announced that beginning January 1, 2020, the agency will reimburse hospitals for a 2019 payment cut to certain off-campus facilities. CMS implemented an expanded site-neutral policy as part of the 2019 Medicare Hospital Outpatient Prospective Payment System (OPPS) final rule, but in September 2019, a federal district court judge ruled that CMS lacked the authority to impose the cuts. Until this week, it was not clear whether the agency planned to reimburse providers, despite a court order that the agency do so. Despite making back payments for 2019, CMS has appealed the district court decision and will implement the payment cuts for 2020 pending resolution of that appeal. CMS argues that the court ruling regarding the 2019 cuts has no bearing on future years.

+ **BIOLOGICS PROTECTIONS CUT FROM TRADE DEAL.** The Administration removed a provision granting a 10-year data exclusivity period for biologics from the final version of the U.S.-Mexico-Canada Agreement (USMCA). Protecting pharmaceutical intellectual property has been an increasing priority in recent trade deals, but House Democrats pushed for removal of the language, which they argued could lead to higher drug costs. Currently, the US offers 12 years of data exclusivity for new biologics, but some Democratic lawmakers have argued that this is too long. Setting a 10-year period in the USMCA would have committed the US to the international standard and prevented congressional efforts to lower the domestic limit further. The final agreement also eliminates protections for brand-name drug companies to extend patents for new uses of existing drugs. Congress is expected to vote on implementing the agreement as early as next week.

COURTS

+ **COURTS RULED IN FAVOR OF PUBLIC CHARGE RULE.** In a rare judicial victory for the Trump Administration, two federal appeals courts upheld a final rule, which changes how the Department of Homeland Security (DHS) interprets and implements the public charge ground of inadmissibility into the country, thus making it harder for immigrants who rely on public benefits to receive visas or green cards. The rule was originally scheduled to take effect in October 2019, but federal district court judges in California, Washington, Maryland, and New York blocked implementation, holding that DHS overstepped its authority in issuing the rule. Last week, a federal appeals court paused the Washington and California injunctions, and on Monday, a second appeals court paused the Maryland injunction. Both courts issued divided rulings holding that implementation of the rule should be allowed to go forward while litigation continues. The government has appealed the nationwide injunction issued by the New York court as well, but it remains in effect while the appeal is pending.

- **SUPREME COURT HEARD ORAL ARGUMENTS IN INSURER RISK CORRIDORS CASE.** The case involves whether the government owes insurers payments under the Affordable Care Act's (ACA) temporary risk corridors program, which was designed to encourage insurers to participate in the ACA marketplace by subsidizing some of their losses. However, in 2014 and 2015, Republicans in Congress eliminated much of the funding for the program by attaching riders to appropriations bills, effectively blocking the financial support for ACA insurers in the exchange marketplace. Dozens of insurers filed suit, claiming they are owed collectively more than $12 billion to cover losses between 2014 and 2016. The central question before the Court is whether zeroing out funding absolves the Administration of responsibility to provide the support given the ACA requirement. During oral arguments this week, a majority of justices reportedly seemed favorable to the insurers' arguments. A decision favorable to the insurers could strengthen insurers' arguments in another ACA-related case, currently before a federal appeals court, dealing with whether the Trump Administration had the authority to stop making cost-sharing reduction payments at the end of 2017.

STATES

- **SOUTH CAROLINA RECEIVED APPROVAL FOR WORK REQUIREMENT.** CMS approved South Carolina's Section 1115 waiver application to establish a Medicaid work requirement, making it the first state to implement a work requirement without fully expanding Medicaid. The South Carolina plan extends Medicaid benefits to parents and caretakers earning up to 100% of the federal poverty line (up from the current 67% threshold). It also authorizes the state to offer 12 months of Medicaid coverage to a Targeted Adult Group who would not otherwise be eligible but are chronically homeless, justice involved or needing substance use disorder treatment. The plan requires that all non-exempt beneficiaries participate in at least 80 hours per month of work or another qualifying activity or have their coverage suspended (exemptions include being pregnant, receiving alcohol or substance use disorder treatment, having a disability, or being a primary caregiver of a child or a disabled person). CMS has approved work requirements in 10 states to date, but several have been blocked in court. The South Carolina requirement will likely face a similar challenge from Medicaid advocates.

QUICK HITS

- The House Judiciary Committee released two articles of impeachment against President Trump. The full House is expected to vote on the articles before the end of the year.
- House and Senate lawmakers reached a tentative deal to fund the government for the rest of fiscal year 2020, to be voted on as early as next Tuesday. Questions remain about which expiring healthcare programs will have their funding extended, and for how long.
- The Energy and Commerce Health Subcommittee held Congress's fourth hearing on Medicare for All along with eight other coverage expansion proposals. Read our summary of the hearing here.

- The Energy and Commerce Oversight and Investigations Subcommittee examined FDA's Foreign Inspection Program.
- The Senate HELP Committee advanced bills aimed at child abuse prevention, expanding the health workforce, childcare safety and addressing racial health disparities.
- The Senate confirmed Stephen Hahn to be FDA Commissioner with a vote of 72-18.
- The Inspector General for the Department of Health and Human Services released a report that suggests Medicare Advantage (MA) insurers may have improperly received billions of dollars from the federal government by adding serious diagnoses to enrollees' medical charts without justification.
- 2016 MA encounter data is now available from CMS. The data offers researchers detailed information about services provided to MA beneficiaries.

M+ Resources

- CMS's Direct Contracting model builds on the Next Generation Accountable Care Organization model, featuring a greater emphasis on beneficiary engagement and a move to capitated payment. We take a closer look at the model here.

Next Week's Dose

Congress is working to complete a final spending package ahead of next Friday's government funding deadline. The House is expected to vote on an appropriations deal on Tuesday.

For more information, contact Mara McDermott, Rachel Stauffer, Katie Waldo and Emma Zimmerman.

To subscribe to the McDermottPlus Check-Up, please contact Jennifer Randles.