McDermottPlus Check-Up: May 17, 2019

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This Week’s Dose: Drug pricing remains in the spotlight, but lawmakers also introduced legislation focused on surprise billing and coinsurance.

Congress

House Votes on Bill Linking Drug Pricing and ACA Fixes.

The House passed H.R. 987, a bill that combined three bipartisan drug pricing policies with Democrat-backed measures designed to shore-up Affordable Care Act (ACA) insurance markets. The bill passed with a vote of 234 to 183, with five Republicans voting in favor. The three drug pricing bills included are the CREATES Act, a ban on pay-for-delay settlements, and a measure to discourage abuse of 180-day exclusivity for first generic applicants. The four bills that shore up the ACA call for a reversal of the Trump administration’s expansion of short-term plans, $200 million in grants to states to help them set up their own exchanges, $100 million a year for ACA navigators, and $100 million a year for ACA outreach and marketing. The drug pricing provisions were approved unanimously by the Energy and Commerce (E&C) Committee in April, so many Republicans voiced frustration that Democrats chose to pair the bills with partisan ACA measures. House Democrats defended the maneuver as a budget necessity, since the drug pricing bills would save about $4 billion over a decade. The Republican-controlled Senate is highly unlikely to take up H.R. 987, but may repackage and advance the prescription drug bills independently.

House Democrats Push For Another Two-Year DSH Cut Delay.

The Democratic majority of the House sent a letter to House leadership asking to delay by two years the $4 billion Medicaid Disproportionate Share Hospital (DSH) payment cuts set to go into effect on October 1, 2019. Medicaid DSH cuts were originally included in the ACA but have been repeatedly postponed by Congress. Most recently, in February 2018, Congress approved legislation that included a two-year delay of the cuts. On the Senate side, Finance Committee Chairman Chuck Grassley (R-IA) has said that Congress should revamp the payment system instead of simply delaying the cuts again. Medicaid DSH is likely to be the biggest driver of a health care extenders package that Congress will be working on this summer and early fall.

House and Senate Surprise Billing Legislation Introduced.

Democratic and Republican leaders of the House Energy & Commerce Committee, Frank Pallone (D-NJ) and Greg Walden (R-OR), released a discussion draft entitled the No Surprises Act. Senators Bill Cassidy (R-LA), Michael Bennet (D-CO), Todd Young (R-IN), Maggie Hassan (D-NH), Lisa Murkowski (R-AK) and Tom Carper (D-DE) introduced the Stopping the Outrageous Practice (STOP) of Surprise Bills Act of 2019. As shown in this _, the two approaches vary. There are a few notable distinctions that are important for stakeholders to consider: (1) what constitutes surprise billing; (2) the process for the provider to challenge the payment rate, if at all; and (3) transparency requirements. In the Senate, it will be important to see if leaders of the Senate HELP Committee include provisions from the STOP Surprise Bills Act in their broader cost containment package expected to be released in the next few weeks. In the House, Representatives Pallone and Walden are seeking feedback on the No Surprises Act discussion draft and have yet to schedule or hold a hearing on the issue.

Romney and Braun Introduce Coinsurance Bill.

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Senators Mitt Romney (R-UT) and Mike Braun (R-IN) introduced a bill (S. 1384) that would require health plans to base coinsurance for consumers on a percentage of prescription drugs’ net price instead of list price. The net price is often lower after rebates and other discounts are negotiated with an insurance company. During the drug pricing hearings over the past few weeks, several witnesses suggested tying patient cost-sharing to net price rather than list price as a way to reduce out-of-pocket costs.

**Bipartisan Bill to Codify HHS DTC Advertising Rule.**

Senators Dick Durbin (D-IL) and Chuck Grassley (R-IA), along with Senators Angus King (I-ME) and Lamar Alexander (R-TN), introduced bipartisan legislation to codify recent regulations from the Department of Health and Human Services (HHS) to require pharmaceutical companies to list prices of their prescription drugs in direct-to-consumer (DTC) advertisements. In 2018, the Senate passed a bipartisan amendment introduced by Senators Grassley and Durbin to the Defense-Labor-HHS-Education appropriations “minibus” package that would have provided HHS with $1 million to implement rules requiring pharmaceutical companies to list prices of their prescription drugs in DTC advertisements. Ultimately, the amendment was stripped from the bill during the House-Senate conference process. Grassley has an opportunity this year to include this bill in any prescription drug legislative package.

**Ways and Means Holds Hearing on Maternal Mortality.**

The House Ways and Means Committee held a hearing entitled “Overcoming Racial Disparities and Social Determinants in the Maternal Mortality Crisis.” Democrats on the committee urged expanding Medicaid coverage and growing the health care workforce to reduce pregnancy-related deaths, while Republicans called for further studies and data to develop an effective response. Lawmakers have already taken some steps to gather such data, passing the Preventing Maternal Deaths Act of 2018 that set up a federal infrastructure and directed resources to collect data on maternal-related deaths. This Congress, Democrats have introduced the MOMMA’S Act (S.916/H.R. 1897), which extends Medicaid coverage for new mothers from its current standard of 60 days after childbirth to a full year of coverage. Social determinants of health seems to be an ongoing area with bipartisan interest and support.

**Administration**

**CMS Issues Final Rule on Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses.**

In the final rule, the Centers for Medicare and Medicaid Services (CMS) did not finalize its suggested changes to six protected classes that would have allowed Part D plan sponsors to exclude a protected class drug from a formulary under certain circumstances. However, the rule does finalize changes relating to step therapy, requires plan sponsors to notify enrollees of drug price increases and lower cost alternatives, and implements statutory requirements on gag clauses. CMS also noted that they received over 4,000 comments regarding redefining negotiated price as the baseline, or lowest possible payment to a pharmacy. CMS notes that it will continue to examine this policy, but does not implement changes in the final rule.

**CMS Releases LOI for New Direct Contracting Models.**

The Center for Medicare and Medicaid Innovation (Innovation Center) posted the letter of intent (LOI) for organizations to indicate an interest in participating in the newly announced Direct Contracting models. The models are intended to test higher levels of risk and reward in traditional Medicare. Organizations interested in participating must submit the non-binding LOI by August 2. CMS and the Innovation Center announced the models in April, but critical details, including the financial elements, have yet to be released, making it difficult to fully size up their attractiveness.

**CMS Issues New Guidance Addressing Spread Pricing in Medicaid.**

CMS issued guidance for Medicaid and Children’s Health Insurance Program (CHIP) managed care plans regarding the calculation of a plan’s medical loss ratio (MLR). CMS regulations require Medicaid and CHIP managed care plans to report an MLR and use an MLR target of 85 percent in developing rates. Regulations also require plans to exclude prescription drug rebates from the amount of actual claims costs used to calculate MLR. It has been unclear whether pharmacy benefit spread pricing (the difference between what a health plan pays a pharmacy benefit manager (PBM) and the amount that the PBM reimburses the pharmacy) should be factored into MLRs. The new guidance states that, for MLR regulation, “prescription drug rebates” means any price concession or discount received by the managed care plan or by its PBM, regardless of who pays the rebate or discount. The underpinning policy is that spread pricing should not artificially inflate a Medicaid or CHIP managed care plan’s
States Petition DOL over AHP Guidance.

Attorneys general (AGs) from twelve states (all Democrats) sent a letter to the Secretary of the Department of Labor (DOL) over its recent guidance stating that association health plans (AHPs) can operate as usual despite a recent court ruling overturning key pieces of the Trump administration’s AHP expansion. The AGs claim that the DOL should clearly state that AHPs created under the now vacated Trump administration rule must meet ACA requirements. They argue that the DOL guidance did not fully inform consumers that certain ACA requirements now apply to individuals and small groups enrolled in AHPs formed under the Administration’s new rule, including coverage of essential health benefits and premium rating requirements. If an AHP violates the ACA requirements, consumers in some states could be denied coverage for life-saving services. The same day that the AGs submitted the letter, the DOL released additional guidance stating that AHPs created under the now-defunct rule can keep current customers but can’t sign up new ones. The new guidance makes no mention of the ACA’s requirements. AHPs created before the Trump administration’s rule are not affected by the recent court ruling.

Next Week’s Diagnosis:

Surprise billing takes center stage next week with the House Ways and Means Committee hearing on Tuesday. But drug pricing isn’t out of the spotlight yet. The House E&C Committee is also planning a hearing on another package of bipartisan drug pricing bills.

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