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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: Congress is back in session following the holiday recess, though the exact Senate schedule remains uncertain as lawmakers negotiate the details of President Trump's impeachment trial.

CONGRESS

+ **LAWMAKERS CONTINUE TO GRAPPLE WITH DRUG PRICING, SURPRISE BILLING IN THE NEW YEAR.** Congress ended 2019 with many healthcare priorities still unfinished, including legislation to address surprise medical bills and prescription drug pricing reform. Even with the Administration and both chambers in Congress aligned on a large number of prescription drug pricing policies, significant policy differences dominated across parties and committees, and ultimately Congress was unable to reach agreement. Similarly, multiple legislative proposals were introduced to address the issue of surprise medical bills, but Congress ultimately failed to get a final package over the finish line, though it was recently reported that a bipartisan group of House lawmakers plan to sit down and try again to reach an agreement on surprise billing. Both of these issues are sure to remain on the table this year as lawmakers and the President look for a policy "win" leading up to the general election. Another factor keeping drug pricing reform and surprise billing policy on the table is the May 22, 2020, funding deadline for several expiring healthcare programs. Come May, Congress will have to decide whether to extend that funding again, and proposals to lower drug costs and prevent surprise medical bills, which save money, are potential offsets. For more on what to expect in 2020, check out our Policy Forecast and the latest episode of the Health Policy Breakroom.

ADMINISTRATION

+ **FDA ISSUED PARTIAL E-CIGARETTE FLAVOR BAN.** After mounting uncertainty that the Administration would follow through on its promise to address the teen vaping epidemic by banning flavored e-cigarettes, the Food and Drug Administration (FDA) released guidance to enforce a ban on some flavored tobacco products used in cartridge-based electronic nicotine delivery system (ENDS) devices on a case-by-case basis. Rather than an outright ban, the guidance allows FDA to evaluate a manufacturer's premarket authorization application to determine whether the product can go to market. According to FDA, the agency will prioritize enforcement against:

- "Any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product);
- All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and
- Any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors."

The ban exempts vaping products that do not use cartridges. A previous version of the proposal that the Administration hinted at but never published included a ban on menthol flavors as well, though the current version does not. Many public health organizations and some members of Congress from both parties pushed for a ban on all flavored tobacco products, and argue that the guidance does not go far enough. In the absence of a comprehensive, nationwide flavor ban, states may continue to take vaping policy into their own hands. The FDA guidance is expected to take effect in early February.

+ **HHS ANNOUNCED BRAD SMITH TO HEAD CMMI.** According to the announcement, Smith will assume the dual role previously occupied by Adam Boehler, becoming Director of the Center for Medicare and Medicaid Innovation (CMMI) and serving as Senior Advisor for Value-Based Transformation to Health and Human Services (HHS) Secretary Alex Azar. In 2019, Boehler stepped down to head the International Development Finance Corporation. Under Boehler's leadership, CMMI pursued new payment models in keeping with the Trump Administration's goal of moving to value-based payment. Smith is likely to pursue the same goal, though it is not clear how much he will steer the organization toward his own agenda versus implementing Boehler's vision.

+ **CMS ANNOUNCED NEW ACO PARTICIPATION AND SAVINGS NUMBERS.** In a blog post, Centers for Medicare and Medicaid Services (CMS) Administrator Seema Verma touted the uptick in participation in two-sided risk arrangements in the redesigned Medicare Shared Savings Program for Accountable Care Organizations (ACOs), which the agency overhauled in 2018. Under the redesigned program, ACOs were encouraged to take on more financial risk in exchange for flexibility in program design. According to the announcement, 192 ACOs will take risk in 2020, compared to 93 at the start of 2019. ACOs now serve approximately 11.2 million Medicare fee-for-service beneficiaries, up from 10.4 million at the start of 2019. Verma also announced savings results in the Next Generation ACO (NGACO) program, a CMMI model which tests higher levels of risk and additional flexibilities. In 2018, the model's third performance year, 38 ACOs (76% of participants) achieved shared savings, while 12 ACOs (24% of participants) had losses. In total, CMS estimates that the NGACO model saved the Medicare program more than $184 million in 2018. CMS also published the second evaluation report for the NGACO model, examining the first two performance years (2016 and 2017). The report found a statistically significant reduction in spending under the NGACO model compared to care outside the model. However, after taking into account the shared savings payments made to ACOs, the report finds the model did not lead to a statistically significant difference in spending for the first two performance years. The NGACO model ends this year and stakeholders have been pushing the agency use its authority to make the model permanent.

COURTS

+ **STATES ASKED SUPREME COURT TO FAST TRACK ACA CONSTITUTIONALITY CASE.** A group of Democratic-led states leading the legal battle to defend the Affordable Care Act (ACA) and the US House of Representatives asked the Supreme Court to review a December 2019 federal appeals court ruling, which found the ACA's individual mandate unconstitutional. In 2018, a federal district judge in Texas held that because Congress eliminated the individual mandate penalty as part of the Tax Cuts and Jobs Act of 2017, the individual mandate was unconstitutional and not severable from the rest of the law, rendering the entire ACA unconstitutional. The appeals court ruling affirmed the district court's decision that the individual mandate was unconstitutional, with little practical effect given that Congress already zeroed out the penalty, but did not address the question of the ACA's validity without the mandate. The appeals court remanded the case back to the district court with instructions for the lower court to reconsider its prior decision as to which parts of the ACA can still stand. The Democratic states asked the Supreme Court to take up the case before the district court issues a revised decision, and proposed an expedited timeline that could result in the Court issuing a final ruling in June. In response, the Court asked the Justice Department and Republican-led states challenging the ACA to submit their response to the request for an expedited schedule by January 10. Though it requires the agreement of only four Supreme Court justices to hear a case, five must agree to expedite review. If the Court does agree to hear the case in the coming months, it is sure to turn up the heat on the politics surrounding the ACA and the chaos that could result from total repeal. Either way, the issue is sure to be front and center in the run up to the 2020 election.

STATES

+ **CMS APPROVED INDIANA WAIVER FOR MENTAL ILLNESSES TREATMENT AT IMDS.** The approved Section 1115 waiver allows Indiana to use federal Medicaid dollars to fund inpatient treatment for serious mental illness at Institutions for Mental Diseases (IMDs), removing the so-called IMD exclusion, which prohibits Medicaid funding for treatment at IMDs. CMS has already approved a number of 1115 waivers to allow federal funding for IMDs. However, most have focused primarily on substance use disorder (SUD) treatment, rather than serious mental illness. In November 2018, CMS sent a letter to state Medicaid directors, encouraging them to seek waivers for serious mental illness treatment. The Indiana waiver is the third of its kind to be approved. CMS previously approved similar waivers in Vermont and Washington, DC, and a waiver from Idaho to cover SUD and/or series mental illness treatment at IMDs is pending. Additionally, Arizona, Colorado, Tennessee and Maine are awaiting approval to cover SUD treatment at IMDs.

QUICK HITS

- The House Energy and Commerce Health Subcommittee considered legislation aimed at improving healthcare coverage and outcomes. Read our summary here.
- CMS extended the public comment period for the Medicaid Fiscal Accountability proposed rule through February 1, 2020.
- CMS extended the public comment period for the Transparency in Coverage proposed rule through January 29, 2020.
- CMS sought feedback regarding eliminating specific Medicare regulations governing supervision requirements that are more stringent than existing state scope of practice laws or that prevent health professionals from practicing at the top of their license. Comments are due by January 17, 2020.
- CMS released Part I of the 2021 Advance Notice, which describes the proposed Medicare Advantage risk adjustment model for the forthcoming plan year. The second part of the Advance Notice is expected on or before February 6, 2020. Comments are due March 6, 2020. The calendar year 2021 capitation rates and final payment policies are expected by April 6, 2020.
- CMS sought banking information from certain Medicare providers who should have received Quality Payment Program bonuses in 2019 for their 2017 performance in advanced Alternative Payment Models.
- CMS issued an Informational Bulletin to state Medicaid programs regarding best practices to avoid duplicate discounts in the 340B program, and the Government Accountability Office published a report recommending ways for the Health Resources and Services Administration to increase its oversight of the program.
- The Administration appealed a federal district court ruling to block the provider conscience regulation allowing healthcare providers to refuse to provide certain healthcare services on religious or moral grounds.
- A federal appeals court sided with a federal district court in New York, maintaining a nationwide injunction against the Administration's public charge rule, which allows immigration authorities to deny visas or green cards based on a person's use of Medicaid or other public benefits.
- The Medicaid and CHIP Access and Payment Commission released the report Oversight of Institutions for Mental Diseases. The report identifies and describes facilities designated as IMDs and includes a summary of state licensure, certification or accreditation requirements, and Medicaid clinical and quality standards.

M+ RESOURCES

- It is sure to be another active year for the healthcare industry. Check out our Policy Forecast and the latest episode of the Health Policy Breakroom to learn what 2020 may have in store.

+ Our Key Dates Calendar provides a look ahead at 2020 through the lens of the Democratic primary schedule. Buckle up! We are in for a busy five months.

NEXT WEEK'S DOSE

The House Energy and Commerce Oversight and Investigations Subcommittee will hold a hearing on state efforts to address the opioid crisis, and the Energy and Commerce Health Subcommittee will hold a hearing on federal cannabis policy.

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

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