

McDermottPlus Check-Up

McDermott+Consulting is pleased to provide the McDermottPlus Check-Up, your regular update on health care policy from Washington, DC.



THIS WEEK'S DIAGNOSIS: Another busy week for prescription drug pricing. Two more hearings took place on the subject, and a handful of bills passed out of the House. Now we watch the Senate to see how it packages and advances prescription drug bills that have moved through the House.

CONGRESS

+ ANOTHER BUSY WEEK FOR DRUG PRICING.

- The Senate Judiciary Committee held a [hearing](#) entitled “Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition,” during which lawmakers laid the groundwork for the Federal Trade Commission (FTC) to investigate drug patents. Senators John Cornyn (R-TX) and Richard Blumenthal (D-CT) are working on legislation that would give the FTC power to bring antitrust lawsuits against drug companies that use patents to stifle competition and extend market exclusivity. Specifically, the bill would target tactics like patent thickets (the use of overlapping intellectual property rights) and product hopping (shifting consumers onto slightly different brand name drugs when older patents run out). Cornyn and Blumenthal, along with other committee members, grilled a panel of industry experts over patents’ roles in high drug prices and pressed them to support measures already on the table, including banning pay-for-delay agreements, fining brand name manufacturers that withhold samples from generic manufacturers and limiting the use of citizen petitions that can stall generics.
- The Energy and Commerce Health Subcommittee held a [hearing](#) entitled “Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain.” Members heard from two panels of witnesses, all stakeholders in the drug supply chain, regarding their roles in determining prices for consumers. Witnesses from the pharmaceutical industry cited pharmacy benefit managers (PBMs) and the current rebate structure for high drug prices, while the PBM representatives called on the manufactures to lower their list prices. The same debate has taken place in previous hearings as Congress has sought feedback on the Administration’s [proposal](#) to end legal protections for rebates in Part D, forcing PBMs to offer point-of-sale discounts instead. Drug companies have been supportive of this change, while PBMs have warned that it would lead to higher premiums and spending in Medicare Part D, as plan sponsors typically use the savings from rebates to lower premiums overall. Read our full summary of the first panel hearing [here](#).

- The House passed two drug pricing bills aimed at making it easier for generic and biosimilar companies to access information on drug patents and marketing exclusivity. The two bills ([Orange Book Transparency Act of 2019](#) and [Purple Book Continuity Act of 2019](#)) take steps to increase the accuracy of documents listing drug and biopharmaceutical patents. Both bills passed with bipartisan support.
 - House Majority Leader Steny Hoyer (D-MD) announced that the House will vote next week on [H.R. 987](#), which packages popular, bipartisan drug pricing policies with Democratic-backed measures designed to shore up Affordable Care Act (ACA) markets. 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, all of which unanimously passed the House Energy and Commerce Committee. The four bills that shore up the ACA call for a reversal of the Trump administration's expansion of short-term plans, \$200 million to assist states that seek to run their own exchanges, \$100 million a year for ACA navigators, and \$100 million a year for ACA outreach and marketing. The package notably does not include Rep. Ann Craig's (D-MN) bill providing \$10 billion a year in federal funds to set up state reinsurance programs. This is the only committee-approved piece of Obamacare-related legislation not in the package. Since the Democrats decided to pair the drug pricing bills with ACA-related bills, H.R. 987 is unlikely to gain significant, if any, Republican support.
- + **HOUSE VOTES TO ROLL BACK 1332 GUIDANCE.** The House passed [H.R. 986](#) by a vote of 230 to 183, with three Republicans voting in favor. The bill would reverse the Trump administration's guidance expanding 1332 waivers. The guidance, among other things, lets states expand the availability of short-term, limited duration (STLDI) plans, which do not cover preexisting conditions. Democrats have argued the guidance allows too much flexibility and further undermines the ACA. No states, however, have taken advantage of the increased flexibility yet.
- + **HELP'S SECOND HEARING ON 21ST CENTURY CURES IMPLEMENTATION.** The Senate Health, Education, Labor and Pensions (HELP) Committee held a [hearing](#) entitled "Implementing the 21st Century Cures Act: Making Electronic Health Information Available to Patients and Providers, Part II." During the hearing, lawmakers discussed proposed rules by the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) that seek to implement several requirements in 21st Century Cures related to interoperability and the sharing of health information. Read the CMS rule [here](#) and the ONC rule [here](#). Several members of the committee suggested that the Department of Health and Human Services (HHS) should delay both rules and take a more phased-in approach. However, National Coordinator for Health IT Don Rucker pushed back on changing the timelines during his testimony, noting that the majority of providers have access to health IT software that meets the interoperability standards.
- + **SENATE FINANCE DOES A MACRA CHECK UP.** The Senate Finance Committee held a hearing entitled "Medicare Physician Payment Reform After Two Years: Examining MACRA Implementation and the Road Ahead." The hearing examined the Medicare

Access and CHIP Reauthorization Act (MACRA) of 2015 and assessed how well that reform legislation is meeting its goals of improving quality of care and value for taxpayers. The committee heard directly from physicians who have participated in the MACRA changes and an academic expert to understand which reforms have been successful and which can be further improved. Read our full summary [here](#).

ADMINISTRATION

- + **CMS ISSUED GUIDANCE ON ENHANCED FMAP FOR SUD-FOCUSED HEALTH HOMES.** CMS released an informational [bulletin](#) to provide guidance to states about the availability of two additional quarters of enhanced Federal Medical Assistance Percentage (FMAP) at 90 percent for certain substance use disorder (SUD)-focused health homes. Section 1006(a) of the SUPPORT for Patients and Communities Act (also referred to as the opioid package) extended the enhanced match period from eight fiscal year quarters to 10 fiscal year quarters for SUD-focused health home state plan amendments approved on or after October 1, 2018. The change reflects the Administration's focus on addressing the country's opioid epidemic.
- + **CMS RELEASED A FINAL RULE ON DIRECT-TO-CONSUMER ADVERTISING FOR DRUGS.** CMS released its [final rule](#) on direct-to-consumer (DTC) advertising for drugs covered under federal programs. This rule, first proposed last October, requires drug manufacturers to include list prices in DTC advertisements. According to the rule, DTC television advertisements for prescription drugs and biological products for which reimbursement is available, directly or indirectly, through Medicare or Medicaid must include the list price of that product. CMS defines the list price as the wholesale acquisition cost (WAC) for a "typical 30-day regimen or for a typical course of treatment" of the drug. Drugs with a WAC of less than \$35 are exempt. Manufacturers may also include the list price of competitors' products if done truthfully. Disclosures must be in legible text at the end of the advertisement and must be displayed long enough to be read easily. CMS will maintain a list of products that violate this requirement and expects to enforce this through monitoring unfair competition in the form of misleading advertising.
- + **PRESIDENT TRUMP ADDRESSED SURPRISE BILLING.** President Trump held a press conference and announced principles to address surprise billing. He was joined by HHS Secretary Alex Azar, patients who have received a surprise medical bill, and key members of Congress working to develop surprise billing legislation. Chairman of the Senate HELP Committee, Lamar Alexander (R-TN), stated that Congress will bring the President a bipartisan bill in July. The Administration's four principles to follow when addressing surprise billing are:
 - Patients receiving emergency care should not be forced to shoulder extra costs billed by a care provider but not covered by their insurer.
 - Patients receiving scheduled care should have information about whether providers are in or out of their network and what costs they may face.
 - Patients should not receive surprise bills from out-of-network providers they did not choose.
 - Federal healthcare expenditures should not increase.

Notably, there already is considerable consensus around these principles. The challenge comes in how to achieve these goals, like who (providers or insurers) should bear the burden of the “extra cost.” This is an area containing opportunity for bipartisan collaboration. With the Administration outlining its principles and addressing the issue, we can expect to see significant legislative action on this in the near future.

STATES

- + **TENNESSEE GOES FOR MEDICAID BLOCK GRANTS.** The Tennessee legislature passed a bill that seeks to convert its Medicaid program into one financed by a federal block grant. The Tennessee bill directs the state to submit a waiver to CMS within 120 days proposing a block grant plan. The plan would establish a fixed amount of federal Medicaid funding that the state could receive, rather than open-ended matching funds as called for by the Medicaid Act. The lump sum from the federal government would be indexed for inflation and population growth. Governor Bill Lee (R) is expected to sign the bill. It is the latest example of a Republican-controlled state seeking to use 1115 waiver authority to implement conservative changes to Medicaid, with several other states instituting work requirements. Alaska officials have also had talks with CMS about implementing block grants, and Utah plans to request per-capita spending caps in its Medicaid program. Many health law experts question the legality of adopting block grants through waivers, and the requests, if approved by CMS, are certain to be challenged in court.

OTHER

- + **COURT ISSUED ORDER ON REMEDIES IN 340B MEDICARE PAYMENT CUT CASE.** The US District Court for the District of Columbia issued its [opinion](#) regarding remedies in the on-going litigation over the Medicare payment cuts to 340B drugs dispensed to hospital outpatients. The change to the Medicare Hospital Outpatient Prospective Payment System went into effect January 1, 2018, and cut Medicare reimbursement for 340B drugs by approximately 30 percent. On December 27, 2018, the Court held that CMS exceeded its authority when making this change, but did not immediately provide a remedy. With this week’s opinion and order, the Court instructed CMS to develop an appropriate remedy to address the payment cuts and provide an update to the Court on their progress on or before August 5, 2019. However, in February, HHS appealed the underlying decision, so it is possible that implementation of any remedy would not occur until the appeal is decided.
- + **CBO PREDICTS THE EXCHANGE MARKET WILL SHRINK BUT REMAIN STABLE THROUGH 2029.** The Congressional Budget Office (CBO) issued a [report](#) which found that the health insurance exchange population is expected to fall from 14 million in 2019 to 11 million in 2029, but the marketplace will remain stable. The report also predicts that about 30 million people will be uninsured in 2019, growing to 35 million by 2029. Additionally, about 7 million people fewer people will be insured in 2019 than if the individual mandate penalty of the ACA had not been repealed. CBO says the effect of the mandate repeal is expected to remain consistent through 2029, and will be partially offset by more states expanding Medicaid and increased enrollment in non-ACA coverage. While the Administration has issued rules to expand access to STLDI and

association health plans, Democrats insist that these amount to “junk” insurance and do not make up for lost coverage.

NEXT WEEK’S DOSE

The House is set to vote on another set of drug pricing bills, this time with Democrat-backed ACA measures included. And we’ll be watching the Senate as the first House-passed drug pricing bills move to the other side of the Capitol.

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

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