Holland & Knight

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A weekly dose of healthcare policy news

Legislative Update

Last week, the Senate passed a $1.5 trillion omnibus spending package (summary) to fund the government through September 30, 2022. The package ultimately was stripped of the proposed $15.6 billion for COVID-19 relief funding due to the refusal of rank-and-file Democrats to partially offset those federal funds with previously allocated yet unspent state and local pandemic relief money. Members who represent states that would lose money pushed back on this pay-for. House Appropriations Committee Chair Rosa DeLauro (D-CT) had indicated Democrats would immediately vote on a stand-alone bill (here) that excludes the state and local funding offset, but that quickly fell through. Notably, a relief funding bill is not on the House schedule this week, and uncertainty remains regarding when and how this bill may move forward. Any relief bill that is not partially offset is unlikely to advance in the Senate.

Congress will hold several healthcare-related mark-ups and hearings this week:

- Today, the Senate Health, Education, Labor, and Pensions (HELP) Committee is holding a mark-up of the *Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act*. The package aims to improve federal and state readiness and preparedness to combat the COVID-19 pandemic and future pandemics.
- Tomorrow (March 16th), the Senate Finance Committee will hold a hearing entitled *"Prescription Drug Price Inflation: An Urgent Need to Lower Drug Prices in Medicare."* Democrats will need to be united for prescription drug pricing reform to advance in the Senate, so the level of agreement expressed at this hearing will be informative regarding what policies have a chance of moving forward.
- On Thursday, the House Energy and Commerce Subcommittee on Health will hold a legislative hearing entitled, *"The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight."* The hearing will focus on 22 bills to streamline development and approval processes for drugs and therapeutics, strengthen program integrity, and improve diversity and equity in biomedical research. Please find a staff briefing memo attached in the e-mail that included this Health Dose for more information.

MDUFA V Package Submitted to Congress

The U.S. Food and Drug Administration (FDA) has reached an agreement with the medical device industry on a $1.784 billion base user fee package for fiscal years (FY) 2023-2027, with the potential for up to $1.9 billion in funding. The package would pave the way for a Total Product Life Cycle Advisory Program pilot funded through a combination of new money and MDUFA IV carryover funds. FDA's carryover balance from MDUFA IV has been a point of contention. At the end of FY 2020, FDA had $209 million leftover. Ultimately, the FDA and industry groups agreed to use $110 million of the carryover balance as the primary source of funding for the Advisory Program, but with some constraints around how FDA accrues and spends its carryover balance moving forward. The package also includes goals for increasing agency staffing. The full MDUFA V commitment letter was formally sent to lawmakers as the latest step in the reauthorization process. The agency and industry missed the January 15 statutory deadline to submit an agreement to Congress. Congress must adopt the new user fee agreements before the current deals expire on September 30.

Quick Legislative Shots

- On March 8th, Members of the House sent a letter to Senate and House leadership urging funds for research on long-COVID in future COVID-19 relief packages. The letter cites estimates that 10% of documented COVID-19 survivors, 7.8 million people, are afflicted with long-COVID.

- On March 9th, Sen. Chuck Grassley (R-Iowa) sent a letter to Federal Trade Commission (FTC) Chair Lina Khan urging the agency to investigate pharmacy benefit managers (PBMs). Grassley argues that there is "widespread bipartisan support" for an investigation into whether PBMs are "causing Americans to pay higher prices for prescription drugs." The FTC had a deadlocked vote in February over whether to initiate a study into the business practices of PBMs.

- On March 10, Sens. Shelley Moore Capito (R-WV) and Jeanne Shaheen (D-NH), and Reps. David McKinley (R-WV) and Mike Thompson (D-CA) introduced the *Access to Prescription Digital Therapeutics Act of 2022*. The bill aims to extend Medicare coverage to prescription digital therapeutics (PDTs).

- On March 11, Sens. Chris Murphy (D-CT) and Debbie Stabenow (D-MI), and Reps. Katie Porter (D-CA) and Debbie Dingell (D-MI) introduced the *Closing Health Coverage Gaps for Public Servants Act*. The bill would sunset self-funded nonfederal governmental health plans from opting out of federal parity requirements for behavioral health. It would apply to health plans for firefighters, police, public school teachers, and state and city workers.

Administrative/Regulatory Updates

Healthcare Landscape Post-PHE Taking Shape as Division Mounts Over When PHE Should Formally End

Thirteen Democratic governors publicly called on HHS Secretary Becerra to extend the public health emergency until at least mid-July, conflicting with earlier calls by Republican Congressional lawmakers to end it. The PHE must be renewed every 90 days and is currently set to expire April 16. Most suspect Sec. Becerra will approve at least one additional 90-day extension because HHS has indicated it will provide at least 60 days' notice, and there has been no such announcement. Several temporary regulatory flexibilities and benefit bumps are tied to the PHE, including telehealth. Notably, the omnibus package that is being signed into law today by the President extends several telehealth-related flexibilities for at least five months following the end of the PHE, including waving geographic and originating site requirements, expanding eligible provider types, delaying in-person requirements for mental health services, and allowing audio-only services. This week, Congress considered a separate provision that would allow state licensing reciprocity for up to 180 days after a PHE and has several longer-term telehealth flexibility extensions on the table, including one that would waive geographic and site of service limitations for a full two years.

White House Shifts Strategy from Mask Wearing to Rapid Access to COVID Treatments

According to the latest CDC data, which was updated last Thursday, only two percent (about 7 million) Americans – live in a county with levels high enough where universal indoor masking is recommended under revised CDC guidelines. As part of its shifting national COVID response strategy, the Biden Administration announced a new initiative this week called "Test-to-Treat," which aims to connect anyone who tests positive with local pharmacies or community health centers for medical consults and treatments such as antiviral pills. More information is available here.

Health System Defeats $411 Million Lawsuit Alleging Anti-Competitive Contract Negotiations

California-based health system Sutter Health defeated a $411 million class-action lawsuit that alleged it used its market power to force payers into including its entire system as in-network, which the plaintiffs argued led to higher patient premiums. Sutter previously reached a $575 million settlement on a separate lawsuit on the same issue last year.

CMS Innovation Center to Host Stakeholder Roundtable on Safety Net Participation in Models

Tomorrow, the CMS Innovation Center will host a roundtable with stakeholders on boosting participation by safety net providers in the Center's payment models. Register here.