Holland & Knight

H&K Health Dose: March 19, 2024

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

The U.S. House of Representatives and U.S. Senate are both in session this week.

In the House, a vote is expected on H.R. 766, a bill that would overhaul the Congressional Budget Office's (CBO) scoring methodology for preventive healthcare legislation. The legislation would allow key committee legislators to request that CBO extend its evaluation period beyond its current 10-year scope to include two additional 10-year periods. This could significantly impact CBO's budgetary projections for health legislation and arguably more accurately reflect long-term healthcare savings for measures that address preventative care and chronic condition management.

Secretary of the U.S. Department of Health and Human Services (HHS) Xavier Becerra will appear before the House Committee on Appropriations' Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, as well as the House Committee on Ways and Means (W&M), on March 20, 2024, to discuss with legislators the president's fiscal year (FY) 2025 Budget for HHS. The House Committee on Energy and Commerce (E&C) will also convene March 20, 2024, for a markup of several public health measures. Finally, the House E&C Committee's Subcommittee on Health will hold a hearing, "Evaluating Approaches to Diagnostic Test Regulation and the Impact of the FDA's Proposed Rule," on March 21, 2024, and witnesses include representatives from diagnostic trade associations and a physician pathologist membership organization.

FY 2024 Appropriations Update

The final bill text of the six FY 2024 annual spending bills that expire on March 22, 2024 (State – Foreign Operations, Defense, Homeland Security, Labor – HHS, Legislative Branch, and Financial Services – General Government) has not yet been made publicly available. The package was expected to be released over the weekend, but legislators were unable to reach an agreement on the Homeland Security bill. Given House rules that provide 72 hours for members to review bills before they are brought to the floor, a vote will likely not be held until March 22, 2024. That gives the Senate very little time to act to avert a partial government shutdown or a (very) short-term continuing resolution (CR).

Efforts to include health legislation in the March 22, 2024, spending package – specifically, policies addressing Pharmacy Benefit Manager (PBM) practices and reporting requirements – were not successful. These reforms and others, like extending certain telehealth flexibilities set to expire at the end of this year, will likely not be addressed until the lame-duck session.

Other healthcare policies left out of the first minibus include reduced payment for drug administration services in grandfathered off-campus hospital outpatient departments, mandatory reporting of ownership information and 340B drug pricing program reporting requirements.

House E&C Committee's Subcommittee on Health Holds Markup of Public Health Legislation; Full Committee Markup Scheduled

On March 12, 2024, the House E&C Committee's Subcommittee on Health convened for a hearing to consider 19 health and public health bills. The subcommittee approved 18 of the 19 bills under consideration unanimously or by voice vote, with only the Kidney PATIENT Act (H.R. 5074) legislation that would delay

implementation of the inclusion of oral-only end stage renal disease (ESRD) drugs in the Medicare ESRD prospective payment system (PPS), receiving a split vote. That measure was approved 16-10.

Legislation approved would reauthorize the National Alzheimer's Project Act (NAPA) and several other Alzheimer's disease research and education programs; the Dr. Lorna Breen Health Care Provider Protection Act; the Stop, Observe and Respond (SOAR) to Health and Wellness program; certain poison control programs; and traumatic brain injury (TBI) rehabilitation and patient advocacy programs, among other measures. A full list of legislation is available online.

The full House E&C Committee will convene on March 20, 2024, to consider these measures.

HHS Secretary Becerra Appears Before Senate Finance Committee

In addition to the two upcoming hearings with the House W&M Committee and the House Committee on Appropriations' Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, Secretary Becerra appeared before the Senate Committee on Finance at a hearing on March 14, 2024, to discuss the president's FY 2025 Budget request. Among other topics, legislators discussed PBM reforms, telehealth extensions, "hospital at home" programs and access to healthcare in rural areas.

House W&M Committee Holds Field Hearing on Emergency Medical Care

The House W&M Committee held a field hearing, "Access to Health Care in America: Ensuring Resilient Emergency Medical Care," on March 20, 2024. Legislators discussed rural access to care, remote patient monitoring, home healthcare, digital health technologies, emergency room wait times and the Rural Emergency Hospital (REH) designation, among other issues.

MedPAC and MACPAC Release March Reports to Congress

The Medicare Payment Advisory Commission (MedPAC) and the Medicaid and CHIP Payment and Access Commission (MACPAC) released their March 2024 Reports to Congress on March 15, 2024, which provide legislators with a list of recommendations regarding updates to Medicare payment systems and improvements to beneficiary engagement on Medical Care Advisory Committees (MCACs), respectively. Among other recommendations, the MedPAC March report includes a recommendation that would tie Medicare physician payment rates to inflation by updating rates annually by 50 percent of projected increases in the Medicare Economic Index (MEI).

The MedPAC report and MACPAC report are available online.

Legislation Addressing 340B Reform Introduced in House

On March 12, 2024, Rep. Doris Matsui (D-Calif.) introduced the 340B PATIENTS Act (H.R. 7635), legislation that would:

- clarify that manufacturers are required to offer 340B discount prices to covered entities regardless of the manner or location in which a drug is dispensed, including if a covered entity uses a contract pharmacy to dispense 340B drugs to the entity's patients
- ensure that manufacturers cannot place conditions on the ability of a covered entity to purchase and use 340B drugs, regardless of the manner or location in which the drug is dispensed, including through contract pharmacies
- impose civil monetary penalties on manufacturers that violate these statutory requirements and prohibitions.

Senate HELP Committee Releases RFI on Regulation of Clinical Tests

Sen. Bill Cassidy (R-La.), ranking member of the Senate Committee on Health, Education, Labor and Pensions (HELP), released a Request for Information (RFI) on March 13, 2024, seeking information from stakeholders on clinical laboratory test regulations. The full RFI is available online. Responses must be submitted by April 3, 2024.

REGULATORY UPDATES

FDA Seeks Increased Authority in 2025 Proposals

The U.S. Food and Drug Administration's (FDA) legislative proposals for FY 2025 recommend increased authority requests that the agency says would help address medical product shortages and build supply chain resiliency. The proposals include increased oversight of dietary supplements, updates to tobacco user fee assessments and increased information sharing across states. Pillars of the proposals include competition, innovation, data, information, post-market safety and medical product shortages.

Executive Order Signed to Advance Women's Health Research and Innovation

President Joe Biden signed an executive order on March 18, 2024, that, according to the administration, aims to "advance women's health research, close health disparities, and ensure that the gains we make in research laboratories are translated into real-world clinical benefits for women." The press release goes on to highlight the intention to ensure access to high-quality, evidence-based healthcare and improve health outcomes for women across their lifespans and throughout the country.

FDA Publishes Paper on Artificial Intelligence and Medical Products

The FDA Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH) and Office of Combination Products (OCR) have released a joint paper which details how the FDA's various centers will collaborate to maintain public health and create responsible and ethical innovations in the face of artificial intelligence (AI). In the paper, the agencies request more authority on AI lifecycle management and marketing submission recommendations, clarifying industry best practices and launching efforts to fill gaps in AI knowledge and regulatory science.

CMS Reopens MIPS EUC Exception Application Window

In response to the cyberattack that targeted the healthcare system in February 2024, the Centers for Medicare & Medicaid Services (CMS) extended the data submission deadline and is now reopening the 2023 Merit-based Incentive Payment System (MIPS) Extreme and Uncontrollable Circumstances (EUC) Exception Application to provide relief to MIPS-eligible clinicians impacted by the cybersecurity incident. The application will be open for the remainder of the extended data submission period, which closes April 15, 2024, at 8:00 p.m. ET. More information is available online.