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 authorized supplemental funding to fight the coronavirus (COVID-19) outbreak as the Administration works to speed diagnostic testing. The US Supreme Court announced that it will review the latest challenge to the Affordable Care Act (ACA) this fall. Fourteen states held Democratic primaries on Super Tuesday, and the Democratic field was significantly narrowed in the aftermath.

CONGRESS

- + CONGRESS PASSED EMERGENCY FUNDING FOR COVID-19 RESPONSE. The bipartisan deal authorizes \$8.3 billion to combat the COVID-19 outbreak, allocated across federal and state governments. The deal includes \$3 billion for the research and development of vaccines, \$2.2 billion for the Centers for Disease Control and Prevention (including \$950 million to support state and local agencies), \$836 million for the National Institutes of Health, and \$61 million for the Food and Drug Administration (FDA). The bill also includes provisions that waive certain telehealth requirements during the public health emergency to ensure Medicare beneficiaries can receive telehealth services at home to avoid placing themselves at greater risk of the virus. The package far exceeds the \$2.5 billion that the Administration requested last week, which members of both parties said was insufficient to address the growing outbreak. The funding bill overwhelmingly passed the House with a vote of 415 to 2 and the Senate with a vote of 96 to 1. President Trump signed the legislation. So far, 11 deaths and more than 200 infections have been reported in the United States, and the number is expected to grow. In an example of the increasing public health concern, the Healthcare Information and Management Systems Society Global Health Conference, an annual event that draws tens of thousands of attendees in the healthcare industry, was canceled for the first time in more than 50 years. As the virus spreads and experts learn more about appropriate and necessary treatment, Congress may need to revisit the need for additional federal resources with further supplemental appropriations.
- + HOUSE PASSED BILL TO BAN FLAVORED TOBACCO PRODUCTS. The Reversing the Youth Tobacco Epidemic Act (H.R. 2339), which passed with a vote of 213 to 195, would prohibit the sale of all flavored tobacco products, including menthol, raise the tobacco purchasing age to 21 and ban all online tobacco sales. The bill goes significantly further than the <u>partial flavor ban</u> that the Administration released in January, which many members of Congress said did not go far enough, and hints at an appetite in Congress to do more to regulate the tobacco industry. House Energy and Commerce Committee Chairman Frank Pallone (D-NJ), who introduced the legislation, has also voiced support for capping the levels of nicotine in tobacco products, a regulation that the FDA

considered in 2017 but has since abandoned. However, H.R. 2339 is unlikely to advance in the GOP-controlled Senate and the White House issued a <u>statement</u> opposing the bill.

ADMINISTRATION

+ ADMINISTRATION TOOK STEPS TO SPEED COVID-19 TESTING. The FDA issued new guidance aimed at increasing diagnostic testing for COVID-19. The policy allows certified hospital labs to begin using validated diagnostic tests they have developed inhouse before getting formal authorization from the FDA. This change will enable certified labs across the country to begin testing thousands more patients. In addition, the Centers for Medicare and Medicaid Services (CMS) created a second Healthcare Common Procedure Coding System code that laboratories can use to bill for certain non-CDC COVID-19 tests, including those developed under FDA's new guidance, and issued information on how Medicare, Medicaid, and individual and small group market insurance will cover COVID-19-related services. These services include diagnostic tests, necessary hospitalizations and certain telehealth services. Medicare claims processing systems will be able to accept this new code starting on April 1, 2020, for dates of service on or after February 4, 2020. Local Medicare Administrative Contractors are responsible for setting the payment amounts. Medicaid and individual and small group market insurance coverage will vary by state, though diagnostic tests are generally covered. Some private insurers have pledged to waive patient cost-sharing for COVID-19 testing to help fight the spread of the illness. Experts have warned that the amount of testing currently being done is not enough to effectively monitor the outbreak and that failure to increase testing could lead to faster spread. Health and Human Services Secretary Alex Azar, CMS Administrator Seema Verma, FDA Commissioner Stephen Hahn and National Institute of Allergy and Infectious Diseases Director Anthony Fauci met with lawmakers this week to brief them on the response to the epidemic, and Hahn indicated that over one million tests would be available soon.

COURTS

+ SUPREME COURT WILL HEAR ACA CHALLENGE. The Supreme Court announced that it will review the latest challenge to the ACA, with oral arguments likely to occur in October or November 2020 and a decision expected no earlier than March 2021. In 2018, a federal district judge in Texas held that because Congress eliminated the individual mandate penalty in 2017, the individual mandate was unconstitutional and not severable from the rest of the law, rendering the entire ACA unconstitutional. A federal appeals court affirmed the district court's decision that the individual mandate was unconstitutional, but remanded the case to the district court with instructions to reconsider which parts of the ACA could still stand. The Supreme Court in January rejected a request from the Democratic-led states defending the ACA to review the case on an expedited timeline (which would have likely led to a ruling before the 2020 election). The Supreme Court's decision ensures that the ACA and its key provisions including protections for people with preexisting conditions—will remain front and center through the 2020 election. Democrats successfully campaigned on preserving the ACA in the 2018 mid-term elections resulting in Democrats reclaiming the House. Democrats hope to similarly use the ACA to their advantage in 2020.

+ COURT BLOCKED MICHIGAN WORK REQUIREMENT. The A federal district court invalidated Medicaid work requirements in Michigan, following a federal appeals court decision last month blocking similar requirements in Arkansas. The Trump Administration has granted 10 state requests to implement Medicaid work requirements, but has faced repeated defeats in court. A federal district court also blocked requirements in Kentucky and New Hampshire, and Arizona and Indiana have suspended implementation of their requirements due to ongoing litigation. Ohio, Wisconsin and South Carolina have received CMS approval but have not yet implemented their programs. Only Utah has work requirements still in place, though enforcement penalties do not kick in until May 1, 2020. CMS has remained committed to the policy and may ultimately seek Supreme Court review.

STATES

+ MISSOURI SUBMITTED WAIVER REQUEST FOR POSTPARTUM MENTAL HEALTH AND SUD COVERAGE. The Section 1115 waiver would extend Medicaid substance use disorder (SUD) and mental health treatment benefits for postpartum women with incomes at or below 196% of the federal poverty line (FPL) for an additional one year after termination of their pregnancy benefits. Currently, women in Missouri who qualify for Medicaid during pregnancy lose their benefits three months after giving birth, potentially interrupting any mental health or SUD treatment they were receiving. It is unclear whether CMS will approve the request. South Carolina requested similar authority in 2019 as part of an 1115 waiver. CMS did not approve the proposal, but said that it would work with the state to authorize coverage for postpartum women under state plan authority. Illinois has also submitted a waiver request to extend postpartum coverage for 12 months for beneficiaries with incomes at or below 213% of the FPL, not just those with SUD, which is currently pending CMS approval. Many lawmakers in both parties have expressed support for expanding postpartum Medicaid coverage, and the issue is likely to remain at the forefront for many maternal health advocates. CMS will accept comments on Missouri's proposal through March 28, 2020.

QUICK HITS

- + Representatives Diana DeGette (D-CO) and Larry Bucshon (R-IN) introduced the <u>VALID</u> <u>Act of 2020</u>. The bill would reform how diagnostic and lab tests are reviewed and approved, putting this authority solely under FDA, and create an expedited review for diagnostic tests that treat unmet needs for patients (which currently exists for drug approvals). It is expected to be considered through regular committee order, but timing is unclear.
- + The House Energy and Commerce Health Subcommittee <u>considered</u> 14 bills aimed at helping patients with SUD.
- + The Senate Finance Committee issued a <u>request for information</u> on ways to improve maternal health. Comments are due March 20, 2020.
- + CMS hosted its annual Quality Conference. Here are our top five takeaways.

- + The US Government Accountability Office released a <u>report</u> on Medicare Dependent Hospitals, which are often located in rural areas, and the role they play in serving patients with complex medical conditions and comorbidities. The report could be a resource for lawmakers as they continue to work on a rural health package
- + The Medicare Payment Advisory Commission held its March public meeting.

M+ **R**ESOURCES

+ <u>Super Tuesday</u> was a turning point for Vice President Joe Biden's campaign, leaving him and Senator Bernie Sanders (I-VT) in a tight race for the Democratic nomination. Our <u>chart</u> compares the candidates' healthcare platforms. For all our latest predictions on the 2020 landscape, be sure to follow our <u>Policy Forecast page</u>.

NEXT WEEK'S DOSE

Now that Congress has authorized emergency appropriations for COVID-19, expect lawmakers to closely monitor the Administration's use of the funds.

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

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

McDermott+Consulting LLC is an affiliate of the law firm of McDermott Will & Emery LLP. McDermott+Consulting LLC does not provide legal advice or services and communications between McDermott+Consulting LLC and our clients are not protected by the attorney-client relationship, including attorney-client privilege. The MCDERMOTT trademark and other trademarks containing the MCDERMOTT name are the property of McDermott Will & Emery LLP and are used under license.